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Adequate Management of Phosphorus in Patients Undergoing Hemodialysis Using a Dietary Smartphone App: Prospective Pilot Study

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Abstract

Background: The renal diet is complex and requires alterations of the diet and careful monitoring of various nutrients. Elevated serum phosphorus is common among patients undergoing hemodialysis, and it is associated with many complications. Smartphone technology could be used to support both dietitians and patients by providing a source of accessible and reliable information.

Objective: The aim of this pilot is to assess the potential efficacy of an intervention using the educational and self-monitoring mobile app KELA.AE on the phosphorous management in hemodialysis patients. Results will be used to improve both the app and a planned, rigorous large-scale trial intended to assess app efficacy.

Methods: This is a prospective pilot study performed at the hemodialysis unit of Al Qassimi Hospital (Emirate of Sharjah, United Arab Emirates). All patients were assessed for eligibility and, based on inclusion criteria, considered for enrollment. Participants met with a dietitian once a week and used the mobile app regularly for 2 weeks. Outcomes (knowledge, self-reported nonadherence, dietary intake, anthropometry, and biochemical data) were measured. This pilot is reported as per guidelines for nonrandomized pilot and feasibility studies and in line with the CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist for reporting pilot or feasibility trials.

Results: Of 26 subjects, 23 successfully completed the pilot. Patient dietary knowledge about phosphorous management improved from 51.4% (SD 13.9) to 68.1% (SD 13.3) after intervention with a large effect size (d=1.22, 95% CI 0.59 to 1.85). Dietary protein intake increased from a mean of 0.9 g/kg (SD 0.3) per day to a mean of 1.3 g/kg (SD 0.5) per day with a large effect size (d=1.07, 95% CI 0.45 to 1.69). Phosphorus to protein ratio dropped from a mean of 18.4 mg/g protein to 13.5 mg/g protein with a large effect size (d=0.83, 95% CI 0.22 to 1.43). There was no evidence of change in phosphorous intake, self-reported nonadherence, and serum phosphorus.

Conclusions: The findings of this prospective pilot reveal the potential efficacy of a smartphone app as a supportive nutrition education tool for phosphorus management in patients undergoing hemodialysis. This pilot study showed that the KELA.AE app has the potential to improve knowledge and dietary choices. A rigorous randomized controlled trial should be performed to evaluate the efficacy, assessing app use of a long-term intervention.

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KEYWORDS

renal diet; mhealth; dietary app

Introduction

Dietary management plays an essential role in slowing down disease progression and improving the quality of life of people with chronic kidney disease (CKD) [1,2]. However, the renal diet is complex and requires targeted attention of the intake of various nutrients [3], and patients often express frustration and confusion about this [4]. Dietary adjustments are made continuously in response to alterations in blood parameters, and patients must be constantly monitored and followed up accordingly [5].

Elevation in blood phosphorus is specifically common among this patient group, and it is associated with many comorbidities such as cardiovascular disease, metabolic bone mineral disease, and mortality [5]. Even a mild hyperphosphatemia (greater than 5.0 mg/dL) is independently associated with an increase in mortality among hemodialysis patients [6]. Therefore, management of hyperphosphatemia is essential during hemodialysis; however, this seems to be particularly challenging. Patients are recommended to consume 1.2 g/kg body weight of protein to achieve protein needs during hemodialysis [3]. Moreover, phosphorus is typically found in protein-rich foods; thus, restricting dietary phosphorus to the recommended 800 to 1000 mg/d while maintaining adequate protein intake is the cornerstone of this diet [3]. Such recommendations are not easily compatible [7] and lead to conflicting and ambiguous information that requires simplification and clarification from the dietitian’s side [8].

Adherence to the renal diet is, therefore, an essential component for the management of hemodialysis patients [9]. Patient knowledge can play a role in compliance with the diet [10]. Therefore, nutrition education and counseling might have a positive effect on blood phosphorous [11]. However, eating habits are complicated and not merely influenced by knowledge, but also by a patient’s readiness to change and their health beliefs [12]. The association between knowledge and adherence is not always clear, and an increase in knowledge does not necessarily lead to improved adherence [13]. Nutrition education can, nevertheless, improve nutrition knowledge, which, in turn, can support increased dietary adherence [14,15]. This knowledge is especially valuable when patients are willing to change their dietary behaviors [13].

From the patient’s perspective, receiving easy to understand individualized nutrition education at the early stages is desired [4]. Educational materials should be theory-based and adapted to the patient [2] to be effective. A thorough education has been listed among the facilitators for improvements of serum phosphorus. Such interventions consist of multiple long encounters with patients and thus may not always be feasible [16]. Time limitation during encounters with dietitians and physicians often act as a barrier to effective nutrition education [17].

A recent study qualitatively explored the experience of renal dietitians. Dietitians expressed frustration, limited resources, and emotional and professional challenges in providing dietary education to CKD patients [8]. Hemodialysis patients show similar frustration and a need for continuous access to reliable nutrition information. Therefore, alternative approaches should be explored that may support both dietitians and patients in overcoming these difficulties. Smartphone technology can provide persons with chronic diseases with accessible and reliable information [18]. Additionally, in-app educational materials allow patients access to nutrition education in different modalities [19]. Accordingly, dietary apps may be effective at improving nutritional outcomes in chronic diseases [20].

Freely accessed educational websites are available to CKD patients, but they target persons with high computer literacy [21]. Commercially, some renal nutrition apps are also available, but they are mostly available in the English language only and may include a subscription fee [22,23]. Research in this area is still scarce as only a few publications have addressed the effectiveness of mHealth in the context of CKD [23]. Additionally, only a few registered clinical trials are active in the area of mHealth in CKD [24].

The IDEAS (integrate, design, assess, and share) framework for the development of effective digital interventions defines the process of assessing the efficacy of a developed product as starting with a pilot study aiming at estimating potential efficacy. Information gathered from the pilot study would then be used to improve the product itself and the study design of a rigorous randomized controlled trial (RCT) [25].

This is a pilot study that aims to explore the potential efficacy of an intervention using a smartphone app in the phosphorus management of patients undergoing hemodialysis. The results of this pilot study will be used to improve the app itself along with the study design of a rigorous RCT. The app used is research-based and includes self-monitoring features, educational features, and CKD-friendly recipes in English and Arabic. The description of the person-centered and theory-based app development is detailed in a separate publication [19].

Methods

Study Design

This is a prospective pilot study conducted using a theory-based educational dietary app Kidney Education Lifestyle Application (KELA.AE). This pilot followed the guidelines for reporting nonrandomized pilot and feasibility studies [26]. This study is also reported in line with the CONSORT (Consolidated Standards of Reporting Trials) 2010 checklist of information to include when reporting a pilot or feasibility trial excluding items pertinent to randomization (Multimedia Appendix 3) [26,27]. Outcome measures include knowledge, self-reported nonadherence, dietary intake, anthropometry, and biochemical data.

Participants, Eligibility, and Recruitment

A list of all patients undergoing hemodialysis was obtained from the hemodialysis unit of Al Qassimi Hospital (Emirate of Sharjah, United Arab Emirates), and all subjects were approached during their scheduled dialysis session to identify those who met the inclusion criteria. The study was explained to eligible participants, and signed consent forms were collected from those who agreed to participate. A total of 26 participants were recruited. Patients undergoing hemodialysis for at least 3 months; free of life-threatening conditions; able to read, write, listen, and communicate in Arabic; owning an Android smartphone; and not having been hospitalized in the past 6 months were eligible to participate in the study. Recruitment and data collection began in February 2019 and ended in April 2019. Post hoc calculations of sample size in pilot studies, assuming detection of unanticipated problems with a probability of at least 15% (π=0.15) and a 95% confidence level, resulted in a required sample of 19 subjects [28].

Ethical Approvals

The study received Institutional Review Board approval (ZU17_066_F) from Zayed University, Dubai.

Procedure

Participants were provided with a username to initiate the sign-in procedure. Upon registration, participants were provided with a brief orientation to the app features, and free access to KELA.AE was provided for 2 weeks. During this period, participants met face-to-face with a research dietitian once a week. The dietitian provided participants with reinforcements of the critical messages relayed by the educational materials and answered questions about the app use and content. The dietitians also collected data from patients before and after app use. Baseline and postintervention outcomes were assessed before app registration (T0) and after the completion of 2 weeks of app use (T1). The trial was stopped when all participants completed 2 weeks of app use. Participants could keep using the app if they wished; however, all data collection was completed 2 weeks after app use.

KELA.AE App

The app consists of an Arabic, theory-based, and culture-specific Android app (KELA.AE). A formative study of the app has been published elsewhere [19]. The app was designed to provide dietary education and traditional renal diet–friendly recipes to hemodialysis patients. The transtheoretical model [29] and constructs from the reasoned action approach [30] were incorporated in the development of the educational materials. Three different stages of change have been included along with the concepts of self-efficacy, norms, and attitudes. Behavior change techniques used included self-monitoring of behavior, problem solving and coping planning, goal setting, social comparison of behavior, and verbal persuasion to boost self-efficacy. The stages and constructs were incorporated based on previously published, validated stage-based materials [31], qualitative data, and brainstorming sessions performed during app development by the research team [19]. Different educational modalities were used to deliver the behavior change techniques: notifications, podcasts, and videos. Each modality is matched to a behavior stage and a construct from the reasoned action approach; an example would be a notification that is delivered to the user stating “Many dialysis patients have benefited from the advantages of exercising and were able to improve their quality of life. You can do it too!” (this is provided to a patient categorized in the action stage and linked to capacity/self-efficacy). Additional examples of educational materials are reported in a separate publication [19]. Self-monitoring features to track food intake and blood tests are also available.

The app was developed as a collaboration between the research team and the design team of an app development company. The technical development of the app software was outsourced by the research team to the development company. Educational materials were prepared by the research team in collaboration with the departments of Arabic and communications of Zayed University. The app is hosted on the servers of the development company.

Self-Reported Nonadherence

The Dialysis Diet and Fluid nonadherence Questionnaire was used to assess self-reported dietary nonadherence [32] (Multimedia Appendix 1). The questionnaire includes 2 simple questions on the frequency and degree of nonadherence. The same questions are asked for overall dietary nonadherence and again for dietary phosphorus nonadherence (total of 4 questions). It requires the patient to report nonadherence as the number of nonadherent days in the last 14 days. The degree of nonadherence is reported on a Likert scale (0 to 4, where 0 means compliant and 4 means severe nonadherence). The questions were translated to Arabic but given their straightforward simplicity further validation was deemed unnecessary. Construct validity of the original tool was reported using a Kendall tau correlation for frequency and degrees of nonadherence (τ=0.495; P<.001) [32]. Adherence via the app was not collected due to the lack of in-app analytics in the current version of the app.

Knowledge

The Knowledge Questionnaire consists of 18 questions assessing knowledge about the renal diet (Multimedia Appendix 2). A total of 18 points can be achieved if all answers are correct; scores were then converted into a percentage. This tool was used in Arabic before [33] based on an adaptation of the original questionnaire [34] and now includes Arabic foods. A score of 60% in overall knowledge (all 18 questions) was considered as sufficient knowledge as recommended by the questionnaire [33]. Questions were clustered by topic, and a subanalysis was performed to understand knowledge in specific areas pertinent to phosphorous management (phosphorus content in food, consequences of hyperphosphatemia, and use of phosphate binders).

Dietary Intake

Dietary intake was assessed by 2 trained research dietitians using face-to-face 24-hour recalls [35]. Participants were asked if the day before was deemed representative of the previous week, and if not, they were asked to report a typical day for better representation of the past week’s intake. The 24-hour recalls were analyzed using the FoodData Central of US Department of Agriculture databases [36]. Phosphorus needs were considered as 1000 mg/d for participants with serum phosphorus below 5.5 mg/dL and 12 mg/g of protein intake for participants with serum phosphorus below 5.5 mg/dL [37].

Biochemical Parameters

Blood parameters were retrieved from patient medical records as part of the routine protocols of the hemodialysis unit (measurements are taken post hemodialysis session). Target values for serum phosphorus in hemodialysis were considered between 3.5 and 5.5 mg/dL based on the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) recommendations [3].

Anthropometric Measurements

Body weight and height were retrieved from patient medical records, as measured postdialysis routinely. BMI was calculated accordingly using measured body weight and height. Comparative standards for body weight were used as suggested by the Nutrition Care Manual [37] based on the NKF KDOQI guidelines [3]. Accordingly, standard body weight from the National Health and Nutrition Examination Study was used for the calculation of nutrient needs. Adjusted edema-free body weight was used for the calculation of nutrient needs for participants with <95% or >115% of standard body weight [37] as recommended by the guidelines.

Statistical Analysis

SPPS (version 21, IBM Corp) was used to perform all statistical analyses. Categorical variables were described using frequencies and percentages, while means and standard deviations were used to represent continuous variables. A Shapiro-Wilk normality test was performed to ensure that data are normally distributed. Paired *t* tests were used to compare the mean scores before and after the intervention. Two-tailed *P* values are reported. Effect sizes were calculated as Cohen *d* (with 95% CI) using mean difference and pooled standard deviations. The effect size was considered small at 0.2, medium at 0.5, and large at 0.8 and above [38].

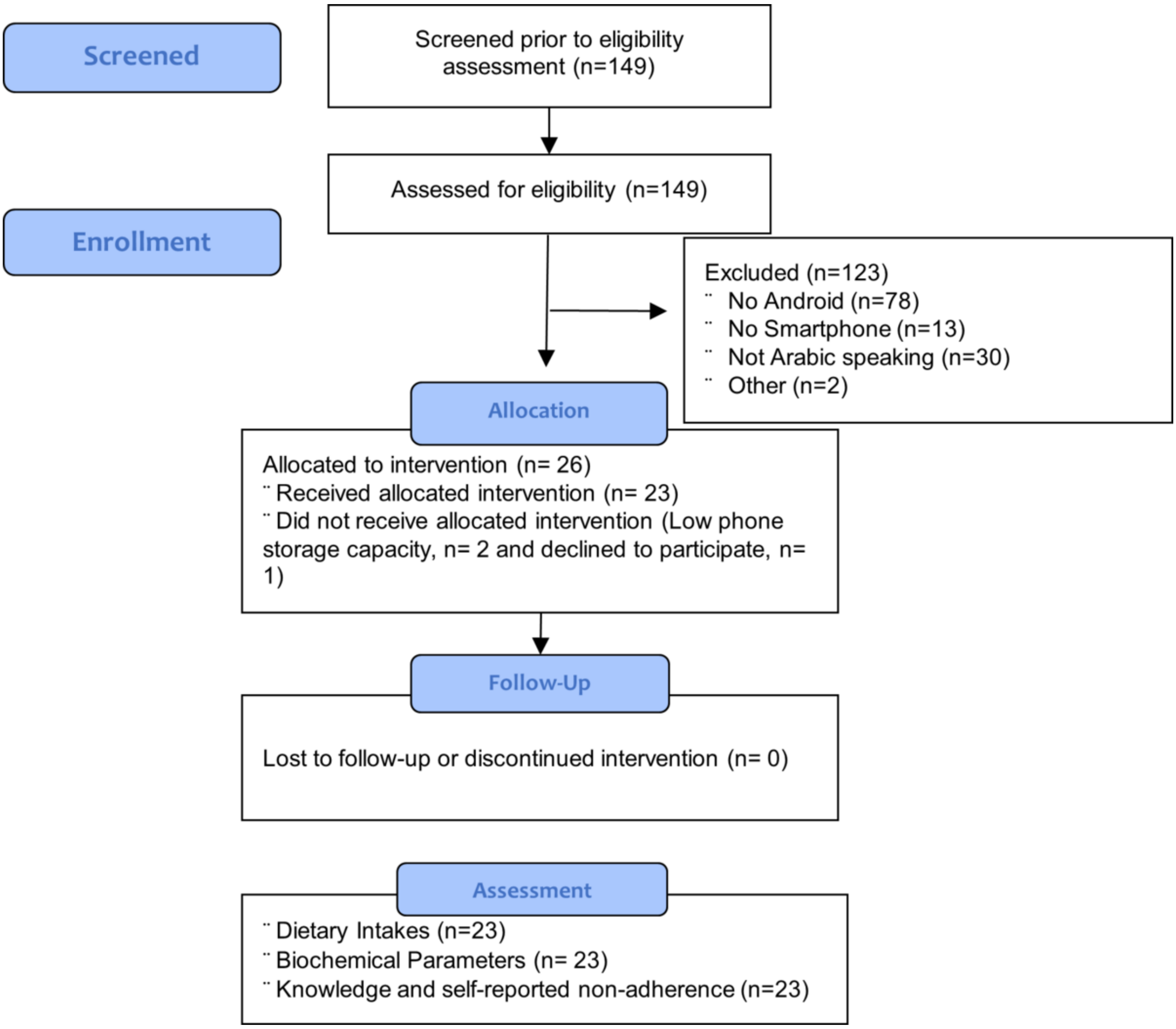
Results

A total of 23 participants completed the app pilot testing. Two subjects were excluded due to issues related to low smartphone storage capacity, and one subject was not interested in downloading the app. The mean age of the participants was 48.5 (SD 13.7) years, mean BMI was 31.9 (SD 7.9) kg/m^2, and mean time on dialysis was over 1 year, with 29.7 (SD 37.3) months of dialysis. More men were enrolled in the study (14/23, 61%), and most participants suffered from hypertension (16/23, 70%) or diabetes (11/23, 48%). Demographics measured at baseline are shown in Table 1. Figure 1 depicts the CONSORT flow diagram.

Table 1. Demographics and baseline characteristics of the study population (n=23).

Characteristic	Value
Age (years), mean (SD)	48.5 (13.7)
BMI (kg/m^2), mean (SD)	31.9 (7.9)
Months on dialysis, mean (SD)	29.7 (37.3)
Gender, n (%)	
Male	14 (61)
Female	9 (39)
Smoker, n (%)	6 (26)
Comorbidities, n (%)	
Hypertension	16 (70)
Diabetes	11 (48)
Dyslipidemia	2 (9)
Cancer	1 (4)
Liver disease	1 (4)

Figure 1. CONSORT study flow diagram.



Knowledge and Nonadherence

Overall, the mean self-reported nonadherence days dropped from 3.2 (SD 4.5) over the past 14 days to 2.0 (SD 3.0) days after exposure to in-app education with a small effect size (*d*=0.33, 95% CI –0.25 to 0.91). The severity of nonadherence was mostly mild and moderate preintervention and postintervention.

The mean perceived days of nonadherence to the phosphorus content of the diet increased from 1.1 (SD 3.2) days to 1.9 (SD 3.0) days with a small effect size (*d*=0.25, 95% CI 0.33 to 0.83). The severity of nonadherence changed from 19 participants reporting no deviation from the diet to only 10 reporting no deviation.

Knowledge was below the 60% cutoff point of adequate knowledge at baseline and improved to reach a mean of 68.1% (13.3) after intervention, with a large effect size (*d*=1.22, 95% CI 0.59 to 1.85). Specific knowledge pertinent to consequences of hyperphosphatemia and phosphate binders also improved (large effect sizes *d*=1.15, 95% CI 0.53 to 1.77, and *d*=1.00, 95% CI 0.39 to 1.61, respectively). Knowledge about the phosphorus content of food improved, with a medium effect size (*d*=0.54, 95% CI –0.05 to 1.12). Results pertinent to adherence and knowledge are detailed in Table 2.

Table 2. Baseline and postintervention self-reported dietary nonadherence and dietary knowledge (n=23).

Questionnaire	Baseline	Postintervention	Cohen *d* (95% CI)	*P* value
DDFQ[a], overall				
Nonadherence (days), mean (SD)	3.2 (4.5)	2.0 (3.0)	0.33 (–0.25 to 0.91)	.32
Nonadherence (degree), n (%)				
No deviation (0)	11 (48)	11 (11)	—[b]	—
Mild (1)	5 (22)	4 (4)	—	—
Moderate (2)	4 (17)	7 (7)	—	—
Severe (3)	2 (9)	1 (1)	—	—
Very severe (4)	1 (4)	0 (0)	—	—
DDFQ, phosphorus				
Nonadherence (days), mean (SD)	1.1 (3.2)	1.9 (3.0)	0.25 (0.33 to 0.83)	.45
Nonadherence (degree), n (%)				
No deviation (0)	19 (83)	10 (44)	—	—
Mild (1)	1 (4)	5 (22)	—	—
Moderate (2)	2 (9)	7 (30)	—	—
Severe (3)	0 (0)	1 (4)	—	—
Very severe (4)	1 (4)	0 (0)	—	—
KnQ[c], mean (SD)				
% Overall knowledge (>18 questions)	51.4 (13.9)	68.1 (13.3)	1.22 (0.59 to 1.85)	<.001
Knowledge of phosphorus content of food (>7 questions)	47.8 (21.4)	57.1 (12.2)	0.54 (–0.05 to 1.12)	.06
Knowledge of consequences of high levels of phosphorus (>4 questionnaire)	43.5 (18.8)	66.3 (20.8)	1.15 (0.53 to 1.77)	<.001
Knowledge of phosphate binders (>4 questions)	48.9 (29.6)	76.1 (24.4)	1.00 (0.39 to 1.61)	<.001

[a] DDFQ: Dialysis Diet and Fluid Questionnaire.

[b] Not applicable.

[c] KnQ: Knowledge Questionnaire.

Serum Phosphorus and Dietary Intake

Dietary protein intake increased from a mean intake of 0.9 (SD 0.3) g/kg per day to a mean intake of 1.3 (SD 0.5) g/kg per day with a large effect size (*d*=1.07, 95% CI 0.45 to 1.69). Phosphorus intake as compared to phosphorus needs did not change. However, the phosphorus to protein ratio dropped from a mean of 18.4 mg/g of protein to 13.5 mg/g of protein with a large effect size (*d*=0.83, 95% CI 0.22 to 1.43). This result is desirable given that it is closer to the recommended 12 mg/g of protein.

No changes were identified in serum phosphorus; however, the number of participants with serum phosphorus above 6 mg/dL increased to become 10 subjects as compared to 6 at baseline. This may be in line with the increase in protein intake and a slight increase in total phosphorus intake. Table 3 illustrates data on serum phosphorus and dietary intake.

Table 3. Baseline and postintervention dietary intake and serum phosphorus level (n=23).

Parameter	Baseline	Postintervention	Cohen *d* (95% CI)	*P* value
Phosphorus intake, mean (SD)				
Dietary phosphorus (mg/d)	1152.5 (489.8)	1343.1 (83.0)	0.42 (–0.15 to 1.01)	.88
% compliance to phosphorus needs	108.3 (44.5)	109.4 (45.5)	0.02 (–0.55 to 0.60)	.72
Dietary protein (g/d)	71.1 (26.4)	103.8 (37.8)	1.00 (0.38 to 1.61)	<.001
Dietary protein (g/kg/d)	0.9 (0.3)	1.3 (0.5)	1.07 (0.45 to 1.69)	<.001
Phosphorus to protein ratio (mg/g)	18.4 (7.9)	13.5 (2.9)	0.83 (0.22 to 1.43)	.01
Serum phosphorus (mg/dL), mean (SD)	5.3 (1.5)	5.5 (2.0)	0.15 (–0.43 to 0.73)	.60
Nonadherence to serum phosphorus, n (%)				
< 5 mg/dL	11 (48)	11 (48)	—[a]	—
5-6 mg/dL	6 (26)	2 (9)	—	—
> 6 mg/dL	6 (26)	10 (43)	—	—

[a] Not applicable.

Discussion

Principal Findings

The main findings of this prospective pilot study show that in-app nutrition education, as a supportive tool to dietitians, can improve knowledge of the renal diet among patients undergoing hemodialysis. Thus, the in-app educational features (notifications, podcasts, videos, and recipes) of the KELA.AE app might have potential as a useful source of nutrition education for patients undergoing hemodialysis. The use of smartphones as supportive tools to deliver education may help overcome the time limitation barrier that is reported during face-to-face encounters with dietitians and physicians [17]. Accordingly, app availability may be beneficial to both patients and health care practitioners as supportive tools for regular care.

However, self-reported adherence to the renal diet was not changed after the use of the KELA.AE smartphone app. Self-reported dietary questionnaires may be a source of bias related to social desirability. Nevertheless, adherence to phosphorus intake (24-hour recalls) and serum phosphorus did not improve either. Knowledge scores were not satisfactory at baseline (below the 60% cutoff used) and increased significantly to reach a mean score of 68.1%. It seems that the association between knowledge and dietary nonadherence in dialysis patients is not always clear [39]. In the results of this prospective pilot, nonadherence to the phosphorus content of the diet increased after the intervention. The increase in knowledge may explain this. Patients might have become more aware of the phosphorus content of food and therefore, their self-perception of nonadherence changed accordingly. A study performed in patients with heart failure reported that despite knowledge on the sodium restriction diet being high, only 40% of participants were adherent to the restrictions based on urine sodium excretion. However, perception of the benefits of the diet was correlated with dietary adherence [40]. Nevertheless, other studies have found that intense nutrition education [41,42] and dietary knowledge [15] improve adherence. Accordingly, longer exposure to continuous education both by dietitians and in-app education material may be needed to understand if increased knowledge may improve adherence and possibly serum phosphorus.

An increase in dietary protein was nevertheless observed as an outcome of the intervention. Protein intake in hemodialysis is essential for the prevention of malnutrition. There is also an association between reduced protein intake and increased mortality [43]. The participants in this pilot study started with low protein intake as compared to the needs of ≥1.2 g/kg/d recommended by NKF KDOQI guidelines [3] and achieved an average intake in line with recommendations postintervention. The contradiction between the protein and phosphorous recommendations of the dialysis diet may lead to protein restriction as a result of decreased phosphorous intake. Baseline and postintervention phosphorus intake were within phosphorus recommendations. Therefore, the increase in protein intake did not negatively impact phosphorus intake. Additionally, the phosphorus to protein ratio postintervention was closer to the recommended ratio of 10 to 12 mg/g of protein [3], meaning that patients increased their protein intake while choosing foods that were lower in phosphorus. These dietary changes may be a result of increased patient knowledge. However, the duration of the intervention may have been too short to detect changes in serum phosphorus, which is a limitation of the pilot. This will be better explored in the future trial.

Adherence to phosphate binders is also an essential component in the phosphorous management of dialysis patients. In this pilot, knowledge pertinent to phosphate binders improved postintervention; however, adherence to binders was not measured directly. Additionally, types of binders and their prescriptions were not investigated and benchmarked with recommendations.

Limitations

Another limitation of the pilot study is the lack of app use data, which was not retrievable due to the lack of in-app analytics. The first and last access for each user are the only data available, and all users had accessed the app at least once during each week. The next version of the app will include in-app analytics to allow the future trial to track if app use influences improvement in outcomes.

Additionally, user acceptability should also be further assessed. A questionnaire was used during this pilot study to explore acceptability; however, all participants provided answers indicating that they strongly agree with all the questions. The team considered the data collected unsuitable for the assessment of acceptability. Acceptability will be assessed in the future trial using the validated Arabic version of the Mobile Application Rating Scale [44]. Qualitative data will also be added to the assessment during the future trial.

Valid interpretation, translation, and generalizability of mHealth interventions also depend on the assessment of treatment fidelity [45]. The future trial will also assess treatment fidelity in-depth to ensure integrity, reliability, and validity of this mHealth intervention before the interpretation and generalizability of the results. During this pilot, we were unable to ensure compliance with all the goals of treatment fidelity proposed by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium [46]. Among the goals that we were able to meet during the pilot are the standardization of treatment and prevention of contamination, participants' ability to use the app, and provider training. The steps included automated notifications delivered equally to all participants, an orientation session for participants, pilot testing of educational materials, and the training provided to the dietitians meeting patients weekly. However, due to the lack of in-app analytics, we were unable to track the enactment of the self-monitoring tools adequately.

The intervention included encounters with dietitians that may have influenced the outcomes. This methodology was opted as this is how the app use is envisioned in the practice setting. The app would be a tool that dietitians use to support patient education and self-monitoring. The reinforcement of the dietitians, however, may have influenced the results. Accordingly, the future trial will include a control group whereby dietitians see patients with the same frequency but without app use.

This pilot aimed to assess and refine the methodology and procedures of a future trial aiming to detect the efficacy of app use in the adequate management of phosphorous in patients undergoing hemodialysis. Similar to the few available studies evaluating dietary apps for CKD on a smartphone [23], our results show potential benefits on dietary intake. However, this study is unique for evaluating the potential of apps as educational tools to support dietitians. Additionally, it is the first intervention reporting the role of dietary apps for CKD in Arabic. Based on the findings, the planned trial should be designed to compare regular dietary interventions with dietary interventions supported by the app to avoid the possible confounding effects of the dietitian. During this study, participants often consulted with the research team throughout the regular weekly visits; thus, it would be important to explore further if the app enhances the phosphorous management or if it is instead the frequent dietary follow-up that leads to improvements. In conclusion, the future trial should also evaluate the use of phosphate binders, app use data, acceptability, and fidelity, and it should be designed in a way to detect if the app provides any advantages in the clinical outcomes of phosphorous management as compared to intensive dietary follow up by a dietitian.

Conclusions

The findings of this pilot study indicate that there is potential in the use of a smartphone app as a supportive nutrition education tool. A rigorous RCT should be performed to evaluate the efficacy, in which app use and long-term impact should be assessed.

Acknowledgments

We acknowledge the staff and students from Zayed University who volunteered by contributing to the app development at many steps. This study was funded by research grant R18060 provided by Zayed University.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Dialysis Diet and Fluid non-adherence Questionnaire.
[DOCX File , 41 KB - formative_v5i6e17858_app1.docx]

Multimedia Appendix 2
Knowledge Questionnaire.
[PDF File (Adobe PDF File), 118 KB - formative_v5i6e17858_app2.pdf]

Multimedia Appendix 3
CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial.
[DOC File , 228 KB - formative_v5i6e17858_app3.doc]

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Abbreviations

CKD: chronic kidney disease
CONSORT: Consolidated Standards of Reporting Trials
IDEAS: integrate, design, assess, and share framework
KELA.AE: Kidney Education Lifestyle Application
NKF KDOQI: National Kidney Foundation Kidney Disease Outcomes Quality Initiative
RCT: randomized controlled trial

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Original Paper

Using a Mobile App–Based Video Recommender System of Patient Narratives to Prepare Women for Breast Cancer Surgery: Development and Usability Study Informed by Qualitative Data

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Abstract

Background: Women diagnosed with breast cancer are often bombarded with information. Such information overload can lead to misunderstandings and hamper women's capacity for making informed decisions about their care. For women with breast cancer, this uncertainty is particularly severe in the period before surgery. Personalized narratives about others' experiences can help patients better understand the disease course, the quality and type of care to be expected, the clinical decision-making processes, and the strategies for coping. Existing resources and eHealth apps rarely include experiential information, and no tools exist that tailor information for individual preferences and needs—offering the right information at the right time and in the right format. Combining high-quality experiential evidence with novel technical approaches may contribute to patient-centered solutions in this area.

Objective: This study aims to design and seek preliminary feedback on a mobile app that will improve information access about surgery for patients with breast cancer, by drawing on a qualitative collection of personal narratives from a diverse sample of Canadian women and using video and audio recordings or audio recordings from the Canadian Health Experiences Research Network.

Methods: In a previous study, we conducted in-depth interviews with 35 Canadian women and used video and audio recordings or audio recordings to collect stories about the lived experiences of breast cancer. The participants highlighted the need for more specific information between diagnosis and surgery that was relevant to their personal situations and preferences. They also wanted to learn from other women's experiences. We worked with patients, clinicians, and informatics experts to develop a mobile app that provides access to tailored experiential information relevant to women's personal situations and preferences. We completed focus groups and qualitative interviews, conducted a further analysis of the original qualitative data, designed novel software using artificial intelligence, and sought preliminary feedback from users on a new app via focus groups and a survey.

Results: The secondary analysis of the breast cancer narratives revealed key themes and their interconnections relevant to the experience of surgery, including preparation, treatment decisions, aftercare, reconstruction, prostheses, lumpectomy and mastectomy, and complications. These themes informed the development of the structure and content of the app. We developed a recommender system within the app by using content matching (user and speaker profiles and user interests and video content) and collaborative filtering to identify clips marked as relevant by the user and by similar users. A 2-minute animated introductory video for users was developed. Pilot testing revealed generally positive responses regarding the content and value of this type of e-tool.

Conclusions: Developing reliable, evidence-based tools and apps that are based on diverse collections of people's experiences of illness offers a novel approach to help manage the plethora of information that women face after a diagnosis of breast cancer.

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KEYWORDS

qualitative research; illness narratives; experiential information; breast cancer; surgery; tailored information; recommender system; patient information and communication; mobile app; mobile phone

Introduction

Background

The last few decades have been marked by the rapid expansion of web-based health information [1], and breast cancer has been noted as the most searched for health topic on the web [2]. This has not only helped to promote the availability of relevant breast cancer information but also exacerbated challenges related to information overload [3]. Therefore, women with breast cancer are particularly vulnerable to experience information overload, which is associated with a negative impact on patients' treatment or behavioral decisions [3-6] and associated with anxiety and distress [6]. In biomedical research, the information bottleneck has shifted from data collection to data management and analysis [7], and it appears that there is a parallel shift regarding information for patients. Tailoring information to individual needs can better support patients in their search and retrieval efforts for securing *appropriate* information [8]. This will not only reduce information overload but also ensure that patients do not miss important treatment information, which is another factor that negatively impacts the health and well-being of women with breast cancer [9,10].

Mobile apps offer innovative solutions for improving health care for various health conditions [11]. Several of these apps include the provision of tailored information [12-15]. This innovation has evolved rapidly in the last decade, and it is estimated that by 2018, nearly 2 billion smartphone and tablet users accessed health care–related apps [16].

Experiential Information in Apps

A recent systematic review of empirical studies on mobile apps (n=29) for breast cancer care [17] and another review on the evidence for mobile app use (n=9) during the treatment of breast cancer [11] identified only one study that included access to experiential information in the form of a personal story forum containing five recorded stories [18]. This is despite evidence that patients turn to the internet and other sources to purposefully search for experiential information [19]. However, the quality and access to this type of information is highly variable, and there is a need to provide rigorously developed, reliable, and tailored information regarding the experiences of others with similar conditions. Experiences of other patients are an important part of the evidence base that is available to patients; experiential evidence increases awareness of various treatment options, normalizes aspects of illness and treatment, and supports and informs decision making. Dismissing personal stories as *anecdotes* is a serious misunderstanding [20]. To date, research findings underscore the value and impact of patients' exposure to experiential information, which includes providing comfort and ensuring a more realistic outlook about the future [21]. Similarly, Ziebland and Wyke [19] reported that experiential information can support people in making better health care choices, raising awareness of certain health issues, improving health literacy, comparing each other's situation, and accessing more appropriate services. From our study on women's experiences of breast cancer, we found that experiential information can complement women's information needs about subjects that are not always communicated through factual and biomedical types of information [22]. It is argued that the inclusion of experiential health information will remain a key feature of eHealth strategies because of the appeal and memorability of stories and the need to make contact with peers [19]. However, there are concerns regarding people's reliance on the internet for experiential information and the quality and reliability of this information [19]. A review of existing apps demonstrated that such resources are scarce. Few of them are evidence-based and many are misleading [23], as apps are often introduced into clinical care before benefits and risks for patients and health care professionals are evaluated [11]. Both the systematic reviews mentioned earlier found that rigorous trials in this area are lacking.

Women not only need to receive the right information at the right time and in the right format but also need to receive information from trustworthy sources, such as health care professionals, patient support organizations, and other patients, especially when information is offered on the web or through a mobile app. The challenge lies in developing evidence-based information tools that respond to women's personal information needs. Such tools are relatively rare to date, and to our knowledge, no tools exist that provide information that is *tailored* to individual preferences and needs**.** Greater insights regarding women's needs at particular times in their cancer journeys and regarding the technical requirements for such a tool would contribute to novel solutions. To our knowledge, there are no tools yet that help patients understand how to prepare for breast cancer surgery based on lived experiences and, in particular, that draw from experiential evidence gathered through rigorous qualitative methods. This paper reports on the development of a new tailored information app called Health Experiences and Real Stories (HERS) that allows women with newly diagnosed breast cancer to retrieve information (in English or French) from an existing database of women's experiences with breast cancer. One of the key findings from previous studies was that women missed important information during the diagnostic phase, especially while preparing for surgery. However, women also reported that they struggled to handle information at the start of their breast cancer journey [22]. Women with suspicious lumps or other symptoms of potential breast cancer may often be seen and treated by a surgeon before they come under the care of a specialized breast cancer team (providing multidisciplinary care and support throughout the *journey* [8]). This diagnostic stage is typically described as one of the most bewildering periods [8,24] when women are usually coming to terms with this new disease and may be seeking information about breast cancer, treatments, and options [25].

Objective

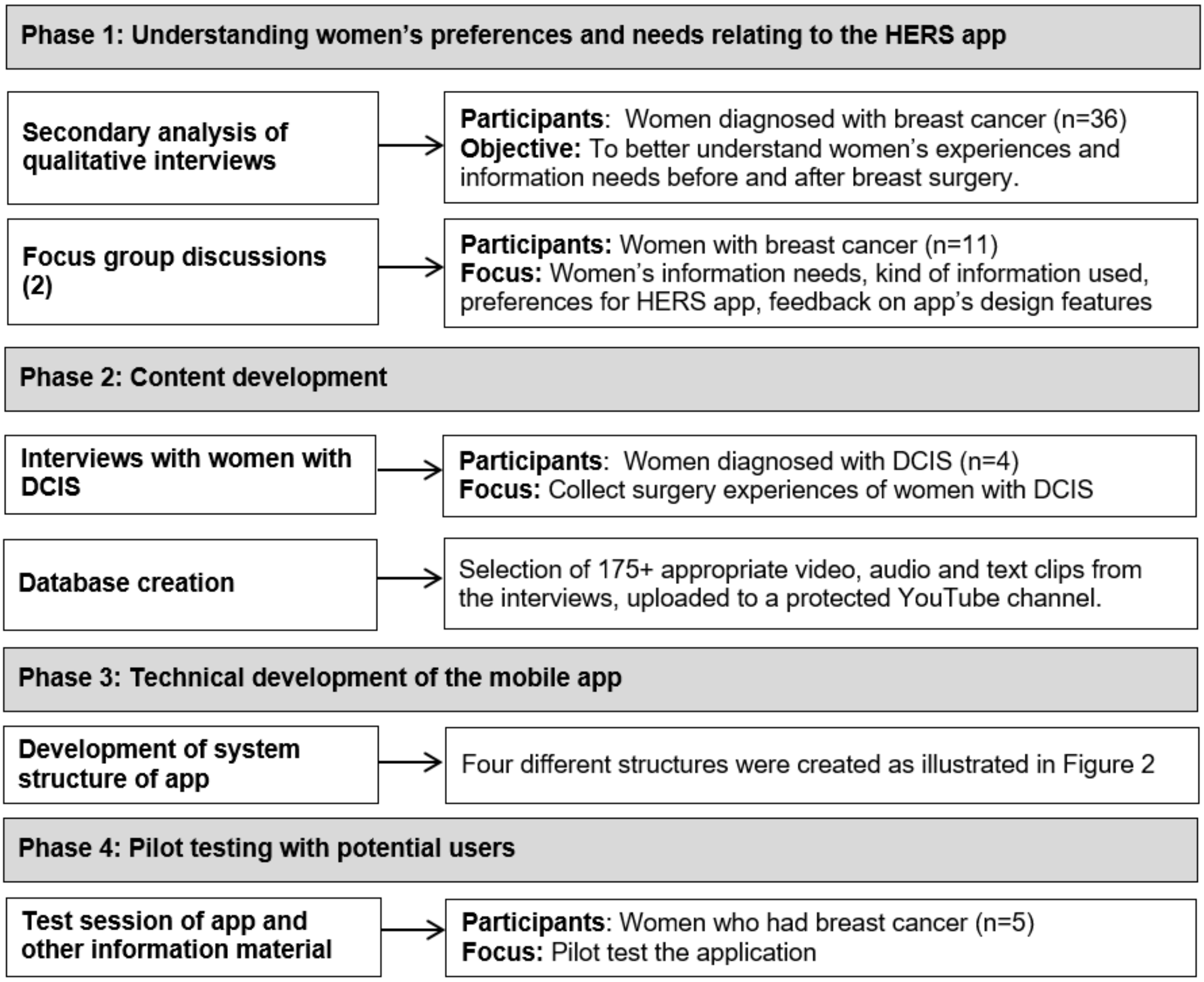
This study aims to contribute to the development of tools that provide patients with tailored experiential information based on rigorous qualitative research. In the following sections, we describe the work undertaken in four phases to conceptualize, develop, and obtain preliminary feedback from users for the HERS app.

Methods

Overview

Our multidisciplinary research team (clinicians, computer engineers, and researchers) worked in close collaboration with an expert advisory panel (patients, representatives of breast cancer organizations, and clinicians) to develop and test the HERS app over the study period from July 2016 to June 2018. The four phases of work consisted of understanding women's preferences and needs related to the app (phase 1), content development (phase 2), technical development (phase 3), and pilot testing (phase 4), as presented in Figure 1. The research ethics committee of Saint Mary's Hospital Center (SMHC) in Montreal, Quebec, Canada, approved the study in June 2016 (reference number 11-22 B, amendment 3). Participants for the interviews and focus groups were recruited through breast cancer patient and community organizations and support groups, personal networks, our expert advisory committee, and social media. Informed consent was obtained from all participants.

Figure 1. Process of the Health Experiences and Real Stories app development. DCIS: ductal carcinoma in situ; HERS: Health Experiences and Real Stories.



Phase 1: Understanding Women's Preferences and Needs Relating to the HERS App

A secondary analysis of the transcripts from 35 interviews previously conducted with women with breast cancer was undertaken to identify women's information needs before and after surgery. This analysis informed the questions developed for the focus group discussions in this study. Details regarding the methods for the original qualitative research have been published elsewhere [22].

Two focus groups involving women with experiences of breast cancer were convened in July 2016 (n=6) and September 2016 (n=5) to (1) consider information needs (helpful information, information needs, and lack of information) related to surgery, (2) review sample videos to understand the value of experiential information, and (3) better understand their preferences regarding design features of a tailored information app. In focus group 2 (different participants), we presented a summary of the results of focus group 1 and discussed the findings further. The women were aged between 43 and 65 years. The participants had been diagnosed with breast cancer and had undergone various surgeries (lumpectomy, single or double mastectomy, and reconstruction). Both focus groups were facilitated by the principal investigator, senior qualitative researcher, and computer scientists.

Phase 2: Content Development

The content for this app was drawn primarily from the data collected in previous qualitative research completed by our team regarding the experiences of 35 Canadian women with breast cancer (Canadian Women's Experiences with Breast Cancer study). These results are presented on the web (Canadian Health Experiences Research Network, 2021 [26]) where we created topic summaries, including illustrative video and audio clips, from our analysis of issues important to the women that we interviewed. Given that we had previously excluded women diagnosed with the earliest form of breast cancer—ductal carcinoma in situ (DCIS), [22]—because of the particular definition of breast cancer adopted for the original collection and the fact that this group also underwent breast surgery (patients with DCIS would therefore be inclusive of potential users of the app), we conducted four additional interviews with women diagnosed with DCIS between October 2016 and September 2017 using the same methods for collecting narrative interviews as per the original study. Women were asked to share their experiences with breast cancer beginning with an open narrative question ("Can you tell me about your experiences with breast cancer from the beginning up until now?") followed by a semistructured set of questions. Participants in the narrative interviews had already consented to the future use of their interview materials (transcript, audio, and video recordings), which included apps such as web-based resources and for research and teaching; all participants were provided with a transcript of their interview for review.

Qualitative analysis of the four DCIS interviews was conducted, along with a secondary analysis of the original 35 interviews (36 interviews were conducted but one participant withdrew from the study) of women with breast cancer, focusing on women's experiences of breast surgery. Using the framework method [27], we selected text from the 39 interviews that were specifically related to breast surgery, such as experiences with surgical procedures, but also topics such as body image, talking to children, sexuality, and information needs. Two senior qualitative researchers analyzed the data, using the analytic software NVivo 10 (QSR International), and then developed a list of relevant topics relating to content (in collaboration with the principal investigator and computer engineers) for the HERS app based on the themes and categories that emerged from the coding framework.

Phase 3: Technical Development of the Mobile App

Working closely with an expert advisory panel and women diagnosed with breast cancer, we built the HERS app based on the needs and preferences of women with breast cancer for tailored information from phase 1 with content from phase 2. We developed the HERS app as a mobile app for Android smartphones or tablets in the Java programming language. The content (video clips) is housed on a YouTube platform on the web. To provide tailored information to users, we developed a recommendation engine as a web service (based on the representational state transfer protocol) powered by a Microsoft structured query language database that stores user information and metadata of available videos. The mobile app accesses the web service and retrieves appropriate content from YouTube to display to users (Multimedia Appendix 1).

After completion of the prototype app, we made further improvements and iterations based on the feedback from a test session (testing the app, focus group, and surveys), as described in phase 4.

Phase 4: Obtaining Preliminary Feedback From Potential Users

The test session took place in June 2018 with 5 women (aged 51-66 years with a minimum of high school education), who had been diagnosed with breast cancer between 2005 and 2016. Two of the women had a recurrence of cancer since their diagnosis and 2 women previously participated in the focus group of phase 1. The goals of the session were as follows:

- To consider women's responses to existing web-based resources for breast surgery that contain more factual information and to the pilot version of the HERS app presenting experiential information
- To gather perspectives on the HERS mobile app regarding what was useful and to gather any recommendations for improvement

The women first explored the information resources offered by the app. These included resources offered by reliable breast cancer organizations such as the Canadian Breast Cancer Foundation, Canadian Breast Cancer Network, and Canadian Cancer Society. These resources mostly offer what we have termed more biomedical or *facts and figures*–type information related to breast cancer (eg, illness stages and surgery procedures) and may occasionally include some experiences of women as testimonials. After reading these resources (20 min), the participants completed a questionnaire (15 min). We considered adopting the questions from the eHealth Impact Questionnaire evaluation tool [28] for this study; however, to align the tool with the content and process used in this study, we substantially adapted the questions but retained the 5-point Likert scale. This process was then repeated for the information on the experiential information in the HERS app. The focus group ended with a discussion of the value of biomedical-oriented information resources and experiential app resources.

Results

In this section, we present a summary of the results for each phase of the project. See Multimedia Appendix 4 for a Powerpoint presentation of the research study.

Phase 1: Understanding Women’s Preferences and Needs Relating to the HERS App

Information Needs Related to Surgery

A synthesis of the analysis of the information needs of women during the surgery phase (secondary analysis and focus groups) is shown in Textbox 1.

Textbox 1. Women’s experiences with information related to breast cancer surgery.

Information received

- Women’s contrasting experiences with regard to the information that they received was striking; some felt that they had received excellent information and others felt they were hardly informed.
- For the majority, it seemed as though there was both too much and too little information.

Information needs

- Women described that they were unaware of their information needs (“I think I didn’t know what I needed to know”) after finding the lump and while preparing for surgery.
- Women were understanding of the limited availability of health care professionals.
- Women described a need for experiential information on issues, such as impact on life, intimacy issues, and how to tell children.
- Women found that biomedical information about breast cancer was covered the best (in comparison with experiential or pragmatic information).
- The flow of information typically improved once patients saw their oncologist.

Lack of information

- Information in relation to care practices and surgery: wound care, preparation for surgery, how it will look, pain, and check-up frequency
- Experiential information: return to work, telling children, and effects on relationships. Women felt that this kind of information should be considered essential for patients.
- Women experienced a lack of information about and support for decisions related to surgery and reconstruction. They did not receive sufficient information about the importance of exercise after surgery.
- Women described feeling misinformed.

Helpful information

- Information from health care professionals: information session on breast cancer in hospital, visual explanations (eg, drawings showing the drains), link to a web-based decision-making tool, referrals to a sexologist and physiotherapist
- Personal resources women used to find information: websites, research articles, support groups, experiences of others, a specialized boutique that provides postmastectomy clothing, and being accompanied by a friend of a family member who can help remember the information shared during appointments with health care providers.
- Support groups: support groups were found to provide helpful resources. However, most women were only informed of the existence of a support group after surgery.

Value of Experiential Information

In the focus groups, women were shown some relevant experiential videos that were published on our website (Canadian Health Experiences Research Network, 2021 [26]) to discuss the value of experiential information; women described experiencing a certain comfort from watching these videos (quote 1), an ability to learn from other experiences (quote 2), and how it may have influenced their decision making (quote 3):

> *It’s nice to see um I would have liked that, you know. To see some real-life women, you know, like really talking about it and saying something about it. It would have been comforting, you know, because sometimes you, you just don’t know. And by the time you get into these support groups you’ve already gone through a lot of the uh stuff, the surgery....* [Quote 1]

> *So a lot of my friends were telling me “Don’t worry, radiation it’s not bad you’re going to be fine.” But I would have liked to have maybe a buddy or a nurse*

> *or somebody who I'm looking for people who have had the same thing that I have. Because I wanted to know what was your experience? Did you have the same symptoms that I had?* [Quote 2]
>
> *But I think before I had my surgery when I was making decisions surgery or chemo and I saw, if I saw her video it might have really influenced that decision.* [Quote 3]

They further said that the videos might help women who are going through a similar experience so that they feel less alone. They also highlighted the fact that women in the videos described real issues (eg, sexuality or talking to children about their diagnosis) that were not always easily discussed.

The videos also raised concerns. One participant felt that video clips may also negatively influence decision making. Another concern was related to how users were to filter and validate this type of anecdotal information. Despite the two challenges raised within the group, participants agreed that there should be a place for these kinds of videos; the participants suggested that the project team should balance more provocative videos with other videos that present solutions or different experiences of similar situations.

Key Design Preferences

Focus group participants were asked to describe their preferences for a mobile app and were also asked to give their opinion to certain proposed features for the app (such as the possibility to take notes); a summary of this discussion can be found in Textbox 2.

Textbox 2. Key design features for the Health Experiences and Real Stories app as discussed in focus groups to inform the development of the app.

General feedback

- Availability of information that relates to user's own situation
- Offer a range of experiences and information
- Important to include different age groups, stages and severities of breast cancer, marital status, and whether they have children
- Include *how to* videos
- Information should help women to normalize their experiences and include the message that each experience is unique

Videos

- Personal features of speakers (eg, age, ethnic background, and educational level) not defining of the information
- Provide culturally sensitive information
- Don't overemphasize or profile certain personal attributes as videos with speakers with different characteristics may still be relevant for users with other characteristics
- Topics should be grouped according to stage and by topic including social impact
- Include information on choices for surgery and posttreatment experiences
- Include a wide variety of experiences

Language use

- Use language that can be understood

Resources

- Provide links to other resources
- Resources should be up to date and cover a wide range of information needs
- Ability to save the link.
- To increase awareness, multiple women suggested using social media outlets such as Facebook

Note-taking

- Could relieve some stress accompanied with getting information
- Helpful to prepare questions

Phase 2: Content Development

More than 175 illustrative clips, with original video, audio, and text clips from the interviews with a length of about 1-2 minutes, were extracted from the recordings of the 39 interviews with women with breast cancer (n=35) and DCIS (n=4). They were related to various topics of breast cancer surgery, including preparation for surgery, types of reconstruction, and body image. These serve as the content of the HERS app.

Topic List: Core Content

The thematic analysis of the interview data defined the core content for the app to be organized within 11 major topics and 23 subtopics (Multimedia Appendix 2). The creation of this framework was an iterative process and was discussed with an interdisciplinary team and advisors. An additional search filter was added for the treatment phase (before surgery, surgery, after surgery, reconstruction, and impact on life). The themes and filter enable the recommender system to provide tailored information. All clips were tagged with keywords from the subthemes and treatment phase in a database server. Clips with medical information were reviewed by our health care professional advisors, such as surgeons, oncologists, and radiotherapists. Clips with potentially distressing information or unusual experiential information were reviewed by a psychologist, a representative of a breast cancer organization, or women diagnosed with breast cancer. After review, a small number of clips were removed from the database to mitigate any potential misinterpretation and an explanatory text was added other clips. The clips were then prepared and uploaded for video storage on YouTube.

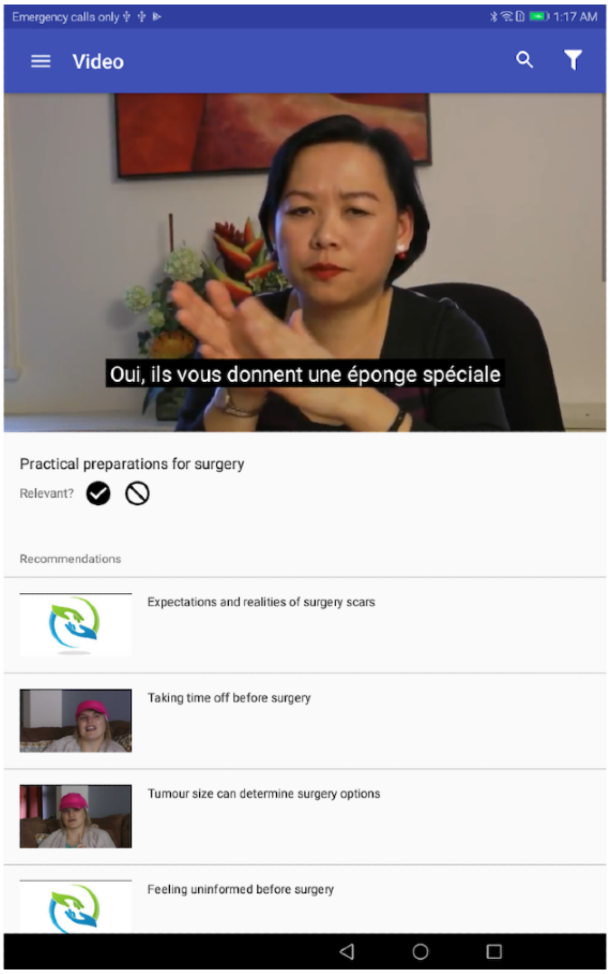
Preparation of an Introductory Instructional Video

Members of the project team used the app *Powtoon* to develop a short plain language introduction video, which was included in the app for users to review as a guide to the HERS app.

Phase 3: Technical Development of Mobile App, Recommender System, and Back End

The requirements and suggestions as described in the former two sections, together with the team's interpretation of the requirements of the app, supported the development of the HERS app (see Figure 2 for a sample screenshot of the app interface).

Figure 2. Sample screenshot of app interface.



Oui, ils vous donnent une éponge spéciale

Practical preparations for surgery

Recommendations

Expectations and realities of surgery scars

Taking time off before surgery

Tumour size can determine surgery options

Feeling uninformed before surgery

Multimedia Appendix 3 details the functionality of the app. As previously described, the ability of the app to provide tailored information was a key design consideration. This was achieved through the development of a recommendation engine.

The recommendation engine performs content-based matching by recommending videos of speakers with similar characteristics as the user (based on user profiles such as age, marital status, and profession) on topics selected by the user and through collaborative filtering (videos related to videos liked by the user and by *similar* users).

The following three key principles informed our approach to recommendations:

1. Make the most informed recommendations initially
2. Increasingly reduce designer bias and let users drive recommendations
3. Account for diversity in recommendations

As expected, in a user's very first session, little is known about what kinds of content the user is actually interested in. Nevertheless, we make informed *guesses* based on the user's demographic information as registered in the user's profile and match that against the speaker profile in the metadata of the videos. After at least one session, the app analyses the user's indication of topics of interest (either done explicitly in the preferences view or implicitly by marking one or more videos as *relevant*). In addition to making recommendations based on similarity matching between users and videos, the app also makes recommendations based on diversity. The idea is to help users discover interesting content even if their preference settings and usage history do not indicate that the content is relevant to them. Heuristics are used to select videos on the diversity criteria, for example, videos that are most marked as relevant by the community.

Phase 4: Exploring Preliminary Feedback From Potential Users

Feedback

The pilot app, containing a total of 175 clips extracted from interviews with 39 women, was tested by potential users (see Textbox 3 for more detailed feedback).

Textbox 3. Feedback on general aspects, videos, and resources of the Health Experiences and Real Stories app after testing the app.

General feedback

- The app could help process information received from doctor (not all information was retained from doctor's visits)
- The app could be so interesting that the user would stay too long—guide users to access videos step by step
- The app looked professional, was well organized, and was easy to navigate. Some technical problems with the app—in some instances, the app would freeze
- The tool could help women be better prepared for the next stage

Videos

- Liked speakers' personalities
- Presentation and tone were described as intelligent and nonpatronizing
- Appreciation of range of topics and realistic videos
- Liked the ability to choose own videos or skip videos
- Length was good (not too long)
- If videos felt short, participant liked that other videos were available or that they could replay videos
- Organization by topic was helpful
- One participant liked the *snippets* of information; it worked for her
- Information well balanced: not too happy nor too sad
- One participant described how she recognized the experiences of one speaker

Resources

- Resources were appreciated and perceived as trustworthy
- Good step-by-step process
- Professional outlook and quality of resources
- Information would have a relaxing and calming effect on women during diagnoses phase
- Add contact information and feature for asking questions
- Appreciation of combination of biomedical and experiential information

Survey Results

In total, 5 female participants were asked to complete the questionnaire twice: first after reading selected biomedical information resources that can be found on reliable websites and then after visiting the experiential section of the HERS information app (see Table 1 for the results). The results revealed that participants positively perceived the biomedical information, and the results were slightly better after viewing the app information, for example, they seemed to feel less overwhelmed with information. However, this is a very small sample, and further testing is required.

Table 1. Results from survey questions (N=5)[a].

Question	After reading biomedical information[b], median (range)	After reading app information[c], median (range)
1. I feel better informed after viewing the resources.	4 (3-5)	4 (4-5)
2.I had a lot of my questions answered by the resources or this app.	4 (3-5)	4 (4-4)
3.I better understand the information I need to prepare for the next steps in treatment or stages of the illness.	4 (3-4)	4 (4-4)
4.I was able to easily find the information I was looking for.	4 (3-5)	4 (4-5)
5.The resources made me feel less lonely or isolated.	4 (3-5)	4 (4-5)
6.If a friend or family member were in a similar position, would you recommend the resources or this app to her?	5 (3-5)	5 (4-5)
7. I have a better understanding of where to seek information about breast cancer and surgery.	4 (4-5)	4 (3-5)
8. Looking at the resources or site raised more questions for me than it answered.	3 (2-4)	2 (2-3)
9. There was so much information here, I felt overwhelmed.	3 (1-4)	2 (1-4)
10. It was difficult for me to relate to the information or the stories in this resource.	1 (1-3)	2 (1-2)
11. The information on this app will not help me feel more confident discussing my questions and concerns with my doctor(s).	1 (1-2)	1 (1-2)

[a] The questionnaire used a Likert scale of 1 to 5 for all questions except question 8 (1=strongly disagree; 2=disagree; 3=neither agree nor disagree; 4=agree; 5=strongly agree). For question 8, the responses represented the following: 1=definitely would not; 2=would not; 3=neither would nor would not; 4=would; and 5=definitely would.

[b] Total criteria satisfied (rated 4 or 5 for question 1 or 7 and rated 1 or 2 for question 8 or 11) was 9.

[c] Total criteria satisfied (rated 4 or 5 for question 1 or 7 and rated 1 or 2 for question 8 or 11) was 11.

Discussion

Principal Findings

This paper describes the development and piloting of a mobile app that provides tailored information for women, based on their preferences and needs, about others' experiences of breast surgery. This system draws upon an existing evidence-based data set of video narratives featuring Canadian women's experiences of breast surgery and uses advanced computing engineering and machine learning in the design of a recommendation algorithm to provide tailored information (similar to the popular Netflix platform). Our aim was to contribute to efforts that provide the right information at the right time and in the right format to help women manage information at a critical time in their care journey for breast cancer. In a preliminary pilot test, we found generally positive responses to questions regarding the content and value of this type of e-tool.

Our findings regarding women's information needs and their experiences related to missing relevant treatment information and information overload are consistent with the existing literature [29-31]. There is a need for the development and assessment of more interventions that help information seekers manage health information overload [3] and a need to develop information filters to help information seekers identify relevant web-based health information [5]. None of the identified articles in a recent systematic review on mobile apps for breast cancer care used a recommender system to generate tailored information and only three mentioned a feature with regard to tailoring information [12,13]. Although the use of recommender systems is still sparse in the health sector, it has the potential to contribute to tailored health interventions [32], and mobile apps for breast cancer could contribute to reducing information overload by offering tailored information and machine learning. This study contributes to the scarce existing knowledge related to evidence-based eHealth apps that are designed to provide information and support for women with breast cancer in addition to the novel application of a recommender system to do so. Scientific literature presenting narrative-based apps designed on the basis of rigorous research is virtually nonexistent, as per our preliminary review of the literature.

Considerations for Future Research

Research in the last decade has demonstrated the challenges of measuring the health effects associated with health information usage of information offered on the web or through web-based tools. These mechanisms are complex and interrelated with many factors. Tools, such as the one described in this paper, offer the potential to contribute to new knowledge and to a better understanding of information-seeking practices because of the ability to relate the user feedback on the videos (relevant or not) to the app usage as well as to the personal characteristics of the user, the speaker, and the content of the video. For example, the app makes it possible to better understand whether certain personal user characteristics, such as age, ethnic background, having children, marital status, and literacy level, influence one's preference for certain speakers with similar characteristics. In the future, it may also be possible to add other important characteristics that influence information needs [29], such as preexisting knowledge of the illness and preference for more basic or advanced illness information. A recently developed narrative taxonomy defines three different kinds of narratives: process, experience, and outcome narratives [33]. The authors argue that, for each type of app (information tool, decision aid, and behavior change information), different narrative types should be used. For example, for an information tool, creators should include narratives about a process or experience but exclude narratives focused on the outcome. Future research should aim to better understand the impact of different types of narratives on the effectiveness and uptake of particular mobile apps for health. Finally, it is important to further test the impact of the app on the users, for example, through a randomized controlled trial.

Our research group is part of a global network of researchers who conduct similar research in their respective countries. This app offers the possibility of expansion by including clips from international collections of breast cancer narratives or by creating similar tools that use scientifically gathered, personal experiences of a variety of health conditions. An international working group is currently formed with member countries of an international network for patients' experiences [34] for the application of the HERS app elsewhere.

In addition, it is important that the app also offers information that the user does not yet know that she needs to know (eg, information on lymphedema exercises and the need to consider fertility treatment). Research on how women can best be introduced to these subjects through the app would be important. For instance, should the recommender system continuously offer clips on these specific subjects or should women be made aware of them through other pathways? It would also be important to consider how other unexpected events or complications during treatment (such as drain tube removal or unclear margins) should be introduced without engendering unnecessary fear or anxiety.

Limitations

The limitations of this study are primarily related to the scale and the limited nature of the pilot study. We convened a small sample of breast cancer survivors to conduct a preliminary *test* of the functionality and user experience of the app. Admittedly, our targeted app users are women who are yet to undergo surgery. In this study, we chose to involve women who had already undergone surgery to provide retrospective insights into how this app would have helped them during their journey. The participants first accessed biomedical information and then experiential information; the order of this information may have influenced their responses to the survey. This would need to be explored in future trials of this product. Although the results were not intended to provide any statistical significance, we were encouraged by the favorable trends in their responses. We will now seek additional opportunities to expand the evaluation of the app to involve more women with breast cancer who are yet to undergo surgery, develop an iOS version of the app for Apple mobile devices, invite other health experience research groups using similar methods to test the addition of an expanded data set (video narratives gathered in other jurisdictions and on different health conditions), optimize the saturation of information within topics identified for this app, and consider a cloud-based deployment to eliminate the need to be bound to a specific server. The aim of our next phase of development will be to formally evaluate the utilization and impact of this eHealth tool on women's shared decision making and the perceived needs for information and support around the time of surgery in their breast cancer journey.

Conclusions

In this paper, we provide preliminary evidence for the feasibility and acceptability of an innovative eHealth app designed to tailor experiential information for women preparing for breast cancer surgery. The HERS app, based on a recommender system, is a unique attempt to ensure that women receive the right information at the right time in the right format; however, further testing is still required to measure the impact of the app.

We believe that these kinds of tools offer great potential to improve health information competence and reduce information overload, while ensuring that women receive timely, relevant information that meets their needs, and they complement more factual, biomedical information about their illness that they receive from their care team and other sources.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
System structure of breast cancer video service.
[DOCX File , 135 KB - formative_v5i6e22970_app1.docx]

Multimedia Appendix 2
Framework for coding and Health Experiences and Real Stories app.
[DOCX File , 14 KB - formative_v5i6e22970_app2.docx]

Multimedia Appendix 3
Description of app functions.
[DOCX File , 13 KB - formative_v5i6e22970_app3.docx]

Multimedia Appendix 4
Bringing Netflix technology to video narratives of experiences of breast surgery: helping women navigate the information tsunami.
[PPTX File , 2263 KB - formative_v5i6e22970_app4.pptx]

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Abbreviations

DCIS: ductal carcinoma in situ
HERS: Health Experiences and Real Stories
SMHC: Saint Mary’s Hospital Center

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Original Paper

Multicultural Adaptation of Mighty Girls for Widespread Dissemination: Pilot Study, App Development and Usability Testing, and Gauging Parent Support With Focus Groups

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Abstract

Background: Taking evidence-based interventions to scale is a challenge for prevention science. Mighty Girls is an evidence-based sexual health intervention program that combines classroom sessions with novel, cutting-edge technology (digital puppetry). The program was developed for 7th grade Latinas, but US school and community demographics rarely allow interventions targeting a single ethnic group. Additionally, digital puppetry is costly to scale up, and parent disapproval often prevents successful dissemination of adolescent sexual health programs. Intervening steps along the scaling-up pathway are needed to adapt the program prior to scaling up for dissemination.

Objective: The aims of this study were to create a multicultural adaptation of the Mighty Girls program using a mobile app that is less costly to disseminate and is acceptable to parents of 7th grade girls.

Methods: This study used a three-phase process to adapt Mighty Girls into Mighty Teens. All phases used purposive (nonprobability) sampling of low-income, multicultural, urban metropolitan groups (7th grade girls and their parents) within central Florida. Phase 1 involved two videotaped implementations of a multicultural adaptation of the classroom sessions, one involving focus groups (N=14) and the other serving as a single-group pretest-posttest pilot study (N=23). Phase 2 involved development of a narrative cell phone app prototype, which was subjected to usability testing (N=25). App usability and engagement were assessed qualitatively (observation, focus group, open-ended questions) and quantitatively. Phase 3 used focus groups to assess parent support for the program (N=6). Qualitative data were analyzed using descriptive content analysis. Quantitative data were analyzed using descriptive statistics and paired *t* tests.

Results: Qualitative findings supported classroom sessions being multicultural, and identified simple changes to improve engagement and learning. Quantitative findings from the second classroom session implementation pilot study indicated a significant pre-post difference in intention to delay sexual intercourse (P=.04). App usability and appeal were supported by a System Usability Scale score of 76 (exceeding 68 per the industry standard) and 83% (20/24) of participants agreeing they would recommend the app to friends. Parents (mothers) expressed only positive regard for program goals, and classroom session and app activities.

Conclusions: This study adapted Mighty Girls into an engaging, easier-to-disseminate, multicultural program, termed Mighty Teens, that uses a narrative-generating app to support behavior change, and is likely to be accepted by parents of 7th grade girls. This study also provides evidence of the preliminary effectiveness of Mighty Teens classroom sessions. The sampling method and sample size were appropriate for adaptation, but research involving a more representative US sample is needed to confirm multicultural fit, parent receptivity, and program effectiveness. Study implications include integrating app use throughout the classroom sessions to build narrative-generating skills across the program and increasing the number of narratives produced, which should in turn increase the program's behavior change potency.

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KEYWORDS

implementation science; mobile apps; peer influence; early intervention; adolescent health

Introduction

Taking evidence-based interventions to scale is a challenge for prevention science [1,2] because scaling up interventions for widespread dissemination is not always straightforward [3]. Scaling up is particularly challenging in sexual health interventions with traditional support from the literature focused on monocultural tailoring [4,5] and the focus of the US National Institutes of Health on innovation. Although these are certainly worthy goals, they are often at odds with achieving scale, particularly for school-based programs. Additionally, political and ideological issues, especially parent disapproval [6], can create barriers to dissemination [7,8]. Failure to consider these issues prior to scaling up for widespread dissemination can threaten the successful dissemination of evidence-based programs [9].

The purpose of this paper is to illustrate the steps taken to adapt Mighty Girls, an evidence-based sexual health intervention program [10], prior to scaling it up for widespread dissemination within US public school systems. Mighty Girl's program design is guided by a theoretical framework that integrates adolescent development theory [11], social cognitive theory [12], and narrative engagement theory [13]. The first two theories define program goals: delaying initiation of intercourse by building efficacy and skills in decision-making, goal-setting, risk evaluation, and resistance to peer pressure and media messages implying teen sex as a common behavior. By contrast, the narrative engagement theory defines the overarching program strategy: using narrative-generating activities to (a) build program skills, and (b) combine and imbed skill knowledge and program messages in memory. The resulting Mighty Girls program includes 6 classroom sessions and a computer game, DRAMA-RAMA, that generates a first-person narrative about responding to peer pressure in a simulated early adolescent world (Textbox 1).

Textbox 1. Mighty Girls program components and corresponding components in the Mighty Teens adaptation.

Sessions began with "Mighty Moments," a kinesthetic learning experience of relationally competent resistance communication skills developed by the second author. Session objectives are listed with the original (Mighty Girls) program session title. Objectives were retained in the adaptation with minor modifications.

Choices & Results (split into two sessions in Mighty Teens: Goals and Choices & Results)

- Identify personal goals (modified as "Goals" in Mighty Teens)
- Understand the results of everyday choices (modified as "Choices & Results" in Mighty Teens)
- Relate choices and results to goals (modified as "Choices & Results" in Mighty Teens)

What's Risky? (maintained as "What's Risky?" in Mighty Teens)

- Explain why some behaviors could be considered risky
- Identify potential results of choosing to engage in risky behaviors
- Discuss what increases or decreases the risk of a specific behavior
- Identify what behaviors are risky for oneself

The Avoid Skill (modified as "Avoid & Leave" in Mighty Teens)

- Define Avoid Skill
- List 3 methods for avoiding an uncomfortable or risky situation
- Avoid the Mighty Girls way: being considerate, confident, and convincing

The Refuse Skill (modified as "Refuse & Explain" in Mighty Teens)

- Explain differences between aggressive, passive, and assertive communication
- Demonstrate matching voice and body language using Refuse Skill
- Refuse the Mighty Girl way: being considerate, confident, and convincing

Media Influences (modified as "Challenging Media Messages" in Mighty Teens)

- Explain purpose of media
- Think critically about advertisements and TV show messages
- Identify positive and negative messages about girls and women in the media
- Identify ways in which teens on popular TV shows are different from and similar to teens in real life

Wrap-up & Review

- Model results–based choices
- Demonstrate Mighty communication: using considerate, confident, and convincing words and body language.

Tech Component to Support and Sustain Behavior Change (modified as a cell phone app in Mighty Teens)

- Digital puppetry computer game, DRAMA-RAMA

The Avoid Skill and The Refuse Skill sessions were adapted from "keepin' it REAL" [14]. Other sessions were cocreated by the first and second authors.

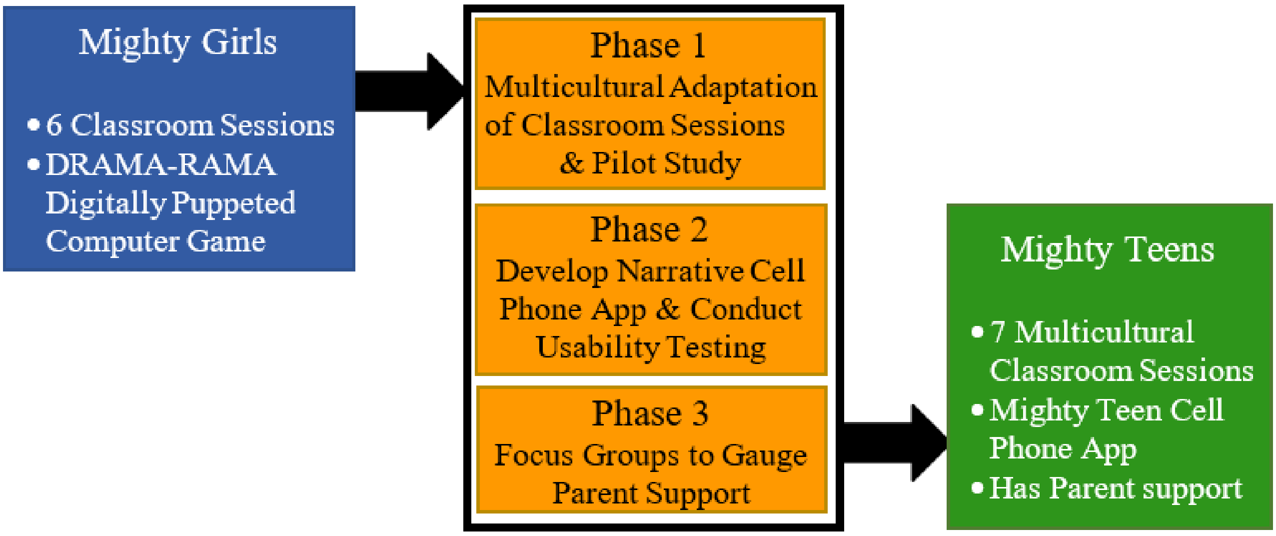
Mighty Girls has three features, which the nonadoption, abandonment, scale-up, spread, and sustainability (NASSS) framework identifies as likely to result in failure to scale up and disseminate [9]. First, the program was developed for Latinas. This monocultural focus is at odds with successful dissemination within US public school systems given US school and community demographics [15]. Additionally, research findings argue for greater effectiveness of multicultural, relative to monocultural, program interventions in general [16] and within US school settings in particular [17,18]. Second, DRAMA-RAMA relies on human-in-the-loop technology (digital puppetry) [10]. Advances in artificial intelligence are not yet sufficient to reduce this cost (current personnel and equipment costs estimated at US $20,000 per school), making the intervention not sustainable within US public school systems. An alternative, less costly narrative-generating technological component such as a smartphone app would address this sustainability barrier. Third, it is wise to gauge potential parent support for any school-based sexual health program [6], particularly one that uses a smartphone app [19], early in the scaling-up process when changes are easier to accommodate.

Methods

Overview

All three phases of program adaptation (Figure 1) used purposive [20] (nonprobability) sampling of groups living in a low-income, multicultural, urban metropolitan area within central Florida. Recruitment and study procedures were approved by the Prevention Strategies LLC Institutional Review Board and participating school district. Below, we present information specific to each phase, one phase at a time.

Figure 1. Adapting Mighty Girls into Mighty Teens, a more scalable and easier to disseminate program.



Phase 1: Multicultural Adaptation of Classroom Sessions and Pilot Study

Design

Phase 1 used an iterative process involving consultation and two implementations of the classroom sessions, with the second implementation serving as a pilot study. After each iteration, the classroom sessions were revised.

Three changes to program materials were made in preparation for phase 1. First, session slide sets were revised to ensure representation of a variety of cultural/ethnic groups. Second, content on narrative writing was added to the final “Wrap-up & Review” session. Third, ordering of the Avoid Skill and Refuse Skill sessions was reversed relative to their positioning in the original program. This last change was driven by insights from implementing the original program [10]. Both sessions were adapted from an efficacious, early-adolescent substance use prevention program, “keepin’ it REAL” [14], which stands for the relationally competent resistance communication skills Refuse, Explain, Avoid, and Leave. Only Refuse and Avoid were taught in Mighty Girls because formative work indicated that Explain could elicit more peer pressure by inviting peers to argue [21], and Leave could not be used in DRAMA-RAMA.

Consultation

Consultants included a female middle school staff member and three adult women in their early 20s (two African American women and one biracial African American/Native American woman). The latter were recruited as research assistants through Indeed, a worldwide employment website for job listings. These young women all lived in the same low-income, multicultural, urban metropolitan area in which the study was being performed. We specifically empowered them by emphasizing during recruitment and task directions that they brought a unique and valuable expertise critical to the success of the research effort (this message was repeated throughout phase 1 and phase 2 for all tasks involving these women). They were tasked with reviewing the Mighty Girls classroom session program manual and slide sets for language, terminology, and image inclusivity (ie, not heterosexist or specific to a particular ethnic group) and making recommendations.

Participants, Procedures, and Measures

Participants in both implementations were girls enrolled in the 7th grade (aged 11-14 years) at two multiethnic middle schools in an urban metropolitan area within central Florida. No participant had difficulty speaking, reading, or writing in English, and on average used only English, or English more than other languages, for these activities (ie, high level of acculturation). Participants of implementation 1 were recruited at a low-income (67% reduced/free lunch, in accordance with criteria to be designated as a “Title I” school: 65% of students/families qualify directly for supplemental nutrition assistance program, homeless, migrant, Medicaid, or foster care as verified by the state) middle school with 80% minority enrollment. Two girls dropped out after session 4 due to repeated disruptive behavioral issues. Participants of implementation 2 were recruited at a second low-income (52% reduced/free lunch) school with 69% minority enrollment (top 5% of state schools for enrollment diversity). Participants at both schools were recruited with: (1) flyers posted at the school; (2) a message sent out via phone by the principal to parents of 7th grade girls; and (3) the three research assistants discussing the study and handing out study packets during 7th grade lunch (packets contained the principal’s letter of support, parental consent forms, and screening form assessing parents’ culture/ethnicity and child’s English language fluency).

Each implementation involved a two-person multicultural teaching team consisting of either the first or third author in the teaching role and one of the three research assistants in the teaching assistant role (ie, Hispanic or non-Hispanic White teacher paired with African American or multiethnic [African American/Native American] teaching assistant). This team also acted as participant observers who made postsession notes about the session they had taught, identifying what worked and did not work, and providing feedback on the cultural relevance of the wording and examples used to explain concepts.

Teaching assistant role training involved completing session activities in the role of a participant, and provided an opportunity to try out a training approach that combined two 2-hour face-to-face sessions with a “homework” assignment similar to what might be used for training when the program is taken to scale. All three research assistants spontaneously reported how much they liked their training, particularly the “homework” (using communication techniques with friends and family).

Both implementations were videotaped. The first implementation involved postsession focus groups, and the second was a one-group, pretest-posttest pilot study (not powered for significance).

First Implementation

Participants at the first school completed a brief demographic questionnaire immediately prior to the first session that assessed age; birth country; race and ethnicity; acculturation (use of first language relative to English for those who spoke more than one language) [22,23]; and whether lunch was free, reduced in price, or full price.

Each Mighty Teens classroom session was delivered and then followed by a short focus group led by the teaching team. Focus group questions were displayed on slides. Participants wrote responses on large pieces of paper posted on walls or on anonymous index cards, depending on the question. They then voted (ie, agreed/disagreed) on themes identified in comments written publicly and anonymously, and responded to probes for more details or new thoughts emerging in response to other teens’ comments.

Second Implementation/Pilot Study

In lieu of focus groups, participants at the second school completed a paper-and-pencil pretest immediately prior to the first session (also containing the same demographic items used in the first implementation) and completed a posttest immediately after the last session. All measures had been pretested or used with this age group previously [10,24].

The pretest and posttest contained a short self-efficacy scale, along with items assessing resistance and sexual intentions, and intention to postpone sexual intercourse. The 9-item self-efficacy scale comprised 5 items from the 12-item measure reported by DiIorio et al [25] (eg, say “no” to sex even if the other person says they will break up with you if you don’t have sex) and 4 items created by the first author to assess self-efficacy regarding specific program resistance behaviors [10]. These 4 items were: (1) stop someone who is pressuring you to do sexual things without making them angry, (2) leave a party or dance club where sexual things are going on without being made fun of, (3) avoid situations where you know other people will be making out, and (4) say no in a serious way and stick to it when someone you like is pressuring you to do sexual things. Response options range from 1 to 4 with labels for endpoints and midpoints (1=not at all sure; 3=moderately sure; 5=completely sure). Higher scores indicate greater resistance self-efficacy. Cronbach α was .84.

All intention items used the same response options: definitely not (1), probably not (2), probably yes (3), and definitely yes (4). Higher scores indicate greater intention. Psychometric analysis argued for treating intention types as measures of separate constructs, not part of a single multi-item intentions scale. Resistance intentions were assessed by a question related to a particular response strategy when asked “to do something you do not want to do.” Response strategies included: not resisting (go along with what they want me to do), resisting by using relationally competent communication strategies (4 items, including suggest doing something else; α=.62), or resisting by using a nonrelationally competent strategy (tell them I don’t want to because it’s stupid). Kirby et al’s [26] 3-item sexual intention measure was used to assess willingness to engage in sexual intercourse (eg, I would have sex now to keep someone I cared about romantically as a boyfriend/girlfriend); Cronbach α was .79. Intention to postpone sexual intercourse was assessed with a single item: I want to wait to have sex until I am older.

Data Analysis

Demographic responses were summarized with descriptive statistics. A paired *t* test was used to assess pretest-posttest differences in self-efficacy, resistance and sexual intentions, and intention to postpone sexual intercourse (second implementation only).

The first and second authors reviewed classroom session videos (both implementations) for signs of engagement, restlessness, and confusion. Engagement was defined as girls raising their hands to participate, smiling, looking at the teaching team or slide presentation when not engaged in a task, working on tasks, or easily redirected from chatting with peer(s) back to the main discussion and remaining attentive. Restlessness was defined as fidgeting, repeatedly talking with peer(s) and not easily redirected back to the task, complaining about the activity, being bored, or not having fun. Confusion was defined as a facial expression in which the nose and forehead were scrunched up in a type of frown, or complaints about being confused or not understanding task directions.

The first author also reviewed and performed a descriptive content analysis [27] of the teaching team postsession notes (both implementations) and postsession focus group videos (implementation 1 only). Content (eg, sentence or section of notes; participant response or portion of response if expressing multiple ideas) was sorted into one of three categories: (1) liking or positive, (2) disliking or negative, and (3) confusing or not clear. Improvement suggestions noticed in this process were also marked. Next, information within categories and improvement suggestions were each reviewed for themes and multiple instances, summarized, and then discussed with the study team.

Phase 2: Development of a Narrative Cell Phone App and Usability Testing

Design

Phase 2 began with app development that culminated in usability testing. The app prototype was initially developed for Android phones given Pew Foundation reports [28] indicating greater Android use by low-income families living in the urban metropolitan area within central Florida in which this research was being performed. However, the next iteration of the app will be built for both Android and iPhone cell phones.

Two theories guided app development. First, the theory of fun [29] stresses the importance of engagement for app uptake, and defines engagement as the result of positive affect, fun, low predictability, novelty, and the right amount of challenge (not too little or too much) experienced while interacting with the app. Second, narrative engagement theory [13] stresses the centrality of engagement to behavior change. According to this theory, engagement mediates overall effectiveness of narrative creation, a phenomenon that builds self-efficacy through cognitive rehearsal [12] while simultaneously imbedding intervention messages (eg, concepts) in a narrative [13]. App use was planned for nonschool settings (eg, home, public library), necessitating a simple and intuitive interface. Additionally, the interface needed to guide users in creating their own “Mighty Teens” electronic story of resistance (similar to the events that occurred with DRAMA-RAMA in the Mighty Girls program). Stories were to be recorded, mirroring natural storytelling.

Both the app and a secure, password-protected dashboard (backend accessible to administration staff) were developed using a collaborative approach, involving the authors and Margaret Broucek, Principal of Tapp.technology who was a phase 2 technology partner (Textbox 2). Tapp.technology iteratively created screen designs in response to feedback from the authors and the three research assistants, arriving at the designs used to create the prototype for usability testing (Figure 2).

Textbox 2. Required prototype features and functionalities.

Mighty Teens app

- Intuitive interface with minimal text or direction
- Record oral story. Text input only required for naming story
- Present users with icons representing places, characters and their emotions, and Mighty Teens skills from which to select
- Provide users with button to click to access definitions of individual Mighty Teens skills
- Provide users with a button to click to record story while viewing selected icon places, people and their emotions, and Mighty Teens skills
- Allow users to listen to their story, and submit, rerecord, or delete it
- Send user stories using secure encrypted transmission to Mighty Teens dashboard

Mighty Teens Dashboard

- Secure, password-protected
- Allow direct entry and edit of information into sortable fields with controlled access to such privileges
- Usernames grouped by implementer and implementation school/clinic site
- Implementation school/clinic site with street, address, state, and zip code information, and grouped by organization
- Store usernames, app access codes, addresses, and story submissions
- Assign various levels of access to all stored information

Figure 2. Mighty Teens app prototype story-creating screen with pop-ups allowing selection of places, characters with as many emotions (represented as emoticons) as needed, and Mighty Teens skills.

What do you want to call your story?
Real Life

Participants and Procedures

Phase 1 participants were invited to participate in usability testing as part of their study participation. However, some were unable to attend due to transportation issues or schedule conflicts (eg, needed for sport team practice), resulting in a sample of 25 participants. Almost all participants (92%, 23/25) created and recorded at least one story. Two participants interacted with the app but did not record (or deleted recordings of) their stories. One of these participants did not want anyone to listen to her story. It is unclear if the other had difficulty with the recording feature or felt similarly. Although 25 girls participated in app testing, only 24 completed written assessments of usability and engagement.

Usability testing was performed at each school involved in phase 1 with hot spots, approximately 1 month apart. Participants accessed the app using either their own Android cell phone or a “testing” cell phone provided by the research team.

When participants arrived at their respective school, they were split into two groups with each group assigned to a different classroom. Once in their classroom, participants were split into dyads and a research team member was assigned to observe each dyad. Those that finished early were free to record additional stories. Research team members took ethnographic field notes describing participants’ verbal and nonverbal behaviors during app use, but were unable to see the participants’ screens unless shown to them. Research team members debriefed immediately after testing. Notes from this meeting became part of the ethnographic field notes.

After using the app, the girls completed written assessments of usability and engagement. Following this, a brief focus group discussion was held with the first or second author in the role of facilitator and a member of the research team in the role of cofacilitator/notetaker.

Measures

Quantitative Measures

Self-reported usability was assessed with an adaptation of the System Usability Scale [30] in which the word "system" was replaced with "app," and wordiness and reading level were reduced to make items more accessible to teens. For example, the original item "I think that I would like to use this system frequently" was revised to "I would use this app a lot." Response options (strongly disagree, disagree, neutral, agree, strongly agree) were unchanged.

Consistent with the original scoring process [30], responses were assigned a value of 0 (strongly disagree) to 4 (strongly agree) with even-numbered items reverse-scored, and scores were summed with the result multiplied by 2.5 to create a usability score ranging from 0 to 100. Cronbach α for the adapted measure was .80. Validity was supported by correlations with the app being interesting (r=0.60, P=.002), task difficulty (r=–0.44, P=.048), and flow (r=0.45, P=.03).

Usability was also assessed with an open-ended question asking what could be done to improve the app, and task difficulty was assessed with a closed-ended question: "It was hard to think of an idea to use for the Mighty Teens app." Response options were strongly disagree (1), disagree (2), agree (3), and strongly agree (4).

Self-reported engagement was measured with 6 items adapted from those used in DRAMA-RAMA development by replacing the word "game" with "app" and referring to writing stories instead of interacting with game characters [10]. A single item assessed whether the app was fun to use. A 5-item Likert scale consisted of the following items: three items describing the app experience (fun way to create a story, interesting, boring [recoded]), one item asking about using the app for a school assignment, and one item asking about recommending the app to friends. Response options ranged from strongly disagree (0) to strongly agree (3), without a neutral midpoint.

Qualitative Measures

Ethnographic field notes were used to assess usability and engagement presence and issues. Research team members were trained to collect these notes and used a checklist as a guide to verify that they had commented on all assessment domains. The checklist prompted assessment of (a) verbal and nonverbal signs of positive and negative affect, and (b) problems with usability indicated by participants having completed the storytelling task (eg, long delays, facial expressions of frustration, asking questions).

Focus group interviews consisted of open-ended questions that asked for general impressions, likes and dislikes, and recommendations for improvement. These questions were followed by requests for feedback on specific screens or parts of screens.

Data Analysis

Ethnographic field notes, focus group notes, and participant responses to the open-ended usability question were analyzed using descriptive content analysis [27], similar to phase 1. However, the first author sorted units into categories, and then identified and presented a summary of themes represented by these categories to the usability testing team, along with copies of the raw qualitative data. The summary was finalized in the resulting discussion.

Participant stories were coded for narrative structure and reference to Mighty Teens program skills using two dichotomous (0, 1) variables. Narrative structure was defined as three complete components (1). A reference to a Mighty Teens program skill (1) required the participant to describe a character correctly using (or teaching another character to use) at least one skill. It was not necessary to use the exact program name for the skill. However, not referencing a skill or naming one without any application were both coded as no reference (0). Interrater agreement was 100%.

Phase 3: Focus Groups to Gauge Parent Support

Participants, Procedures, and Measures

Mothers and fathers of 7th grade girls involved in the second implementation were invited to participate in a focus group (a) by flyers included in the study packets given out to their daughters, and (b) during the parental consent process for their daughters' participation. No fathers expressed interest in participating or were involved in the consenting process.

Scheduling of focus group participation coincided with the first national lockdown in response to the COVID-19 pandemic. Parents were distracted, under distress, with other activities competing for their attention, complicating consenting and scheduling (eg, parents who had previously expressed interest did not return phone calls). Scheduling and COVID-19 accommodations resulted in two focus groups involving 6 mothers as participants.

Focus groups were conducted using Zoom conference technology, which was challenging because the participants seemed unfamiliar with Zoom and video conferences in general. However, the facilitator (second author) was able to assist by phone, and familiarize participants with the process and importance of confidentiality and privacy once they opened Zoom.

Focus group interviews consisted of open-ended questions about (1) what the parents had heard about Mighty Teen classroom sessions or the app from their daughters, and (2) the parents' feelings about and challenges related to their daughters' use of apps and cell phones. Information about classroom session topics and activities, and about the app was provided once parents shared what they had heard. Feedback was then solicited, followed by specific probing related to their daughters' use of the app, her doing so privately, and supervision preferences and concerns.

Data Analysis

Descriptive statistics are used to summarize the mothers' ethnicities. Focus group recordings were transcribed verbatim and analyzed using descriptive content analysis [27], similar to phases 1 and 2. However, the first and second authors independently sorted units into positive/negative categories and summarized themes within the categories. No differences in categorization or meaning of theme labels were noted.

Results

Participant Characteristics

Participant demographic characteristics for all three study phases are provided in Table 1.

Table 1. Demographic characteristics of participants by study phase.

Characteristic	Phase 1: Implementation		Phase 2: Usability testing (N=25)	Phase 3: Parent focus groups (N=6)
	1 (n=14)	2 (n=23)		
Age (years), median (range)	13 (12-14)	13 (11-14)	13 (11-14)	—[a]
Qualifies for reduced/free lunch, n (%)	11 (85)	16 (70)	19 (76)	N/A[b]
Cultural/ethnic group, n (%)				
African American	5 (36)	5 (22)	8 (32)	2 (33)[c]
Arab American	0 (0)	1 (4)	1 (4)	0 (0)
Bahamian/Black Caribbean	2 (14)	2 (9)	2 (8)	1 (17)[c]
Haitian	0 (0)	4 (17)	3 (12)	1 (17)[c]
Hispanic/Latino	4 (29)	5 (22)	5 (20)	1 (17)[d]
Indo-American	1 (7)	1 (4)	1 (4)	0 (0)
Non-Hispanic White	1 (7)	2 (9)	2 (8)	1 (17)[d]
Multicultural (African American and Haitian; African American and Hispanic/Latino; Navajo and Non-Hispanic White; Bahamian and Haitian)	1 (7)	3 (13)	3 (12)	0 (0)
US (mainland)-born, n (%)	11 (79)	20 (87)	21 (85%)	—
High level of acculturation, n (%)	12 (86)	20 (87)	22 (88%)	—

[a] Data not collected.

[b] N/A: not applicable.

[c] Part of same focus group.

[d] Part of same focus group.

Phase 1: Multicultural Adaptation of Classroom Sessions

Consultation

The consultants recommended taking more time in session 1 to explain the program, and making two changes to increase program language inclusivity: (1) replace "girls" with "teens" (including in the program title); and (2) use nongender-specific names and pronouns to avoid gender identity and sexual orientation biases. These changes were recommended to make teens feel included regardless of gender identity or sexual orientation. The only exception was in the Media Influences session, where the focus on how girls and women are depicted in advertisements was viewed as valuable. The three young adult consultants also reported (without prompting) how much they liked the program and wished it had been offered to them when they were in middle school, lending support for its multicultural potential.

Implementations

Overview

Review of classroom session videos and teaching impression notes from both implementations failed to identify instances indicating a lack of multiculturalism in terminology or directions, including those related to resisting peer pressure. For example, expressions of confusion tended to be made by multiple teens who were not more likely to be of a particular cultural/ethnic group than other participants. Moreover, the teaching teams of implementations 1 and 2 failed to report any instances of program content, directions, or examples feeling "off," "needing to be translated," and similar. Below, we discuss the implementation-specific findings.

First Implementation

Analyses of focus group and classroom session videos, and teaching impression notes identified two pedagogical issues and one opportunity to fine-tune the content. First, participants appeared to be confused when identifying goals in session 1, indicating that more time was needed for teaching this content, resulting in the decision to split this session in two, with the first objective retained in the new Goals session and the remaining two objectives addressed in the new Choices & Results session (Textbox 1). Second, fidgeting and restlessness were noted during the session 3 content when the resistant communication skill Refuse was presented, indicating a need for physically active learning (eg, having the class stand and share in acting out the Refuse skill). Aside from these issues, all other disengagements could be linked to one or two participants with a preexisting peer conflict documented in teaching impression notes. Third, review of Refuse and Avoid session videos led to a discussion with the teaching team that resulted in (a) adding a clear definition of Explain, but restricting it to a type of vague explanation that is difficult for peers to argue with (eg, "I'm not into that"); and (b) defining Leave as a response that can be combined with Refuse, Explain, or Avoid. In the original program, this content has been presented more as a type of Refuse or Avoid skill but with little emphasis. As a result of this change, session objectives were slightly modified to include defining and applying Explain and Leave, respectively, and session titles were modified to "Refuse & Explain" and "Avoid & Leave."

Second Implementation and Pilot Study

The teaching team reported that splitting session 1 into two different sessions increased class discussion time and allowed for the goal content to be covered more slowly, improving participants' grasp of this content. Review of videos indicated that any confusion initially present declined over the period in which the goal content was presented. Similarly, fidgeting and restlessness during the Refuse skill content presentation appeared to be eliminated by increasing the physical learning of this skill. Nevertheless, the teaching team reported that, overall, it was difficult to deliver all content within 45 minutes and still have sufficient time for discussion. This was particularly true for sessions 4 and 5, which had been revised to include content on Explain and Leave, respectively, and also for session 7 to which content on narrative writing had been added. In other words, all three sessions need to be revisited to streamline/reduce their content.

Engagement was evident across all sessions. Any disengagement could again be linked to a preexisting peer conflict noted in the teaching impression notes.

Quantitative analyses identified a significant pre-post increase in intention to delay sexual intercourse (t_{14}=–2.26, *P*=.04). No significant pre-post increases in resistance self-efficacy (*P*=.71) or resistance intentions (*P*≥.30), or decreases in sexual intentions (*P*≥.17) were observed.

Phase 2: Narrative Cell Phone App Usability Testing

Qualitative and Quantitative Measures

We could not detect any substantive differences between the results obtained for the two usability testing sessions. Hence, results presented herein are combined across sessions. The observed time to complete a task ranged from 6.30 to 13 minutes (median 6.67). The prototype did not track the time spent between opening the app and submitting a story, and teens were offered the opportunity to record their stories outside if they did not want to be overheard. Hence, the observed time to complete a task may be confounded with the time spent visiting with friends, a behavior observed at the same time the recording was presumed to be occurring, arguing for it being a "high-end" estimate of the actual time required.

Only 24% (6/25) of the participants created a story with a beginning, middle, and end, and less than half of the participants (44%, 11/25) created a story in which Mighty Teens skills were used. The stories reflected both same and opposite sex orientations, consistent with the tailoring expected in self-generated narratives.

Usability

The System Usability Scale score was 76 despite 55% (12/22) of the participants agreeing that it was hard to think of an idea to use for the Mighty Teens app. Content analysis of open-ended question responses and focus group notes indicated that about half of the participants wanted the app to have a tutorial, more directions, or prompts, whereas about half felt that it was "simple," "easy," or "very straightforward."

Analysis of ethnographic field notes described some participants as frowning and stopping, as if concentrating, and others clearly stuck at the initial step of identifying a title until told they could use "My Story" as the title if they wanted to. Regardless, these participants quickly transitioned to a rush of tapping and swiping with brighter affect, and focus group notes indicated that all but one participant (disgruntled by a preexisting peer conflict) were pleased with their experience. Nevertheless, many did not like how their recorded voice sounded.

Slightly more than a third (9/24, 38%) of the participants stated in their written responses to the usability open-ended question that there was nothing needed to improve the app (eg, "no," "nope," "nothing"). Less than half (11/24, 46%) made one or more comments concerning actual or desired app features, and 17% (4/24) made no comments.

Descriptive content analysis of responses to the usability open-ended question ethnographic field notes or focus group notes identified ways to improve usability (Textbox 3). Triangulation of these data sources indicated that a majority of participants (80%, 20/25) were frustrated or disappointed that they could not type their story. In contrast, 20% (5/25) expressed joy and astonishment that they could record (they had expected text entry) and had quickly begun using the app with gusto. However, this latter group agreed in the focus groups that text entry would be useful if a teen was concerned about being overheard, or was mute or stuttered.

Four unsubmitted stories were found in the testing phones after the session supported participants' suggestion to add confirmation of a successful story submission. Additionally, the focus group discussion helped clarify other usability improvements. For example, all participants wanted the character set to be more representative but some also felt that the numbers of icons in the current character set was overwhelming, arguing for customizing over expanding the existing set.

Similarly, the importance of adding an “other” category for character emotions was emphasized by comments indicating that participants considered qualities such as courageous, shy, and determined to be emotions. In contrast, comments regarding places suggested adding both icons (eg, corner store, fast food place, “jumping place” [a place for teen parties with trampolines]) and an “other” option to accommodate places that might be more regional or seasonal (eg, pool, beach).

Textbox 3. App improvement categories and themes identified in descriptive content analysis.

Usability improvement categories and themes

- Allow both recording and text entry of stories.
- Label emoticons (cannot tell what some of the faces mean).
- Improve ability to select story elements:
  - Allow multiple selections without exiting and reentering screen.
  - Increase differentiation between skill versus skill definition selection (add a question mark for definition).
- Improve ability to delete characters.
- Make “controls” (pause, record, submit) on recording screen clear.
- Confirm story submission, so you know it worked.
- Increase choices and/or allow more customization:
  - Current character set not sufficiently representative (nobody looked like me).
  - Add selection of various different intensities of particular emotions (eg, a little angry, extremely angry).
  - Add more places.
  - Add “other” option for emotions and places similar to what is available for characters.
- Change to blue and red colors if app to be used by both boys and girls at some point; current colors are “girly.”

Engagement improvement categories and themes

- Make possible to anonymously share and chat about stories to help other teens or obtain feedback on how story creator responded (or could have responded) to a particular situation.
- Increase the fun:
  - Add emoticons floating across login page.
  - Have app “read back” in a male or female voice, according to user’s choice.
  - Animate stories (have characters act out story).

Engagement

Descriptive content analysis indicated smiling, intense focus, and constant interaction with the app for 23 out of 25 (92%) participants with these same participants asking if they could use the app to make multiple stories. At least 4 out of 23 (17%) participants who requested this option did so in the time available with one participant creating 4 stories.

The word “fun” was used multiple times in all focus groups to describe the app; 83% (20/24) of participants reported they would recommend the app to their friends. Mean Fun and Like scores were 3.0 (SD 0.75) and 3.2 (SD 0.60), respectively, indicating that the participants agreed that the was app fun and liked using it. Additionally, both ethnographic and focus group notes indicated that participants found selecting icons for characters, character emotions, and places very appealing. Selecting emotions was stated as a “favorite part.”

Analysis of open-ended question and focus group data identified changes that could increase engagement (Textbox 3). One such change (sharing and chatting about stories with other teens) appeared part of a larger theme of wanting the app to have a purpose; otherwise, “why should we use it?”

Phase 3: Focus Groups Gauging Parent Support

Descriptive content analysis of focus group transcripts indicated no obvious group differences, and no ethnic or racial differences. Hence, results for each group are combined with participants referred to as mothers because no fathers participated (Table 2). There were no negative comments about any aspect of the program.

Table 2. Themes identified in parent focus groups.

Theme	Exemplar quote[a]
Mothers liked program goals and content	"…she [referring to daughter] was just saying, 'You got to be careful when you're on social media, because you don't know who you're talk to who they are.'…I was Okay, she must have mentioned it because of the session…now they're having a session and all of a sudden, they know what to do so, that I did appreciate."
Mothers liked the Mighty Teens app	"What I find different about yours versus the others is that she can either make up a story or use her own story…The other thing that I find that your app is interesting about is the fact that it brings in emotions, which I don't think the others do that. I like the emotional aspect of your app."
Mothers want Mighty Teens app use monitored	"Sometimes they're not willing to talk about it themselves,…if they shared something like that in a story, then it may put up a red flag: 'Hey, this person needs help.'"
Sharing is a benefit to daughter and other teens	"I think if it's in a controlled environment, as far as your company or whomever, I think that will be something that is great for the kids to share whether it's a fictitious or whether it's a true story…to kind of make awareness to other children…"

[a] Each exemplar quote is from a different focus group participant. Participant race or ethnicity is not reported to protect confidentiality.

Discussion

Scaling up culturally tailored sexual health interventions can be challenging and not always straightforward [3]. This study addressed three barriers that the NASSS framework [9] argued would impede successfully scaling up and disseminating the Mighty Girls program: lack of multiculturalism, cost, and parent receptivity. Phase 1 used an iterative process involving consultation, focus groups, and pretest-posttest evaluation to produce a multicultural adaptation of the classroom sessions and a new program name, Mighty Teens. The iterative process increased program language inclusivity with respect to gender identity, sexual orientation, and culture/ethnicity, consistent with best practices for creating multicultural programs [16]. Phase 1 also provided preliminary support for efficacy of the multicultural Mighty Teens classroom sessions.

Phase 2 used a combination of qualitative and quantitative methods to evaluate app usability and engagement potential. The usability score (76) exceeded the minimum industry standard (68) for minimum or average usability [31]. Additionally, the app enabled users to self-tailor their narratives to the level of sexual orientation, which was not possible using the original program's technical component. The app is less costly to disseminate than the Mighty Girls DRAMA-RAMA game, and potentially more powerful, because it affords a greater level of tailoring [13].

Finally, phase 3 parent focus groups demonstrated not only parent receptivity but also positive regard for the Mighty Teens program. This argues for the program's ability to surmount the political and ideological issues surrounding sex education that typically impede sexual health program dissemination and uptake [6-8].

Looking across the findings from all three phases of this study, two themes stand out. First, the study findings suggest that Mighty Teens has high engagement potential. This argues for program success and impact because engagement predicts program participation [32], learning [33], and behavior change [13]. Second, both mothers and daughters liked and valued a narrative-generating app that allows teens to (a) select emotions for characters in a story and (b) share their stories with peers in a monitored environment. Although it is unclear if fathers would feel similarly, mother-daughter agreement suggests parents would support their daughters' app use in the home environment. This conclusion is also consistent with the technology acceptance model's premise that user value for particular app functionalities is critical to app acceptance and uptake [34].

This study did have limitations. Participants were purposively selected to represent various cultural and ethnic groups living within a low-income, urban metropolitan area within central Florida, and sample sizes were small, preventing us from statistical evaluation of possible cultural or ethnic differences. All parent focus group participants had previously consented to their daughters' participation in a sexual health program, and may have been more likely to approve of sex education in general, as well as this program. Further, only mothers participated in the parent focus groups. However, research shows that fathers often defer to mothers when it comes to their daughters' sexual health [35], and our sampling methods were suitable for adaptation purposes. Nevertheless, more cultural/ethnic differences might emerge in larger samples. Hence, we will evaluate both multicultural fit and parent receptivity in a future efficacy trial involving a more representative US sample.

Despite these limitations, this study illustrates how program developers can adapt a program prior to scaling up for dissemination so that clear barriers to implementation by targeted user organizations (ie, public schools) are addressed. Our three-phase approach models the use of specific guidelines and best practices for creating cultural [36] and multicultural adaptations [16] of evidence-based preventive interventions. For example, we involved a multicultural team of consultants (school counselor and three young adult women) familiar with and representative of a multicultural community. Our three young adult women were all intimately involved with the process of adapting the intervention in phases 1 and 2 in their roles as research assistants, and were empowered to shape this process. Our pilot study, usability testing, and parent focus groups provided data regarding intervention acceptability and efficacy as well as feasibility. Moreover, the empowered role of our research assistants illustrates how to extend the principle of coproduction of public health interventions from intervention development to adaptation of an existing evidence-based intervention [37].

Additionally, the study findings provide clear directions for three app-related program improvements. First, there are clearly two different teen subgroups that need to be accommodated: those that prefer to record a story and those that prefer to use text. Second, story creation can be a difficult task for this age group. More support for structuring stories, including a prompt to use a Mighty Teens skill, needs to be designed into the app. Our findings suggest that either narrative writing is not consistently taught in 7th grade, despite being part of the US 7th grade common core standards [38], or, if it is taught, the content and related skills can be challenging for early adolescents to master. The ability of a sexual health program to support learning of an academic skill should increase the program's appeal to parents and public schools, thereby facilitating dissemination [6]. Third, the app should be introduced earlier and used to build narrative-generating skills over the course of the program, opening up possibilities for classroom activities to move into the app, and creating more time for class discussion. This change also enhances relevance and synergy between the app and classroom session activities, and increases the number of narratives participants create. Meanwhile, increasing the number of narratives increases Mighty Teens behavior change potency [13].

In conclusion, this paper describes a three-phase process for adapting an evidence-based monocultural sexual health program to increase the ease and success of scaling up and dissemination. Specifically, this process (a) created a multicultural version of the classroom sessions (phase 1); (b) replaced a costly technological component with a less costly easier-to-disseminate narrative-generating cell phone app (phase 2); and (c) obtained preliminary parent support for the adaptation, including their child's use of the program's app component (phase 3). Findings generated by this process provide preliminary support for Mighty Teens program efficacy, and insights for increasing program engagement, potency, and perceived value.

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Conflicts of Interest

MLH is President of REAL Prevention LLC, owns the intellectual property rights to the intervention, and will market it in the future. AEN and RDT are former employees of REAL Prevention LLC. Commercialization of Mighty Teens and its derivatives results in shared revenues involving REAL Prevention LLC, RDT, and AEN.

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Abbreviations

NASSS: nonadoption, abandonment, scale-up, spread, and sustainability

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Original Paper

Testing the Feasibility of Sensor-Based Home Health Monitoring (TEC4Home) to Support the Convalescence of Patients With Heart Failure: Pre–Post Study

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Abstract

Background: Patients with heart failure (HF) can be affected by disabling symptoms and low quality of life. Furthermore, they may frequently need to visit the emergency department or be hospitalized due to their condition deteriorating. Home telemonitoring can play a role in tracking symptoms, reducing hospital visits, and improving quality of life.

Objective: Our objective was to conduct a feasibility study of a home health monitoring (HHM) solution for patients with HF in British Columbia, Canada, to prepare for conducting a randomized controlled trial.

Methods: Patients with HF were recruited from 3 urban hospitals and provided with HHM technology for 60 days of monitoring postdischarge. Participants were asked to monitor their weight, blood pressure, and heart rate and to answer symptomology questions via Bluetooth sensors and a tablet computer each day. A monitoring nurse received this data and monitored the patient's condition. In our evaluation, the primary outcome was the combination of unscheduled emergency department revisits of discharged participants or death within 90 days. Secondary outcomes included 90-day hospital readmissions, patient quality of life (as measured by Veterans Rand 12-Item Health Survey and Kansas City Cardiomyopathy Scale), self-efficacy (as measured by European Heart Failure Self-Care Behaviour Scale 9), end-user experience, and health system cost-effectiveness including cost reduction and hospital bed capacity. In this feasibility study, we also tested the recruitment strategy, clinical protocols, evaluation framework, and data collection methods.

Results: Seventy participants were enrolled into this trial. Participant engagement to monitoring was measured at 94% (N=70; ie, data submitted 56/60 days on average). Our evaluation framework allowed us to collect sound data, which also showed encouraging trends: a 79% reduction of emergency department revisits post monitoring, an 87% reduction in hospital readmissions, and a 60% reduction in the median hospital length of stay (n=36). Cost of hospitalization for participants decreased by 71%, and emergency department visit costs decreased by 58% (n=30). Overall health system costs for our participants showed a 56%

reduction post monitoring (n=30). HF-specific quality of life (Kansas City Cardiomyopathy Scale) scores showed a significant increase of 101% (n=35) post monitoring ($P<.001$). General quality of life (Veterans Rand 12-Item Health Survey) improved by 19% (n=35) on the mental component score ($P<.001$) and 19% (n=35) on the physical component score ($P=.02$). Self-efficacy improved by 6% (n=35). Interviews with participants revealed that they were satisfied overall with the monitoring program and its usability, and participants reported being more engaged, educated, and involved in their self-management.

Conclusions: Results from this small-sample feasibility study suggested that our HHM intervention can be beneficial in supporting patients post discharge. Additionally, key insights from the trial allowed us to refine our methods and procedures, such as shifting our recruitment methods to in-patient wards and increasing our scope of data collection. Although these findings are promising, a more rigorous trial design is required to test the true efficacy of the intervention. The results from this feasibility trial will inform our next step as we proceed with a randomized controlled trial across British Columbia.

Trial Registration: ClinicalTrials.gov NCT03439384; https://clinicaltrials.gov/ct2/show/NCT03439384

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KEYWORDS

telemonitoring; heart failure; home health monitoring; technology; telehealth; emergency care; community care; emergency department; quality of life; self-efficacy

Introduction

Heart failure (HF) is common, life-limiting, and the leading cause of hospitalization in North America and Europe [1]. Patients with HF are affected by debilitating symptoms and impaired quality of life. The median survival after hospitalization is 2.5 years, while rehospitalization rates exceed 20% at 30 days [1]. Telemonitoring has been proposed to support patients with HF in the community. Clinical studies to date have demonstrated promising but inconsistent evidence for this strategy. A recent meta-analysis of 17 studies of telemonitoring found mixed results with benefits reported in some areas and no significant change in others [2]. Two large randomized controlled trials (RCTs) failed to find a reduction in death or hospitalization [3,4]. These studies did not examine issues such as patients' level of familiarity and adoption of these technologies [3], or integration of technology-enabled monitoring in the context of convalescent care [4]. The Telemedical Interventional Management in Heart Failure II (TIM-HF2) trial demonstrated significant reductions in all-cause mortality and days lost due to unplanned cardiovascular hospitalization 1 year after monitoring [4]. Further, a meta-analysis concluded that a subpopulation of patients with HF recently discharged from hospital within 28 days of admission benefited preferentially from home telemonitoring and showed reduced mortality and all-cause hospitalizations [5]. Further trials of home telemonitoring for patients with HF are required to clarify these findings and their underlying factors.

Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring (TEC4Home) is a 4-year research initiative to evaluate the efficacy of home health monitoring (HHM) as an integrated component of health care delivery to support the transition of patients with HF from hospital to home. The initiative consists of a feasibility study followed by a pragmatic, multicenter, RCT [6]. The purpose of this paper is to report the results of the feasibility study conducted in preparation for the RCT, to test the clinical and technical monitoring protocols in hospital and community settings, and to refine the evaluation framework. We hypothesized that the study procedures would be acceptable to both patients and providers; that the evaluation framework would capture useful metrics for outcome evaluation; and that the results would suggest a trend toward decreasing 90-day emergency department (ED) revisits and hospital admission rates, enhancing quality of life, improving self-efficacy, and reducing health care costs for patients and the health care system.

Methods

Recruitment Procedures

The feasibility study was an unblinded trial. Participants were prospectively recruited from EDs and inpatient units at 3 large urban hospital sites in British Columbia from November 2016 to July 2017. As this study was designed to assess the feasibility of the study protocol and refine procedures with a purposive sample gleaned from the feasibility study sites, no power calculation was conducted. Rather, the sample size was estimated from the recruitable number of patients with HF presenting at the ED sites based on administrative data with HF diagnosis and factoring in estimation of eligibility and attrition rates.

The inclusion criteria were as follows: one or more typical clinical HF symptoms; one or more typical clinical HF signs; one or more objective measures of HF, such as brain natriuretic peptide elevation or chest x-ray findings; currently receiving diuretic therapy; and age of 19 years or above. The exclusion criteria were as follows: inability to complete study procedures; no access to a reliable phone for communicating with a nurse; coronary or structural heart intervention during admission that would alter the course of HF convalescence with medical therapies alone; patients not expecting to present back to hospital for further deterioration, such as those wanting to die at home (see Multimedia Appendix 1 for the patient participant eligibility criteria of the feasibility).

Potential participants were first identified via referrals from hospital ED staff and screening hospital ED lists. Throughout recruitment, the study team expanded referral streams to include hospital in-patient wards to increase recruitment numbers. Eligible patients were contacted in the hospital when possible or immediately after discharge. Participants completed the consent process and were enrolled within 7 days from hospital discharge.

This study obtained ethics and associated approvals (no. H16-01076) from the regions where the 3 hospitals operate: University of British Columbia (UBC), Vancouver Coastal Health, and Interior Health Authorities.

HHM Intervention

The HHM device kits were provided by TELUS Health (technology partner). The kit included a touch screen tablet computer and Bluetooth-connected sensors that included a blood pressure cuff, a pulse oximeter, and a weighing scale. Upon enrollment and after patients returned home, monitoring nurses aimed to contact all participants within 1-3 days by telephone. Nurses trained to provide monitoring during the study period were seconded from cardiac clinics and had extensive experience managing patients with HF. During the first call, the nurse confirmed eligibility and scheduled the delivery of the HHM device kit. Kits were provided free of charge for 60 days and were delivered and set up in participants' homes by a technician. The protocol sought to have kits delivered within 7 days of discharge from the hospital; however, this varied depending on the individual patient's scheduling preference.

Participants were taught how to use the device kit by the technicians at the time of delivery and were observed submitting their first set of biometric measurements (ie, blood pressure, oxygen saturation, pulse, and weight) and answering 10-12 yes-or-no questions regarding symptoms (eg, "I feel more short of breath today") in the technician's presence. Participants were then asked to continue daily submissions of 1 set of this data per day for the next 60 days. The monitoring nurse sent an enrollment letter to the participant's primary care provider (PCP) and other health care team members (eg, specialists), if appropriate, to notify them of their patients' participation in the monitoring program and research study. PCPs or specialists were also asked to review and change the default monitoring limits of the patients (eg, blood pressure, heart rate limits, or oxygen saturation levels) to customize to patients' needs if required. Dry target weight was also requested if known.

Monitoring data were reviewed by a single monitoring nurse Monday through Friday between 8:00 AM and 4:00 PM (excluding statutory holidays) via a web-based dashboard. The primary monitoring nurse performing the monitoring was a cardiac specialty nurse with over 20 years of experience working in cardiac care settings, such as a heart function clinic.

The platform listed and flagged patient measurements falling outside of predefined default (or customized) values (eg, weight gain of more than 5 lbs in 2 days), changes in symptoms, or missed data submissions. Alerts were flagged as red/severe (eg, systolic blood pressure < 85 mm Hg or >160 mm Hg) or yellow/caution (eg, systolic blood pressure 85-89 mm Hg or 141-160 mm Hg). The monitoring nurse followed up by telephone with the participants on all concerning flags and alerts. The monitoring nurse was authorized to advise the patient on better managing their condition and to provide education on management of the patient's condition. For medication changes, the monitoring nurse would connect with the most responsible physician (eg, PCP) of the patient to facilitate these changes. In addition, the monitoring nurse would connect with other specialists with whom the patient was attached, if needed. For urgent situations, such as severe shortness of breath, the monitoring nurse was advised to direct the patient to their closest urgent care center or to call 911. Interventions that resulted from consultations between patients and monitoring nurses were documented in monitoring nurses' notes, and summaries were shared via fax with the participants' PCP every 2 weeks or as needed. The nurse also provided HF self-management education including advance care planning discussions to participants over the telephone, referring to a binder of HF self-management materials provided to participants upon enrollment into the study. Participants were discharged from the monitoring program after 60 days with a final report summarizing the monitoring data sent to the PCP. Participants were contacted again 30 days after discharge from the HHM program by telephone to complete a follow-up survey and to obtain their feedback on the HHM monitoring program.

Primary and Secondary Outcomes

Key metrics were drawn from the Triple Aim Plus framework [7], and both quantitative and qualitative data were collected from patient participants, participants' PCPs, and the monitoring nurses. The primary outcome was the combination of unscheduled ED revisits in discharged participants within 90 days of discharge or all-cause death. Secondary outcomes included hospital readmission, patient participant health status (eg, quality of life, self-efficacy), end-user experience, and health system cost-effectiveness (including cost reduction and hospital bed capacity).

Data Collection

Patient Participant Experience and Outcomes

Administrative data and data regarding patient participant experience and 90-day outcomes were collected via presurveys (at the time of consent) and postsurveys (30 days after monitoring discharge), with participants serving as their own controls.

Participants completed presurveys at enrollment and postsurveys from home via mail or over the telephone. The surveys, as outlined below, comprised multiple validated scales to assess pre-to-post changes in quality of life, self-efficacy, and health care utilization.

The Veterans Rand 12-Item Health Survey (VR-12) was included to measure health-related quality of life (general) [8,9]. The scale assesses 8 domains of health to produce a physical component and a mental component score.

The Kansas City Cardiomyopathy Scale (KCCQ-12) measures HF-specific quality of life [10]. The shortened 12-item scale assesses "patient-reported symptoms, function and quality of life for patients with heart failure." Agreement between the KCCQ-12 and the full KCCQ 23-item scale, which it is derived from, has previously been tested and results in a construct validity of 0.93-0.96 in quality of life scores, 0.97 in physical limitation scores, 0.98 in social limitation scores, and 0.98-0.99

in summary scores. Test–retest reliability calculations of KCCQ-12 have resulted in scores ranging from a 0.76 to 0.91 correlation across all domains. Scoring is calculated on a 100-point scale, with a higher score indicating a better overall health status.

The European Heart Failure Self-Care Behaviour Scale 9 (EHFScBs-9) was employed to assess self-care self-efficacy [11]. Internal reliability of this scale has been previously tested with a test score of 0.80 [11]. This scale consists of a 9 to 45-point scale, with lower scores indicating better self-care. For this trial, the method of standardizing the score to a 0-100 scale was used to make interpretation easier [12].

The My Healthcare Utilization Survey was included, as it assesses health care resource utilization and can collect information about the type and frequency of health-related services used within a specified time period. This scale was developed for this trial in collaboration with the UBC School of Population and Public Health

The System Usability Scale (postsurvey only) was also used, as it can evaluate the usability of a technology-based application [13]. The scale is scored on a 0 to 100-point scale, with higher scores representing better usability.

Basic demographic data (presurvey only) were also collected from participants and included age, sex, education level, and ethnicity.

Optional interviews were offered to all patient participants who completed the 90-day follow-up survey to gather additional feedback about their overall experience.

Health Care Provider Experience

After study completion, the monitoring nurses were interviewed to explore their overall experience with the monitoring model, the benefits and challenges, and suggestions for improvement (see Multimedia Appendix 2 for the monitoring nurse interview protocol).

Participants' PCPs were invited to provide feedback regarding the HHM intervention's impact on care delivery and workload through surveys, which were faxed to them (see Multimedia Appendix 3 for the primary care physician survey protocol).

Statistical Analysis

Patient Participant Experience and Outcomes

Survey data were entered into a Research Electronic Data Capture (REDCap) database [14,15] hosted at the Centre for Health Evaluation & Outcome Sciences (CHEOS) and were analyzed using R statistical package version 3.5.3 (R Foundation for Statistical Computing). The pre-to-postsurveys were coded and scored according to the validated scales' instructions, and paired *t* tests were used to assess pre-to-post difference across the outcome measures. The results are described as means with SD for parametric data and medians with IQRs for nonparametric data.

Pre–post analysis of administrative data was performed using Microsoft Excel (Microsoft Corporation). To determine pre–post change, we calculated the absolute risk reduction. Pre- and posthealth care costs and impacts were calculated using the self-reported health care utilization surveys. To calculate out-of-pocket costs, we used participants' self-reported data on expenses related to their health condition, which included information on drugs, aids to daily living, housekeeping or home care, and transportation to and from medical appointments.

Interviews with patient participants about the overall experience were recorded and transcribed verbatim. Transcripts were coded, and content analysis was performed to summarize the interviews into themes (see Multimedia Appendix 4 for the patient participant interview analysis codebook).

Health Care Provider Experience

Survey and interview data collected from the monitoring nurses and the PCPs were summarized using content analysis to draw out themes and recommendations to guide future HHM implementations. Interview data were recorded and transcribed verbatim. Transcripts were coded and summarized by 2 researchers (AB and an undergraduate student) into main themes, including level of satisfaction for providing care, communication with participants, impact, and areas for improvement (see Multimedia Appendix 5 for the monitoring nurse interview analysis codebook).

Results

Recruitment

From October 2016 to June 2017, 519 patients who met the criterion of presenting to the hospital with shortness of breath were referred and screened for further HF eligibility screening: 219 met the study eligibility criteria for HF, and 70 were enrolled. Out of these 70, 47 (67%) participants completed the enrollment survey and thus provided demographic information. The median age of these participants was 75 years (range: 44-93 years), 24/47 (51%) participants identified as male, 36/47 (76%) identified as White (of European descent), and 45/47 (96%) identified English as their language of preference for health care matters.

The top 3 reasons for nonparticipation included patients declining, patients not meeting clinical eligibility criteria, and inability to provide informed consent (see Multimedia Appendix 6 for a summary of the most common reasons for patients not participating). Of the 121 patients who declined to participate, most did not provide a reason (see Multimedia Appendix 7 for a summary of reasons provided by eligible patients who declined to participate).

Of the 70 participants, 47 completed and returned the enrollment survey, 49 completed and returned the 90-day survey, and 35 completed and returned both the enrollment and 90-day survey. The subsamples providing data for each area of analysis are specified in the following section.

HHM Adherence

Participants were expected to be in the monitoring system for 60 days, submitting data once per day. Actual monitoring adherence (ie, the actual days data were entered) averaged 56 days across our sample, which is a 94% adherence rate based on the 60 days of baseline expectation.

Satisfaction with the monitoring platform as measured by the System Usability Scale [13] resulted in a mean score of 80.0 and a median of 81.4 on a 100-point scale (n=49).

Patient Participant Experience and Outcomes

Health Care Utilization

Administrative data were available for 2 of the 3 participating sites that included 36 of the 70 participants (51%). ED visits, rehospitalizations, and length of stay all decreased for these participants. Furthermore, the overall duration of rehospitalization decreased (see Table 1).

There was a 71% reduction in hospitalization costs ($P<.001$), along with a 58% reduction in ED visit costs, although the latter did not reach statistical significance. PCP and specialist costs were similar in the pre–post analysis.

For the 30 participants (43%) who completed survey items included in the cost analysis, we estimated a 49% reduction in out-of-pocket costs (Table 2).

Table 1. Administrative data of change in ED visits, hospital admissions, and length of stay (n=36).

Data type	90 days pre-TEC4Home[a]	90 days post-TEC4Home	Pre–post change (%)
ED[b] visits	66	14	–79
Hospital admissions	54	7	–87
Length of stay (days), total (median)	440 (5.0)	71 (8.0)	–84 (60)

[a] TEC4Home: Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring.

[b] ED: emergency department.

Table 2. Per-patient aggregate health care utilization cost.

Cost type	Mean pre-TEC4home[a] cost (US$)	Mean post-TEC4home cost (US$)	Cost reduction (US$), n (95% CI)	Pre–post change (%)
ED[b] visits cost[c]	618	262	–376 (–87 to 799)	–58
PCP[d] visits cost[e]	126	129	3 (–52 to 47)	2
LoS[f] cost (ie, overall hospital cost)[g]	10,792	3091	–7701 (–3772 to 11,631)	–71
Specialist visits[h]	160	132	–28 (–72 to 128)	–18
Patient-reported out-of-pocket cost	357	185	–175 (–49 to –395)	–49

[a] TEC4Home: Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring.

[b] ED: emergency department.

[c] Costs calculated based on standard outpatient cost from the Canadian Institute for Health Information: US $314.15.

[d] PCP: primary care provider.

[e] Standard PCP visits cost obtained from the Ministry of Health Medical Services Commission payment schedule.

[f] LoS: length of stay.

[g] Per diem ward (1 night in hospital) from the Canadian Institute for Health Information: US $1520.20.

[h] Special visits cost obtained from the Ministry of Health Medical Services Commission payment schedule.

Participant Experience and Outcomes

For the 35 participants who reported a complete set of pre- and postoutcomes, disease-specific quality of life demonstrated the greatest improvement, and mental and physical general quality of life also significantly improved (Table 3). No significant change occurred in HF self-care behavior.

Table 3. Patient-reported outcomes pre- and post-TEC4Home.

Patient-reported outcome	Pre-TEC4Home[a] (score out of 100)	Post-TEC4Home (score out of 100)	Pre–post change, mean (95% CI)	Pre–post change (%)	*P* value
Heart failure–specific quality of life (KCCQ-12[b])	33.4	67.1	33.7 (40.05-23.84)	100.8	<.001
Health-related quality of life (VR-12[c] mental component)	43.1	51.4	8.3(12.48-4.08)	19.2	<.001
Health-related quality of life (VR-12 physical component)	26.7	31.7	5.0 (0.83-8.12)	18.7	.02
Heart failure self-care behavior (EHFScBs-9[d])	70.2	74.3	4.1 (14.59-3.48)	5.84	.22

[a] TEC4Home: Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring.

[b] KCCQ-12: Kansas City Cardiomyopathy Scale.

[c] VR-12: Veterans Rand 12-Item Health Survey.

[d] EHFScBs-9: European Heart Failure Self-Care Behaviour Scale 9.

Participant Experience

Participants who completed the postsurvey were invited to take part in a telephone interview to discuss their experiences further: 11 out of the 49 participants (22%) who completed the postsurvey participated in telephone interviews to further discuss their experiences in the study. The findings are summarized in Textbox 1. Most notably, they described TEC4Home as contributing to a sense of safety and security after the transition from the hospital:

> *I wasn't afraid to come home [from the hospital]…it actually brought me a lot of comfort and security once I came home.*

Participants also expressed that they felt more involved in their own care as a result of participating in the home monitoring intervention:

> *The TEC4Home program taught me how valuable it is* [to monitor my condition]

Textbox 1. Summarized findings from patient interview feedback by themes.

Project satisfaction

- Overall, all (11/11) participants described being pleased with their participation in the project.

Experience

- Most (9/11) reported ease of use with the technology and training provided.
- Most (8/11) expressed they were content with the support and education provided by the monitoring nurse.
- All (11/11) expressed feeling more involved in their own care.

Perceived impact

- A few (3/11) participants expressed that they perceived that their primary care provider appreciated the regular patient reports (most participants felt that the program did not impact the relationship, positively or negatively, with their primary care provider in any significant way).

Challenges

- A few (3/11) participants expressed some technical difficulties with the equipment (eg, blood pressure cuff ripped, blood pressure cuff not fitting properly, oximeter not working, weight scale not accurate).
- Some (4/11) participants wished the monitoring was a 7-day support service.

Health Care Provider Experience

Interviews were also conducted with the 2 monitoring nurses and covered satisfaction, patient–care provider interactions, procedures and usability, and perceived impact. Findings are summarized in Textbox 2. Monitoring nurses emphasized that they perceived positive impacts on participants quality of life and confidence:

> *Patients were definitely more engaged with their self-management. They're able to report changes in their symptoms and their weights and things like that.*

PCPs were invited to participate in surveys, but we did not receive any responses from them.

Textbox 2. Summarized findings from monitoring nurse feedback by theme. Monitoring nurse feedback (n=2).

Satisfaction

- Both (2/2) monitoring nurses expressed satisfaction with the project and their experiences working with patient participants.

Patient–care provider interactions

- Monitoring nurses expressed satisfaction with the level of care they were able to provide through the program.
- The nurses described how some primary care providers were more responsive than others but that the overall coordination of care improved because of her communications with nurse practitioners at the HF clinics, home care clinicians, and specialist physicians.

Procedures and usability

- The remote patient monitoring clinician station interface could have been more streamlined.
- Graphical visualizations of patients' biometric data were mentioned as an area of improvement.
- Consenting of patients too early led to dropout or ineligibility issues later on.
- For the HF protocol, questions could be modified to understand the patient's condition relative to the previous day (eg, "Is your shortness of breath the same, better or worse today?").

Impact

- The clinicians expressed a perceived impact on their patients in quality of life and self-management and confidence.

Discussion

This TEC4Home feasibility study, a precursor to the full TEC4Home RCT to follow, focused on exploring 3 key issues: (1) Would the study procedures be acceptable to both patients and providers? (2) Would the evaluation framework capture useful metrics for outcome evaluation? (3) Did the results suggest a trend toward HHM improving the care of patients with HF?

Insights From the Results of the Feasibility Study

The purpose and scope of this feasibility study were not designed to determine the efficacy of HHM. Nevertheless, we observed important trending of the data showing benefits across all 3 domains of the Triple Aim Plus framework. Most importantly, fewer patients had unscheduled ED revisits, fewer were readmitted to hospital, and the overall length of hospitalization decreased. In terms of quality of life, participants reported improved scores for both HF and general questionnaires. Furthermore, in economic terms, a cost consequence analysis showed that in all health care utilization factors measured, TEC4Home participants demonstrated decreased cost to the health system and decreased out-of-pocket costs. Finally, both participants and providers felt an improved experience in managing the patient's HF.

The observation that our participants felt better while being monitored was similar to clinical case series and studies demonstrating high participant satisfaction when patients with HF were monitored at home [16]. Critically, our positive results differ from those of previous studies that suggested no benefit [3,4]. We hypothesize that TEC4Home was designed to support a patient in the postdischarge period for 60 days, which may be a reason for our promising results. Our study also measured participants' quality of life and end-user experience, and both were found to increase. These findings have not been frequently reported in the literature.

Acceptability of the Conduct of Research

This study, conducted in 3 urban sites in British Columbia, enrolled motivated patients. Of the 219 patients fulfilling eligibility criteria, only 70 patients enrolled, resulting in a recruitment rate of 32.0%. It would, therefore, be important to increase identification, recruitment, and enrollment of eligible patients. One challenge experienced was attempting to recruit patients at the height of their exacerbation in the ED. Indeed, other studies have encountered similar challenges in recruiting from the ED with common difficulties, such as time-consuming health record searches, limited research nurse support, and lack of face-to-face communication between patient and researcher [17]. The results we provide in Table 1 helped us to understand some of the factors that led to eligible patients declining participation, such as not feeling well enough to participate and not feeling comfortable using HHM or having someone to help them use it.

We presented these findings to our research study patient advisory committee and collectively developed the following ways to improve recruitment of eligible patients: increase engagement with the hospital staff members to raise awareness of TEC4Home to improve referral rates of potential patients, and identify optimal times to approach patients during patients' hospital stays (eg, when they begin to feel better) or being careful to avoid recruiting while in the ED, especially when patients are being admitted to hospital.

The feasibility study also helped us to devise the following refinements to recruitment procedures: refining recruiter materials, including brochures, videos on how to use the HHM tool kit, and other materials to demystify study procedures and pique the participants' interest; reviewing and clarifying the eligibility criteria with recruiters so they can conduct the screening and enrolment of patients more effectively; and establishing an ongoing support-and-feedback loop for site recruiters to promote consistent understanding and support for patient engagement.

Although a before–after analysis using administrative data is appropriate for a feasibility study, a more definitive trial design with a true control comparison is required. One site was unable to provide administrative data. Further, the discrepancy in responses and return rates between administrative data and survey data will be addressed in the RCT with an emphasis on provincial databases being the definitive source for our primary outcome.

Our results suggests that participants are generally able to perform self-monitoring routinely over 2 months postdischarge from the hospital. Our participants submitted data on nearly 95% of days, which compares favorably to similar studies. A recent telemonitoring feasibility study with patients with type 2 diabetes mellitus found lower adherence rates compared to our trial [18]. We further found the success rate of presurvey completion to be 67% (47/70), postsurvey completion to be 70% (49/70), and pre- and postsurvey completion by the same participants to be 50% (35/70). We identified ways, such as using scheduled reminders, to increase survey returns in our RCT.

Comments from patients in the survey revealed that those who persisted in using the HHM found the experience very helpful to support their self-management. Technology usability was another area that needed improvement—how to make the equipment more user friendly. Survey comments from monitoring clinicians were also highly useful to improving the types of data we needed to include in the dashboard, the workflow of monitoring nurses when contacting participants and their PCP, and how often the monitoring report summary should be sent to PCPs. We were unable to obtain feedback from participants' PCPs in this feasibility study and needed to understand the reasons for it. We conducted a focus group with the PCPs to explore this issue prior to conducting the full RCT.

Evaluation Framework

This study allowed us to examine our data collection procedures and scope. Overall, our evaluation framework was able to guide the collection of metrics to assess the outcomes that we would like to measure: patient outcome, end-user experiences, and health system cost-effectiveness. The data we collected helped us determine the primary outcome differences before and after monitoring, a basis for hospital utilization and cost comparisons, and end-user experiences based on the validated scales that we selected. This study also guided us in improving the scope of data we would be collecting, such as additional provincial databases covering clinical baseline measures to learn more about our participants at enrollment (eg, severity of illness, comorbidities), more health care utilization indicators (eg, specialized medical services), health care system and patient costs (eg, prescription drugs dispensed), and vital statistics that include accurate and more detailed mortality data. Additionally, the lack of data from a control comparison is a true limitation of any feasibility study design and will be addressed in the upcoming RCT. We also lengthened the period of data collection from just 90 days before and after enrollment to include 3 additional 3-month periods, up to 1 year before and after enrollment to provide insight into long-term effects. A shift from the VR-12 to the EuroQol-5D (EQ-5D) quality of life assessment tool will allow for the calculation of quality-adjusted life-year analysis. All of these refinements based on the feasibility results were implemented in the second phase of TEC4Home, a large-scale RCT designed to further examine home health monitoring across 22 British Columbia hospitals from urban, regional, and rural communities.

Conclusions

This feasibility study better prepared us for a planned multicenter RCT by helping us understand how best to engage patients in eligibility assessment, recruitment, and retention and how to refine our evaluation framework and metrics collection. Furthermore, analysis of the data we collected provided encouragement that HHM can be beneficial for patients with HF post discharge. Findings from this feasibility study provided practical lessons that allowed us to conduct the multicenter RCT as well as identify early positive signals of the benefits of HHM for patients with HF.

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Conflicts of Interest

KH is a full professor in UBC Faculty of Medicine leading the Digital Emergency Medicine Unit and, as part of his academic salary from UBC, his academic research work is on digital health technologies including the subject matter in this paper. This TEC4Home project is funded by grants from the Canadian Institutes of Health Research, the Michael Smith Foundation for Health Research, the BC Ministry of Health, TELUS Health, and private donations from the VGH & UBC Hospital Foundation. With the exception of the Health Professional Investigator Award from the Michael Smith Foundation for Health Research, from which KH received partial funding support through the UBC Department of Emergency Medicine for his research salary earnings, all other grants and supports are to fund the implementation and evaluation of this project without benefiting KH directly. TS is an employee of TELUS Health, the technology partner for TEC4Home, which has been compensated for providing the hardware and software for the project as well as for professional services support.

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Multimedia Appendix 1
Feasibility study patient participant eligibility criteria.
[DOCX File , 16 KB - formative_v5i6e24509_app1.docx]

Multimedia Appendix 2
Monitoring nurse interview protocol.
[DOCX File , 15 KB - formative_v5i6e24509_app2.docx]

Multimedia Appendix 3
Primary care physician survey protocol.
[DOCX File , 15 KB - formative_v5i6e24509_app3.docx]

Multimedia Appendix 4
Patient participant interview analysis code book.
[DOCX File , 13 KB - formative_v5i6e24509_app4.docx]

Multimedia Appendix 5
Monitoring nurse interview analysis code book.
[DOCX File , 13 KB - formative_v5i6e24509_app5.docx]

Multimedia Appendix 6
Summary of most common reasons (not exhaustive) for patients not participating.
[DOCX File , 15 KB - formative_v5i6e24509_app6.docx]

Multimedia Appendix 7
Summary of reasons provided by eligible patients who declined to participate.
[DOCX File , 12 KB - formative_v5i6e24509_app7.docx]

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Abbreviations

CHEOS: Centre for Health Evaluation & Outcome Sciences
ED: emergency department
EHFScBs-9: European Heart Failure Self-Care Behaviour Scale 9
EQ-5D: EuroQol-5D
KCCQ-12: Kansas City Cardiomyopathy Scale
HF: heart failure
HHM: home health monitoring
PCP: primary healthcare provider
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
Tec4Home: Telehealth for Emergency-Community Continuity of Care Connectivity via Home Telemonitoring
TIM-HF2: Telemedical Interventional Management in Heart Failure II
UBC: University of British Columbia
VR-12: Veterans Rand 12-Item Health Survey

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Original Paper

Expanding the Reach of Research: Quantitative Evaluation of a Web-Based Approach for Remote Recruitment of People Who Hear Voices

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Abstract

Background: Similar to other populations with highly stigmatized medical or psychiatric conditions, people who hear voices (ie, experience auditory verbal hallucinations [AVH]) are often difficult to identify and reach for research. Technology-assisted remote research strategies reduce barriers to research recruitment; however, few studies have reported on the efficiency and effectiveness of these approaches.

Objective: This study introduces and evaluates the efficacy of technology-assisted remote research designed for people who experience AVH.

Methods: Our group developed an integrated, automated and human complementary web-based recruitment and enrollment apparatus that incorporated Google Ads, web-based screening, identification verification, hybrid automation, and interaction with live staff. We examined the efficacy of that apparatus by examining the number of web-based advertisement impressions (ie, number of times the web-based advertisement was viewed); clicks on that advertisement; engagement with web-based research materials; and the extent to which it succeeded in representing a broad sample of individuals with AVH, assessed through the self-reported AVH symptom severity and demographic representativeness (relative to the US population) of the sample recruited.

Results: Over an 18-month period, our Google Ads advertisement was viewed 872,496 times and clicked on 11,183 times. A total amount of US $4429.25 was spent on Google Ads, resulting in 772 individuals who experience AVH providing consent to participate in an entirely remote research study (US $0.40 per click on the advertisement and US $5.73 per consented participant) after verifying their phone number, passing a competency screening questionnaire, and providing consent. These participants reported high levels of AVH frequency (666/756, 88.1% daily or more), distress (689/755, 91.3%), and functional interference (697/755, 92.4%). They also represented a broad sample of diversity that mirrored the US population demographics. Approximately one-third (264/756, 34.9%) of the participants had never received treatment for their AVH and, therefore, were unlikely to be identified via traditional clinic-based research recruitment strategies.

Conclusions: Web-based procedures allow for time saving, cost-efficient, and representative recruitment of individuals with AVH and can serve as a model for future studies focusing on hard-to-reach populations.

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KEYWORDS

digital health; research procedures; recruitment; mobile phone

Introduction

Background

Auditory verbal hallucinations (AVH; or *voices*), or erroneous perceptions of speech, are a hallmark symptom of schizophrenia spectrum disorders (SSDs). They are experienced by 5% to 28% of the general population [1-4], including many people with a range of psychiatric diagnoses as well as many people who are otherwise considered healthy. In their most severe form, AVH are linked to anxiety, depression, and functional impairment [5,6]. AVH present unique challenges for research. First, individuals with SSDs who hear voices are considered a hard-to-reach population or a group that faces geographical, social, or economic barriers to participation [7,8]. SSDs are overrepresented in economically deprived and socially isolated groups [9,10], and treatment resources for them are scarce [11]. Many have no contact with mental health providers [12-14]. Others are reluctant to engage with the mental health system because of concerns about stigma [15], disagreement with diagnosis [16,17], or negative attitudes toward services [18]. Second, common clinical research practices often fail to access individuals with less severe or non-clinical AVH. Most individuals with AVH do not meet the criteria for an SSD; they often present with a range of diagnoses, including major depressive disorder, bipolar disorder, or may have never received a diagnosis at all [19,20]. Due to their reduced impact and increased independent coping skills, individuals with nonclinical AVH may be less likely to engage in research through traditional clinical settings. They may also opt against self-identifying because of concerns about stigma [21].

Digital technologies may help address these barriers. The average American adult is estimated to spend 3 hours and 48 minutes per day on a smartphone, tablet, or computer, with the majority of that time (62%) spent on the internet and using an app on a smartphone [22]. More than 1 in 3 adults report that they have gone on the internet to better understand a health condition [23]. Although smartphone ownership tends to lag behind the general population, many individuals with serious mental illnesses report owning a smartphone [24], and this number has rapidly increased over the past two decades [25]. Individuals with SSDs report similar levels of health-related internet and web-based engagement [26] and are willing to engage in a variety of research or clinical activities on the web, including assessments [27,28], interventions [29-31], and peer communication [32,33]. Web-based approaches allow participants to covertly self-identify and thus could reduce the impact of stigma on research participation [34]. Furthermore, the COVID-19 pandemic has revealed additional vulnerabilities in in-person research recruitment procedures. During the pandemic, many of these activities have halted; however, research engagement through digital technology can continue while remaining adherent to physical distancing guidelines.

One particularly promising approach to address these issues is the use of technology-assisted remote research. This term describes a constellation of web-based tools (eg, advertisements posted in search engine results and email listservs) that require no face-to-face interactions with prospective participants and thus obviate many of the barriers common in traditional research. These differ from traditional recruitment methodologies that require partnerships with partner organizations with brick-and-mortar locations or other recruitment tools such as flyers. These efficient and cost-effective [35,36] tools have been used to recruit research participants from several psychiatric populations, including people with depression [35], bipolar disorder [36], and suicidality [37]. These tools may be specifically well suited to address the extant challenges in recruiting and engaging individuals who experience AVH. As it is not situated within a health care system, technology-assisted remote research may be less susceptible to overrepresenting individuals engaged in treatment. It also potentially removes economic and social barriers faced by hard-to-reach populations (eg, time constraints and travel time) and allows for anonymous participation, thus reducing the impact of stigma.

Web-based methodologies are not without challenges. Research has examined the extent to which web-based research participants (eg, users of web-based platforms such as Amazon Mechanical Turk) are representative of the general population [38-40]. Others have raised concerns about participants' *gaming* or earning payments without honest and effortful participation [41]. For example, participants may attempt to complete web-based studies multiple times by masking their identifiers (eg, name and email address). Few studies have presented methods and models to engage difficult-to-reach populations while preserving the security, privacy, and validity of research data.

Objectives

In this paper, we report on the use of a technology-assisted remote research approach designed to recruit people who experience AVH. These procedures combine public-facing technologies (eg, Google Ads) with automated digital tools (eg, coding scripts to filter prospective participants) and available remote human support to efficiently recruit a difficult-to-reach population while preserving data security and quality. We describe the structure of that system and report several metrics assessing its performance, including (1) the number of web-based advertisement impressions (ie, number of times the web-based advertisement was viewed); (2) clicks on that advertisement; (3) engagement with web-based research materials; and (4) the extent to which it succeeded at representing a broad sample of individuals with AVH, assessed through self-reported AVH symptom severity and demographic representativeness (relative to the US population) of the sample recruited.

Methods

Overview

These digital tools were built for a primary study described elsewhere examining the real-time, real-place phenomenology of AVH [42]. This involved downloading and carrying a smartphone app for a 30-day study period that deployed brief ecological momentary assessment questionnaires and captured data through smartphone sensors. Study inclusion criteria included speaking English, being 18 years or older, living in the United States, experiencing AVH at least once per week, and ownership of an Android smartphone. Exclusion criteria included previous participation in the study and being unavailable for 30 days of consecutive data collection. The internal review boards at the University of Washington and Dartmouth College approved all the study procedures.

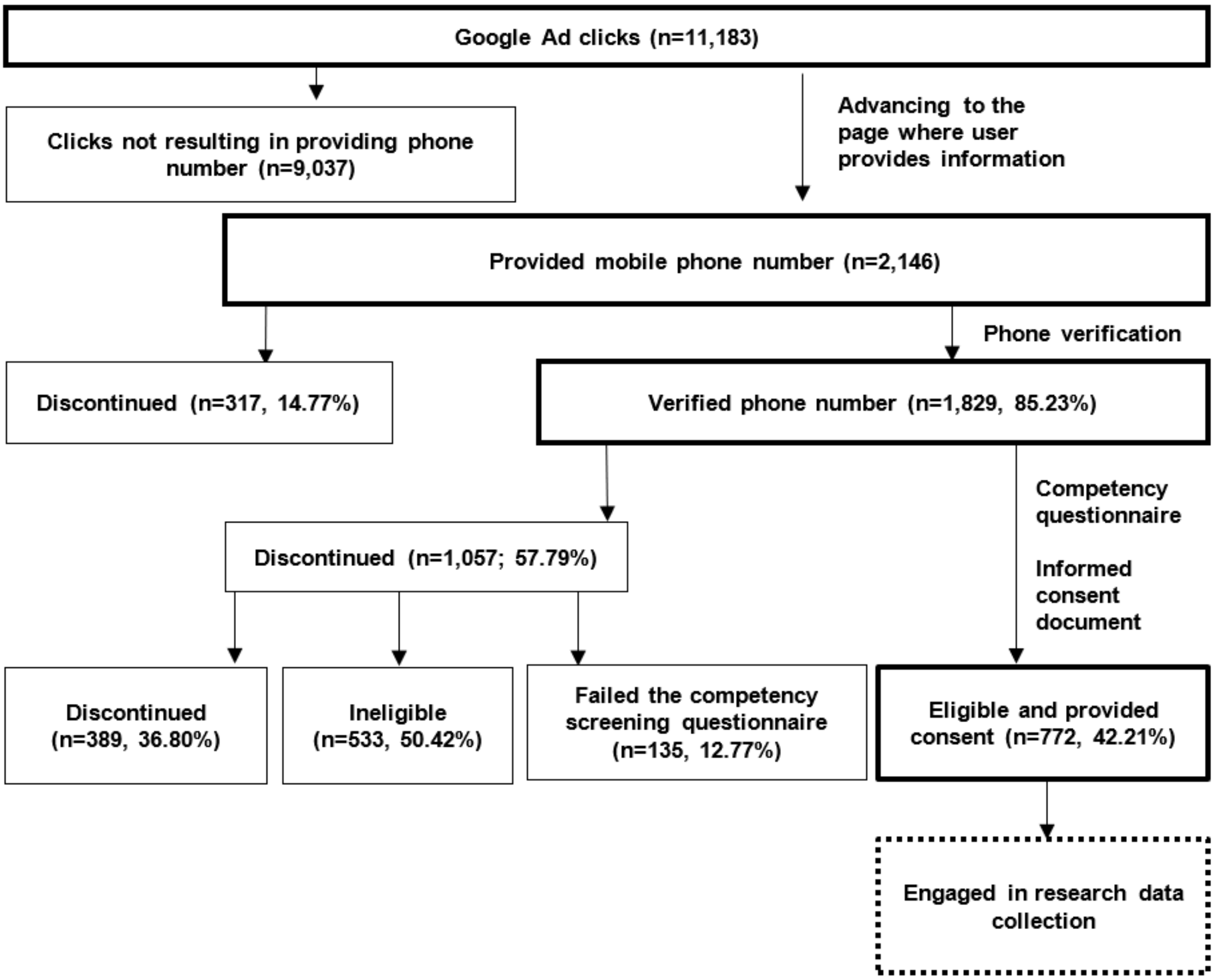
Google Ads and Keywords

To recruit individuals reporting AVH, we used Google Ads, a system of web-based advertisements wherein advertisements are viewable by individuals who use terms that match preselected keywords provided by the advertiser. Advertisements are designed to resemble a typical Google search result and thus comprise a title, URL, and brief description. In addition to keywords, the system allows for the entry of *negative keywords*, which function in the opposite way, ensuring that the advertisements are not viewable by individuals who search one of the negative keywords. Google Ads records the number of impressions, keywords used, number of clicks linked to the landing page and cost per click, and basic demographics of those who clicked on the advertisement (eg, age, gender, and household income, if reported to Google by the user). For this study, we selected keywords based on several sources: qualitative responses during our early work [43] as well as a rapid review of the academic literature, consultation with researchers focused on serious mental illness, and a review of blogs of people with lived experience. These keywords included descriptors that involved both clinical language (eg, *schizophrenia* and *bipolar disorder*) and nontraditional appraisals of AVH or related terms (eg, *talking to ghosts* and *going crazy*). Positive keywords were allowed to have a *broad match* with search terms, according to which search terms could be reordered or accompanied with other terms. Negative keywords were entered with a *phrase match* setting, according to which the exact phrase must be included in the search for the user to be blocked. Negative keywords were selected to prevent individuals from attempting to complete the study a second time (eg, *hearing voice research* and *bipolar studies that pay)*.

Web-Based Recruitment Materials

Once users clicked on the advertisement, they were taken to the study landing page that provided written and video descriptions of the study. The consent form was available for download on this page. Participants were instructed to click on a "see if I am eligible" button if they were interested; this button then triggered a pop-up message requesting their email and a valid mobile phone number. This number received a text message with a code that prospective participants had to enter on the study website to gain access to the eligibility questionnaire. Once found eligible, participants were again given access to the consent form to download and review and asked to answer all competency questions correctly within 3 attempts. Participants were excluded if they were unable to complete this step successfully, as they were deemed unable to provide informed consent. Participants were also excluded if they had previously participated in the study. Therefore, the server ran the email and phone numbers provided through the participant database and automatically blocked people with repeat phone numbers from continuing the enrollment process. If participants met eligibility criteria via the screening questions and provided informed consent, their participation in the study officially began (ie, access to baseline assessments and the study app was provided). If at any point their responses indicated that they were ineligible (eg, 3 failed attempts to answer competency questions or previous participation), they were taken to a page where they were thanked for their interest but informed that they were ineligible to participate. Throughout this process, a staff member was available by phone and email for participants to call if the prospective participant faced barriers or had questions. Figure 1 provides an overview of the flow of interested individuals from the landing page to the consent and initiation of the study.

Figure 1. Participant flow and attrition at each stage of the web-based engagement procedure.



Data Security and Validity Procedures

In addition to the phone verification process, other procedures were also used to deter *gamers* or participants aiming to earn payments through duplicate or otherwise dishonest participation. These involved identifying prospective participants based on suspicious digital activity; when such users were identified, a research coordinator contacted them to conduct additional live screening by telephone. We identified this suspicious activity by (1) reviewing their means of access to the study landing page and (2) assessing duplicate emails, phone numbers, and email addresses. First, as a user cannot ensure that a Google Ad will appear in their search terms, it was expected that gamers would attempt to access the study landing page by entering the study URL directly, as opposed to honest participants who would only respond to the link listed in Google Ads. Thus, different links distinguished those who accessed the page via Google Ads versus those who accessed it directly. When a direct arrival initiated the screening process, a research coordinator would receive a notification and conduct additional screening of the prospective participant by phone; they were only allowed to proceed if cleared by the research coordinator. Second, the research coordinator would also receive an automated email if a participant attempted to enter the study with (1) an identical IP (internet protocol) address to a previous participant or (2) an email address for which characters matched the email of a previously enrolled participant by >90%. The study responses of these suspicious participants were reviewed on an ongoing basis (ie, identifiers and patterns in survey responses) and discussed at subsequent team meetings to determine whether additional screening was warranted by these patterns of responses. Participants were discontinued from the study if it was determined after additional screening that they were attempting to participate in the study for a second time (n=44) or were otherwise dishonest about their eligibility (n=2). No adverse events occurred throughout the course of the study.

Results

Overview

The aim of this study is to examine the efficiency and effectiveness of web-based recruitment of individuals who experience AVH, according to a number of metrics, including (1) the number of web-based advertisement impressions (ie, number of times it was viewed) and clicks; (2) engagement with web-based research materials (ie, whether and how participants enrolled); and (3) the extent to which it succeeded in representing a broad sample of individuals with AVH, assessed through self-reported AVH symptom severity and demographic representativeness (relative to the US population).

Advertisement Impressions and Clicks

Advertisements were posted from February 2018 to September 2019, with a total budget of US $4429.25. The advertisement was viewed 872,496 times and was clicked on 11,183 times, reaching a click-through rate (clicks per impression) of 1.28% at an average cost of US $0.40 per click. The cost of a successfully recruited participant, that is, one who completed the screening processes and informed consent portions completely, was US $5.74 per person. The top 5 advertisement keywords were *mental illness*, *schizophrenia*, *mental health*, *bipolar*, and *hear voices*. Table 1 presents the number of impressions, clicks, click-through rate, and cost per click by advertisement keyword. Of the individuals who clicked on the advertisement and had available demographic information, most (9896/11,223, 88.18%) clicked on the advertisement through mobile phones, whereas few used desktop computers (700/11,223, 6.24%) or tablets (627/11,223, 5.59%).

Table 1. Measures of advertisement engagement for all keywords included to reach people who hear voices[a].

Keywords	Impressions[b], n	Clicks, n	Click-through rate (%)	Average cost per click (US $)	Total cost (US $)
Mental illness	188,766	2263	1.20	0.42	951.33
Schizophrenia	97,872	1945	1.99	0.41	794.19
Mental health	146,438	1753	1.20	0.43	757.05
Bipolar	82,815	931	1.12	0.44	410.64
Hear voices	59,321	881	1.49	0.33	294.16
I hear voices	55,629	815	1.47	0.35	286.64
Hearing sounds	47,702	610	1.28	0.37	226.86
Hearing voices in head	22,234	445	2.00	0.34	151.06
Mental illness hearing voices	19,685	422	2.14	0.35	148.30
Schizoaffective	8787	181	2.06	0.39	70.28
Hearing voices disorder	9972	175	1.75	0.39	67.77
Auditory hallucinations	6479	158	2.44	0.33	51.59
Hearing things	39,836	148	0.37	0.33	48.90
Delusional	22,321	130	0.58	0.33	42.88
Going crazy	11,880	78	0.66	0.33	25.49
Talking to ghosts	9904	67	0.68	0.37	24.96
Stress relief	21,329	64	0.30	0.46	29.12
Spirits talking	13,142	58	0.44	0.42	24.09
Musical ear syndrome	3767	19	0.50	0.44	8.39
Am I crazy	1644	19	1.16	0.31	5.95
Am I insane	942	12	1.27	0.45	5.43
Disembodied voices	227	3	1.32	0.28	0.84
I’m not crazy	1591	3	0.19	0.39	1.18
Hearing voices[c]	122	3	2.46	0.71	2.15
Voice hearing[c]	91	0	0	0	0

[a] The total number of impressions was 872,496; the total number of clicks was 11,183; average click-through rate was 1.28%; average cost per click was US $0.40; and the total cost was US $4429.25.

[b] An impression is counted each time the advertisement is shown on a search result page.

[c] These keywords were included for only a portion of the study period because of concerns related to repeat study participants searching for and finding the study advertisement.

Study Enrollment

The flow of interested users from Google Ads through informed consent is shown in Figure 1. Of the 11,183 clicks on the study Google Ad, a total of 2146 individuals provided their mobile phone number to be verified for participation in the study. Of the 2146 participants who provided a phone number, 1829 (85.23%) verified this phone number with a code. Of the 1829 individuals with a verified phone number, 772 (42.21%) provided consent to participate in the study. Most individuals who verified their phone number but did not provide informed consent, did not meet the eligibility criteria (533/1057, 50.43%), whereas the remainder either failed a competency screening questionnaire (135/1057, 12.77%) or chose not to participate (389/1057, 36.8%).

Participant AVH Frequency and Severity

Results related to participants' AVH frequency and severity are presented in Table 2. Most individuals who provided consent to participate reported that they had sought treatment for their AVH at some point in their lifetime (492/756, 65.1%) but over one-third had not (264/756, 34.9%). The most common self-reported diagnoses were depression (488/749, 65.2%), bipolar disorder (352/749, 47%), and posttraumatic stress disorder (328/749, 43.8%). Most participants reported hearing voices at least once a day (666/756, 88.1%) and that the voices interfered with their daily activities in some way (697/755, 92.4%), with almost half of the participants reporting "quite a bit" or "extreme" interference (346/755, 45.9%). Most reported that the voices they hear are distressing (689/755, 91.3%) and more than half reported "quite a bit" or "extreme" distress (416/755, 55.1%). Participants varied in terms of how open they were about these voices with others. Most participants (443/756, 58.6%) had shared their experience of voices with a medical professional. Approximately half of the participants had immediate family members (376/755, 49.8%) or a significant other (350/754, 46.4%) who knew about their experience of voices. One-tenth (75/753, 10%) of the sample reported that no one else knew about their experience of voices. These figures suggest that this remote recruitment strategy successfully engaged a broad continuum of people with AVH experiences, including individuals with significant and severe AVH as well as those who had never engaged in treatment for them.

Table 2. Participants' diagnoses, experience, frequency, severity, and behavioral interference of auditory verbal hallucinations.

Clinical characteristics	Participants, n (%)
Lifetime treatment seeking (n=756)	
Yes	492 (65.1)
No	264 (34.9)
Self-reported diagnosis[a]	
Alzheimer or Parkinson disease (n=747)	4 (0.5)
Bipolar disorder (n=749)	352 (47.0)
Depression (n=749)	488 (65.2)
Traumatic brain injury (n=746)	50 (6.7)
Migraines (n=747)	141 (18.9)
Schizoaffective disorder (n=748)	210 (28.1)
Schizophrenia (n=749)	208 (27.8)
Posttraumatic stress disorder (n=749)	328 (43.8)
Substance use (n=747)	228 (30.5)
Seizures (n=748)	54 (7.2)
None of the above (n=749)	61 (8.1)
Other (n=772)	87 (11.3)
Who knows about your voices?[a]	
No one knows (n=753)	75 (10.0)
People you know online but not in person (n=756)	63 (8.3)
Medical professionals/primary doctor/therapist (n=756)	443 (58.6)
Significant other (ie, boyfriend, girlfriend, or spouse) (n=754)	350 (46.4)
Some of my friends (n=756)	333 (44.0)
All my friends (n=755)	83 (11.0)
Extended family (n=756)	105 (13.9)
Immediate family (n=755)	376 (49.8)
How frequently do you hear a voice or voices? (n=756)	
No voices	2 (0.3)
Less than once day	88 (11.6)
Once or twice a day	199 (26.3)
Several times a day	242 (32.0)
All the time/constantly	225 (29.8)
How much do the voices interfere with your daily activities? (n=755)	
No interference	58 (7.7)
A little bit	162 (21.5)
Moderately	189 (25.0)
Quite a bit	187 (24.8)
Extremely interfering	159 (21.1)
How distressing are the voices that you hear? (n=755)	
No voices are distressing me	66 (8.7)
A little bit	116 (15.4)
Moderately	157 (20.8)

Clinical characteristics	Participants, n (%)
Quite a bit	205 (27.2)
Extremely distressing	211 (27.9)

[a] Participants could select multiple options.

Participant Demographics and Representativeness

The demographics of the study sample (Table 3) broadly reflect a number of US population trends. The average age of consented participants was 38.14 years (SD 9.86), which closely mirrored the median US age of 38.2 years [44]. In comparison with population estimates, the sample of individuals providing consent included larger percentages of multiple populations that are traditionally underrepresented in research, including Black or African American participants (108/760, 14.2% in our study, estimated at 12.7% of the US population [45]), multiracial participants (90/760, 11.8% vs 3.4% of the US population [45]), sexual minorities (156/766, 20.3% gay, lesbian, or bisexual vs 5% [46]; 12/771, 1.6% transgender vs 0.6% [47]), and the homeless (69/767, 9.0% vs 0.2% [48]). Other groups appeared underrepresented relative to the general population, including individuals who identified as Asian (9/760, 1.2% vs 5.6% [45]), Hispanic or Latino (101/765, 13.2% vs 18.3% [45]), and male (292/771, 37.9% vs 49.2% [45]).

Table 3. Demographics of participants who provided consent to participate.

Demographic characteristic	Values
Age (years; n=768), mean (SD)	38.14 (9.86)
Sex or gender (n=771), n (%)	
Female	470 (61.0)
Male	286 (37.1)
Transgender	12 (1.6)
Transgender woman	6 (0.8)
Transgender man	6 (0.8)
Other	3 (0.4)
Race (n=760), n (%)	
White	537 (70.7)
Black or African American	108 (14.2)
Pacific Islander	2 (0.3)
American Indian or Alaskan Native	14 (1.8)
Asian	9 (1.2)
More than one race	90 (11.8)
Hispanic (n=765), n (%)	
Yes	101 (13.2)
No	664 (86.8)
Sexual orientation (n=766), n (%)	
Heterosexual or straight	591 (77.2)
Gay or lesbian	50 (6.5)
Bisexual	106 (13.8)
Other	19 (2.5)
Housing status (n=767), n (%)	
Independent or living on my own	348 (45.4)
Living with family	313 (40.8)
Assisted or supported living	33 (4.3)
Substance treatment institution	4 (0.5)
Homeless	69 (9.0)

Discussion

Principal Findings

Digital technologies are rapidly reshaping mental health research and services. One particular benefit of these approaches is their capacity to increase the reach of research to underserved populations. Previous work has demonstrated the potential of web-based engagement to facilitate help seeking among individuals at risk for psychosis by linking them to web-based resources about symptoms and treatments (eg, the *Strong365* campaign [49]). This study builds on this earlier work by demonstrating that web-based tools can remotely facilitate research participation of individuals with psychotic symptoms at both clinical and nonclinical levels. The recruited sample reported clinically significant experiences with voices that were frequent, distressing, and functionally interfering, and over one-third had never received treatment for them. Overall, the results suggest that these web-based procedures allow for the efficient, affordable, and representative recruitment of research participants without reliance on a clinical setting.

Web-based digital recruitment methods compare favorably with extant approaches for engaging hard-to-reach populations in several ways. First, such methods appear to reduce costs. Traditional recruitment methods incur several costs in the process of raising interest and awareness of a study, such as increased staff time, flyers, mailings, and presentations to clinical or educational facilities [50]. These needs are obviated through remote recruitment. Our web-based advertisements were viewed by over 870,000 individuals for 18 months for less than US $4500, a fraction of the cost that such exposure would necessitate using offline approaches. The approach of this study appeared to reduce costs relative to previous work using social media to recruit individuals with psychotic experiences [43]. Second, beyond increasing efficiency, these methods may improve representative sampling when the members of a group face barriers to participation. Research in other health-related populations has demonstrated that digital technologies may address these barriers [7,8,51], in particular, accessing broader geographic regions [52,53] and more diverse respondents [35,54]. This study provides support for these benefits and suggests that they may also reduce barriers specific to individuals on either end of the continuum of AVH severity. Individuals with psychosis are difficult to engage in clinical research, given social isolation and economic hardship [10,12,13]. Those with undiagnosed and untreated AVH may be even more difficult to engage, given a lack of contact with typical clinical research settings as well as potential concerns about self-identifying with stigmatized experiences. This approach appeared to engage participants from both ends of this continuum; one-third of the participants reported never seeking treatment for their voices, a similar proportion reported that they experienced highly distressing voices daily. This finding also provides additional support for the utility of these approaches to engage individuals at risk either in programs that encourage help seeking [49,55] or in remotely delivered interventions [33]. Although a few examples provide support for the feasibility of these initiatives, future work should examine remote treatment-seeking support and intervention for the psychosis continuum at a population level. Furthermore, notable in these data were the number of participants who were also members of other underrepresented populations, including racial minorities, sexual minorities, and the homeless. Although it remains an open question why these groups are better represented using these methods, it is possible that web-based engagement reduces barriers for underrepresented groups that may face additional intersectional experiences of stigma on top of those related to their mental health concerns alone.

Limitations

This study had some limitations. Although web-based methods may ameliorate some recruitment biases, they may worsen others. Web-based recruitment strategies rely on participants' ownership and adeptness to use technology to engage. Individuals who lack either may struggle to engage in these new avenues. This may be particularly pronounced among individuals who face economic barriers to several needed services. Most visitors to the research study landing page did not provide informed consent to participate. Specific factors may predict a lack of willingness to persist through automated screening steps (eg, persecutory ideation and cognitive functioning). If this is the case, this could limit the representativeness of the sample. Although our approach successfully engaged members of several typically underrepresented groups, others accounted for smaller proportions than their proportion of the US population, including Hispanic and Asian individuals. The prevalence of AVH in specific racial or ethnic groups is not clear in the academic literature at present; thus, it is not clear from these data whether overrepresentation of these groups relative to population demographic estimates is the result of a greater prevalence of AVH in specific groups, characteristics of our recruitment strategies, or other causes. Overall, however, our results suggest that web-based recruitment methods engage a diverse sample of individuals with AVH experiences.

Conclusions

Technology-assisted remote research procedures address several barriers that are common in traditional research. Engaging prospective participants outside of typical clinical settings removes existing sampling biases, allowing for greater representation of psychiatric populations. These procedures have also been able to continue despite the halted in-person research activities in light of social distancing measures imposed by the COVID-19 pandemic. This expansion of access and reach has been a principal contribution of digital health technologies, and health care institutions have only just begun to witness their potential impact [56]. Just as digital technologies create considerable opportunities for treatment engagement, such tools can also enhance clinical research.

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Conflicts of Interest

DBZ has an intervention content licensing agreement with Pear Therapeutics and has financial interest in FOCUS technology. He has consulted for Trusst Health Inc, eQuility, and Otsuka Pharmaceuticals Ltd. The other authors have no conflicts of interest to disclose.

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Abbreviations

AVH: auditory verbal hallucinations
IP: internet protocol
SSD: schizophrenia spectrum disorder

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Original Paper

Racial Discrimination, Sedentary Time, and Physical Activity in African Americans: Quantitative Study Combining Ecological Momentary Assessment and Accelerometers

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Abstract

Background: A growing number of studies indicate that exposure to social stress, such as perceived racial discrimination, may contribute to poor health, health behaviors, and health disparities. Increased physical activity (PA) may buffer the impact of social stress resulting from racial discrimination. However, to date, data on the relationship between racial discrimination and PA have been mixed. Part of the reason is that the effect of perceived racial discrimination on PA has primarily been examined in cross-sectional studies that captured retrospective measures of perceived racial discrimination associated with individuals' current PA outcomes. The association between real-time perceived racial discrimination and PA among African Americans remains unclear.

Objective: The purpose of this study is to examine the relationship among demographic, anthropometric and clinical, and psychological factors with lifetime racial discrimination and examine the within- and between-person associations between daily real-time racial discrimination and PA outcomes (total energy expenditure, sedentary time, and moderate-to-vigorous PA patterns) measured by ecological momentary assessment (EMA) and accelerometers in healthy African Americans.

Methods: This pilot study used an intensive, observational, case-crossover design of African Americans (n=12) recruited from the community. After participants completed baseline surveys, they were asked to wear an accelerometer for 7 days to measure their PA levels. EMA was sent to participants 5 times per day for 7 days to assess daily real-time racial discrimination. Multilevel models were used to examine the within- and between-person associations of daily racial discrimination on PA.

Results: More EMA-reported daily racial discrimination was associated with younger age (*r*=0.75; *P*=.02). Daily EMA-reported microaggression was associated with depressive symptoms (*r*=0.66; *P*=.05), past race-related events (*r*=0.82; *P*=.004), and lifetime discrimination (*r*=0.78; *P*=.01). In the within-person analyses, the day-level association of racial discrimination and sedentary time was significant (β=.30, SE 0.14; *P*=.03), indicating that on occasions when participants reported more racial discrimination than usual, more sedentary time was observed. Between-person associations of racial discrimination (β=−.30, SE 0.28; *P*=.29) or microaggression (β=−.34, SE 0.36; *P*=.34) with total energy expenditure were suggestive but inconclusive.

Conclusions: Concurrent use of EMA and accelerometers is a feasible method to examine the relationship between racial discrimination and PA in real time. Examining daily processes at the within-person level has the potential to elucidate the mechanisms of which racial discrimination may have on health and health behaviors and to guide the development of personalized interventions for increasing PA in racial ethnic minorities. Future studies with a precision health approach, incorporating within- and between-person associations, are warranted to further elucidate the effects of racial discrimination and PA.

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KEYWORDS

racial discrimination; physical activity; ecological momentary assessment; African American; pilot study; mobile phone

Introduction

Background

African Americans continue to experience disproportionately higher rates of cardiovascular disease and metabolic disorders than their White counterparts [1]. Although health disparities have been attributed to multiple factors, African Americans have been more likely than other racial and ethnic groups to report perceived racial discrimination (eg, 71.3% vs 24% in non-Hispanic Whites) [2-4]. In extensive research, exposure to racial discrimination events or perceived racial discrimination contributes to poor health, health behaviors, and health disparities [4,5].

Social stress derived from systems of inequality, such as racial discrimination, may provoke severe psychological and physiological responses and has been associated with unhealthy behaviors [6,7]. Studies have shown that perceived racial discrimination is linked to the consumption of fatty foods, smoking, and alcohol intake [4,8].

Increased physical activity (PA) may buffer the impact of social stress resulting from racial discrimination [9,10]. To date, studies on the relationship between racial discrimination and PA have shown inconclusive findings. For example, in a multiethnic study of PA, racial discrimination was not associated with PA as measured by pedometers when examined among the full sample or separately by race and ethnicity [11]. An unexpected finding was reported in the Jackson Heart Study cohort [12], with higher daily and lifetime racial discrimination associated with more PA in women based on their self-reported PA.

In addition, although not in the context of racial discrimination, some studies of psychological stress in other populations have linked perceived stress with less PA [13,14]. In recent studies that examined both between- and within-person effects of daily stress on PA, there was significant between-person variability in the relationship between PA and stress [15,16]. For example, the relationship may be bidirectional for some people; for others, it may be unidirectional or have no association, suggesting that examining the within-person effect of stress on PA may address the limitations of between-person analysis that predominate in traditional research [15,16].

To date, data on the relationship between racial discrimination and PA are sparse and inconsistent. Part of the reason is that the literature to date on the effect of perceived racial discrimination on PA comprises mostly cross-sectional studies that capture retrospective measures of lifetime discrimination associated with individuals' current health outcomes. Such data may be subject to recall and rumination biases. Furthermore, racial microaggressions—the brief and commonplace daily verbal or nonverbal denigrating messages directed toward racial and ethnic minorities that carry the offending party's implicit or unconscious bias—have been shown to disempower racial minorities and may negatively impact health outcomes [17,18]. However, this subtle form of racial discrimination may be difficult to capture by retrospective measures and has been understudied in research on perceived racial discrimination and health. In this study, we prospectively examined racial microaggression (hereinafter microaggression) as a subtle form of racial discrimination as well as lifetime racial discrimination. Examining perceived racial discrimination or microaggression at a single point in time—not incorporating the perspective that this experience fluctuates but combining with cumulative past experience of racial discrimination—may have limitations in examining the differences in behavioral responses across settings and time.

Ecological momentary assessment (EMA) is a real-time, self-report data-capturing method in which people report behavior in real time at multiple time points in their natural environment. It may reduce recall biases and enhance ecological validity by collecting self-report data that are more proximal to the time and place (ie, real world) in which stressful events and behaviors occur [19]. Recently, a growing number of studies that explore discrimination and health outcomes using EMA have been published; for example, the relationships between real-time discriminatory experiences and health behaviors have been examined in various sexual and gender ethnic minority groups [20-22]. The EMA method provides the opportunity to examine how fluctuations in daily perceived racial discrimination or microaggressions are associated with PA among African Americans at the within-person level. In addition, the use of accelerometers can minimize the weakness of self-report measures of PA.

Objectives

Therefore, the purpose of this pilot study is (1) to describe the relationship among demographic (age, sex, income, and education), anthropometric and clinical factors (BMI, blood pressure, and body composition), and psychological factors (depression) with lifetime racial discrimination and (2) to examine the effects of real-time racial discrimination on total energy expenditure, sedentary time, and moderate-to-vigorous physical activity (MVPA) patterns of objectively measured PA using accelerometers and a real-time data capture strategy, that is, EMA in healthy African American adults at both the group (eg, between-person level) and individual (eg, within-person level approach or N-of-1) level.

Methods

Study Design

This study is a substudy of an intensive, observational, case-crossover design to examine the effects of perceived racial discrimination on physiological (ie, stress biomarkers) and behavioral responses in African Americans. Details of the overall study protocols have been published elsewhere [23]. In a case-crossover design, each participant serves as their own control to assess the within-person effects on repeatedly measured PA outcomes [24]. Within-person analysis of effects on PA occurred at the 2-hour interval level (using EMA at the end of the interval querying participants about racial discrimination over the duration of the interval) and day level (using average scores of EMA response across the day).

Participants and Recruitment

Building on a relationship developed over the past 10 years, the research team recruited participants from greater New Haven communities in Connecticut via flyers and word-of-mouth communication within African American communities. Before implementing the study, we held meetings with community stakeholders to discuss an effective recruitment plan and the details of the pilot study protocols. Potential participants were called in and were screened by phone and scheduled for a baseline orientation visit. The inclusion criteria were (1) self-reported African American or Black, (2) aged between 30 and 55 years, (3) currently employed, (4) ownership of a smartphone, (5) able to respond to smartphone-based random survey prompts (ie, EMA) at least 3 times per day, and (6) English speaking. We excluded participants who were pregnant or who had serious acute or terminal medical conditions that would preclude PA. The sample size (n=12) was largely based on guidelines for pilot studies that suggest 10 to 40 participants per cell [25]. Even assuming moderate attrition of 20% (2/12), we would have 10 subjects, which is still within the guidelines for pilot studies [26]. We also estimated the minimum detectable effect sizes of other outcomes (ie, stress biomarkers—data not shown; [23]). Our observations would be able to detect medium effect sizes of 0.53-0.60 on primary outcomes (stress biomarkers) repeatedly measured within the individual with 80% power at a 5% significance level, based on a previous study using stress biomarkers [27].

Baseline Measures

Baseline surveys included sociodemographic characteristics; current smoking status (yes or no); and alcohol consumption by the Alcohol Use Disorders Identification Test [28], which includes frequency of drinking and amount of alcohol consumption. We also used validated self-report measures collected at baseline that are mentioned below.

Perceived racial discrimination was measured at baseline using 2 scales. The *Major Life Discrimination* (MLD) scale is a 9-item self-report measure of past exposures to lifetime discrimination in diverse domains. Respondents indicated whether they had ever experienced each listed major discrimination event (eg, denied a bank loan, unfairly fired, getting a job, at work, and stopped by police; Cronbach α≥.88) [29]. The MLD score represented the sum of each yes or no item (range 0-9). Higher scores indicate more lifetime discriminatory experiences. The *Race-Related Events Scale* (RES) has 22 items to assess exposure to stressful and potentially traumatizing experiences of race-related stresses in adults. Respondents indicated whether they had ever experienced each event (yes or no), and the items were summed for a total RES score ranging from 0 to 22 (Cronbach α=.78-.88) [30]. Higher scores indicate more experiences of race-related stressful events.

> *The Black Racial Identity–Centrality subscale (Cronbach α>.77) is an 8-item, 7-point Likert scale (ranging from strongly disagree=1 to strongly agree=7). The centrality dimension of racial identity refers to the extent to which individuals normally define themselves with regard to race. It is a measure of whether race is a core part of an individual's self-concept [31]. After reverse-scoring 3 items, the overall score was calculated by averaging all items, with higher scores indicating stronger racial identity.*

For *subjective social status*, participants were asked to place an “X” on the rung that best represented where they thought they stood on the ladder, with 10 rungs described as follows: at the top of the ladder are people who are the best off, those who have the most money, those who have the most education, and those who have the best jobs, and at the bottom are people who are the worst off, those who have the least money, those who have the least education, and those who have the worst jobs or no job (test-retest reliability, ρ=0.62) [32,33].

> *The Center for Epidemiological Studies Depression Scale (CES-D) is a 4-point Likert scale that captures current depressive symptoms with 20 items on how respondents have felt or behaved during the past week by selecting 1 of the 4 options (0=rarely, 1=some of the time, 2=occasionally, and 3=most of the time). The items were summed to obtain a total score. Higher numbers indicate greater depressive symptoms (Cronbach α>.85) [34]. A recent meta-analysis [35] showed that a cutoff point of 20 yields a more adequate trade-off between sensitivity and specificity, compared with the cutoff point of 16, which has been used to indicate probable clinical depression.*

EMA Measures

Perceived racial discrimination was measured using the Experiences of Discrimination (EOD; Cronbach α>.88) [29] and Racial Microaggression Scale (RMAS; Cronbach α>.85) [36,37] adapted for EMA data collection. The EOD has subscales for worry, global, filed complaint, response to unfair treatment, day-to-day discrimination, and skin color [29]. The RMAS has subscales for invisibility, criminality, low-achieving or undesirable culture, sexualization, foreigner or not belonging, and environmental invalidations [36]. As the EOD and RMAS measure experiences of unfair treatment over the past month to year, of which response options are not relevant for real-time EMA assessment, response choices were revised for the EMA time frame using yes or no answers or Likert scale options. We also used a random subscale inclusion strategy so that only 60% of the items would be included in each EMA survey to reduce the subject burden and survey fatigue [38]. When prompted, participants were asked to report whether they had experienced any unfair treatment from a list of 11 common daily racial discriminations since their last prompt or within the past 2-3 hours if they missed or did not complete their last prompt (eg, “treated with less courtesy than other people because of your race or ethnicity,” yes=1 or no=0) and also from a list of 32 microaggression experiences (eg, “people mistake me for being a service worker simply because of my race or ethnicity,” 1=strongly disagree to 7=strongly agree). Possible daily scores of the EOD range from 0 to 10, with higher scores indicating more racial discriminatory experiences. Possible daily RMAS scores range from 15 to 105, with higher scores indicating more microaggression. Each survey (5 times per day) consisted of 8-15 different combinations of questions varying by time of day (sequentially from the first survey to the fifth survey throughout the day).

PA Measures

PA was measured using a triaxial hip accelerometer (ActiGraph GT9X), which samples movement at 30 Hz and aggregates data into 60-second epochs. The intensity cut points for PA were defined using validated thresholds for vertical axis accelerometry (sedentary<100 counts/min, moderate=2020 counts/min, and vigorous=5999 counts/min) [39]. Energy expenditure was calculated using respective validated triaxial vector magnitude (VM) equations for >2453 VM counts per minute [40] and ≤2453 VM counts per minute [41]. The nonwear periods were defined as ≥60 consecutive minutes of zero activity intensity counts, with allowance for 1-2 minutes of counts between 0 and 100. We considered a day valid if ≥10 hours of activity counts were collected [39] and a 2-hour interval valid if the full time was collected. Accelerometer data were downloaded into ActiLife software (ActiGraph) using the software’s normal filters and scored to create the following variables: total wear time (min), daily wear time (hour/day), total daily energy expenditure, MVPA (min/day), and sedentary time (hour/day). For within-person analyses, these were normalized to the wear time (eg, percent time in MVPA).

Procedures

Institutional review board approval was obtained from Yale University, and written informed consent was obtained from all participants. At the initial study visit, face-to-face baseline interviews were completed using validated questionnaires. Body weight and height were measured using a portable electronic scale (Omron HBF-514C body composition monitor and scale) and a stadiometer (Seca) following standard procedures. BMI was calculated as weight (kg)/height squared (m^2). Percent body composition was measured using the same digital scale that measures foot-to-foot bioelectric impedance. This method has demonstrated significant correlations with the gold standard of body fat calculation (ie, dual energy x-ray absorptiometry scan) [42]. After 5 minutes of rest, blood pressure was measured twice with an automated cuff (Omron HEM 780 IntelliSense automatic blood pressure monitor), with 1 minute between readings, and the average of the 2 readings was recorded.

To tailor the EMA survey delivery time, we asked participants for their sleep, wake, or commuting schedules by phone before the baseline study visit. At the baseline visit, we loaded the mEMA app, which is compatible with both iOS and Android operating systems, into each participant’s smartphone. The EMA survey prompted each participant at a random time within the 5 preprogrammed windows daily (ie, signal-contingent sampling) for 7 days (a total of 35 signals) to ensure adequate spacing throughout the day, except for nighttime and commuting time. Upon hearing the signal or vibration, the participants were instructed to complete a short electronic question sequence using their smartphone. Each EMA survey took approximately 3-4 minutes to answer. The EMA data collection system recorded the date and time it took each participant to respond to a random prompt survey and the date and time the survey expired. The survey expired after 40 minutes of nonresponse. After no entry was made, the EMA program became inaccessible until the next recording opportunity.

Participants were instructed to wear an accelerometer on their right hip during waking hours for 7 consecutive days to obtain at least three weekdays and one weekend day to determine the daily variability [39,43]. A paper diary was provided, and participants were instructed to fill out the diary on the time they took off (eg, shower) and wore their accelerometers. All participants received one-on-one in-person training in the EMA surveys and accelerometers. We also provided pictures and step-by-step written instructions on the use of EMA, accelerometers, a tiered payment schedule, and research staff contact information. In addition to the study questions, we sent reminders through EMA to wear their accelerometer daily for all 7 days. We also assessed the risks and symptoms of participants with a risk for depression (based on CES-D>16) and suggested primary care office visits or made referrals per study protocol.

Data Management and Analysis

EMA data were exported from the mEMA server to a comma-separated values file format. We entered the EMA and accelerometer data as well as the baseline surveys and anthropometric and clinical data into a database uploaded into SAS for analysis. We reviewed the data and corrected errors, missing data, outliers, and skewness and calculated the scale scores for the EMA responses. Descriptive analysis was used for demographic characteristics, anthropometric and clinical data, and the average values for EMA and PA data. Pearson and Spearman correlation coefficients were calculated at the individual level using the following variables: age, sex, BMI, CES-D, RES sum, MLD sum, annual income, education, blood pressure, body fat, racial identity, subjective social status, smoking and alcohol consumption, EMA survey data, and accelerometer data. EMA and PA data were scored for daily and individual (average in subject) levels. Intraclass correlation coefficients were calculated to quantify the proportions of total variance of PA explained by within- and between-person variances. Multilevel models for predicting PA (percentage sedentary time and percentage MVPA) were developed to examine the associations with EMA survey data (racial discrimination and microaggression) at the 2-hour interval (within-person), daily (within-person), and individual (between-person) levels. The models included within- and between-person levels of racial discrimination (model 1) or microaggression (model 2) with covariates (eg, age, sex, and BMI). Compound symmetry was used as a within-person correlation structure. Standardized coefficients were obtained using standardized outcomes and covariates with 0 mean and 1 SD.

Results

Overview

The mean response rate for EMA surveys was 83% (29/35; SD 16%), and the mean number of EMA responses per day was 4.0 (SD 1.2) out of a possible maximum of 5 per day. A total of

83.3% (10/12) of participants met the inclusion requirements for valid accelerometer data (≥10 hours/day wear time) and wore the accelerometer on the hip 6 out of 7 days. The mean EMA-reported daily racial discrimination was 0.61 (SD 0.85) per day, with a range of 0-2.28 (possible range: 0 to 10 times/day). Three participants reported no daily racial discrimination over the 7-day period (ie, their 7-day mean racial discrimination was 0). For the EMA-reported daily microaggression, the mean score was 50.26 (SD 18.11), with a range of 19.14-76.71 (possible range: 15-105/day).

Participant characteristics and descriptive statistics from the survey and anthropometric and clinical and accelerometer data are presented in Table 1. The mean age was 43.4 (SD 7.73) years. The majority worked full-time. Approximately 67% (8/12) had an annual income of less than US $60,000. The mean CES-D score was 21.08 (SD 8.36). The mean Black racial identity (centrality) was 5.21 (SD 1.46), indicating that most of our participants self-defined Black race as a core part of their self-concept. The mean subjective social status was 7.08, indicating that most rated their social status as high in the community. The mean BMI was 34.19 (SD 11.41) kg/cm^2; approximately 42% (5/12) of the participants were obese. The mean MVPA was 18.5 minutes/day, and the mean sedentary time was 8.6 hours/day. Paired data, including both EMA and valid accelerometer data, resulted in a sample size of 9.

Table 1. Characteristics of the participants (n=12).

Characteristic	Value
Age (years), mean (SD)	43.4 (7.7)
Woman, n (%)	8 (67)
Work, n (%)	
Working full-time	10 (83)
Working part-time	2 (17)
Annual income (US $), n (%)	
0-39,999	2 (17)
40,000-59,999	6 (50)
60,000-79,999	1 (8)
80,000-99,999	2 (17)
>100,000	1 (8)
Education, n (%)	
Some high school	1 (8)
Vocational or technical school	1 (8)
Some college	5 (42)
College graduate	5 (42)
BMI (kg/m^2)	
Mean (SD)	34.1 (11.4)
18.5-24.9 (normal), n (%)	3 (25)
25-29.9 (overweight), n (%)	4 (33)
30-34.9 (class 1 obesity), n (%)	0 (0)
35-39.9 (class 2 obesity), n (%)	1 (9)
>40 (class 3 obesity), n (%)	4 (33)
Systolic blood pressure (mm Hg), mean (SD)	123.0 (16.1)
Diastolic blood pressure (mm Hg), mean (SD)	82.5 (13.0)
Total body fat (%), mean (SD)	38.8 (14.2)
Visceral fat (%), mean (SD)	10.8 (5.3)
RMAS[a] (1-7), mean (SD)	4.5 (1.0)
EOD[b] (0-9), mean (SD)	5.1 (2.5)
Racial identity (1-7), mean (SD)	5.2 (1.5)
Depression>(by CES-D[c]; 0-60)	
Mean (SD)	21.1 (8.4)
≥Cutoff value of 16, n (%)	8 (67)
≥Cutoff value of 20, n (%)	5 (42)
Subjective social status (1-10), mean (SD)	7.1 (2.4)
Smoking, n (%)	
No	11 (92)
Yes	1 (8)
Alcohol consumption, n (%)	
Never	3 (25)
Monthly or less	5 (42)

Characteristic	Value
2-4 times a month	4 (33)
MVPA[d] (min/day)[e], mean (SD)	18.5 (16.3)
Total energy expenditure (kcal/day)[e], mean (SD)	547.3 (280.2)
Sedentary time (hour/day)[e], mean (SD)	8.6 (2.1)

[a] RMAS: Racial Microaggression Scale.

[b] EOD: Experiences of Discrimination.

[c] CES-D: Center for Epidemiological Studies Depression Scale.

[d] MVPA: moderate-to-vigorous physical activity.

[e] Indicates accelerometer data (n=9).

Between-Persons Survey and EMA Analyses

In the bivariate analysis, using baseline surveys and anthropometric and clinical data, depressive symptoms were associated with major lifetime discrimination (*r*=0.58; *P*=.04) and a higher frequency of major lifetime discrimination (*r*=0.67; *P*=.04). Visceral fat was associated with diastolic blood pressure (*r*=0.62; *P*=.04) and sedentary time (*r*=0.73; *P*=.04) but was not associated with major lifetime discrimination. Income level was not significantly associated with Black racial identity (centrality; *r*=−0.26; *P*=.41).

Table 2 shows the bivariate correlations between the baseline sample characteristics and the average of the EMA-reported daily racial discrimination variables or PA variables. Greater EMA-reported daily racial discrimination was significantly associated with younger age (*r*=−0.75; *P*=.02). Black racial identity was not significantly associated with EMA-reported daily racial discrimination (*r*=0.21; *P*=.58) or microaggression (*r*=0.06; *P*=.88). Daily EMA-reported microaggression was associated with depressive symptoms (*r*=0.66; *P*=.05), past race-related events (*r*=0.82; *P*=.004), and major lifetime discrimination (*r*=0.78; *P*=.01). A higher total energy expenditure was significantly associated with less major lifetime discrimination (*r*=−0.92; *P*=.004). Less sedentary time was significantly associated with a stronger Black racial identity (*r*=−0.68; *P*=.04). More MVPA was significantly associated with lower levels of subjective social status (*r*=−0.75; *P*=.02).

Table 2. Correlations between demographic characteristics and the average scores of the ecological momentary assessment survey or physical activity.

Variables	EMA[a] survey				Physical activity					
	Racial discrimination		Microaggression		Total energy expenditure		Percentage sedentary time		Percentage MVPA[b]	
	Correlation, *r*	*P* value	Correlation, *r*	*P* value	Correlation, *r*	*P* value	Correlation, *r*	*P* value	Correlation, *r*	*P* value
Age[c]	*−0.75*[d]	*.02*	−0.04	.92	0.42	.26	−0.01	.97	0.05	.89
Sex[c]	−0.39	.30	0.21	.59	−0.07	.86	0.24	.54	−0.31	.42
BMI[c]	0.09	.82	0.05	.90	0.65	.06	0.52	.15	0.23	.55
Depression (CES-D[e])[c]	0.60	.08	*0.66*	*.05*	−0.53	.14	0.46	.22	−0.53	.14
Annual income[f]	−0.45	.22	−0.04	.91	−0.09	.82	0.47	.20	−0.31	.42
Education[f]	−0.30	.42	−0.33	.38	0.52	.15	0.19	.63	0.33	.38
Systolic blood pressure[c]	0.32	.41	0.04	.92	0.30	.43	0.64	.06	−0.45	.23
Diastolic blood pressure[c]	0.43	.24	0.00	.99	0.30	.44	0.61	.08	−0.23	.55
Total fat[c]	−0.22	.56	0.10	.79	0.52	.15	0.5	.17	0.00	.99
Racial identify[f]	0.21	.58	0.06	.88	−0.02	.95	*−0.68*	*.04*	0.04	.91
Subjective social status[f]	−0.14	.72	0.30	.44	−0.22	.57	0.22	.57	*−0.75*	*.02*
Smoking[f]	0.42	.26	−0.14	.72	−0.14	.72	0.00	.99	0.14	.72
Alcohol consumption[f]	−0.13	.74	−0.10	.82	−0.59	.09	−0.54	.13	0.00	.99
Past RES[g] (RES sum)[c]	0.52	.15	*0.82*	*.004*	−0.60	.09	−0.18	.64	−0.12	.75
MLD[h] scale (MLD sum)[c]	0.40	.28	*0.78*	*.01*	*−0.92*	*.004*	−0.11	.77	−0.59	.09

[a] EMA: ecological momentary assessment.

[b] MVPA: moderate-to-vigorous physical activity.

[c] Indicates Pearson correlation coefficients.

[d] Italicized values denote significance.

[e] CES-D: Center for Epidemiological Studies Depression Scale.

[f] Indicates Spearman correlation coefficient.

[g] RES: Race-Related Events Scale.

[h] MLD: Major Life Discrimination.

Within- and Between-Person EMA Analyses

Intraclass correlation coefficients were calculated to represent the proportion of the total variance of the PA outcomes explained by the between-person levels. They were 0.54, 0.26, and 0.66 for total energy expenditure, sedentary time, and MVPA, respectively.

The within-person interval-level analysis found that during the 2-hour windows in which people reported more perceived racial discrimination, they had moderately greater sedentary time (β=.30, SE 0.21; *P*=.18) and slightly more MVPA (β=.04, SE 0.13; *P*=.77). Similarly, during the 2-hour windows in which they reported more perceived microaggression, they had less sedentary time (β=−.11, SE 0.16; *P*=.51) and less MVPA (β=−.34, SE 0.18; *P*=.10). However, none of these relationships during the 2-hour windows reached statistical significance.

The within-person daily levels and between-person analyses are presented in Table 3. In the within-person daily-level analyses, the association of racial discrimination and sedentary time was significant (β=.30, SE 0.14; *P*=.03), indicating that during days when participants reported more perceived racial discrimination, they had moderately more sedentary time.

Table 3. Multilevel model of mean daily physical activity outcomes (multilevels: level 1=daily and level 2=subject).[a]

Predictor variables and level	Outcome variables					
	Total expenditure (kcals) daily		Percentage sedentary time daily		Percentage MVPA[b] daily (log-transformed)	
	Coefficient (SE)	*P* value	Coefficient (SE)	*P* value	Coefficient (SE)	*P* value
Model 1: racial discrimination						
Within-person	0.12 (0.12)	.31	*0.30 (0.14)* [c]	*.03*	0.09 (0.11)	.41
Between-person	−0.30 (0.28)	.29	−0.07 (0.24)	.76	−0.07 (0.31)	.81
Model 2: microaggression						
Within-person	−0.05 (0.28)	.84	−0.05 (0.34)	.87	−0.25 (0.26)	.33
Between-person	−0.34 (0.36)	.34	0.13 (0.39)	.73	0.03 (0.39)	.93

[a] The predictor and outcome variables were standardized for 0 mean (SD 1).

[b] MVPA: moderate-to-vigorous physical activity.

[c] Italicized values denote significance.

Discussion

Principal Findings

Perceived racial discrimination is a significant psychological stressor that is hypothesized to have negative mental and physical health consequences with potential interactions with unhealthy behaviors. The relationship between overall psychological stress level and PA using EMA and objective measures has been evaluated in the general population; however, in what we believe to be the first published study of its kind, we examined momentary- and daily-level perceived racial discrimination and PA levels using EMA and accelerometers in African Americans. We collected repeated real-time racial discrimination exposure data in the natural environment while simultaneously collecting objective measures of sedentary behaviors and PA among African Americans. We also demonstrated the utility and feasibility of EMA coupled with accelerometers in studying the relationship between daily racial discrimination and PA in African Americans. Conventional accelerometer protocols require only 4 valid days for a 7-day wear period to be considered valid [39,43]. Approximately 83% (10/12) of our participants met the inclusion requirement for valid accelerometer data (≥10 hours/day wear time) and wore the accelerometer 6 out of 7 days, and they also showed high adherence to the EMA protocol.

In the examination of within-person level data, on days when participants reported more perceived racial discrimination than usual (ie, higher than their personal mean), more sedentary time was observed in the accelerometer data. The between-person analysis did not duplicate this finding in our study. However, this is consistent with the findings of between-person analysis in a prior study examining the relationship between general psychological stress and sedentary behaviors in other populations: end-of-day general stress ratings were not associated with sedentary time in the between-person analysis (at the group level) [16]. The influence of stress on sedentary behavior varies according to the source of stress within individuals [16,44]. Heterogeneity in the effect of stress on the amount and pattern of sedentary behaviors has been documented; for example, argument-related stress was associated with increased sedentary time, whereas work-related stress was associated with decreased sedentary time [16,45]. Similarly, in a study of sexual and gender minority individuals, between-person associations of discriminatory experiences and substance use were not significant, whereas more discriminatory experiences were significantly associated with more nicotine, alcohol, and drug use within the person [21]. This highlights the potential limitations of between-person methods (nomothetic) that predominate in research and suggests that the within-person level (idiographic) precision health approach may be highly relevant to target reductions in sedentary time and other unhealthy behaviors [16,44].

An important advantage of the EMA methodology is its ability to examine the frequency of racial discrimination experiences in real time and assess the impact of the experiences in a microtemporal relationship (eg, repeated assessments across minutes or hours). In our study, participants reported, on average, 0.61 overt racial discrimination experiences per day, and most participants experienced substantial daily microaggressions. The reported frequency of racial discrimination varies widely across studies [46-49]. In earlier cross-sectional studies using retrospective measures, discrimination was reported to occur only infrequently [50]; however, recent studies using EMA or other types of daily diaries have revealed that discrimination may occur multiple times per day. For example, in a study using EMA, African American participants reported about 2 experiences per day of racism [20]. In another study using EMA among African American adolescents [22], participants reported 5 experiences of racial discrimination per day when comprehensive measures of racial discrimination were used, including social media, vicarious, and teasing experiences, along with the more commonly measured individual and general forms of racial discrimination.

In several studies of psychological stress, not specific to racial discrimination-related stress in the general population, episodic stress predicts less PA, more sedentary behaviors, and reduced total energy expenditure [15,51]. Consistent with these studies, we found that major lifetime discrimination (from a retrospective measure) was significantly associated with lower total energy expenditure measured by the accelerometer. However, EMA-reported microaggressions were not associated with PA outcomes in our within-or between-person analyses. The nonsignificant relationship may be because of the small sample size and lack of variability in terms of the frequency of microaggression experiences within and across days. Overall, our participants reported frequent daily microaggressions, which may not have had a significant impact on their daily PA levels. However, the observed effect size based on standardized β coefficients [52] suggests the need for more studies to examine the determinants of PA and sedentary behaviors with a larger sample size and a longer assessment period.

Consistent with other studies [46,53,54], retrospectively measured exposure to race-based discrimination over a lifetime (assessed at baseline) was significantly associated with more depressive symptoms and with more daily microaggression experiences measured by EMA. Given the different data collection methods (retrospective surveys vs EMA) in this study, we could not determine the temporal relationship between racial discrimination or microaggression and depressive symptoms, and the findings may reflect a reverse causal relationship (eg, people with more depressive symptoms or such traits may perceive more microaggression). However, lagged effects of racial discrimination on depressive symptoms in subsequent days were reported among African Americans and Hispanics or Latinos in other studies [49,55], suggesting that individuals may not easily or fully recover from discrimination, and racial discrimination may have lasting effects on mental health [50,56]. Taken together, our findings highlight the important association between racial discrimination and mental health. Furthermore, future studies examining additional psychological factors, such as traits and personality, are needed to determine both the concurrent and lagged effects of racial discrimination on health and health behaviors. Such studies may inform the development of individualized interventions that can buffer the harmful effects of racial discrimination on health.

Strengths and Limitations

This study had several limitations. Although we found similar trends in within- or between-person effects on sedentary behaviors and PA, compared with other studies of general psychological stress, our small sample size offers limited evidence supporting racial discrimination as an antecedent to sedentary behaviors or PA. EMA minimizes recall bias and errors. However, it is also possible that our study findings may have been influenced by vigilance to discrimination from the repetitive assessment involved in EMA. In addition, the high CES-D scores observed in our participants may have influenced the associations with perceived racial discrimination or PA. Although findings are mixed, previous studies have shown that neighborhood environments such as walkability, safety, or crime were associated with individuals' PA levels in the general population [57,58]. We obtained walkability (Walk Score) and crime index data based on participants' zip codes (data not shown); however, the predominantly Black neighborhoods in our sample showed a lack of variability. Future studies with measures of social environment, segregation, and perceived neighborhood environments, in addition to objective built environments, would be helpful in understanding the relationship between PA and relevant correlates. Owing to the exploratory nature of our pilot study with the scarcity of EMA studies of racial discrimination, we conducted a 2-hour within-person, prompt-level analysis; however, assessment may need longer time frames to determine the association between racial discrimination and PA levels. In addition, using event-contingent sampling (ie, EMA is reported when a discrimination event occurs) may be helpful in determining the frequency of racial discrimination; one caveat is that it may not accurately measure events if many participants forget to report them (missing EMA). In addition, our study included only in-person and individual racial discrimination experiences. Including web-based (eg, communication in social media) and vicarious discrimination experiences (eg, watching traumatic videos of police brutality) may provide more valid frequency estimates [22,59]. Future efforts should include studies with a large sample, more extensive racial discrimination measures, and EMA sampling to determine the optimal frequency of EMA to accurately capture discriminatory experiences and to examine its relationship with health behaviors.

Despite these limitations, this study provides valuable insights into examining the within-person effects of racial discrimination on health behaviors and suggests the need to examine a more complex relationship between racial discrimination and lifestyle behaviors with time-varying factors.

There is a growing emphasis on within-person examination of health behaviors and psychosocial correlates and on the importance of leveraging these data to develop personalized, *just-in-time* interventions [50,60]. Examining this daily process using a within-person approach has the potential to elucidate the mechanisms of which racial discrimination may have on health and health behaviors and to guide the development of personalized interventions for increasing PA and decreasing depressive symptoms in racial ethnic minorities.

Conclusions

In conclusion, the results of this study highlight the utility and feasibility of a within-person approach to target reductions in sedentary time and improvements in PA associated with daily racial discrimination by using EMA and an objective measure of PA. Further studies are needed to confirm the observed findings in light of the limitations of this study, including its small sample size. A precision health approach that incorporates between-person associations and accounts for within-person variations in the relationship between racial discrimination and health behaviors is warranted to mitigate race-based health disparities.

Conflicts of Interest

None declared.

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Abbreviations

CES-D: Center for Epidemiological Studies Depression Scale
EMA: ecological momentary assessment
EOD: Experiences of Discrimination
MLD: Major Life Discrimination
MVPA: moderate-to-vigorous physical activity
PA: physical activity
RES: Race-Related Events Scale
RMAS: Racial Microaggression Scale
VM: vector magnitude

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Original Paper

Multimodule Web-Based COVID-19 Anxiety and Stress Resilience Training (COAST): Single-Cohort Feasibility Study With First Responders

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Abstract

Background: Since the emergence of COVID-19, health care workers and first responders have been at a high risk for mental health symptoms owing to their exposure to the virus and increased work stress during the pandemic. Although interventions exist to address mental health issues following exposure to disasters, emergencies, and humanitarian crises, considerably less is known about web-based unguided interventions to help mitigate the negative impacts of such events. Additionally, in contexts in which emergencies reduce access to in-person care, remote forms of support are critical, yet there are limited studies on the use of such interventions. Evidence-based, easy-to-use, scalable interventions are direly needed for this population.

Objective: This study aimed to develop and test the feasibility of an unguided electronic mental health program, COVID-19 Anxiety and Stress Resilience Training (COAST), tailored to first responders and health care personnel, based on scientific evidence and empirically based techniques.

Methods: We developed COVID-19–specific training modules focusing on several domains that are previously reported as key to resilience and stress recovery: self-efficacy, mindfulness, sleep quality, and positive thinking. The program was made available to 702 first responders between May and August 2020, during the COVID-19 pandemic. Sociodemographic, work-, and COVID-19–related information was collected, and psychometric questionnaires were completed. We examined user acceptance and user activity, including module choice and participant feedback.

Results: In total, 52 of 702 (7%) first responders to whom we reached out used the program at least once. COAST use was independent of age, sex, or baseline levels of self-efficacy, mindful awareness, sleep quality, and positive thinking (for all, $P>.39$). First responders who had tested positive and those who had been quarantined were more likely to engage in the program. A click count analysis per module showed that participants used the self-efficacy and mindfulness modules most often, with 382 and 122 clicks, respectively, over 15 weeks. Overall, first responders expressed satisfaction with the program.

Conclusions: Engagement of first responders in the multimodule web-based COAST program was feasible and the first responder cohort expressed overall satisfaction with the program. Those in more difficult circumstances, including those in quarantine and those who tested positive, may be more likely to engage in such programs. Further controlled studies could pave the way for efficacy studies and the development of additional modules, including just-in-time interventions or blended interventions combining individual use of an unguided self-help intervention, such as COAST, with subsequent individual psychotherapy for those who continue to experience stress and psychological symptoms.

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KEYWORDS

anxiety; COVID-19; electronic mental health; feasibility; first responder; mental health; mindfulness; resilience; self-efficacy; sleep quality; stress; training

Introduction

Since early 2020, COVID-19 began to severely impact the daily lives of a majority of the world's population after a cluster of infections was first identified in China as early as December 2019 [1]. In most countries, including Switzerland, severe measures were taken to prevent the further spread of SARS-CoV-2, including strict safety and hygiene rules and physical distancing. Lockdown and physical distancing measures, along with perceived unpredictability and uncertainty, may lead to social isolation, loss of income, loneliness, inactivity, limited access to basic services, and other compromises. COVID-19 has thus resulted in an increase in known risk factors for psychiatric disorders such as depression and anxiety [2]. A number of studies documented significant effects on the population's mental health, with studies reporting higher levels of depression in the general population [3]. Health care workers and first responders were often found to be at high risk for mental health issues owing to increased exposure to the virus and higher work stress during the pandemic [4-7], and they experience increased mental health symptoms [8].

With physical distancing and other restrictions in place and a decreased mental health system capacity, calls for increased investment in telehealth and telepsychiatry, as well as other digital mental health solutions, have emerged [9-11]. Digital mental health prevention and intervention programs offer effective, often unguided, and scalable solutions to improve mental health. These can often be used anonymously, making their use lower threshold than that of in-person therapy [12-14], and are acceptable by users [15]. Early interventions could be key to prevent overburdening mental health care systems during and after the COVID-19 pandemic [16,17]. Indeed, some electronic mental health (e-mental health) interventions have already been implemented in different countries during the pandemic [18-20]. Studies on the feasibility and effectiveness of e-mental health interventions for medical personnel and first responders, however, remain scarce. A recent review reported 3 studies on mental health programs specifically targeted at medical personnel during the pandemic through e-mental health approaches [21]. However, there is evidence for the efficacy of e-mental health approaches for these populations in other circumstances. A blended e-mental health intervention to manage weight was effective in a sample of first responders and included interventions on sleep and psychological symptoms [22]. Another 3-month web-based intervention to reduce work-related fatigue and improve work function resulted in a small positive effect on overall stress in health care workers [23]. E-mental health interventions are thus a promising way to support health care workers and first responders in general and possibly during crises, including the current COVID-19 pandemic. Not all current approaches are based on empirical evidence or employ principles of evidence-based treatment approaches for psychiatric disorders, such as cognitive behavioral therapy [24]. To help bridge this gap, we developed a research-based e-mental health program tailored to first responders and health care personnel, which is based on robust scientific evidence and empirically based techniques, is self-paced and unguided, and can be delivered anonymously. Our study aimed to (1) develop research-based, web-based, COVID-19–specific training modules focusing on the key areas of self-efficacy, mindfulness, sleep quality, and positive thinking to increase resilience in health care workers and first responders; (2) assess sociodemographic, COVID-19–, and stress-related characteristics of first responders opting into the program; and (3) examine user acceptance and activity, including their choice of different modules and feedback.

Methods

Study Design

This study was designed as single-cohort feasibility study to evaluate a COVID-19 Anxiety and Stress Resilience Training (COAST) program and receive user feedback for future adaptation of our modules. The study was approved by the ethics committee of the philosophical faculty of the University of Zurich. We included first responders who were offered free and unlimited access to the program. The first users and study participants joined COAST in May 2020, and final questionnaires were completed in July 2020. Our analyses encompass an overall period of 15 weeks, during which participants were followed-up during their individual use of the program.

The COAST Program

COAST comprises 4 intervention modules to increase resilience to stress due to the COVID-19 pandemic. These modules were made available on a website for free and self-paced perusal by our participants. The self-paced option appeared relevant to adapt to the busy schedule of health care workers during the pandemic. All 4 modules are standalone modules, targeting (1) self-efficacy, (2) sleep quality, (3) mindfulness, and (4) gratitude and positive reframing. The choice of these module topics was based on previous reports that identified them as useful targets to improve resilience to stress and adversity [25-28] and on the target population's documented preference for e-mental health interventions to be focused on well-being rather than on ill health [29].

Each module contained explanations and mini-interventions that users could engage with in their daily lives, based on previous results and protocols and adapted for web-based use. The self-efficacy module was based on the findings that activating autobiographic memories of perceived self-efficacy can help strengthen clinically relevant factors for tolerating distress [30] and promote relevant cognitive processes and problem-solving that might help patients recover from stress [31] [Multimedia Appendix 1]. Users are asked to recall 3 memories of situations that they handled well and write down which hurdles they overcame and which traits, qualities, and strengths helped them overcome these hurdles. The sleep module consists of a worry diary and tips for better sleep hygiene, both proposed by Altena et al [32] and the European Academy for Cognitive-Behavioral Therapy for Insomnia. The module on mindfulness includes various audio files with guided meditations. Studies on populations of health care workers found mindfulness to be associated with reduced depressive symptoms, more adaptive defense mechanisms against stress, lower burnout and stress levels, and higher life satisfaction [33-35]. These findings are supported by a meta-analysis that reported mindfulness-based interventions to be an effective tool to help medical personnel cope with stress [26]. COAST's gratitude module involves a gratitude diary, which users can fill in daily. Killen and Macaskill [36] reported that a gratitude diary could positively influence well-being and found no difference in efficacy between the paper-based and web-based versions of this intervention. The use of interventions that train gratitude has further been proven effective in various studies [36-38], partially focusing on health care workers.

Decisions in favor of shorter interventions and questionnaires were taken considering previous reports highlighting the occasional low participation rates of health care workers and first responders and their high workload [39].

Recruitment

We recruited first responders from Schutz & Rettung Zürich, an urban first responder organization that provides first aid services in the Greater Zurich Region. For our study, all 702 first responders in the service, mostly including ambulance workers and fire fighters, were invited to use COAST via email. In total, 52 of them used COAST at least once and were included in the study. The emails contained an invitation to take part in the study, with the purpose of evaluating COAST, and a link to the first set of study questionnaires (baseline) immediately after registration. Furthermore, users were asked to fill in a short questionnaire on the website and were sent reminders to do so. Inclusion criteria were being a first responder at the abovementioned institution, providing consent to participate in the study, and signing up for the COAST program. Participants in the study were offered to enter a raffle and win 1 of multiple vouchers by entering a draw at the end of each external questionnaire. Owing to the exploratory nature of the study and our interest in feasibility indices that are largely independent of sample size, power analysis was not conducted.

Procedure

Participants chose an anonymous username, as the privacy of e-mental health interventions had been previously raised as an important issue pertaining first-responder interventions [22]. They were also asked to complete self-report questionnaires that were sent via email and could be completed on the internet. These links were sent at three timepoints: at baseline (ie, after registration and prior to starting COAST) (questionnaire 1), at 2 weeks (questionnaire 2), and at 4 weeks (questionnaire 3). Questionnaires 2 and 3 also included a user experience questionnaire. They also were asked to complete several items covering each module's target outcome (self-efficacy, mindfulness, sleep, and optimism) on the COAST website.

First responder personnel in Zurich, who were interested in engaging with the COAST program, were sent a log-in code for the program via email. The program was delivered via a custom-built university website. For those participating in the study, the code was also used to match program-based data (including user indices and questionnaire items on the website) from the COAST website, with other questionnaires that were sent to participants via a link to their browser, and completed on the internet to ensure anonymity. The users agreed to the use of their data for research purposes when entering their code prior to their engagement with the COAST program and at the beginning of each questionnaire that was filled in outside of the program. All questionnaires were filled in on the internet. A total of 3 reminder emails were sent for questionnaire completion.

Measures

Participants filled in items embedded in the COAST program as well as separate questionnaires at baseline and at 2 and 4 weeks' follow-up. Questionnaire completion was not mandatory for participating in the program, and the number of users who completed questionnaires varied. We thus report on different subsamples.

We used standardized, validated, self-reported measures at baseline (questionnaire 1) and follow-up (questionnaires 2 and 3), including the Perceived Stress Scale [40] (Cronbach α=.95), the 9-item Patient Health Questionnaire [41] (Cronbach α=.83), the 7-item Generalized Anxiety Disorder Scale [42] (Cronbach α=.89), the General Self-Efficacy Scale [43] (Cronbach α=.76), and the Posttraumatic Stress Disorder Checklist of the Diagnostic and Statistical Manual of Mental Disorders (5th edition) [44] (Cronbach α=.95). An adapted version of the 8-item Client Satisfaction Questionnaire (CSQ-8) [45] was used in questionnaires 2 and 3 to assess the users' satisfaction with the web-based program. For our study, we adapted CSQ-8 items to refer to the web-based program rather than the service, the clinic, or the treatment. No further modifications were made. In our sample, the measure had a high internal consistency (Cronbach α=.94). We also employed an open question on potential further suggestions to optimize the program (eg, "Do you have ideas, suggestions, or criticism for us that could help us make COAST better?").

Within the COAST program, sociodemographic, work-, and COVID-19-related questions were completed by the participants. We also included key questions corresponding to each of the target modules obtained from the validated questionnaires. Users were asked to fill in the questions when they started using the program. The questions measured stress ("How nervous or stressed do you feel today?”), perceived self-efficacy (“How much do you currently believe in being able to change things in your life?”), mindfulness (“I am in contact with my experiences here and now”), sleep quality (“How would you judge your sleep quality since the last log-in?”), and optimism or positive thinking (“I have a positive outlook on the future”). Users answered the questions on a scale of 0-10 for stress, self-efficacy, and optimism and 0-3 for sleep quality and mindfulness.

Activity scores were calculated over 15 weeks on the basis of the users’ activity in the program, reflecting the number of times individual pages of the program were accessed, including repeated access to the same page.

Statistical Analysis

All statistical analyses were conducted in RStudio (version 1.3.959) for Mac OS [46]. We calculated mean (SD) and percentage values for sociodemographic and COVID-19–related variables and for other questionnaire and activity scores. The number of clicks per page was grouped per module, and clicks per module were counted to determine the differences in user activity (n=52). Correlations were calculated among questionnaire item scores and user activity. Pearson correlation analysis was used where normality distribution assumptions were met and adjusted to nonparametric testing in all other cases. We applied 1-sided significance testing and a *P* value of .05 to indicate significance.

Results

Characteristics of First Responders Opting Into the COAST Program and Their Association With User Activity

Sociodemographic information and scores for in-program questions are displayed in Table 1. The sample comprised 52 first responders, of which 42 (42.9% female) completed in-program questionnaires. The mean age was 43 (SD 10.53) years, with 14 (26%) participants having been quarantined at some time point, and 1 (2%) was quarantined at the time of filling in the questionnaire. Moreover, 21% worked or had worked in direct contact with patients with COVID-19. In total, 1 (2%) participant had tested positive for COVID-19, and 6 (24%) stated that they belonged to a COVID-19 risk group for severe disease progression. Single questions within COAST yielded low perceived stress and sleep problems in our sample while showing high self-efficacy and optimism, as well as an intermediate level of mindfulness.

Table 1. Descriptive statistics (N=42).

Characteristic	Value
Sex, n (%)	
Female	18 (42.90)
Male	24 (57.10)
Age (years), mean (SD)	43.79 (10.53)
Quarantine, n (%)	
At any time	11 (26.19)
At time of study	1 (2.38)
Direct contact with patients with COVID-19, n (%)	9 (21.43)
Member of a risk group, n (%)	10 (23.81)
Tested positive for COVID-19, n (%)	1 (2.38)
Activity score, mean (SD)	15.46 (10.31)
Question scores, mean (SD)[a]	
Perceived Stress	3.39 (2.83)
Perceived Self-Efficacy	6.85 (2.27)
Sleep	1.16 (0.85)
Mindfulness	1.63 (0.97)
Optimism	7.23 (2.20)

[a] Questionnaires were based on single items completed within the program while working on COAST modules. Scores ranged 0-10 for stress, self-efficacy, and optimism and 0-3 for sleep quality and mindfulness, with higher scores indicating more perceived stress, self-efficacy, lower sleep quality, and greater mindful awareness.

COAST participants were representative in terms of age and sex, for the overall population of first responders from the aforementioned first responder organization, one of the largest urban first responder units in Switzerland, and there were no significant differences between the 2 populations in these variables. However, the proportion of positive COVID-19 tests was higher among COAST participants than among the total sample of 702 first responders in the organization (2.4% vs 0.7%, respectively), and 26% of COAST participants reported having been in quarantine at some time, while this number was at less than 1% in the overall first responder population.

Participant Acceptance, Activity, and Feedback

We found no significant correlations between user activity (ie, number of clicks) and sociodemographic, COVID-19–, or work-related items (ie, previous COVID-19 infection, age, sex, current quarantine, etc). Perceived stress and self-reported scores relating to module targets (self-efficacy, mindfulness, sleep quality, and optimism) were also unrelated to user activity scores (Table 2).

Analysis of the click count per module indicated that the self-efficacy module was used the most (amounting to 382 clicks), followed by the mindfulness (122 clicks), sleep (103 clicks), and gratitude (47 clicks) modules. The mean activity score of all users was 15 (SD 11.11) clicks in the program, assessed over a period of 15 weeks. Activity scores ranged 0-54 clicks, while the time spent on the pages was not measured. We detected 3 outliers through visual analysis of the boxplot and excluded them from the activity scores.

On average, users were satisfied with the program, as indicated by a mean score of 21.42 (SD 4.08; range 8-32) on the CSQ-8, representing “mild satisfaction.” Some participants reported difficulties using a web-based format or wanted more visualization of the content. One user was concerned about confidentiality, specifically with regard to work-related answers.

Table 2. Association between program activity levels (ie, click count score) and sociodemographic variables, perceived stress, and scores mapping on module targets.

Variable	Association with program activity[a,b,c,d]	*P* value
Age	0.03[c]	.57
Sex	0.02[a]	.56
Quarantine (at any time)	0.02[a]	.44
Direct contact with patients with COVID-19	0.13[a]	.21
Member of a risk group	0.05[a]	.38
Perceived stress	–0.18[b]	.81
Perceived self-efficacy	–0.06[b]	.39
Sleep quality	–0.05[a]	.60
Mindfulness	0.05[a]	.40
Optimism	–0.03[b]	.55

[a] Point biserial correlation coefficients.

[b] Spearman correlation coefficients.

[c] Pearson correlation coefficients.

[d] Correlations with positive COVID-19 test results could not be determined because only 1 person in the group that responded to the respective questionnaires had received a positive test result.

Discussion

Principal Findings

We developed an evidence-based, multimodule, web-based COAST program to increase resilience to stress among health care workers and first responders during the COVID-19 pandemic. Here we report data from a feasibility study. COAST was actively used by 52 first responders, which accounts for 7% of the overall first responder group targeted and invited to participate during the COVID-19 pandemic. COAST use was independent of age, sex, and perceived stress, as well as scores mapping on the content of the module target of the respective intervention (including self-efficacy, mindfulness, sleep quality, and optimism). First responders who had tested positive for COVID-19 and those who had been quarantined were more likely to engage with the program. This suggests that we indeed may have reached those who are more and directly affected by the COVID-19 pandemic and are potentially in need of an intervention; however, a decreased workload during quarantine may also have contributed to this. Individual users mostly engaged in the self-efficacy memory module, followed by the mindfulness, sleep quality, and gratitude modules. Overall, first responders expressed satisfaction with the program.

The use of web-based technology is gaining popularity in mental health care, and these technologies have become increasingly available and affordable, thus lending themselves to implementation in the current first responder setting. Owing to their busy and challenging work environment, we expected to face challenges with regard to the engagement of this population with our program. Previous studies have indeed confirmed that first responders [29] and medical personnel working at a hospital [39] may have very specific needs as well as expectations from interventions. Hence, we developed COAST to be easily accessible and self-paced and to fit to individual needs. Indeed, we found large interindividual variability in COAST participation, with the number of clicks and activity low among some but regular and high among other first responders. Interestingly, activity was independent of self-reported self-efficacy, mindfulness, sleep quality, optimism, and perceived stress. As expected, some modules were used more than others. The self-efficacy memory module was used most often. Self-efficacy may emerge as a key construct underlying risk and resilience in relation to COVID-19, given the unpredictability of the COVID-19 pandemic and lack of controllability and agency experienced by some individuals. Theoretical models [25] and numerous studies with trauma-exposed individuals have found that self-efficacy is an important mechanism underlying risk and recovery among first responders and emergency personnel [47-49]. Participants in this study may have been drawn to this module in an attempt to improve self-regulation and to experience a sense of control by recalling previous challenges and obstacles that had been overcome. Although these data do not include self-efficacy–related outcomes, interest and engagement in this module may offer a promising strategy for reducing distress and maintaining well-being, as studies have shown that perceptions of self-efficacy can be increased among healthy [50,51] and clinical populations [30,31]. Higher levels of self-efficacy have been associated with greater problem-solving abilities [51] and a higher level of persistence, as well as changes in the activity of brain regions linked to emotional regulation [52]. By instructing and supporting first responders' recall of autobiographical self-efficacy memories, such adaptive phenomena may have been activated, and self-efficacy may have been increased. While these studies support these assumptions, processes in the field, such as those investigated here among the first responder population, will have to be investigated further to elucidate the precise mechanisms of action of individual modules, such as the self-efficacy module.

The second-most frequently used module was mindfulness. This is in line with recent efforts and success of implementing mindfulness interventions for mental health and other health workers [53,54]. Previous studies have reported significant effects of mindfulness programs in scalable, practical ways, including successful delivery of web-based mindfulness training in high-risk workplace settings and first responders in an entirely web-based version, as in our study [50]. Again, we can only speculate the mechanisms of action of this training program. In a previous study on frontline medical workers, we found that lower activation of the arousal system, indexed by activation of the arousal system during an emotion regulation task, was associated with increased resilience during subsequent stressful medical work [55]. Since one demonstrated effect of mindfulness is a change in gray matter concentration in several brain regions, including the locus coeruleus arousal system [56], such changes may well underlie the effects of mindfulness interventions and could be important to the first responder populations. In other words, successful engagement in mindfulness may lead to changes in brain regions that contribute to a more adaptive arousal system and enhanced well-being after mindfulness practice. However, we might have hastened to draw further conclusions about the precise effects of our modules. The same applies to ranking activity in the modules. In addition to personal choice informed by module content, module choice may also reflect the position of the module on the web layout of our program, rather than reflecting the preferences of individual users.

Only a subgroup of participants provided feedback through questionnaires, however this could potentially be of use for further program development. Among the points raised by the participants were privacy concerns, which is commonly reported in such populations [22,29] and should be included in future developments. Specifically, users were concerned about information they provided and that might be fed back to line managers and employers. This was not the case in our program and should be approached similarly by future programs. Our and other future programs should also consider user preferences in terms of graphics and design and should increase and optimize graphical module features, which were rather basic in our program and could be enriched and animated in several ways and include elements of personalization; that is, users would create their very own character that accompanies them, guides them through the modules, and potentially encourages individual engagement.

Our sample was representative of the targeted population of first responders, but the health care system in Switzerland may not be comparable with those in other countries; hence, our findings may not be generalizable to other health care professionals during the COVID-19 pandemic. A country's economy and socioeconomic differences and the severity of the outbreak in the country have been shown to influence the impact of the COVID-19 pandemic on a population [17,18,57]. All our study participants were employed as of this writing, thus also limiting the generalizability of our findings to health care workers and first responders from low-income countries or those with lower job stability.

Limitations

Our study is not without its limitations. First, while we noted significant interest in COAST among our study participants and subsequent activity in the program among those who registered, the response rate to the external questionnaires (questionnaires 1-3), which we administered to our participants for program evaluation, was low and these could therefore not be evaluated. Future programs should make module use conditional on completion of a core set of questionnaire items. Second, all questions were self-reported questionnaire items and were thus associated with known challenges, including a retrospective response bias, social desirability [58], and being affected by current mood states [59]. Further, the scores reported here have been obtained from single questions on each subject, and although these were based on full-length questionnaires, their separate use is not validated. Third, the exact timing of in-program questions and their relation to user progress in COAST could not be determined. We also did not obtain exact results on how long users spent in a given module. Our results are thus preliminary and future studies will need to assess larger samples and test for controlled effects of the program's effectiveness, which could then help establish the program's effectiveness in decreasing the symptoms of stress and change scores in our target processes for self-efficacy, mindfulness, sleep quality, and positive thinking. Finally, and perhaps most importantly, the response rate of the overall population of first responders was 7% and thus rather low. Such challenges to engage health care workers (and indeed other groups) in e-mental health interventions during the COVID-19 pandemic have been well documented. Chen et al [39] reported the reluctance of hospital staff in China to use available support. They adjusted their program to include staff feedback and established resting rooms and provided in-person counseling services. Ketelaar et al [23] suggest using blended care to reduce attrition and boost participation, and this option should be considered for the current program. Another study from Wuhan [37] reported that difficulties with engagement might stem from issues with reduced trust and a heightened sense of stigma, as well as a high workload, and implemented anonymous interventions and daily reminder messages. Additional suggested challenges and reasons for low participation could be low perceived need, technical problems, and unattractive channeling toward their intervention [23]. While we are not aware of any technical problems in the COAST program, the low perceived need could have contributed to low participation, as our baseline questionnaire indicated low mental health symptoms among most respondents. In the future, stepwise approaches could be implemented, including screening for at-risk participants, who will then be offered further interventions rather than a one-size-fits-all approach. Privacy concerns seem to be key in the target population [22,29], and participants often requested that a web-based intervention should be independent from their employer. While COAST was in fact developed, run, and analyzed entirely independently from the employer, the program and study was announced and offered to the participants through their institutional email.

Conclusions

Despite these limitations, our study has practical and clinical implications for prevention and intervention science. We reached a small, albeit significant subgroup of first responders who actively used the program and provided feedback. Advantages of such e-mental health interventions include their application and use without physical contact and their scalability, as we can reach more clients than would be possible face-to-face. These are critical features during crises, such as the current pandemic. More controlled studies on developing and adapting web-based interventions tailored to the preferences and needs of health care workers and first responders during the COVID-19 pandemic are needed. Such studies could also pave the way for additional novel interventions, such as just-in-time interventions or blended interventions combining individual use of a self-paced intervention with subsequent individual psychotherapy for those who continue to experience stress and psychological symptoms.

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Authors' Contributions

JMH and BK conceived the study. TB provided the online platform. JH, NW, BK, and TB developed the web-based modules, and all authors provided feedback and support for program development. SM and UE supported the study implementation and recruitment. JMH conducted the study. JMH and BK conducted the data analyses. JMH and BK wrote the manuscript, and all authors edited the manuscript and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Exemplary screenshot: COAST Self-efficacy module.
[DOC File , 267 KB - formative_v5i6e28055_app1.doc]

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Abbreviations

COAST: COVID-19 Anxiety and Stress Resilience Training
CSQ-8: 8-item Client Satisfaction Questionnaire
e-mental health: electronic mental health

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Original Paper

Development of the 12-Item Social Media Disinformation Scale and its Association With Social Media Addiction and Mental Health Related to COVID-19 in Tunisia: Survey-Based Pilot Case Study

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Abstract

Background: In recent years, online disinformation has increased. Fake news has been spreading about the COVID-19 pandemic. Since January 2020, the culprits and antidotes to disinformation have been digital media and social media.

Objective: Our study aimed to develop and test the psychometric properties of the 12-item Social Media Disinformation Scale (SMDS-12), which assesses the consumption, confidence, and sharing of information related to COVID-19 by social media users.

Methods: A total of 874 subjects were recruited over two phases: the exploratory phase group had a mean age of 28.39 years (SD 9.32) and the confirmatory phase group had a mean age of 32.84 years (SD 12.72). Participants completed the SMDS-12, the Internet Addiction Test, the COVID-19 Fear Scale, and the 10-item Perceived Stress Scale. The SMDS-12 was initially tested by exploratory factor analysis and was subsequently tested by confirmatory factor analysis.

Results: The test supported the three-factor structure. In addition, no items were removed from the measurement scale, with three factors explaining up to 73.72% of the total variance, and the items had a lambda factor loading ranging from 0.73 to 0.85. Subsequently, confirmatory factor analysis confirmed the robustness of the measure by referring to a wide range of goodness-of-fit indices that met the recommended standards. The construct validity of the scale was supported by its convergent and discriminant validity. The reliability of the instrument examined by means of three internal consistency indices, and the corrected item-total correlation, demonstrated that the three dimensions of the instrument were reliable: Cronbach α values were .89, .88, and .88 for the consumption, confidence, and sharing subscales, respectively. The corrected item-total correlation ranged from 0.70 to 0.78. The correlation of the instrument's dimensions with internet addiction and mental health factors showed positive associations.

Conclusions: The SMDS-12 can be reliably utilized to measure the credibility of social media disinformation and can be adapted to measure the credibility of disinformation in other contexts.

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KEYWORDS

COVID-19 pandemic; media disinformation; social media addiction; mental health; scale validation

Introduction

During the COVID-19 pandemic, caused by the emerging SARS-CoV-2, people around the world have been leaning toward an excessive use of the internet [1] and social media. This is the case because, on the one hand, this activity can lower their feelings of loneliness and, on the other hand, it can provide them with information on the states of emergency in their countries and globally [2].

This pandemic is characterized by a high potential for contagion, a low availability of vaccines, an absence of specifically effective drugs, and an exponential spread, which has impacted people's lifestyles and led to feelings of insecurity [3,4], fear [5], and even community panics in several populations [6-10].

Almost everyone is interested in hearing reliable, updated information concerning the pandemic, vaccines, and anything related to COVID-19. This is because during the pandemic, in addition to seeing their usual activities restricted, people are exposed to a wide range of information, including official messages, as well as erroneous and misleading news from a range of unreliable sources [11,12]. The global spread of the COVID-19 pandemic has been reflected in the dissemination of misinformation on social media and conspiracy theories about its origins [13].

Indeed, since the beginning of the spread of the disease, several fake news items related to the outbreak have been shared on social networks. Examples include that the virus was caused by 5G cell phones, was deliberately disseminated for political or financial reasons, was a biological weapon, or was not more dangerous than influenza, with the threats being exaggerated as a way of limiting freedom [14].

Sharing false news that contains biased, emotionally charged information tends to capture more attention and interest than detached, positive, or neutral information [15]. Communication is of crucial importance in the control of outbreaks, and misinformation represents a major public health concern in that the use of social media as a means of keeping abreast of all the pandemic-related news is becoming very popular for several categories of people, due to its capacity of providing information in real time [16]. Likewise, social media can be utilized as platforms and venues for disseminating false information in times of crisis [16].

From another perspective, according to Alheneidi et al [17], besides information and communications technologies, psychosocial factors seem to play a key role. Personal negative feelings, such as loneliness, experienced during the COVID-19–induced lockdown have been shown to promote internet addiction behaviors, resulting in a significantly increased number of hours spent online. The study was conducted in two Arabic countries—Kuwait and the Kingdom of Saudi Arabia—and showed that people who experienced greater loneliness were more likely to consume pandemic-related news from social media.

Governments have been implementing behavioral strategies and nonpharmaceutical interventions (NPIs), including social and physical distancing and stay-at-home orders, to control the spread of COVID-19 and flatten the epidemic curve [18,19]. As a consequence, addiction to social media has increased, as it is the most accessible and easy-to-use means of communication and social interaction, resulting in excessive news consumption, which can lead to acute psychological distress and mental health problems, such as anxiety and depression [20].

The public health measures thus taken and enforced by governments, such as the compulsory wearing of masks, quarantine, mobility restrictions, social and physical distancing, the closures of several public places, bans on gatherings, partial curfews, and isolation of sick people, risk being compromised because of erroneous information constantly propagated on social media platforms. Indeed, Wang et al [21] have found that health-related misinformation is a very common phenomenon on social media and tends to be more prevalent than the diffusion of accurate information, in general.

As a matter of fact, significant amounts of disinformation and conspiracy theories have been disseminated through several social media platforms and consumed by users willing to learn about the COVID-19 pandemic. In general, the COVID-19 outbreak was accompanied by a large proliferation of fictitious and inaccurate information on the virus, which was spread, in particular, by social networks [22].

In a descriptive study by Cinelli et al [23] on the dissemination of COVID-19–related information on five social media platforms—Twitter, Instagram, YouTube, Reddit, and Gab—analyses highlighted a great amount of information about the COVID-19 outbreak disseminated on social networks, a large part of which was false information or disinformation.

COVID-19–related misinformation can bring not only high stress rates and serious mental consequences [24], but can also have a negative impact on the effectiveness of government strategies, such as the compulsory wearing of masks, confinement, and social and physical distancing. For instance, the false belief that the virus threat is being exaggerated may result in poor compliance and adherence to NPIs and, therefore, jeopardize the fight against the coronavirus. In the health field, dissemination of spurious news poses serious challenges because it can delay or prevent the delivery of effective care provisions or even threaten people's lives.

Unfortunately, many fake news items are accepted by the general population. For instance, a recent US study on COVID-19 conspiracy speculation found that over 80% of participants surveyed believed a particular conspiracy theory to be "probably" or "certainly" true [25]. In another study conducted in the United States, Uscinski et al [26] found that 29% of subjects believed that the communication on COVID-19 was biased for political reasons, in order to place then–US President Donald Trump at a disadvantage against his competitors.

If false news is accepted as true, dissemination of scientifically proven and evidence-based narratives to amend such fake news would not have a significant impact on belief in disinformation [27].

Although governments, public health decision makers and policy makers, and other stakeholders are suffering from the dissemination and sharing of misinformation on social media, there exists no scale that enables the quantitative assessment of the behavior of social media users in the face of misinformation related to COVID-19.

Therefore, the objective of this study was to develop and validate an ad hoc measurement tool to measure the behavior of social media users in terms of consumption, credibility, and sharing of information related to COVID-19.

Methods

Ethical Declaration

The protocol for this study received approval from the Ethics Committee of the Higher Institute of Sport and Physical Education of Kef, University of Jendouba, Jendouba, Tunisia. The study protocol also received ethical authorization from the UNESCO (United Nations Educational, Scientific and Cultural Organization) Chair in Health Anthropology Biosphere and Healing Systems, University of Genoa, Genoa, Italy, as well as from the Higher Institute of Sport and Physical Education of Sfax, Sfax, Tunisia. The proposal was also approved by the Ethics Committee of the University of Jendouba. This study was undertaken in accordance with the ethical standards of the Declaration of Helsinki in 1964 and its subsequent amendments.

Participants and Data Collection

A total of 874 subjects, with a mean age of 30.62 years (SD 11.37), who were recruited from social media platforms over two time periods participated in this study. Participants were interviewed by means of an online questionnaire distributed via two social media platforms: Facebook and Twitter. The characteristics of the participants (ie, gender, student or employment status, academic level, and marital status) are presented in Table 1.

Table 1. Sociodemographic characteristics of the participants selected for this study.

Characteristic	Value (N=874), n (%)
Gender	
Male	415 (47.5)
Female	459 (52.5)
Student or employment status	
Student	297 (34.0)
Public function employee	211 (24.1)
Unemployed	94 (10.8)
Private function employee	233 (26.7)
Retired	39 (4.5)
Academic level	
Secondary	252 (28.8)
University	622 (71.2)
Marital status	
Single	446 (51.0)
Married	304 (34.8)
Other	124 (14.2)

Study participants were randomly divided into two groups with the same number of individuals in each: one group participated in the exploratory phase and the other participated in the confirmatory phase.

The exploratory phase group consisted of 437 out of 874 (50.0%) participants, of which 248 (56.8%) were female and 189 (43.2%) were male; the mean age of the participants in this group was 28.39 years (SD 9.32). The confirmatory phase group consisted of 437 out of 874 (50.0%) participants, of which 211 (48.3%) were female and 226 (51.7%) were male; the mean age of the participants in this group was 32.84 years (SD 12.72).

Instruments

Sociodemographic Questionnaire

The sociodemographic questionnaire consisted of questions about age, gender, level of education, the city in which the participant was currently living during the COVID-19–induced restrictions, student or employment status, and marital status.

Development of the 12-Item Social Media Disinformation Scale

A thorough review of the literature showed that information consumption includes a series of behaviors and processes, such as information seeking and information encounter (ie, *finding without seeking*). The first is defined as the intentional acquisition of information, while information encounter describes how individuals come across information without deliberately seeking or retrieving news [28].

Understanding social media consumption has proven to be a very important dimension to incorporate into the measurement instrument, as it can help analyze how people may face disinformation. The literature has shown that individuals who consume disinformation make a judgment on the credibility of the message, depending on the source of the information, the story, and the context [29]. Indeed, the work of Rosnow [30] has shown that if disinformation circulates repeatedly, it will be absorbed, reinforced, and accepted as credible.

A further step in the process of information consumption is news sharing. Previous studies have reported various personal predictors of sharing misinformation, such as fear of missing out, social media fatigue, lack of skills in verifying the reliability of information, and information overload on social media. When news about a rumor is collectively shared by communities, the dissemination of that message is amplified.

Based on these theoretical findings, we operationalized the measurement of disinformation through the 12-item Social Media Disinformation Scale (SMDS-12) instrument. The first dimension of the SMDS-12 assesses the degree to which COVID-19 information is consumed from social media. The second dimension reports users' judgments about their degrees of belief, confidence, and trust in information related to COVID-19 shared on social media. The third dimension describes how one interacts with such news; in this case, sharing of information related to COVID-19.

Each dimension is made up of four items that are rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree).

Subsequently, a construct evaluation was carried out by a focus group made up of seven experts: two professionals in social networks, both administrator and content creators; two professors in human sciences; two experts in linguistics; and an expert in information and communications technology. Members of the focus group discussed the components of the items and were invited to collectively modify and validate a usable version of the instrument.

The COVID-19 Fear Scale

The Arabic-language adapted short version of the COVID-19 Fear Scale from Alyami et al was used [31]. This version has been translated and adapted into Arabic from the initial version of Ahorsu et al [32]. The scale assesses fear of COVID-19 using a one-dimensional factor tool divided into seven items, which are assessed on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Concomitant and confirmatory reliability and validity were examined on a set of Saudi participants.

The internal consistency of the Arabic version examined using Cronbach α was satisfactory (α=.88), with strong concurrent validity indicated by significant and positive correlations with the Hamilton Anxiety and Depression Scale (*r*=0.6). Likewise, examination of the factor structure according to Alyami et al [31] was adequate (comparative fit index [CFI]=0.995; root mean square error of approximation [RMSEA]=0.059; standardized root mean residual [SRMR]=0.024).

The 10-Item Perceived Stress Scale

An Arabic-language version of the 10-item Perceived Stress Scale (PSS-10) by Cohen et al [33], adapted by Almadi et al [34], was used to assess stress. The PSS-10 is divided into two subscales: the first assesses perceived psychological distress, while the second measures coping strategy. Scores are obtained on a 5-point Likert scale, ranging from 0 (never) to 4 (very often). The reliability and validity of the Arabic version of the PSS-10 presented a two-factor structure adequate for exploratory factor analysis, and their Cronbach α coefficients were .74 and .77, respectively. In addition, the test-retest reliability had an intracorrelation coefficient of 0.90.

For the purpose of our study, we considered only the related negative factor, which is distress; as such, the coping strategy was not taken into consideration.

The Arabic Internet Addiction Test

To measure internet addiction, we used the Arabic language–adapted scale from Hawi [35]. The Arabic version of the Internet Addiction Test (IAT) is an adapted version of the instrument originally developed by Young [36]. It consists of 20 items, each of which is scored on a 6-point Likert scale, ranging from 1 (strongly disagree) to 6 (strongly agree). The scale exhibits a unidimensional construct with robust psychometric properties: the goodness-of-fit indices demonstrated by the confirmatory factor analysis were all adequate (normed fit index [NFI]=0.96; CFI=0.98; Tucker-Lewis index [TLI]=0.98; goodness-of-fit index [GFI] and adjusted goodness-of-fit index [AGFI] above the recommended thresholds of 0.90). In particular, the internal consistency examined using the classical Cronbach α statistical index was satisfactory (α=.92).

Statistical Tools

Data normality was tested by skewness and kurtosis tests during the exploratory phase, while multivariate normality was examined during the confirmatory phase. Asymmetry values greater than 7 or kurtosis values greater than 3 were judged to be non-Gaussian [37] and possessing low psychometric sensitivity [38]. In addition, the Mardia coefficient of multivariate normality was calculated during the confirmatory phase.

The exploratory analysis was carried out by unweighted least squares with a direct oblimin rotation. To assess whether the data were suitable for factor analysis, the sampling adequacy was examined by the Kaiser-Meyer-Olkin (KMO) statistic. According to the suggestions of Hair et al [39], the KMO value must be greater than 0.50 to accept the factorial solution. Furthermore, the chi-square value of the Bartlett sphericity test, which should be not significant, was calculated [40]. The factors were retained for eigenvalues greater than 1 and by examining the scree plot. In addition, an item was deleted if its factor loading was less than 0.5 [39-41]. The scale relationships have been examined through Pearson correlation tests between the SMDS-12, the COVID-19 Fear Scale, and the PSS-10.

First-order confirmatory factor analyses were performed to examine the factor structure of the instrument. The reliability of the instrument was examined by evaluating three internal consistency indices simultaneously: McDonald ω, Cronbach α, and Gutmann λ6. Convergent validity and discriminant validity were assessed, respectively, by calculating the average variance extracted (AVE) and comparing the square roots of the AVE values to the correlation coefficients. The relationships between instrument dimensions, internet addiction, and mental health parameters were assessed by the Pearson correlation matrix.

Descriptive statistical analyses of the factor structure were performed with SPSS for Windows, version 26 (IBM Corp), and Amos software for Windows, version 23 (IBM Corp). Internal consistency indices were calculated using JASP open source software, version 0.8.5 (JASP Team).

Results

Exploratory Factor Analysis

Table 2 shows the descriptive statistics, with means and standard deviations; the skewness and kurtosis coefficients of normality; and the lambda factor loadings. The coefficients of normality support the normality of the distributions.

The results indicate that the SMDS-12 was appropriate for proceeding with factor analysis (KMO=0.89; Bartlett test of sphericity=2988.98; *df*=66; P<.001). Exploratory factor analysis indicated a three-factor solution (eigenvalues were 5.45, 2.004, and 1.39 for the first, second, and third factor, respectively), explaining up to 73.72% of the total variance, with items having lambda factor loadings ranging from 0.73 to 0.85. The first factor explained 45.42% of the total variance, the second factor explained 16.70% of the variance, and the last factor explained 11.60% of the variance. In addition, the examination of the scree plot confirms the three-factor solution; a distinct change in the slope can be seen in the plot in Multimedia Appendix 1.

Table 2. Exploratory factor analysis of the 12-item Social Media Disinformation Scale (SMDS-12) (n=437).

SMDS-12 item No.	Mean (SD)	Skewness	Kurtosis	Lambda factor loading
1	2.94 (1.25)	0.02	2.94	1.25
2	2.95 (1.21)	0.04	2.95	1.21
3	2.89 (1.17)	0.00	2.89	1.17
4	2.83 (1.18)	0.11	2.83	1.18
5	2.76 (1.09)	0.10	2.76	1.09
6	2.80 (1.13)	0.12	2.80	1.13
7	2.65 (1.11)	0.15	2.65	1.11
8	2.64 (1.04)	0.07	2.64	1.04
9	2.45 (1.12)	0.31	2.45	1.12
10	2.45 (1.12)	0.23	2.45	1.12
11	2.42 (1.11)	0.27	2.42	1.11
12	2.41 (1.06)	0.31	2.41	1.06

Confirmatory Factor Analysis

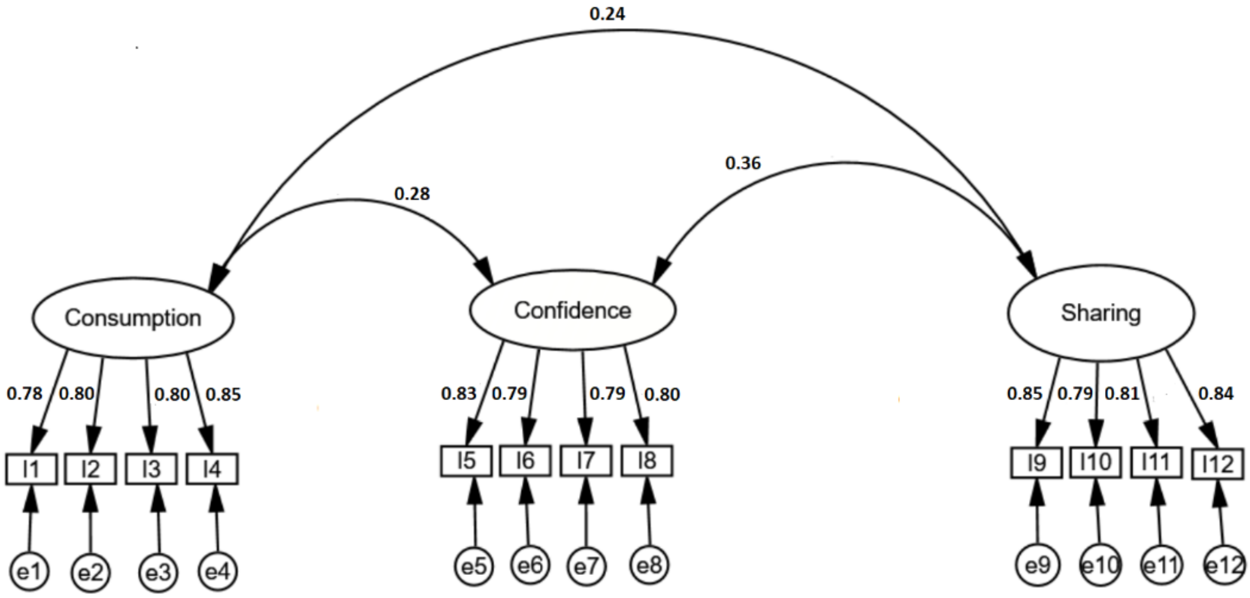
Before proceeding with the confirmatory factor analysis, univariate and multivariate tests of normality were performed. The results indicate that the item distribution followed a Gaussian distribution (Table 3), while the Mardia coefficient of multivariate normality indicated a value of 7.98 with a critical ratio of 4.55. These results suggest that multivariate normality was violated; on the other hand, the Mardia coefficient is sensitive to the size of the sample.

Table 3. Confirmatory factor analysis of the 12-item Social Media Disinformation Scale (SMDS-12) (n=437).

SMDS-12 item No.	Mean (SD)	Skewness	Critical ratio	Kurtosis	Critical ratio
1	3.16 (1.16)	–0.1	–0.5	–0.7	–3.1
2	3.20 (1.12)	–0.2	–1.4	–0.7	–2.9
3	3.12 (1.08)	–0.1	–0.7	–0.6	–2.5
4	3.05 (1.11)	0.0	–0.2	–0.7	–2.8
5	2.88 (1.13)	0.0	–0.3	–0.8	–3.4
6	2.91 (1.13)	0.1	0.6	–0.8	–3.2
7	2.80 (1.08)	0.1	0.7	–0.6	–2.7
8	2.78 (1.05)	0.1	0.7	–0.6	–2.7
9	2.43 (1.14)	0.27	2.85	–0.85	–4.57
10	2.43 (1.13)	0.28	3.02	–0.82	–4.39
11	2.35 (1.11)	0.33	3.58	–0.78	–4.21
12	2.38 (1.10)	0.29	3.11	–0.85	–4.58

Figure 1 shows an overview of the model of the confirmatory factor analysis for the SMDS-12; following guidelines and recommendations [40,41], which suggest that a factorial weight greater than 0.71 can be considered to be excellent, we note that all items adequately contributed to the pre-established theoretical constructs. The confirmatory factor analysis results provided evidence for the three-factor structure of the SMDS-12. The factor loadings were acceptable and good (range 0.78 to 0.85).

Figure 1. The final confirmatory factor analysis (CFA) of the 12-item Social Media Disinformation Scale. Factor correlation coefficients are 0.24 (between consumption and sharing), 0.28 (between consumption and confidence), and 0.36 (between confidence and sharing). Factor loadings range from 0.78 to 0.85. e1 to e12 represent the error variance for each item (I). CFA statistics: χ^2_{51}=62.5, *P*<.001; χ^2/df=1.2; goodness-of-fit index=0.977; adjusted goodness-of-fit index=0.965; Tucker-Lewis index=0.995; comparative fit index=0.996; root mean square error of approximation=0.023 (90% CI 0-0.04); standardized root mean residual=0.036.



The chi-square value obtained (χ^2_{51}=62.5; *P*<.001) may be due to the size of the sample. However, the chi-square divided by degrees of freedom value (χ^2/df=1.2) respects the usual recommended threshold. The values of GFI and AGFI are 0.977 and 0.965, respectively. These two values must be greater than or equal to 0.90. In addition, the two indices TLI and CFI tend toward 1 and respect the threshold value of 0.95. Finally, the error indices—RMSEA=0.023 (90% CI 0-0.04) and SRMR=0.036—show that the measurement errors are tolerable.

Reliability

The internal consistency and reliability of the three scale factors were calculated by the three indices: McDonald ω, Cronbach α, and Gutmann λ6. Examination of the indices for the three components of the scale yielded values greater than or equal to 0.80. This provides evidence for the internal consistency of the scale. Likewise, a good internal consistency was supported by the Cronbach α indices, which had values of .89, .88, and .88 for the consumption, confidence, and sharing subscales, respectively, as well as by the Gutmann λ6 coefficients, which were greater than or equal to 0.84. In addition, the corrected item-total correlation was calculated for each latent variable. The results show that the values were adequate, since they were located between 0.72 and 0.78 for the first component (ie, consumption), between 0.70 and 0.76 for the second component (ie, confidence), and between 0.73 and 0.76 for the last component (ie, sharing). These results confirm that the instrument has good reliability (Table 4). The internal consistency of the component is considered good if the value is equal to or greater than 0.70 [41].

Table 4. Internal consistency of the 12-item Social Media Disinformation Scale (SMDS-12).

Latent variable and SMDS-12 item No.	Corrected item-total correlation	McDonald ω	Cronbach α	Gutmann λ6
Consumption		0.89	.89	0.86
1	0.75			
2	0.72			
3	0.76			
4	0.78			
Confidence		0.88	.88	0.85
5	0.76			
6	0.73			
7	0.70			
8	0.74			
Sharing		0.88	.88	0.85
9	0.76			
10	0.75			
11	0.73			
12	0.74			

Construct Validity

Convergent Validity

The convergent validity was assessed following the Fornell-Larcker criterion [42] by the calculation of the AVE. AVE values above 0.7 are considered very satisfactory, whereas a level of 0.5 is considered acceptable. The AVE values were 0.67 for consumption, 0.64 for confidence, and 0.67 for sharing.

Discriminant Validity

Discriminant validity is ensured when the variance shared by two different latent variables is less than the variance shared by the latent variable and its indicators (ie, items). This implies that the square root of the AVE must be greater than all correlations between latent variables. The comparison of the square roots of the AVE values presented on the diagonal of the matrix (Multimedia Appendix 2) with the correlation coefficients shows that the discriminant validity of the scale was adequate.

The square roots of the AVE values for consumption, confidence, and sharing were 0.82, 0.80, and 0.81, respectively. The comparison of each AVE value with correlation coefficients with the other constructs shows that they were of higher value.

Relationship Between the Credibility of Disinformation and Mental Health During the COVID-19 Pandemic

The correlation matrix (Table 5) provided positive, significant, and moderate associations between the dimension of consumption and internet addiction (r=0.22), perceived stress (r=0.16), and the fear of COVID-19 (r=0.21). For the confidence subscale, a moderate correlation was demonstrated with internet addiction (r=0.34), while the correlations with perceived stress and fear of COVID-19 were 0.14 and 0.23, respectively. The sharing dimension resulted in a correlation coefficient 0.19 with internet addiction and lower coefficient values for perceived stress (r=0.093) and fear of COVID-19 (r=0.16).

Table 5. Correlation matrix between the 12-item Social Media Disinformation Scale subscales and mental health parameters related to COVID-19.

Variable	Consumption	Confidence	Sharing	Internet addiction	Perceived stress	Fear of COVID-19
Consumption						
r	1	0.35[a]	0.27[a]	0.22[a]	0.16[a]	0.21[a]
P value	—[b]	<.001	<.001	<.001	<.001	<.001
Confidence						
r	0.35[a]	1	0.33[a]	0.34[a]	0.14[a]	0.23[a]
P value	<.001	—	<.001	<.001	<.001	<.001
Sharing						
r	0.27[a]	0.33[a]	1	0.19[a]	0.093[c]	0.16[a]
P value	<.001	<.001	—	<.001	.014	<.001
Internet addiction						
r	0.22[a]	0.34[a]	0.19[a]	1	0.14[a]	0.21[a]
P value	<.001	<.001	<.001	—	<.001	<.001
Perceived stress						
r	0.16[a]	0.14[a]	0.093[c]	0.14[a]	1	0.33[a]
P value	<.001	<.001	.014	<.001	—	<.001
Fear of COVID-19						
r	0.21[a]	0.23[a]	0.16[a]	0.21[a]	0.33[a]	1
P value	<.001	<.001	<.001	<.001	<.001	—

[a] The correlation is significant at a significance level of .01 (two-tailed).

[b] Not applicable.

[c] The correlation is significant at a significance level of .05 (two-tailed).

Discussion

Principal Findings

The objective of this study was to develop and test the psychometric properties of the SMDS-12 measurement scale to assess consumption, confidence, and sharing of information related to COVID-19 by social media users. The 12-item scale was initially tested through exploratory factor analysis.

The test supported the three-factor structure; in addition, no items were removed from the measurement scale. Subsequently, confirmatory factor analysis confirmed the robustness of the measurement tool. The results also supported the construct validity of the scale by its convergent and discriminant validity, both of which were adequate. The reliability of the instrument examined by means of three internal consistency indices and the corrected item-total correlation demonstrated that the three dimensions of the instrument are reliable.

The correlation between the three dimensions of the instrument with the internet addiction scale and mental health factors showed positive associations, which lay in a range from small, for the relationship of the sharing dimension with stress, to moderate, for the association of the other two factors with internet addiction, perceived stress, and fear of COVID-19.

Regarding the links between the consumption of disinformation and internet addiction, similar results have been reported by Priego-Parra et al [43]. The authors found that internet addiction and overexposure to rapidly spreading disinformation are associated with anxiety and depression. In addition, internet addiction resulting in obtaining information about COVID-19 has increased stress and anxiety levels.

Furthermore, in other studies of COVID-19 related to disinformation spread on social media [44-48], aimed at identifying the prevalence and factors associated with the concept, disinformation was shown to be linked to demographic variables, such as age, gender, and academic level. Moreover, consistent with our findings, misinformation beliefs were significantly associated with fear of COVID-19 in addition to other variables, such as lower levels of health education, trust in government, and confidence in science.

During the COVID-19 pandemic, internet addiction and the use of social media in particular have increased significantly [44-48]. Also, time spent on the internet was associated with sharing misinformation related to the context of the illness [44-49].

Moreover, some studies [50-52] examined the association between social media and mental health linked to the COVID-19 pandemic. The results showed that social media use was linked to depression, and excessive social media use led to mental health issues.

Our findings are also in line with a pilot study by Zhong et al [20], which examined the possible association between social media use and the mental health toll linked to the COVID-19 pandemic in China. This study found that social media use was linked to both depression and secondary trauma, which also predicted a change in health behavior.

On the contrary, in a cross-sectional survey by Agley and Xiao [14], COVID-19–related information sharing behaviors were clustered, and four belief profiles emerged from the analysis. A total of 70% of the subjects surveyed believed in scientifically accepted theories (ie, zoonotic origin of the outbreak) and not in conspiratorial theories. Other profiles disagreed with the zoonotic explanation, and instead believed in misinformation, although to varying degrees. Briefly, trust in science was a strong and significant predictor of news sharing behavior.

Regarding the acquisition of disinformation and the subsequent sharing of this information, Chua and Banerjee [53] showed that gullible users had a greater propensity to share health rumors online. For that reason, Li and Sakamoto [54] suggested that exposing individuals to collective opinion measures may reduce the tendency to share false health messages. To explain the mechanism, the theory of cultural attraction can be utilized. Indeed, this theory postulates that the spread of rumors results from psychological pull factors. The reasons for the propagation of this false information are mainly due to the recruitment of cognitive pull factors that are likely to increase social interactions [55]. Indeed, on these platforms, content creators produce their works with a strong psychological appeal to encourage users to react to them and increase their audiences.

This highlights the need for much more research into the cultural, psychological, and social characteristics of users who trust and disseminate this content on social media. In particular, it is crucial to better understand the roles of thinking and belief systems. For example, they should also be explored in empirical studies, in particular, relying on mathematical models based on big data and artificial intelligence. This would be of paramount importance, given the potential impact of COVID-19–related misinformation on the public health measures implemented to curb the pandemic [56-61].

Conclusions and Recommendations

The results of this study provided a first demonstration for assessing behaviors related to use, consumption, and sharing of information related to COVID-19 on social media. The SMDS-12 exhibited acceptable psychometric properties and can be utilized in Tunisia and other Arabic countries to explore user engagement with social media, credibility of information, and interaction with information in terms of sharing. Furthermore, the instrument could be translated, culturally validated, and utilized by other scholars from other countries.

Limitations of the Study

The main limitation of this study is the lack of concurrent validity testing of the instrument with similar instruments. In addition, the instrument has only been tested on a single population living in a single country. Also, the study was observational and not interventional; it did not investigate ways that could reduce credibility and counteract the sharing of rumors and misinformation. Another limitation relates to the study population, as the data were collected from a group of Tunisian social media users. Although we have confirmed the validity and reliability of the measurement instrument for these participants, a certain specificity linked to the cultural context does not allow for the generalization of the results.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Scree plot for the principal component analysis of the 12-item Social Media Disinformation Scale (SMDS-12).
[PNG File , 16 KB - formative_v5i6e27280_app1.png]

Multimedia Appendix 2
Discriminant validity of the 12-item Social Media Disinformation Scale (SMDS-12) subscales.
[DOCX File , 13 KB - formative_v5i6e27280_app2.docx]

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Abbreviations

AGFI: adjusted goodness-of-fit index
AVE: average variance extracted
CFI: comparative fit index
GFI: goodness-of-fit index
IAT: Internet Addiction Test
IDRC: International Development Research Centre
KMO: Kaiser-Meyer-Olkin
NFI: normed fit index
NPI: nonpharmaceutical intervention
PSS-10: 10-item Perceived Stress Scale
RMSEA: root mean square error of approximation
SMDS-12: 12-item Social Media Disinformation Scale
SRMR: standardized root mean residual
TLI: Tucker-Lewis index
UNESCO: United Nations Educational, Scientific and Cultural Organization

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Original Paper

Perceptions of Endocrine Therapy in African-American Breast Cancer Survivors: Mixed Methods Study

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Abstract

Background: Although the incidence of breast cancer is lower in African-American women than in White women, African-American women have a decreased survival rate. The difference in survival rate may stem from poor endocrine therapy adherence, which increases breast cancer recurrence. Therefore, accessible and culturally sensitive interventions to increase endocrine therapy adherence are necessary.

Objective: The purpose of this concurrent convergent mixed methods study was to provide further data to guide the development of the proposed culturally sensitive mHealth app, STORY+ for African-American women with breast cancer.

Methods: We recruited 20 African-American women diagnosed with estrogen-positive breast cancer and currently prescribed endocrine therapy. We used a concurrent convergent data collection method to (1) assess the use of smartphones and computers related to health care and (2) identify foundational aspects to support endocrine therapy adherence for incorporation in a mobile health app.

Results: Overwhelmingly, the participants preferred using smartphones to using computers for health care. Communicating with health care providers and pharmacies was the most frequent health care use of smartphones, followed by exercise tracking, and accessing the patient portal. We identified 4 aspects of adherence to endocrine therapy and smartphone use for incorporation in app development. The factors that emerged from the integrated qualitative and quantitative data were (1) willingness to use, (2) side effects, (3) social connection, and (4) beliefs about endocrine therapy.

Conclusions: Further research is needed to develop a culturally sensitive app for African-American women with breast cancer to improve adherence to endocrine therapy. Our work strongly suggests that this population would use the app to connect with other African-American breast cancer survivors and manage endocrine therapy.

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KEYWORDS

mHealth; breast cancer survivors; medication adherence; cultural considerations; mobile health applications

Introduction

Breast cancer is the second-most common cancer among women in the United States and results in the second-highest cancer death rates [1]. Earlier detection through screening and advances in treatments have contributed to an increase in the 5- and 10-year breast cancer survival rates [2]; however, African-American women have decreased survival rates and higher mortality rates compared to White women despite lower incidence rates [3]. One potential explanation for the differences in survival rates and mortality among women with estrogen-positive breast cancer is adherence to long-term endocrine therapy, which may last for 5 to 10 years [4]. Endocrine therapy, which blocks estrogen receptors in breast cancer cells, can reduce recurrence by 40% and lower the risk of dying by one-third [5]. Overall, African-American women have low long-term adherence rates to endocrine therapy [6,7]. Therefore, interventions to assist this vulnerable population with endocrine therapy adherence are essential [4,8].

We conducted a literature review on interventions that improve endocrine therapy adherence, which identified 2 consequential gaps in existing intervention research: use of education only interventions and a lack of cultural adaptations [9-16]. Next, we examined commercially available cancer and medication adherence mobile health (mHealth) apps as a possible option to address these gaps and assist African-American women with endocrine therapy adherence [17-21]. Unfortunately, available cancer and medication adherence apps also have several areas that cause concern: (1) a lack of adequate development or testing in clinical practice [17,22,23], (2) a lack of input from patients or providers resulting in significant usability problems [24-26], and (3) a lack of scientifically valid information, with the majority of cancer-related apps created to promote a pharmacy or organization and not to assist African-American women with endocrine therapy adherence [20,26]. Importantly, over 90% of medication adherence mHealth apps were simple reminders and not effective in improving adherence [20]. Cancer mHealth apps research has explored functionality and acceptability, but only one evaluated effectiveness or clinical outcomes [17-19].

To address these gaps in endocrine therapy adherence and mHealth apps for medication adherence, we propose to extend our earlier teleconferencing work, Sisters Tell Others and Revive Yourself (STORY), a culturally tailored intervention that connected African-American women with breast cancer to support and educated them during initial diagnosis and treatment [27]. We wanted to explore how STORY components could assist endocrine therapy adherence in a more accessible platform such as an mHealth app. The purpose of this concurrent convergent mixed methods study [28] was to provide further data to guide the development of the proposed culturally sensitive mHealth app, STORY+ for African-American women with breast cancer. Our initial work has been reported [14,29-34]. The aims of this study were to (1) assess the use of smartphones and computers related to health care in African-American women with breast cancer, and (2) identify foundational aspects to support endocrine therapy adherence for incorporation in an mHealth app.

Methods

Overview

The concurrent convergent mixed methods design of our study incorporated the simultaneous collection, analysis, and interpretation of qualitative and quantitative data to inform the design of an mHealth app to increase adherence to endocrine therapy in African-American women with breast cancer. We recruited 20 African-American women with a diagnosis of estrogen-positive breast cancer and prescribed endocrine therapy. We conducted an ex-ante study (ie, before the design and construction of the app). Prior to the start of the study, the University of South Carolina Institutional Review Board approved the study (Pro00085557).

Sampling Strategy and Inclusion Criteria

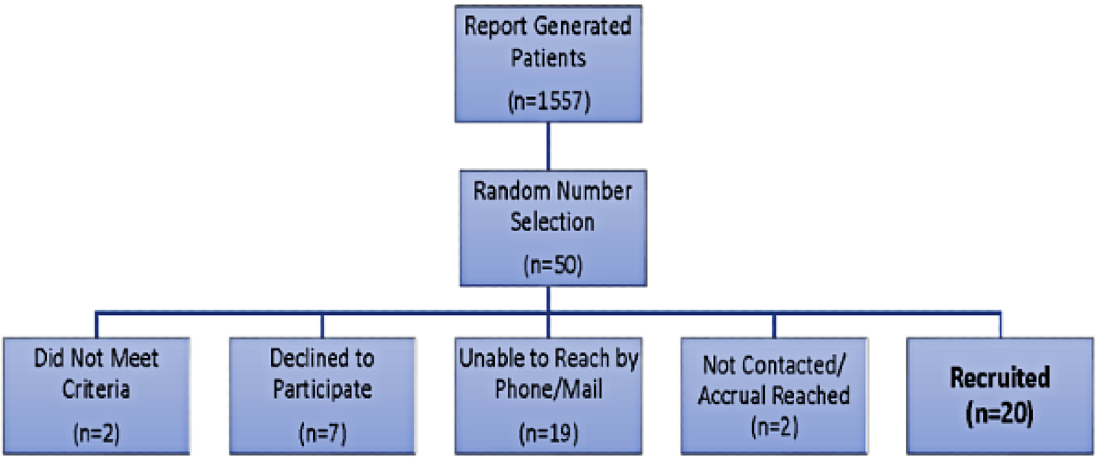
We combined 2 sampling schemes (ie, criterion and convenience) to select our sample. These strategies followed the works of Onwuegbuzie and Collins [35], who established typologies for sampling designs in social science research and suggested appropriate sample sizes. We also used design science research criteria (ie, innovation and evolution) to establish the legitimacy of our sample size. A sample of 20 or fewer for formative research is often employed [36,37]. We needed women who met our enrollment criteria, but we wanted heterogeneity in the sample. We used a random number generator to select potential participants for recruitment from a pool of 1577 patients. We reviewed the potential participants' medical records and selected the first 50 patients who met the inclusion criteria. This process created our first batch of potential participants. From previous recruitment efforts, we had estimated that 50 potential participants would supply our recruitment goal of 20 participants. We planned to recruit until we reached informational redundancy [38,39] (ie, both qualitative and quantitative data provided no new information). If the initial batch did not supply sufficient participants, the process was to be repeated, and data collection would be continued.

Inclusion criteria were African-American women who were 18 years of age or older, had been diagnosed with estrogen-positive breast cancer in the past 10 years, were currently prescribed endocrine therapy, and were able to speak and understand English. Reading English was not a requirement because the researcher read the informed consent and questions to the participants. Exclusion criteria were individuals with a diagnosis of psychosis, with significant cognitive impairment, or undergoing current treatment for another cancer excluding squamous cell (any type).

Recruitment and Retention

Women who were eligible based on the inclusion and exclusion criteria were recruited through a comprehensive oncology outpatient practice in South Carolina (500 new breast cancer patients annually). Our recruitment plan was covered by a Health Information Portability and Accountability Act waiver with the oncology outpatient cancer physician practice. We used the Heiney-Adams Recruitment Framework to guide our recruitment efforts [40]. The principal investigator mailed a personal letter to potential participants with a colorful and readable frequently asked questions flyer using the STORY logo (designed by focus group participants in STORY). Within 5 days of the mailing, a racially concordant researcher contacted participants by telephone. The researcher followed a script that asked if the patient had a diagnosis of estrogen-positive breast cancer and had been prescribed tamoxifen or an aromatase inhibitor. To improve recruitment and retention in the study, participants received a gift card for their time and effort. We successfully recruited 20 patients. From the original list of 50 potential participants, 19 could not be reached by phone or mail, 7 declined to participate, 2 did not meet the criteria, and 2 were not contacted because accrual was reached (Figure 1).

Figure 1. Study flow diagram.



Data Collection

The research team, which included nurses and software computer engineers, developed a data collection tool using Research Electronic Data Capture (REDCap [41]; Vanderbilt University). The data collection tool consisted of a qualitative interview guide (Multimedia Appendix 1) and quantitative (open- and closed-ended) questions (Multimedia Appendix 2). Data collection, which we digitally recorded, began with structured questions and ended with semistructured questions. The researcher pilot tested the REDCap data collection tool with 1 African-American breast cancer survivor before the data collection process, resulting in minor adjustments of the tool based upon the feedback. This pilot testing established the ease of data collection using REDCap during an interview, not reliability or validity.

Once the researcher received verbal consent from the participant during the telephone conversations, she scheduled the assessment appointment at the participant’s choice of location, usually in the home or a meeting room in the local library. During this assessment appointment, the researcher (1) read all interview questions to the participant, (2) recorded the responses directly in the REDCap data collection tool via a tablet for the quantitative questions, and (3) digitally recorded the qualitative interview questions and participants’ responses. A professional transcriptionist transcribed the deidentified recordings verbatim.

Data Analysis

Quantitative Data

We exported the data from REDCap into Excel (Microsoft Inc) for analysis. For continuous variables, we calculated means, standard deviations, and ranges. For categorical variables, we calculated frequencies and percentages.

Qualitative Data

We used thematic analysis [42]. No software was used to analyze the qualitative data. Briefly, data analysis began by listening to the digital recordings of participant responses to the semistructured interview questions. Next, 2 researchers read and reread the transcripts and began open line by line coding of the data. We coded significant and salient phrases and words within each transcript. We identified and discussed themes from these codes until consensus was reached.

Data Integration

For clarity, we organized the findings by aim. Most findings are reported with quantitative data and supporting qualitative quotes [39]. In some instances, qualitative themes emerged that were not explored in the quantitative questions and vice versa. In these cases, the results are displayed separately.

Results

Sample Description

Participants’ (n=20; age: mean 59 years, SD 10) mean length of time diagnosed with breast cancer was 4 years (Table 1). Most participants had stage 1A breast cancer (9/20, 45%). Over 50% of participants (11/20) were prescribed tamoxifen, which did not change during their treatment period. The length of time on endocrine therapy was evenly split between more than 2 years (10/20, 50%) and 2 years or less (10/20, 50%).

Table 1. Participant characteristics.

Characteristics	Value, n (%)
Age (years)	
Mean (SD)	59 (10)
Range	46-82
Length of time since diagnosis/recurrence[a] (years)	
Mean (SD)	4 (4)
Range	1-17
Stage of breast cancer	
0	4 (20)
1A	9 (45)
1B	2 (10)
2A	1 (5)
2B	2 (10)
3A	1 (5)
4	1 (5)
Medications	
Tamoxifen	11 (55)
Anastrozole	8 (40)
Letrazole	1 (5)
Length of time on medication	
<2 years	10 (50)
>2 years	10 (50)
Always prescribed same medication	
Yes	14 (70)
No	6 (30)

[a] One patient experienced recurrence within the past 5 years.

Smartphone and Computer Use for Health Care

Overwhelmingly, the participants preferred using a smartphone for health care over using a computer.

> *I pretty much do everything on my cell phone because it's always with me.* [Participant 13]

With respect to health care use, participants reported communicating with health care providers and pharmacies most frequently, followed by exercise tracking, and accessing the patient portal (Table 2).

Table 2. Smartphone and computer use for health care.

Use	Quantitative data		Qualitative data
	Smartphone, n (%)	Computer, n (%)	Quotations
Communicate with health care provider	15 (75)	2 (10)	"... sometimes my provider will send me a message or tell me they put something out on the portal for me to go and check." [Participant 14]
Communicate with pharmacy	13 (65)	0 (0)	”My pharmacist will contact me via text mail."[Participant 7] "The prompt I got today from [the pharmacy] was that I needed a refill and would I allow them to call my doctor. Of course which I said yes." [Participant 12]
Exercise tracking, coaching, or management	7 (35)	0 (0)	"The only health aid I use is a Fitbit to help keep up with my steps. I'm supposed to make at least 10,000 steps per day." [Participant 13] "I got an Engage app from my job with my insurance and stuff. It is a program we have on the job. Well, I went through the program with a dieting thing. It was to help you lose weight and it sets you up. They send you a scale. You weigh every day. They give you a coach. She logs in every day with different ideas and stuff for you to do meals to plan and it also helps, but my insurance will come down instead of paying a surcharge." [Participant 18]
Patient portal	7 (35)	7 (35)	"I use my patient portal..." [Participant 1] ”But I do a lot on my phone. If I want to check my medical records, I go to the patient portal for the various organizations that have my medical records where I can check." [Participant 19]
Connect or manage wearables	5 (25)	0 (0)	"I'm just mainly [monitor] with my Fitbit." [Participant 5] "I use the Fitbit..." [Participant 19]
Medication management or reminders	2 (10)	0 (0)	"Just the pharmacy's [app] for my medication reminders." [Participant 13] "I feel if I ever took that reminder off my phone that I will miss one [medication dose]..."[Participant 4]
Diet tracking, coaching, or management	1 (5)	3 (15)	"...Samsung app for fitness. You can put your food diet, your food thing in it. It counts your calories, your steps, your pulse, and all of that. And it's the app that automatically comes with a Samsung phone."[Participant 1] "Well, I went through the program with a dieting thing. It was to help you lose weight and it sets you up. They send you a scale. You weigh every day. They give you a coach. She logs in every day with different ideas and stuff for you to do meals to plan and it also helps, but my insurance will come down instead of paying a surcharge." [Participant 20]
Personal health records	1 (5)	2 (10)	—[a]

[a] A representative quotation is not available.

Factors

Overview

We identified 4 aspects of endocrine therapy adherence and smartphone use that may guide app development. The factors that emerged from the integrated qualitative and quantitative data included (1) willingness to use, (2) side effects, (3) social connection, and (4) beliefs about endocrine therapy.

Willingness to Use an App for African-American Breast Cancer Survivors

The majority of participants (17/20, 85%) stated that they would use an mHealth app to assist with endocrine therapy adherence. They specifically mentioned an online community of other breast cancer survivors and African-American–tailored graphics (ie, emojis, videos). The qualitative interviews provided additional details on the importance of an app for African-American breast cancer survivors:

> *On the [majority] of apps, I see it is still [for] white [women]. I don't normally see too many blacks that I can reach out to. I would love to share with an African-American female [with breast cancer] what I've been through. Every app that I [see] dealing with breast cancer shows white [women], and I would love to talk to African-American women, women of color.* [Participant 9]
>
> *I think the other thing is, when people see people like them, not like they're not out there, because they are, then they'd be more apt to reach out.* [Participant 19]
>
> *It seems like a lot of women that have it [breast cancer] are ashamed to tell other women about it [breast cancer] and you're in the dark when you get it [breast cancer]. The only time you find out about it [breast cancer] is when you're in a conversation and you say, oh, I had breast cancer, then she'll share hers [diagnosis] with you. But other than that, they [women] don't like to say this, open with their answer.*

> *No, and so to see that and then see what other women are going through it'll help me too.* [Participant 8]
>
> *I feel like with my story...Sharing it [my story] with others... it [sharing my story] might brighten their day or it might help them to understand that just because you had cancer it's nothing to be ashamed of.* [Participant 10]

Self-Reported Side Effects

In patients' self-reported experiences (ie, reports were not verified by health care providers) with the side effects of endocrine therapy (Table 3), almost one-third (6/20, 30%) of participants stated that they called their health care provider about the side effects, with 15% (3/20) reporting they made an appointment with the health care provider to discuss the side effects. In addition, 80% (16/20) of participants talked with a family member, friend, or significant other about the side effects.

Table 3. Self-reported endocrine therapy side effects.

Side effect	Quantitative data, n (%)	Quotations
Hot flashes	17 (85)	"So, sometimes I put a cool towel around my neck, but it's just, I just get hot around the neck. It's like I'm on fire." [Participant 13] "I've been using a lot of air-conditioning. But it [hot flash] doesn't last long, and I usually get it like once a day. At any time. And it will last about like 15 minutes and then it's gone." [Participant 6]
Bone/joint pain	13 (65)	"I actually had to get referrals for some of the pain. I actually had to end up going to the orthopedic. I had problems with my left hand. The pain, I couldn't hold anything [in my left hand] and I was in severe pain." [Participant 5] "So, then you look up like, all right, God, my joints are hurting, what the hell?" [Participant 12]
Fatigue or lack of energy	11 (55)	"The biggest problem I had with side effects, the fatigue I would try to kind of pace myself when I'm doing certain things especially after coming home from work instead of just getting right into it doing some laundry or doing, I kind of take a break." [Participant 14]
Weight gain	11 (55)	"I have gained much weight. I hate it [weight gain]." [Participant 17] "I can deal with the weight gain because I can continue to walk and it just helps me see the nature outside,..." [Participant 4]
Hair thinning	10 (50)	"...I did experience, um, hair thinning." [Participant 14]
Increased sweating	10 (50)	—[a]
Mood swings	10 (50)	—
Leg cramps	9 (45)	—
Dry skin and/or eyes	7 (35)	—
Insomnia	7 (35)	"...some nights I sleep five hours and some, but I know if I got at least six to seven hours that was a good night's sleep for me because there are times when I'm say, but if I'm up at night..." [Participant 14]
Loss of sex drive	7 (35)	"God, I gotta have an orgasm, this is ridiculous. This is pissing me off. That almost made me quit." [Participant 12] "I do have to say that I was gonna talk to my doctor about, you know, anything she can do with the part that comes to like my loss of sex drive, like, that bothers me a lot because I know, like, I know my husband, not that anything is wrong." [Participant 4]
Constipation	6 (30)	—
Depression	5 (25)	"When I started, the depression almost made me quit. For sure. Because I'm not a depressed person." [Participant 12]
Vaginal dryness	5 (25)	—
Vision problems	5 (25)	—
Back pain	4 (20)	"Like I said, when I get up in the morning my back hurts me, but I go to a 9:30 class at Rec Center, so by the time I've exercised it's not hurting me as much. I was leaving there [Rec Center] and going two times per week for the dry needling and stuff and that has helped..." [Participant 15]
Dizziness	4 (20)	"It, um, you do get a little dizzy with them because taking this medicine. I mean, I think any hormone medicine will make you feel a little woozy at times. Um, it's not, it's not every day though. I don't have it every day. I have it every now and then." [Participant 8]

[a] A representative quotation is not available.

Beliefs About the Value of Endocrine Therapy

There were many motivators, especially external motivators, for patients to continue endocrine therapy. The most prominent motivators for endocrine therapy adherence included the desire to live longer (16/20); children (16/20); and religion, church, or a higher being (15/20). Other motivators included friends (13/20), extended family (13/20), and significant others (11/20). Both quantitative and qualitative data demonstrated similar themes in motivators to endocrine therapy adherence, including increased mortality and living for family.

> *I must say life. Because if I didn't take it [endocrine therapy] then that would make my body more [likely] to [have] what I've had in the past. So, when it was told for me to take it this is what I needed to do and that is what I'm doing. So, I'm gonna say life.* [Participant 9]
>
> *I take it [endocrine therapy] because they say I need to take it with the medicine because of my situation with the breast cancer. They say I have to take that. I didn't want to take it because I said I felt like it wasn't helping me. And she [the doctor] said, well, yeah you need to take that. You have to continue taking that. So, I'm just saying like they say I gotta take it [endocrine therapy]...Because it's gonna help me with my situation. I'm gonna do what I gotta do for me.* [Participant 3]
>
> *Well, I was told that it [endocrine therapy] would keep the cancer away. It's a tool, I guess it's considered as a chemo agent to keep your hormonal level down. That's what was explained to me.* [Participant 13]
>
> *Well, I know I have to take it [endocrine therapy] for the next five years. That's part of my treatment. I know it's part of my treatment, so I'm willing to do whatever is necessary to follow the treatment plan.* [Participant 6]
>
> *My family. My grandson. My son. I only have one child and he's everything to me and my grandson - he gives me life. My grandson gave me life. I got diagnosed the year that he was born, so it was like, oh no, no, no, no, no, I gots to be here for him.* [Participant 4]

Social Connections

Qualitative and quantitative data supported the importance of connecting with other African-American women with breast cancer. Participants valued digital social connections and face-to-face interactions. They used smartphones to connect and interact with other individuals including survivors with 85% (17/20) using smartphones for communication (ie, phone calls, email, texting). Participants used smartphones for instant messaging (12/20, 60%) and video chat (11/20, 55%). Facebook was the most popular social media platform among the participants, with 65% (13/20) accessing Facebook via smartphones and computers. Instagram was the next popular social media platform with 25% (5/20) accessing Instagram via smartphone and 15% (3/20) accessing Instagram via computer. Interviews with the participants substantiated the variety of ways African-American women with breast cancer connected and their importance in the breast cancer survivor journey. Participants discussed the need for connecting with other African-American breast cancer survivors and described supportive interactions.

> *We talk a lot because actually in my job it was quite a few of us that were diagnosed in a short period of time.* [Participant 1]
>
> *We have a group, we still hang together after 52, 53 years, two of my friends, my classmates had already had breast cancer, so I certainly reached out to them to talk to them, and that helped, so that was it.* [Participant 5]
>
> *Well, I only have a few people I connect with and we all work in the same department. We [are] all in it with the same type of cancer.* [Participant 13]
>
> *I'd like to see what other women, African-American women are going through and see if, you know, if we're all going through the same thing or if it's, you know, different.* [Participant 2]
>
> *It's [Livestrong Program] through the Y[MCA] and that's a program that you should share with other African-American women. I was the only African-American woman that was in it.* [Participant 15]
>
> *But, when you talk to people, you really want support not sympathy. A person can empathize with you... But not sympathy and you need someone that's going to be strong in the support when you are talking to them.* [Participant 5]
>
> *Find their support system whether it be family, group meetings and there's a bunch of them out there... Church, co-workers. I had all of that. Definitely, don't try to go through it alone. Have your support system. That's the most important thing because there's gonna be days you just feel like, why me. I mean, there's just gonna be those days. That's all I can say. You need somebody to talk to, talk to them.* [Participant 17]

Discussion

General

This concurrent convergent mixed methods study provides additional data to guide the development of STORY+. We assessed the use of smartphones and computers related to health care in the targeted population and identified foundational mHealth features to support endocrine therapy adherence. Overall, the participants used smartphones more frequently than they used computers for health care, especially for social interactions such as social media, messaging, and email. This finding suggests that African-American breast cancer survivors are more likely to use an mHealth app than they are to use a webpage via computer to assist with endocrine therapy adherence. Overwhelmingly, African-American breast cancer survivors use smartphones in managing their health through communication with their health care provider and pharmacy to promote their health.

While fewer participants reported using mHealth apps for medication tracking and health care record management, qualitative results indicated that combining social and cultural features with mHealth functions would be desirable. Other researchers have also identified the need for racial and cultural content [43-49]. Our study verifies that African-American women do not have a culturally sensitive mechanism to track symptoms and discuss symptoms with health care providers. We concluded that foundational STORY+ features should include the following: an online community of other African-American breast cancer survivors, tailored graphics, information about prescribed endocrine therapy and its potential side effects, and a method for tracking side effects, sharing the frequency and severity of side effects, and recording medication adherence. Previous findings [50] have also supported the use of interactive features to promote positive health outcomes—participants overwhelmingly supported the development of an mHealth app to assist with endocrine therapy adherence and social connections with other African-American breast cancer survivors.

Limitations

The study is not generalizable beyond the immediate needs of the research team; however, the results of this study provide a foundation for the mHealth app development, STORY+. The literature suggests that other breast cancer survivors experience similar endocrine therapy side effects [51].

Conclusions

This concurrent convergent mixed methods study established the use of smartphones by African-American breast cancer survivors for health care management. We also identified foundational features for STORY+. This work recognizes that one app does not fit all needs and advances the science of cultural and racial appropriate mHealth apps. Future work will include the development and testing of STORY+ for African-American breast cancer survivors to promote endocrine therapy adherence.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Qualitative questions.
[DOCX File , 16 KB - formative_v5i6e23884_app1.docx]

Multimedia Appendix 2
Quantitative survey.
[DOCX File , 33 KB - formative_v5i6e23884_app2.docx]

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Abbreviations

mHealth: mobile health
REDCap: Research Electronic Data Capture
STORY: Sisters Tell Others and Revive Yourself

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Original Paper

A 5-Minute Cognitive Assessment for Safe Remote Use in Patients With COVID-19: Clinical Case Series

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Abstract

Background: Early clinical experience during the COVID-19 pandemic has begun to elucidate that the disease can cause brain function changes that may result in compromised cognition both acutely and during variable recovery periods. Reports on cognitive assessment of patients with COVID-19 are often limited to orientation alone. Further assessment may seem to create an inappropriate burden for patients with acute COVID-19, which is characterized by fatigue and confusion, and may also compromise examiner safety.

Objective: The aims of this study were to assess cognition in patients with COVID-19 as comprehensively as possible in a brief format, while observing safety precautions, and to establish a clear face value of the external validity of the assessment.

Methods: We adapted a brief cognitive assessment, previously applied to liver transplant candidates and medical/surgical inpatients, for remote use in patients hospitalized for COVID-19 treatment. Collecting quality assurance data from telephone-administered assessments, this report presents a series of 6 COVID-19 case vignettes to illustrate the use of this 5-minute assessment in the diagnosis and treatment of brain effects. Primary medical teams referred the cases for neuropsychiatric consultation.

Results: The age of the patients varied over four decades, and none of them were able to engage meaningfully with their surroundings on admission. On follow-up examination 6 to 10 days later, 4 of the 6 patients had recovered working memory, and only 1 had recovered calculation ability. Of the 6 patients, 2 were capable of complex judgment responses, while none of the cases completed frontal executive function testing in the normal range.

Conclusions: Cognitive assessment in patients with COVID-19 using this remote examination reveals patterns of cognitive recovery that vary among cases and are far more complex than loss of orientation. In this series, testing of specific temporal, parietal, and frontal lobe functions suggests that calculation ability, judgment, and especially frontal executive functions may characterize the effects of COVID-19 on the brain. Used widely and serially, this examination method can potentially inform our understanding of the effects of COVID-19 on the brain and of healing from the virus.

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KEYWORDS

cognition; COVID-19; safety; remote use; delirium; brain injury, brain; diagnosis; assessment; test; telehealth; telemedicine

Introduction

Early clinical experience with the COVID-19 pandemic has begun to elucidate that the disease can cause brain function changes, resulting in compromised cognition. These changes occur both acutely and during variable recovery periods. High frequencies of delirium and other brain phenomena in patients with COVID-19 [1,2] require adequate assessment of the patients' cognitive functions while preserving the health of caretakers. Safety is paramount for all caregivers, especially those with risk factors such as advanced age or physical vulnerability to the respiratory effects of COVID-19. Early literature reports, however, present only minimal cognitive assessments that are frequently confined to orientation [3]. A more complex assessment of specific cognitive functions enables better characterization of the extent to which factors such as the "cytokine storm" or other forms of inflammation, concurrent delirium, stroke, or virus infection of the brain may be at work in the course of recovery [4].

We defined three characteristics for a safe, workable cognitive assessment: (1) brevity, (2) remote administration, and (3) comprehensive content. First, the examination should not be burdensome, especially in fatigued patients with COVID-19 and their caregivers. Second, the examination must be conducted through remote communication, such as by telephone or a video telehealth session, that observes patient and caregiver distancing. Third, the examination should be capable of assessing mental functions related to specific brain structures in a short span of time.

Over the past several years, in consulting on patients admitted to medical and surgical inpatient units, we developed a 5-minute cognitive examination [5] adapted and extended from other instruments [6,7] that can characterize a panoply of brain disorders. These disorders include subtle forms of hepatic encephalopathy. Neuroanatomically, the examination tests temporal lobe memory functions, parietal lobe calculation ability, and each of the three frontosubcortical tracks that mediate (1) anterior cingulate engagement versus indifference, (2) anterior frontal lobe judgment, and (3) dorsolateral prefrontal executive functions [8,9]. The examination also assesses a series of standard mental status functions, such as basic orientation, concentration, fund of information, and ability to abstract meaning from concrete details. This brief examination can be expanded upon when responses indicate that further investigation is necessary.

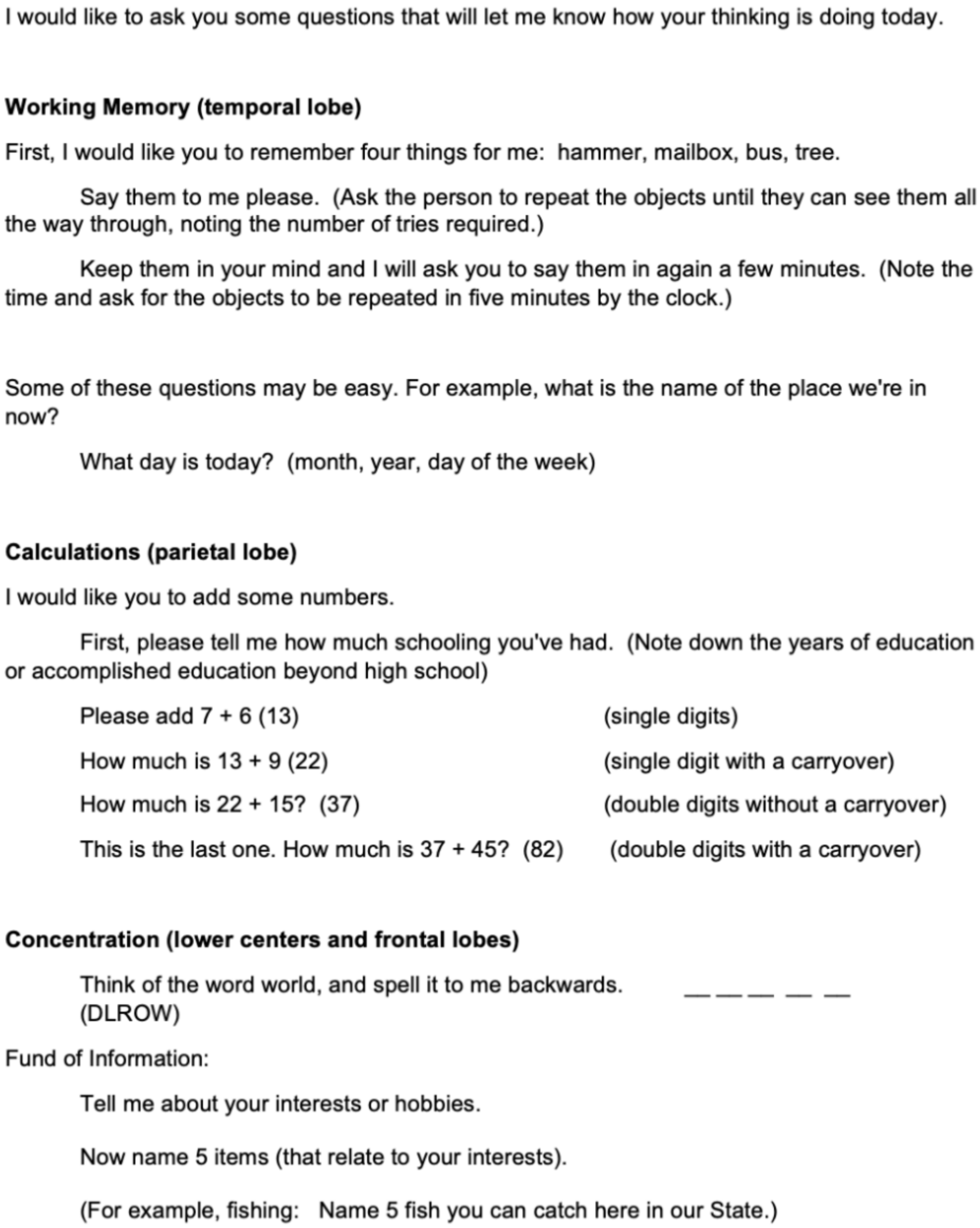
Although most items on the examination can be found in other standardized formats, we have added two items that are particularly clinically useful. The first item is an ascending series of addition problems requiring mental calculation. Mathematics problems test parietal lobe functioning. The second item makes use of the Verbal Trails B Test in its entirety; this is a timed, standardized test of frontal executive functions [8] with a statistically derived cutoff point determining normal versus abnormal test responses.

Viewed as a quality assurance exercise, the purpose of this study was to afford early, proof-of-concept clinical data on the use and clinical implications of this 5-minute cognitive assessment with respect to patients with COVID-19. Here, we begin more rigorously to establish the validity of this assessment by providing clear-face value demonstrations of its external validity.

Methods

We report here a series of 6 patients admitted for COVID-19 treatment to illustrate our experience with this telephone-based cognitive assessment. These case studies simply demonstrate the use of the assessment and do not quantitatively assess its validity or reliability. All patients were admitted for respiratory or fatigue symptoms to our Department of Veterans Affairs Medical Center, a large tertiary hospital that shares a campus with its university affiliate hospital. Examinations were conducted remotely during periods of hospital quarantine. For this review, all patients in this convenience sample were male and aged between 40 and 90 years. The same psychiatric consultant (TB) delivered each brief cognitive examination, as presented in Figures 1-3. Results were abstracted from our hospital records with Institutional Review Board approval. The cases have been disguised to preserve confidentiality. For brevity, we have included only details that are pertinent to assessing cognition. Our general hypothesis stated that we would find evidence of impaired cognition among patients with COVID-19.

Figure 1. Part 1 of the brief cognitive examination for remote use (working memory, calculations, and concentration).



I would like to ask you some questions that will let me know how your thinking is doing today.

Working Memory (temporal lobe)

First, I would like you to remember four things for me: hammer, mailbox, bus, tree.

Say them to me please. (Ask the person to repeat the objects until they can see them all the way through, noting the number of tries required.)

Keep them in your mind and I will ask you to say them in again a few minutes. (Note the time and ask for the objects to be repeated in five minutes by the clock.)

Some of these questions may be easy. For example, what is the name of the place we're in now?

What day is today? (month, year, day of the week)

Calculations (parietal lobe)

I would like you to add some numbers.

First, please tell me how much schooling you've had. (Note down the years of education or accomplished education beyond high school)

Please add 7 + 6 (13)	(single digits)
How much is 13 + 9 (22)	(single digit with a carryover)
How much is 22 + 15? (37)	(double digits without a carryover)
This is the last one. How much is 37 + 45? (82)	(double digits with a carryover)

Concentration (lower centers and frontal lobes)

Think of the word world, and spell it to me backwards. (DLROW) __ __ __ __ __

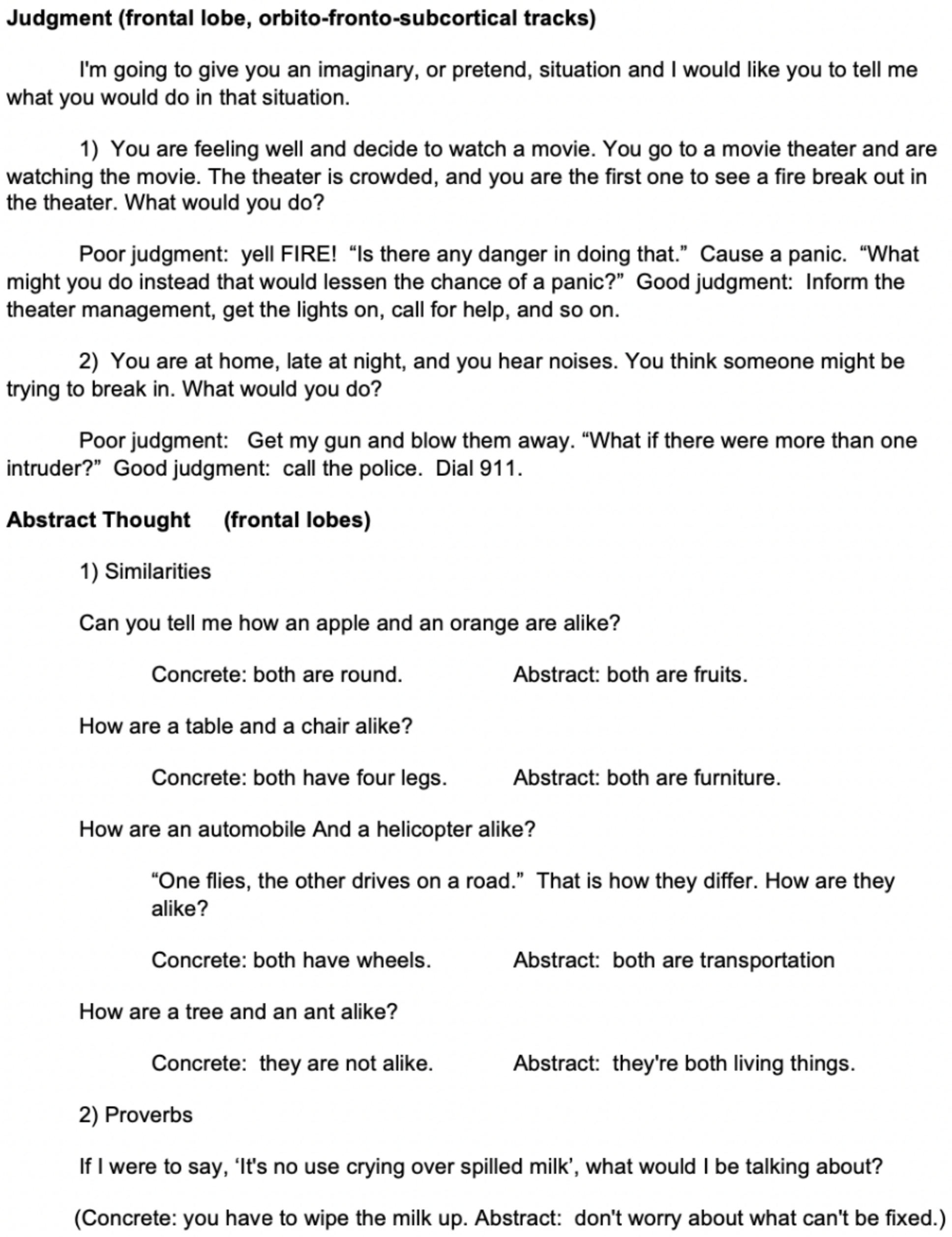
Fund of Information:

Tell me about your interests or hobbies.

Now name 5 items (that relate to your interests).

(For example, fishing: Name 5 fish you can catch here in our State.)

Figure 2. Part 2 of the brief cognitive examination for remote use (judgment and abstract thought).



Judgment (frontal lobe, orbito-fronto-subcortical tracks)

I'm going to give you an imaginary, or pretend, situation and I would like you to tell me what you would do in that situation.

1) You are feeling well and decide to watch a movie. You go to a movie theater and are watching the movie. The theater is crowded, and you are the first one to see a fire break out in the theater. What would you do?

Poor judgment: yell FIRE! “Is there any danger in doing that.” Cause a panic. “What might you do instead that would lessen the chance of a panic?” Good judgment: Inform the theater management, get the lights on, call for help, and so on.

2) You are at home, late at night, and you hear noises. You think someone might be trying to break in. What would you do?

Poor judgment: Get my gun and blow them away. “What if there were more than one intruder?” Good judgment: call the police. Dial 911.

Abstract Thought (frontal lobes)

1) Similarities

Can you tell me how an apple and an orange are alike?

Concrete: both are round.	Abstract: both are fruits.

How are a table and a chair alike?

Concrete: both have four legs.	Abstract: both are furniture.

How are an automobile And a helicopter alike?

“One flies, the other drives on a road.” That is how they differ. How are they alike?

Concrete: both have wheels.	Abstract: both are transportation

How are a tree and an ant alike?

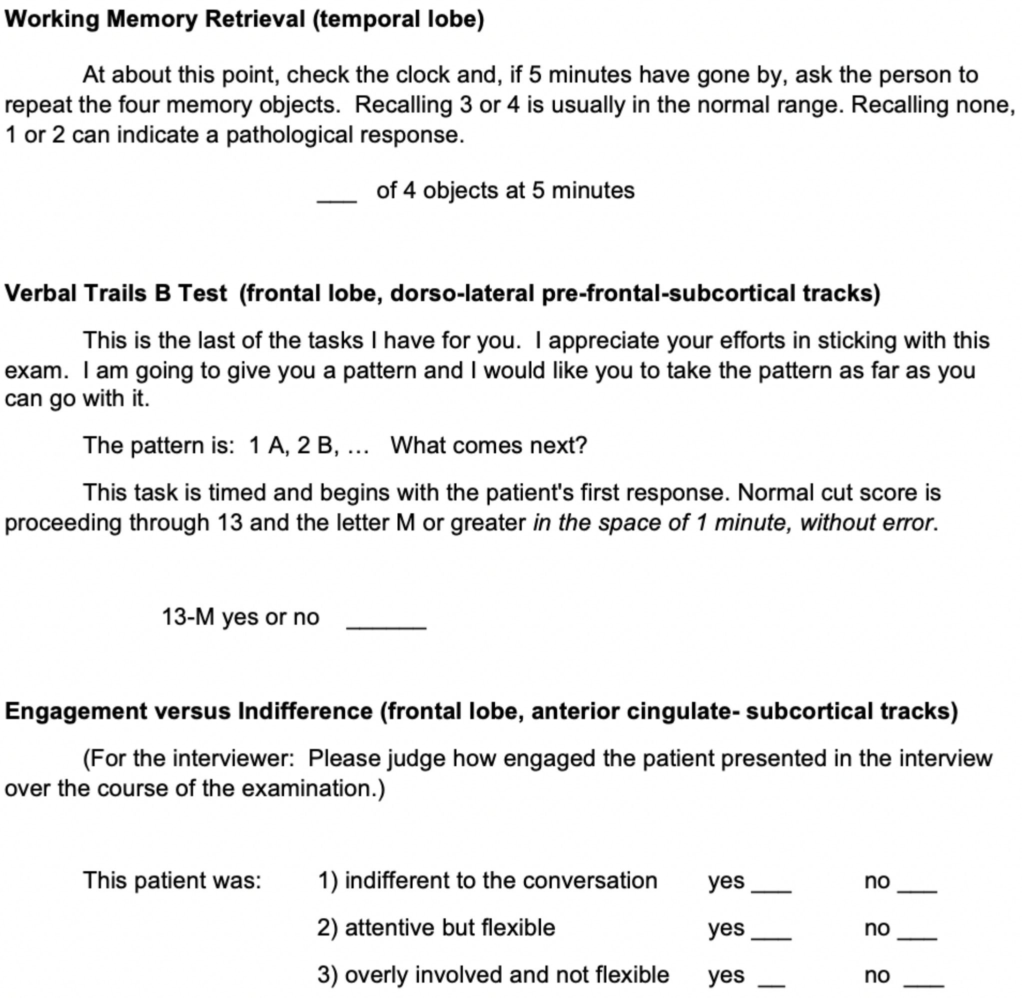
Concrete: they are not alike.	Abstract: they're both living things.

2) Proverbs

If I were to say, ‘It's no use crying over spilled milk’, what would I be talking about?

(Concrete: you have to wipe the milk up. Abstract: don't worry about what can't be fixed.)

Figure 3. Part 3 of the brief cognitive examination for remote use (working memory retrieval, verbal trails B text, and engagement versus indifference).



Working Memory Retrieval (temporal lobe)

At about this point, check the clock and, if 5 minutes have gone by, ask the person to repeat the four memory objects. Recalling 3 or 4 is usually in the normal range. Recalling none, 1 or 2 can indicate a pathological response.

___ of 4 objects at 5 minutes

Verbal Trails B Test (frontal lobe, dorso-lateral pre-frontal-subcortical tracks)

This is the last of the tasks I have for you. I appreciate your efforts in sticking with this exam. I am going to give you a pattern and I would like you to take the pattern as far as you can go with it.

The pattern is: 1 A, 2 B, … What comes next?

This task is timed and begins with the patient's first response. Normal cut score is proceeding through 13 and the letter M or greater *in the space of 1 minute, without error*.

13-M yes or no _______

Engagement versus Indifference (frontal lobe, anterior cingulate- subcortical tracks)

(For the interviewer: Please judge how engaged the patient presented in the interview over the course of the examination.)

This patient was:			
	1) indifferent to the conversation	yes ___	no ___
	2) attentive but flexible	yes ___	no ___
	3) overly involved and not flexible	yes __	no ___

Results

Case #1

This male patient, aged in his 70s, was admitted with shortness of breath, fever, chills, dry cough and malaise for 2 days. On Day 3, his nurses reported profound malaise and new onset of confusion. On Days 2-5, he received dexamethasone 6 mg daily. Psychiatry consultation on Day 5 revealed marked difficulty sustaining attention, a relative indifference to his medical condition, and an inability to understand simple directions. By Day 10, the patient was awake, alert, and attentive. His mood was one of relief with appropriate affect. His speech was fluent and logical. Other than fleeting shadows in his room, he experienced no hallucinations. He had lost the senses of both taste and smell.

Responses to the patient's Day 10 telephone cognition assessment are listed below:

- Orientation: person, place, and date
- Memory: registered 4 objects, recalled 3 out of 4 after 5 minutes
- Calculations: complex addition intact (37 + 45 = 82)
- Concentration: "DLROW"
- Fund of information: the patient, a book collector, named 5 standard authors
- Judgment:
  - fire-theater: "Contact help by phone or the theater personnel."
  - burglar noises at night: "Call 911."
- Similarities/proverb:
  - similarities: 3/3 abstract
  - proverb: abstract
- Verbal Trails B [10]: lost track after 6-F

Case #2

This male patient with schizophrenia, aged in his 60s, stable on clozapine for many years, presented with increasing confusion and profound malaise, and he had not taken his clozapine for approximately the past week. The admission diagnosis was COVID-19 pneumonia; the patient was awake but poorly responsive to conversation. On Day 2, he could not focus his attention for testing and was unable to use his phone. On Day 3, a 3-week clozapine up-taper began at 50 mg/day, gradually increasing to his regular dose of 450 mg/day, while monitoring neutrophil counts.

By Day 6, the patient was awake, alert, and able to converse by telephone. Responses to the assessment on Day 6 are listed below:

- Mood: calm and upbeat
- Affect: appropriate
- Speech: logical progressions
- Hallucinations/delusions: none endorsed on specific inquiry
- Orientation: person, place, and date
- Memory: registered 4 objects and recalled 3 at 5 minutes
- Calculation: unable to add double digits with carryover but could identify right/left and the fingers of both hands
- Concentration: “DROLW”
- Judgment: appropriate answers to fire-theater and burglar-noises, getting help in both cases
- Similarities/proverb:
  - Similarities: 3/3 concrete
  - proverb: concrete (“It’s about crying.”)
- Verbal Trails B: 10-J and then lost track

Case #3

This male patient, aged in his 50s, was admitted with COVID-19 pneumonia; by Day 3, he required oxygen and was given dexamethasone. The nursing staff found him incontinent, with soiled clothes, to which he was indifferent, saying “I feel fine.” He needed assistance in showering and in understanding what the water knobs were for. During a telephone cognitive examination, he reported his mood as “good,” and he did not recall his confusion in the shower. He did not endorse hallucinations or paranoia. His thought process regarding similarities and a proverb was very concrete. Responses to the assessment are listed below:

- Orientation: to self and “hospital”
- Memory: could not register 4 objects on 3 tries
- Calculation: added single digit numbers only
- Verbal Trails B: could not understand the test directions

Responses to the Day 9 examination are listed below:

- Orientation: person, place, and date
- Memory: registered 4 items, recalled 3 after 5 minutes
- Calculation: added 2-digit numbers without carryover but not with carryover on 3 tries
- Judgment: fire-theater: “I'd leave the theater.” No further insight as to danger
- Similarities/proverb:
  - Similarities: 3/3 concrete
  - proverb: concrete (“You have to wipe the milk up.”)
- Verbal Trails B: unable to grasp the test directions on 3 tries

Case #4

This male patient, aged in his 40s, with a history of polydrug abuse was referred from another hospital with a positive COVID-19 test during treatment for peripheral cellulitis and “minimal” COVID-19 symptoms. On Day 5, he developed psychosis with paranoia, disorganized speech, hyper-religiosity, mood lability, and insomnia. These symptoms required increasing haloperidol doses over 2 days to 10 mg/day. There was no hyperactivity, and the patient complained of profound fatigue.

Responses to the telephone evaluation on Day 5 are listed below:

- Orientation: person, place, and date
- Memory: registered 4 objects and recalled 3 at 5 minutes
- Calculation:
  - unable to add 2-digit numbers
  - stereognosis and finger naming were clear
- Concentration:
  - “DLOW”
  - did not see the error
- Fund: named 5 Super Bowl–winning teams
- Judgment: fire-theater: “Run out, call 911, run back in and get people out. Break down a wall if I had to.”
- Similarities/proverb:
  - similarities: 3/3 abstract
  - proverb: concrete (“Drink what's left.”)
- Verbal Trails B:
  - grasped the instructions on the second try
  - lost the sequence after 5-E

Case #5

This male patient, aged in his 80s, was COVID-19–positive and admitted with “altered mental status,” malaise requiring oxygen, and supportive care with gradual improvement over 1 week. Responses to the Day 8 telephone assessment are listed below:

- Mood: “pretty good.”
- Hallucinations/delusions or suicidal concerns: none endorsed
- Speech: fluent and logical if somewhat slowed
- Orientation: person, place only
- Memory: registered 4 objects, recalled 2 at 5 minutes
- Calculation: added single digits with carryover only
- Concentration: “DOWOLW”
- Judgment: fire-theater: “Don’t yell FIRE!”; saw the panic danger but no alternative actions
- Verbal Trails B: lost track after 9-I

Case #6

This male patient, aged in his 50s, was admitted with COVID-19 and malaise but no respiratory compromise. Responses to the Day 2 telephone assessment are listed below:

- Mood: demoralized state with slow, sparse speech
- Hallucinations:
  - deprecatory voices
  - “shadows, like ghosts” intermittently
- Orientation: person, place, and date
- Memory: registered 4 objects, recalled none at 5 minutes
- Verbal Trails B: unable to grasp the directions on 2 tries

On Day 7, the patient’s fatigue lifted. Responses to the Day 7 assessment are listed below:

- Mood: no demoralization
- Speech: fluent and logical
- Hallucinations: occasional nondeprecatory voices

- Orientation: person, place, and date
- Memory:
  - registered 4 objects, recalled 1 of 4 objects at 5 minutes
  - digit repetition: 5 numbers forward, not 6 on 2 tries
- Concentration: “DLROW”
- Calculations: unable to add double digits with or without carryover
- Fund of information: named 5 musicians he admires
- Judgment:
  - fire-theater: “Yell FIRE!”; did not see the panic danger or appropriate actions
  - burglar noises at night: “Call 911.”
- Similarities/proverb:
  - similarities: 3/3 abstract
  - proverb: abstract
- Verbal Trails B: understood the directions but lost track at 6-F

Overall Results

Table 1 presents a collated listing of the cognitive presentations of the case patients. On admission, none of the patients were capable of meaningful engagements with the clinical staff; 5 were awake, if confused, and confusion with psychosis developed in the sixth patient (Case #4). This finding suggests involvement of the anterior cingulate cortex, which mediates engagement with one’s surroundings versus indifference to them [8,9]. This changed in the range of 1 week, as demonstrated by further assessment.

By that time, working memory had returned in 4 cases, indicating temporal lobe/hippocampal recovery. Judgment, which is associated with the anterior medial frontal lobe, returned to an extent in 3 cases, remaining poorly functional in 3. By contrast, 5 of the cases could not perform the ascending addition tasks, and 0 of the 6 performed normally on the Verbal Trails B Test. The latter finding is associated with impaired frontal executive function, such as planning and executing tasks. This impairment is associated with the dorsolateral prefrontal cortex.

Taken together, the case studies and Table 1 suggest a process of cognitive recovery over a short term of 5 to 10 days; however, questions on intermediate and long-term recovery remain unanswered. The data suggest the necessity of assessing higher cognitive functions that are associated with the neocortex in this brief format, with the goal of characterizing a series of cognitive functions differentially and in detail.

Table 1. Selected cognitive results of patients with COVID-19 (N=6).

Case #	Age (decade)	Examination day (hospitalization)	Temporal lobe: working memory (≥3 of 4 objects)	Parietal lobe: calculation (2 digits with carryover)	Frontal lobe engagement on Day 1	Frontal lobe: judgment (basic, complex)	Frontal lobe: Verbal Trails B (13-M without error)
1	70s	10	Yes	Correct	No	Complex	Poor
2	60s	6	Yes	No	No	Complex	Poor
3	50s	9	Yes	No	No	No	Poor
4	40s	5	Yes	No	No	No	Poor
5	80s	8	No	No	No	No	Poor
6	50s	7	No	No	No	Basic	Poor

Discussion

As expected, this inquiry found specific evidence of cognitive impairments among this case series of patients with COVID-19. Unexpectedly, however, the differential characteristics of COVID-19 cognitive recovery appeared. We were surprised to observe that some cognitive components recovered more quickly than others. This observation raises questions regarding the timing and return of those items that appeared least likely to recover in the short term of 5 to 10 days, most notably parietal lobe calculation ability and frontal lobe executive functions. It also raises concerns over the recovery timing for temporal lobe working memory and frontal lobe judgment.

In the face of a neuropsychiatric pandemic [1], the principle clinical advantages of this examination lie in its ability to provide a rapid, brief assessment of several anatomically based cognitive functions in the least invasive manner possible to preserve both patient and caregiver safety. In our view, it offers a much wider array of easily administered tests compared to orientation alone or generic comments such as “altered mental state.” This examination offers a reasonable degree of brain function specificity and can be administered in approximately 5 minutes by telephone or videoconference.

This approach is not that of a screening examination that provides a series of tasks and delivers an overall score. Rather, it provides a first assessment of cognitive impairment that then directs further assessments in working through differential diagnoses toward a working or final diagnosis. For example, impaired working memory suggests the necessity to test registration functions further, such as through digit recall in Case #6, to clarify more generalized conditions such as memory impairment in delirium versus that in specific pathological conditions such as Wernicke-Korsakov Syndrome. Similarly, impaired calculation ability calls attention to the need to evaluate other parietal lobe functions, such as right/left orientation and finger agnosia, as in Cases #2 and #4.

This adapted format does not require a pencil and paper or in-person tasks; therefore, it is amenable to a telephone conversation. In contrast, the Frontal Assessment Battery (FAB) [11] must be performed in person, for example, when assessing the FAB's judgment test of go/no-go responses. In contrast, the assessment reported here relies on assessing the cognitive process involved in judging what to do in a hypothetical situation.

Although the examination results are not diagnostic of specific causes [12], they do point to specific syndromes, such as delirium, that indicate further examination based on specific cognitive deficits. The syndromes themselves, including delirium, are frequently amenable to treatment, often with very low doses of antipsychotic agents such as haloperidol or olanzapine.

Although much more could be said about the increments of this 5-minute telephone cognitive assessment, its principal purpose is to characterize the nature and extent of impairment in patients with COVID-19 for both here-and-now assessment and follow-up recovery as the extent of illness lessens [4]. All the cases reported some form of cognitive impairment, whether profound, as in Cases #1 to #3, or more subtly, as in the other cases. Although all of the cases improved, 2 (#2 and #4) required antipsychotic medication to restore what was likely their preinfection baseline. Working memory, calculation ability, and especially Verbal Trails B performance—testing frontal executive abilities ascribed to dorsolateral prefrontal cortex functioning [8]—were most often impaired and slower to approach normal baseline capabilities. As our experience with COVID-19 develops, we suspect that longitudinal follow-up of brain functions will take on considerable import as we address recovery at pandemic population levels [12].

Beginning with a brief, multifaceted approach to recognizing cognitive impairment can open the way to more specific assessments and investigations. From this baseline, a longitudinal, prospective study can guide understanding of longer-term recovery. In the acute setting, as noted here, treatment trials targeting return of function, such as through low-dose neuroleptic agents aimed at cognitive dysfunction relief, can guide treatment efforts.

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Conflicts of Interest

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Abbreviations

FAB: frontal assessment battery
NIMH: National Institute of Mental Health

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Original Paper

A Caregiver Digital Intervention to Support Shared Decision Making in Child and Adolescent Mental Health Services: Development Process and Stakeholder Involvement Analysis

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Abstract

Background: Parents and caregivers are generally recognized by literature and the law as key to child and adolescent mental health decisions. Digital interventions are increasingly being used to support care and treatment in child and adolescent mental health services (CAMHS). However, evidence of the design and development process is generally not made available.

Objective: In light of calls for more transparency, this paper aims to describe the development of an evidence-based, theoretically informed digital decision support intervention for parents and caregivers of young people accessing CAMHS.

Methods: The intervention was developed in line with the UK Medical Research Council framework for developing complex interventions. The process incorporated the steps for developing patient decision aids, as follows: assessing need, assessing feasibility; defining objectives; identifying the framework of decision support; and selecting the methods, designs, and dissemination approach. We synthesized theory, research, international guidelines, and input from relevant stakeholders using an iterative design approach.

Results: The development steps resulted in Power Up for Parents, a decision support intervention, with five key features (ie, decisions, goals, journey, support, and resources). The intervention aims to encourage discussion, allow parents to ask questions during sessions or seek further information between sessions, and allow service providers to tailor the shared decision-making process to accommodate the needs of the parent and child.

Conclusions: We confirmed that it is possible to use input from end users—integrated with theory and evidence—to create digital interventions to be used in CAMHS. Key lessons with implications for practice, policy, and implementation science, along with preliminary findings, are presented.

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KEYWORDS

digital health intervention; caregivers; parents; child mental health

Introduction

Background

Digital health interventions have been increasingly used in child and adolescent mental health services (CAMHS) [1-3]. Power Up, a mobile phone app for supporting young people in shared decision making (SDM), has shown some evidence of promise; young people who used Power Up reported greater levels of SDM after the intervention period [4,5]. SDM is central to person-centered care and describes a process in which service users and service providers collaborate to make treatment decisions [6]. Depending on the age of the child, parents (including nonbiological primary caregivers) sometimes report feeling excluded from the decision-making process and therefore may also benefit from receiving additional support [7]. Previous research has highlighted that parents' decision support needs include obtaining information, talking to others, and feeling a sense of control over the decision-making process [8,9].

In addition, parents of children with mental health difficulties report experiencing an *emotional roller coaster* [10]. Furthermore, researchers identified parents' emotions as a possible influencing factor in the SDM process [11-13]. A review of parent-targeted SDM interventions for use in CAMHS revealed that existing interventions rarely addressed this concern, and only one available intervention explicitly addressed emotional support [14]. Counseling in Dialogue is a face-to-face intervention found to lower decisional conflict and promote the acceptance of recommended treatments [15]. However, concerns about stigma and confidentiality, shame or embarrassment in attending services, financial costs, time, appropriateness, or limited access to services are usually among the many barriers to accessing in-person CAMHS [16,17]. As a result, existing efficacious face-to-face interventions are adopting digital technology as a means of addressing these barriers [18,19]. Three interventions identified in a previous review [14] were considered to be digitally accessible. Two of those interventions targeted parents of children with autism spectrum disorders [20,21], and one intervention targeted parents of children with attention-deficit/hyperactivity disorders [22]. However, recommendations to develop interactive digital interventions that promote well-being factors, in addition to targeted behavior change, are gaining momentum [23].

Despite the growing interest in digital health interventions, detailed descriptions of the development process of digital interventions used in CAMHS are limited [24], with implications for clinical and research reproducibility. Nonetheless, recent reviews of the extant literature have described innovative technological applications in parent management training programs [25,26] and programs to promote child health [27]. Although this research shows great efficacy for the use of parent-targeted technology in child health care, to the best of our knowledge, there are presently no parent-targeted interactive mobile apps designed for and tested in CAMHS that support an affective-appraisal SDM process [14]. The affective-appraisal approach refers to the ability to include key decision makers (ie, child or young person, parents, and service providers) and incorporate and address the influence of parental affective states on the SDM process [13].

Furthermore, health care quality standards and guidelines identify and define SDM as an essential characteristic of good quality care, endorsing support and interventions for both service users and service providers [28]. Experts highlight that for SDM to occur, the process should include the following nine essential elements: patient values and preferences, options, professional knowledge and recommendations, make or explicitly defer a decision, define and explain the problem, check and clarify understanding, explore benefits and risks, discuss patient's ability and self-efficacy, and arrange follow-up [29]. However, available interventions meet an average of 4.57 (SD 1.93) SDM elements [14]. Furthermore, most of the work on defining, facilitating, and supporting SDM has focused on adult health care and dyad relationships between primary service users and health care providers [29,30]. In CAMHS, parents are sometimes surrogate decision makers or the parent, child, and health care provider engage in a triad decision-making process [13]. Owing to the many perceived challenges associated with decision making in pediatric care, researchers commonly highlight the lack of an evidence-based holistic conceptualization of SDM [31]. Therefore, in line with the broader health literature, it is recommended that all efforts are made to improve SDM. In so doing, experts call for clinicians to recognize SDM as an ethical imperative, stimulate a bidirectional flow of accurate and tailored information, and give patients and their families resources that facilitate an effective SDM process [32].

Objectives

Given the importance of SDM and the feasibility of digital interventions in CAMHS, it is essential to develop theoretically informed interventions. The overall aim of this paper is to describe the development of an evidence-based digital intervention for use by parents accessing CAMHS. Consequently, the following subobjectives are addressed:

1. Develop a logic model outlining how the intervention is proposed to work.
2. Consolidate evidence-based content to support the affective-appraisal model of SDM.
3. Involve end users in the design and development of an SDM intervention for use in CAMHS.
4. Highlight key learning and recommendations.

Methods

Framework for Intervention Development

The UK Medical Research Council (MRC) framework for the development and evaluation of complex interventions was adopted. The intervention was described as complex, in line with the conventional definition describing complex interventions as interventions with several interacting components. The MRC framework proposes that during the development stage, it is important to identify the evidence base, identify the theory, and model the process and outcomes [33]. Alongside the MRC framework, activities are guided by the steps for developing decision aids [34].

Assessing Need

A broad overview of the literature explored existing evidence for the prevalence of child mental health problems, factors influencing SDM, and potential impact on the family. Another systematic review aimed to better understand the emotional experiences of having a child with mental health problems and explored how those experiences may influence parental involvement in care and treatment decisions (findings submitted for publication). In addition, existing decision support interventions available for parents of children with mental health problems were identified and assessed against SDM elements [14]. Qualitative interviews were also conducted to obtain insight into how clinicians and parents perceived and described experiences of SDM and to identify the support systems used [13].

Assessing Development Feasibility

First, as this research was part of a PhD project, it was agreed that the 3-year timeline was appropriate to develop and evaluate an intervention. Second, a preexisting relationship with the technology company (Create Health) made it suitable for the development of a digital intervention [5]. In addition, the financial resources necessary to develop the intervention were available through the PhD project funding. Furthermore, preliminary evidence from the original Power Up for young people suggested that it was feasible to develop and evaluate a novel digital intervention for CAMHS [4].

Defining the Objectives of the Decision Support Tool

On the basis of an overview of the literature and feedback from parents, practitioners, and researchers (described later in the paper), the following primary objectives were considered necessary to guide the intervention's development process:

1. Encourage discussion (ie, three-talk model proposed by Elwyn et al [35]).
2. Allow parents to ask questions during sessions or seek further information within sessions.
3. Provide a space for parents to identify their feelings and moods and receive support.
4. Allow service providers to tailor the SDM process to accommodate the needs of the parent and child (eg, informed vs involved).

Identifying the Framework of Decision Support

In general, the development process of the intervention was conducted in line with the International Patient Decision Aids Standards. These guidelines encourage the use of a systematic development process, disclosing conflicts of interest, internet delivery, using plain language, and basing information on up-to-date evidence, among others [36,37]. More specifically, in line with an affective-appraisal approach [13], the Youth SDM model [38], the Integrative Model of SDM in medical encounters, highlighting the nine essential elements of SDM [19] and the Ottawa Decision Support Framework [39] informed the content of the intervention. The Ottawa Decision Support Framework has been used to develop and evaluate over 50 patient decision aids, measures (eg, Decisional Conflict Scale), and training in providing decision support.

The Youth SDM model highlights three key SDM functional areas: setting the stage for youth SDM, facilitating youth SDM, and supporting youth SDM. The authors recommended that setting the stage for youth SDM should involve providing an introduction to the concept of SDM and inviting and acknowledging the service user's preference for involvement. To facilitate this, a co-design process to develop a webpage to define and explain SDM was undertaken (discussed in the *Stakeholder Involvement* section). Consequently, the webpage became the welcome screen for the intervention to *set the stage* for SDM.

The Integrative Model of SDM was used to *facilitate the SDM process*. The current intervention was designed to incorporate all the nine elements of SDM. Examples are presented in the Results section. In addition, the Ottawa Decision Support Framework was used to inform *support* for the SDM process. The framework proclaims that participants' decisional needs will affect decision quality, which in turn affects actions or behaviors (eg, delay), health outcomes, emotions (eg, regret or blame), and appropriate use of health services. This framework was pertinent to the intervention, as previous research highlighted the potential impact of parents' emotions on the SDM process.

Selecting the Methods, Designs, and Planning for the Feasibility and Pilot Study

Overview

The remaining three steps outlined by O'Connor and Jacobsen [34] were collapsed under the subheading *stakeholder involvement*. There is an overarching consensus that involving end users in the development of health interventions is critical for successful implementation. Developers and researchers converge on the understanding that patient and public involvement (PPI) can benefit the uptake and usage of interventions. More specifically, the involvement of end users is known to improve idea generation and creativity [40-42]. The following sections describe how various stakeholders are involved in the development of the intervention.

Stakeholder Involvement

Steering Committee

From conception, a steering committee was formed comprising a senior researcher, a colleague with experience in the development of digital interventions, and 3 parents with experience of having a child with a mental health problem; the committee was chaired by the primary author (SL). The parents were appointed as part of the steering committee after expressing interest in this study at various presentations undertaken by the primary author. The committee was ideal for consensus forming and was mainly responsible for ensuring that the development process was transparent and unbiased. The steering committee also guided the feasibility and pilot study of the intervention by offering strategies to promote recruitment. Meetings convened on a web-based platform for a total of 6 times throughout the intervention design and development phase.

Patient and Public Involvement

The overall objective of the consultations was to obtain parents' expert advice on the research and intervention design. However, gaining insight into how parents may use digital health interventions and obtaining input on how to improve the intervention before this study began was necessary. First, an email consultation was conducted with the Family Research Advisory Group at the National Children's Bureau. Information about the aims of this study and plans for an intervention with specific questions to generate ideas were shared with the research team at the National Children's Bureau. The team contacted 9 parents who provided input on the value of the intervention, what support might be needed, and which group of parents we should target for recruitment. Prototype development was initiated based on the input received. Second, the study design and an example of how the intervention might be used were presented to the group at a scheduled meeting. The pros and cons of digital versus other formats of decision-making tools were discussed along with general thoughts and concerns regarding the study and intervention design. The prototype was refined and updated before the final meeting. At the final meeting**,** a group discussion, including a presentation of the prototype, was conducted to examine the penultimate version of the intervention and study design. There were further discussions on how parents could use and benefit from the intervention in practice. Further refinement of the prototype was carried out based on the feedback received.

Showcase Pollinator Event With Clinicians and Researchers

At a showcase pollinator event, which was held in Austria at the Technology Enabled Mental Health Summer School, the prototype was then presented to clinicians, researchers, and intervention developers who were asked to provide feedback and specifically provide input to improve the interactivity of the intervention. Three roundtable discussions followed, and input was obtained from a total of 12 experts in the area of child mental health. Attendees at the event had a specific interest in digital interventions to prevent, treat, and promote policies for children and youth mental health.

Public Engagement

A collaborative approach was adopted to develop and design a webpage to promote SDM in CAMHS. First, a survey to elicit the public's opinion on the preferred mode of delivery for an SDM resource was conducted via social media. Responses from clinicians, parents, children and young people, school staff, and others were in favor of a web resource. Consequently, 3 parent champions and 4 young champions from the Anna Freud National Centre for Children and Families attended two workshops and provided email feedback on two versions of the webpage before agreeing to the final versions. At the first workshop, participants explored what SDM meant, and a consensus was reached for a family friendly definition that could be displayed on the webpage. In the second workshop, participants were involved in designing the paper prototypes of the webpage. Consequently, the webpage was designed, and the content was updated based on the feedback received. The communications team at the Centre was then involved to ensure that the content and design were in line with the Centre's standards. Consequently, the webpage was presented as the welcome screen for the intervention.

App Developers

The app developers at Create Health were responsible for the technical development of the intervention. However, design-specific components such as swipe versus touch features, labels for the settings menu of the app, and data security were proposed by the developers and included only after they were agreed upon by the primary author and the steering committee. On the basis of feedback from the steering committee, PPI sessions, and parent experts, a series of paper prototyping and digital designs were developed before the final version was adopted.

Ethics

Ethical approval for the development and pilot testing of Power Up for Parents was granted by the University College London and by the London Surrey Research Ethics Committee (IRAS 236277).

Results

Evidence Base

The development process highlighted the need for an SDM intervention targeting parents of children with mental health concerns. Decisions could include, but not be limited to, medications, types of therapy, or service needs. The literature reviews revealed a high prevalence of child mental health problems, several decision-making opportunities, barriers to and facilitators of SDM, and positive outcomes when SDM was adopted in care. The potential influence of a parent's emotional state on the decision-making process was also identified [8-13,43-45]. Quantitative findings also highlighted a large number of parents reporting involvement in SDM and possible associations among ethnicity, their relationship to the child, and the presence of conduct problems or learning difficulties. Nonetheless, parents and service providers expressed the importance of including parents in the decision-making process. The existing parent-targeted decision support tools identified met an average of 4.57 (SD 1.93) SDM elements out of a possible nine elements [14]. Furthermore, that review reported time, accessibility, and appropriateness of the intervention as factors influencing usage and implementation of interventions, providing additional support for a digital mode of delivery. Table 1 presents an overview of how the evidence informed the intervention's design objectives and key features.

Table 1. Overview of the intervention's objectives and key features.

Research evidence	Intervention design objective	Key features of the intervention
Recognizing the need for help can be challenging, as carers' perceptions of their child's mental health difficulties differ from those of their child, teachers and health professionals. These disagreements are reflected in carers reporting not feeling listened to or respected, further adding to frustrations and disappointment.	• Encourage discussion • Allow parents to ask questions during sessions or seek further information within sessions	• Decisions and goals • Decisions and resources
Findings suggest that parents are "expected to, but not always able to" engage with CAMHS[a] due to the "emotional roller coaster" they experience.	• Provide a space for parents to identify their feelings or moods and receive support	• Support and journey
Findings suggest that the triad relationship is unique and can be challenging in CAMHS. Recommendations are made to explore opportunities for varying levels of involvement, such as "informed" versus "actively involved" parents.	• Allow service providers to tailor the SDMb process to accommodate the needs of the parent and child (ie, informed vs involved)	• Decisions and resources
Findings indicated that time, accessibility, and the appropriateness of the intervention emerged as factors influencing the usage and implementation of parent-targeted SDM interventions.	• Be suitable and accessible to parents	• Digital mode of delivery

[a] CAMHS: child and adolescent mental health services.

[b] SDM: shared decision making.

Logic Model

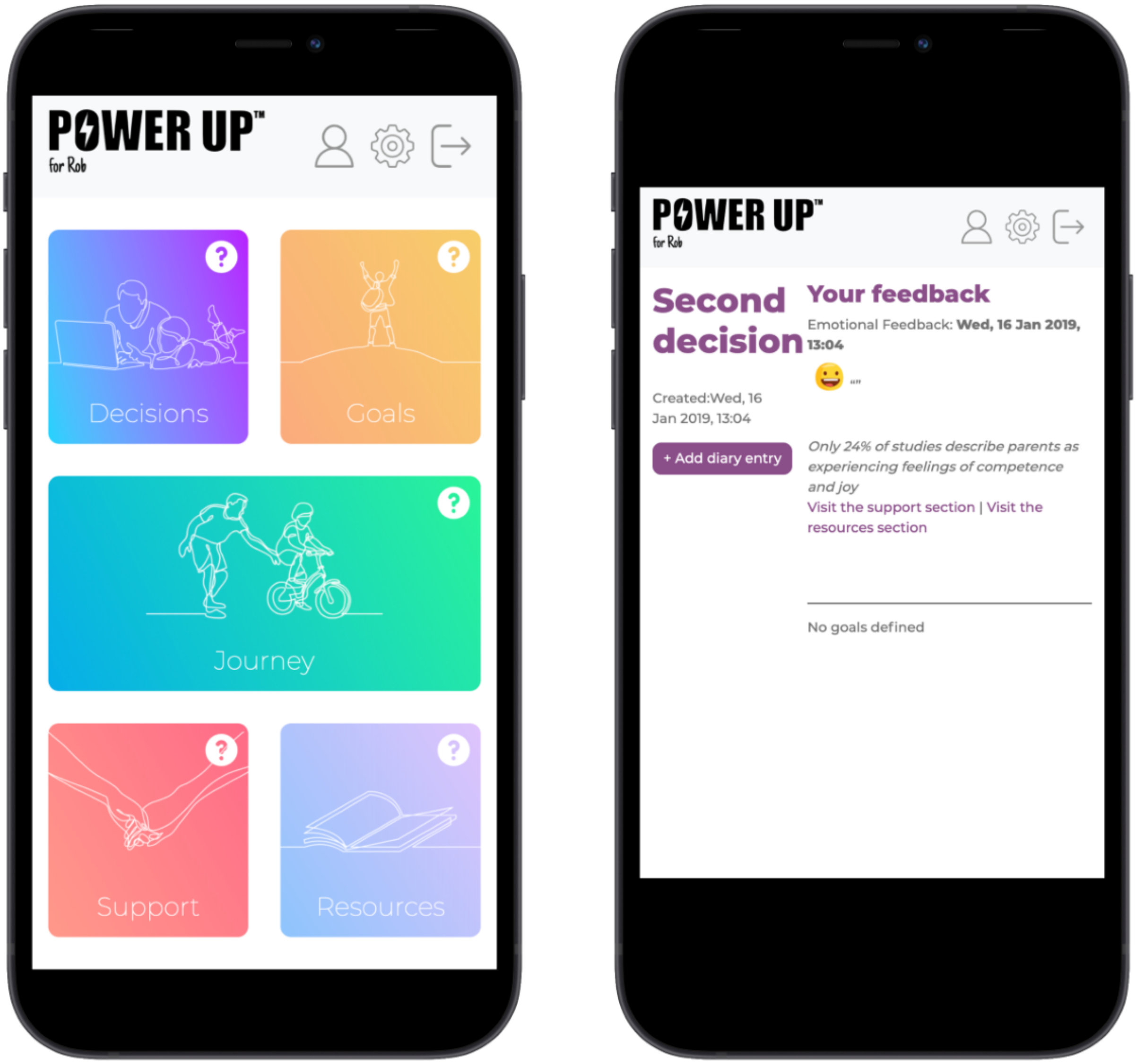
The abovementioned evidence was explored in detail and presented in a logic model to outline the purpose of the intervention. Multimedia Appendix 1 provides an overview of the adapted Evidence-Based Practice Unit Logic Model [46], consisting of four parts that describe the intervention and target audience. The logic model also highlights the aims of the intervention and expected outcomes once implemented. In addition, a list of potential moderators that may influence usage and implementation were reported.

Outline of the Intervention

Overview

This section summarizes the key features of the resulting prototype and the user manual (Multimedia Appendix 2). The Power Up for Parents title was adopted as this project was an emended version of the original Power Up intervention for young people that supports and promotes SDM in CAMHS [4,5]. Although the current prototype is referred to as Power Up for Parents, feedback from PPI sessions indicated that nonbiological caregivers may feel excluded. In response to this, the prototype included a customization feature to change the word *Parents*. Therefore, it can be labeled *Power Up for Rob* to reflect the child's or parent's name (Figure 1). The overall structure of the app content is as follows.

Figure 1. Examples of the home screen and decision tab.



Second decision

Created:Wed, 16 Jan 2019, 13:04

Your feedback

Emotional Feedback: **Wed, 16 Jan 2019, 13:04**

Only 24% of studies describe parents as experiencing feelings of competence and joy

Visit the support section | Visit the resources section

No goals defined

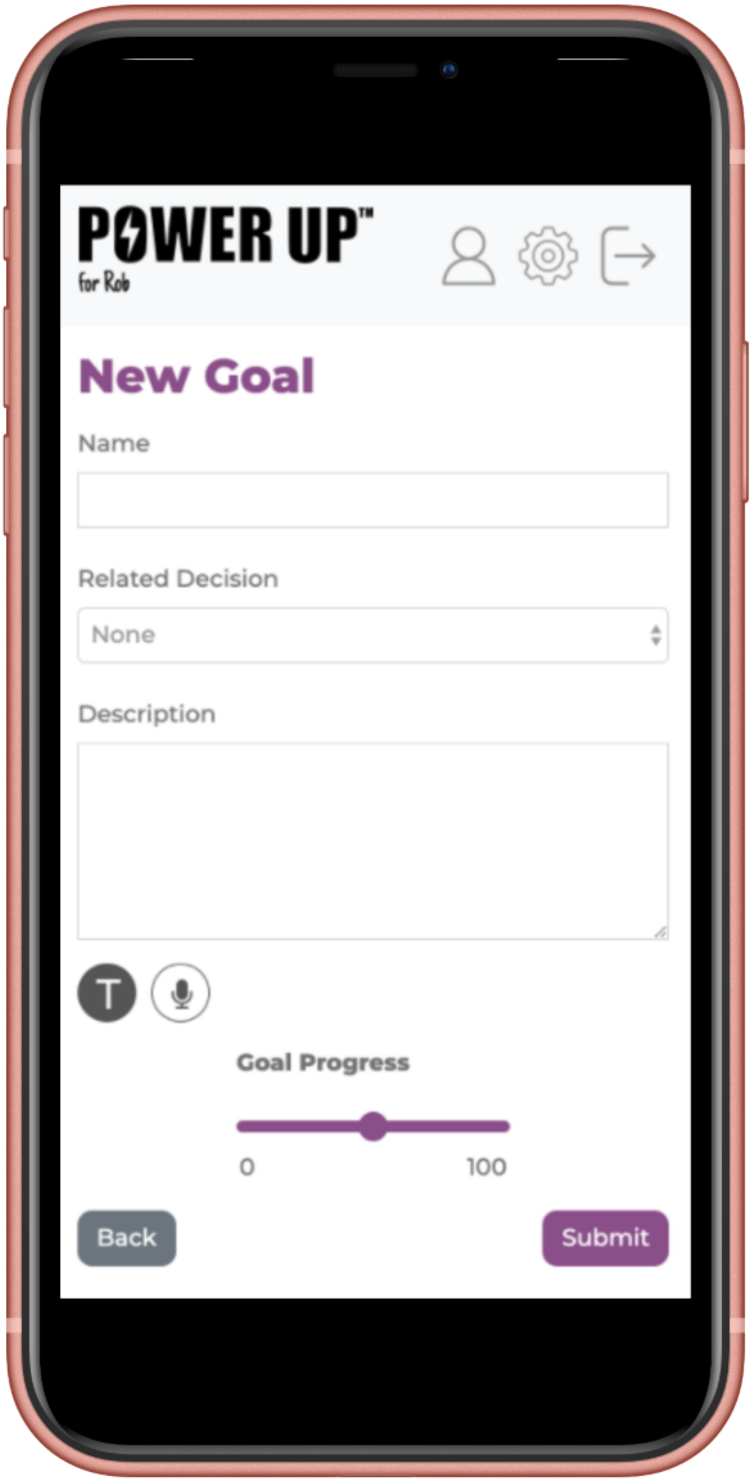
Decisions

This is a decision aid that guides users to seek information about treatment options, to review the benefits and risks of each option, to track decisions, and to record where more information or support is needed (Figure 1). In addition, as the research focused on the triad relationship, parents were encouraged to involve others in the decision-making process by seeking preferences from the clinicians, their child, or other relevant persons. This section uses the nine essential elements of SDM to “walk” users through the decision-making process, prompting users to answer questions such as “Do you have sufficient information about the options available to you?” and “ Do you feel ready to make this decision?” The other sections below provide additional support throughout the decision-making process that is in line with the affective-appraisal model of SDM.

Goals

This feature is used in sessions or between sessions to record and track goals, as they are discussed with service providers and young service users. It allows users to set individual or consensus goals and explore plans to achieve these goals (Figure 2). In addition, parents could record any questions or concerns to address in the following session. Research findings suggest that goal-setting and tracking progress are associated with higher self-efficacy [47], and this is one approach to promote SDM in CAMHS [48].

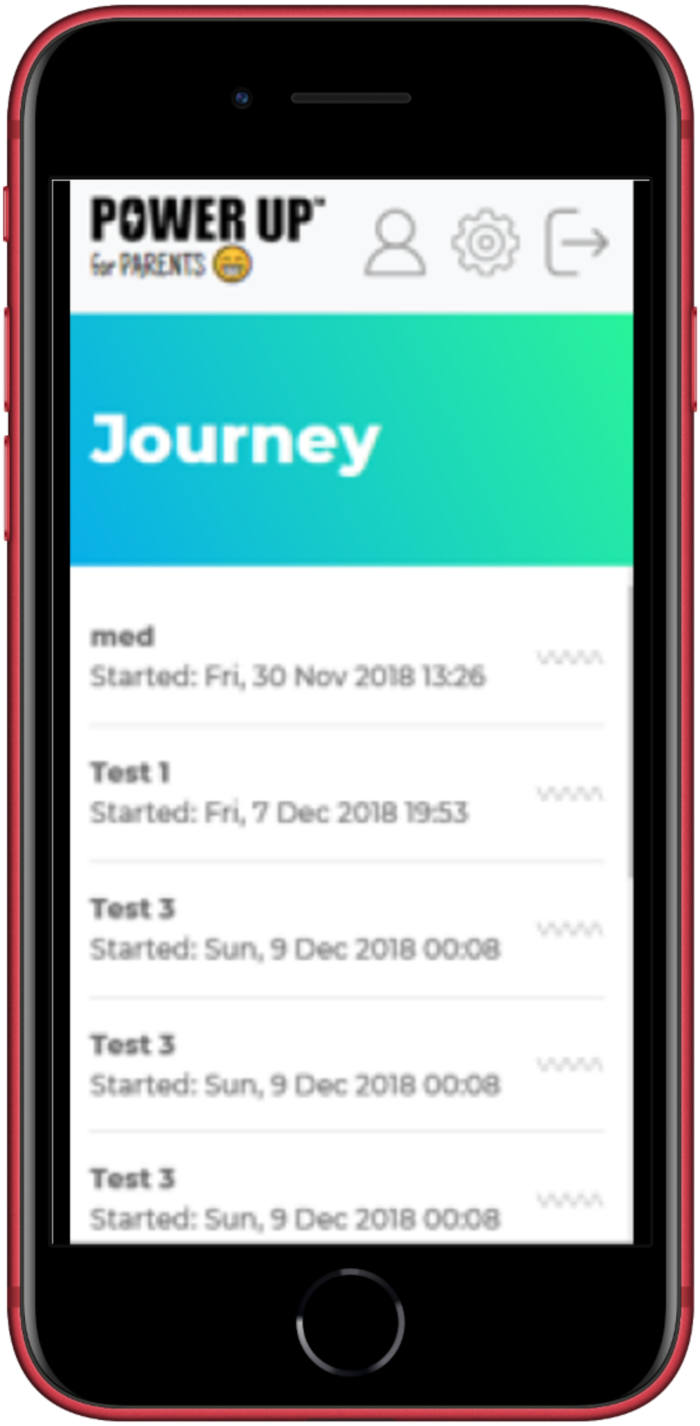
Figure 2. Examples of the goal tab.



Journey

This feature allows parents to reflect on their emotions or issues that may affect their decision-making process. A parent could decide to share the content with the child and the clinician, and it could be used during and within sessions to keep track of the decision-making journey from user readiness to outcomes. Expectations, experiences, and reflections are recorded using the diary function (Figure 3). The usefulness of implementing case tracking and documenting client journeys has been highlighted in previous research [49]. Although previously explored in primary care services, those authors highlighted the importance of monitoring the comprehensiveness of service responses and the experiences of clients.

Figure 3. Examples of the journey tab.



med
Started: Fri, 30 Nov 2018 13:26

Test 1
Started: Fri, 7 Dec 2018 19:53

Test 3
Started: Sun, 9 Dec 2018 00:08

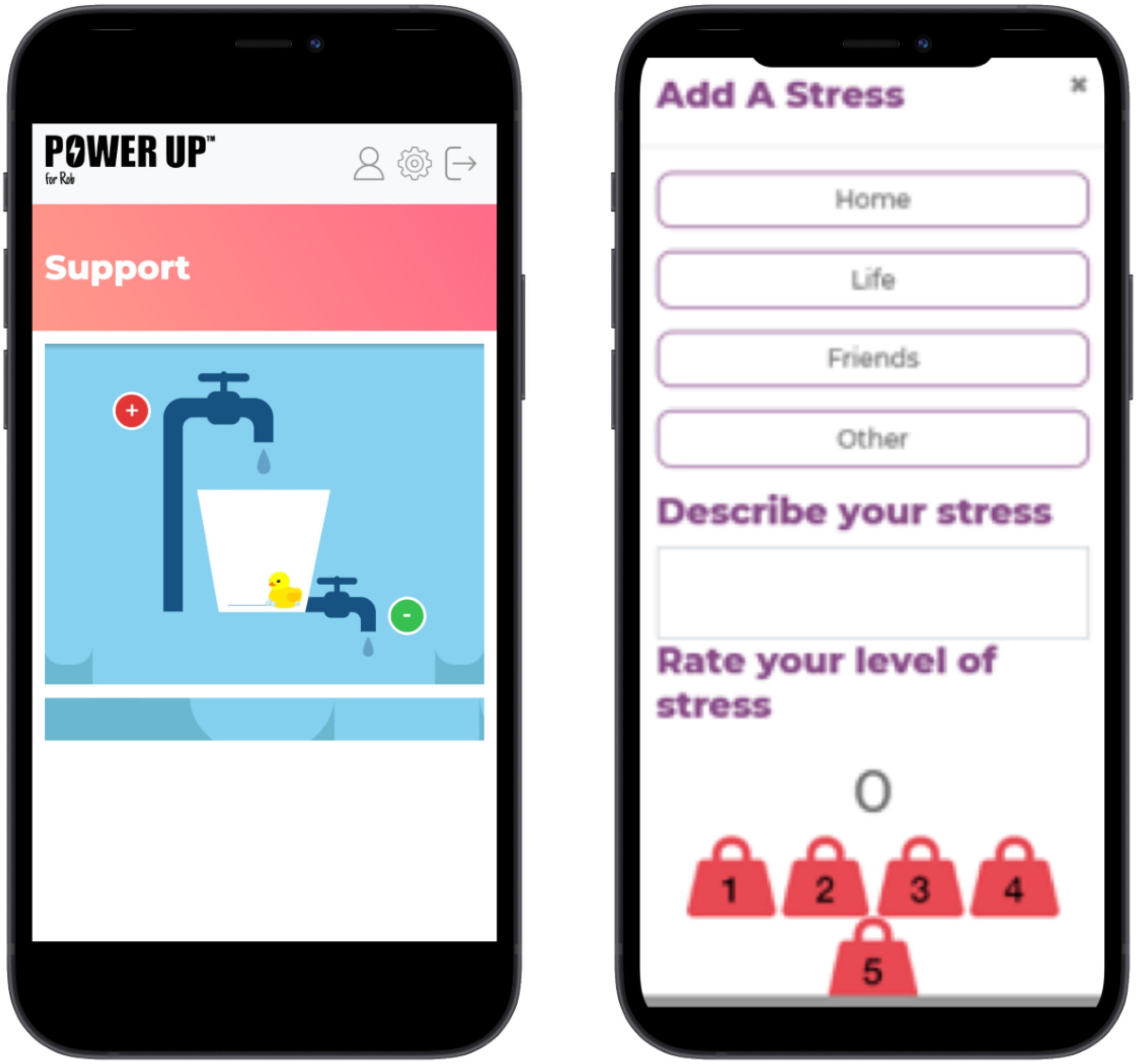
Test 3
Started: Sun, 9 Dec 2018 00:08

Test 3
Started: Sun, 9 Dec 2018 00:08

Support

This section hosts a tool to allow parents to identify and express their views on various stressors affecting the decision-making process. Users are encouraged to think about stressful things and explore ways to manage them. They are able to track feelings toward decisions and explore where additional emotional support is required (Figure 4). The stress bucket concept has been endorsed across health care and well-being settings with positive feedback across age groups [50].

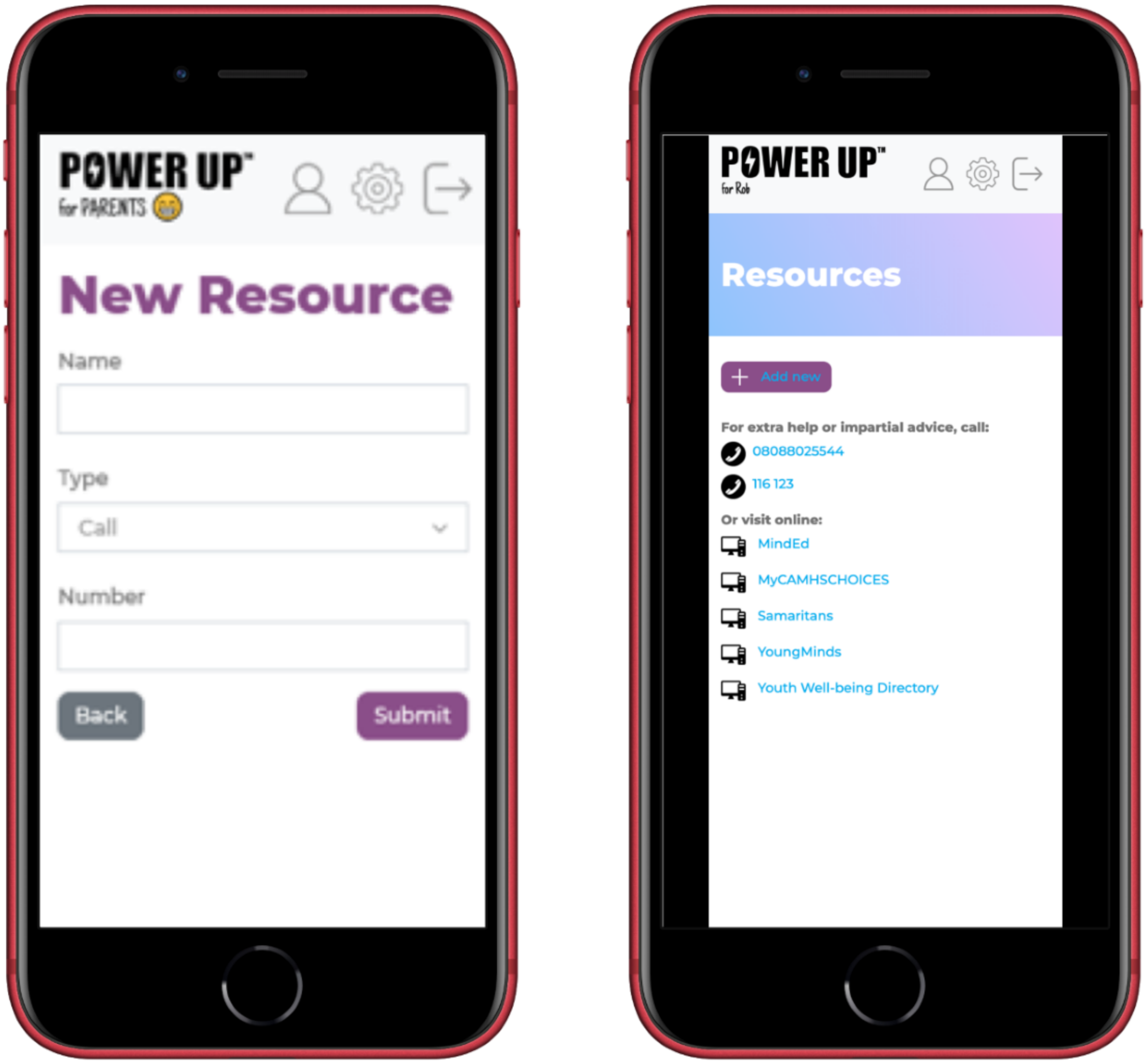
Figure 4. Examples of the support tab.



Resources

This section includes useful contact details that signpost users to provide further support and guidance. Parents could upload their own resources to help with the decision-making process and include contacts they find most helpful (Figure 5). Parents involved in previous child and adolescent mental health research indicated the benefits of receiving information and expressed feeling more included when provided with adequate evidence [7]. However, parents reported feeling overwhelmed when too much information was given at once. This section allows parents to work with service providers to identify and obtain tailored resources.

Figure 5. Examples of the resources tab.



For extra help or impartial advice, call:
☎ 08088025544
☎ 116 123

Or visit online:
- MindEd
- MyCAMHSCHOICES
- Samaritans
- YoungMinds
- Youth Well-being Directory

Discussion

Principal Findings

This paper describes an evidence-based process for the development of a complex intervention—referred to as Power Up for Parents—based on the MRC framework [33] and guided by the workbook for developing and evaluating decision aids [34]. Stakeholder input from parents and carers, service providers, researchers, and young service users informed the design and content of the intervention. The intervention was developed in accordance with the International Patient Decision Aids Standards and guidelines [36,37] and grounded in the following four SDM models: the Youth SDM model [38], the Ottawa Decision Support Framework [39], the Integrative Model of SDM in medical encounters [29], and the affective-appraisal approach to SDM in CAMHS [13]. The objectives of the intervention were informed by empirical studies and literature reviews, which highlighted the need to provide additional support for parents of children with mental health problems who are involved in child mental health decisions [13]. The resulting prototype aimed to (1) encourage discussion, (2) allow parents to ask questions during sessions or seek further information within sessions, (3) provide a space for parents to identify their own feelings or moods and receive support, and (4) allow service providers to tailor the SDM process to accommodate the needs of the parent and child. To address the design aims, five key sections were embedded into the intervention. These features were the *Decisions*, *Goals*, *Journey*, *Support*, and *Resources* sections.

Comparison With Existing Literature

The development process described in this paper is consistent with the development process briefly outlined in other parent-targeted SDM interventions [51-54]. Developers generally reported using end-user feedback, literature reviews, established guidelines, and empirical studies to inform the intervention. Overall, researchers have reported adopting one or a subset of these approaches to inform the intervention development process. However, only Hayes et al [54] reported using the MRC guidelines to inform the development of the i-THRIVE Grids. The current development process is in line with recommendations to promote well-being factors (eg, emotional regulation) in addition to targeted behavior change (eg, SDM) [23]. The iterative and collaborative approach adopted also supports other *user-based* frameworks embedded in human-computer interaction, such as the multiphase optimization strategy framework [55].

Key Learnings

Common themes were identified across the steps of the development process of Power Up for Parents. These were interpreted to develop a list of eight recommendations to inform policy and practice guidelines. The recommendations were initially developed by the primary author and reviewed using an iterative process by 6 independent reviewers (ie, 2 practitioners, 1 child development policy officer, 1 parent with experience of having a child with mental health problems, and 2 child mental health researchers) before reaching a consensus to include. In line with the Salzburg statement on SDM [32], the following eight perceived key learnings were highlighted:

1. Ensure that primary carers and young service users are invited to be part of the care and treatment decision-making process while considering the following: the age and capacity of the child; how much the child wishes to have the parent involved or informed; and how much or what support the family needs to be involved.
2. Review clinicians' time schedules so that they can provide sufficient time and encourage primary caregivers to ask questions and raise concerns during and within sessions.
3. Highlight the need for emotional support to be provided to primary caregivers, especially at the initial stages of accessing CAMHS or at crucial decision-making time points.
4. Propose a need for a key person in CAMHS who can provide answers to more general questions or be a liaison between clinicians and families, especially during periods when there is a change in service providers.
5. Consider the inclusion of the primary caregiver or key person (ie, an advocate for the family who is not the primary service provider) at multidisciplinary meetings when care and treatment options are being considered.
6. Review the role of parent support groups and explore the potential for further responsibilities.
7. Highlight the need for SDM support interventions as an adjunct to routine care.
8. Consider PPI activities at the core of design, development, testing, and implementation when SDM interventions are being developed. In doing so, it is also important that equal voices are given to service users and service providers, while ensuring interventions are accessible, acceptable, suitable and appropriate for the population, easy-to-use, useful, and do not incur additional time burden to service providers and service users.

Implications for Implementation Science

Interventions addressing mental health concerns or SDM could replicate this development process if the intervention was found to be effective in later studies. With the high prevalence of child mental health problems and the alarming emotional state of parents, CAMHS could benefit from offering web-based support to parents in the absence of resources to facilitate face-to-face sessions with such large numbers of families. In addition, developing an intervention that encourages service users to collaborate with service providers can empower service users.

Implications for Research

In keeping with the MRC framework, the intervention then entered the pilot and feasibility phase for testing the intervention, as discussed in the study protocol [56]. Preliminary results of the feasibility study [57] indicated that the intervention itself is generally acceptable by parents, carers, and health care professionals. The findings also indicate that there is scope for further development of Power Up for Parents. Results from the feasibility and pilot study have been integrated into refinements of the intervention and plans for further research.

Strengths and Limitations

First, the main strength of this development process is the adoption of participatory design methods, where researchers, app developers, service providers, parents and carers, and young people were involved as partners at various stages to determine the content and design of Power Up for Parents. Second, adhering to the MRC framework and following the workbook for developing decision aids provided a solid foundation for evidence-based intervention. In addition, the theoretical underpinning and evidence base informing the content of Power Up for Parents provide a basis for potential success when the intervention is tested for effectiveness in future studies. Another strength is the dynamic nature of web applications to integrate into electronic health record systems or be embedded in National Health Services' websites if found to be effective. Finally, the incorporation of all nine elements of SDM instead of the average 4.57 that is contained in similar interventions was viewed as a major strength.

However, the complexity of the intervention and the comprehensive approach taken to inform development resulted in a process that lasted almost 28 months. Although this may be viewed as a time-consuming process, developers aiming to develop similar interventions can use fewer empirical studies and incorporate rapid prototyping techniques [58]. In hindsight, another possible limitation could be the selection and combination of SDM models and theories. Other researchers in the field of SDM may criticize the chosen models and have a preference for alternatives. However, for the purpose of this research project, they seemed appropriate, and because they overlapped in some areas, they were readily combined. Similarly, the parents and young persons involved in the PPI sessions could represent a biased sample of persons who volunteered their time and expertise to inform research [59]. Therefore, they may not provide a broad representative view of families having a child with mental health problems. Moreover, the development of digital interventions can be costly. For this reason, it is recommended that cost-effectiveness be integrated into future study designs when evaluating interventions. Once proven effective, the cost can be justified as digital interventions have the ability to be scalable, affordable, and easily accessible to users [60-62]. Finally, the key learning and recommendations were based on a synthesis that went beyond the individual steps in the development process and a brief consultation exercise, and as such should be taken with caution.

Conclusions

A multidimensional process was adopted, including an in-depth exploration of existing literature, empirical studies, theoretical underpinnings, and patient and public input to develop an evidence-based intervention to support parents involved in child and adolescent mental health decisions. The resulting intervention demonstrates and confirms that it is possible to use input from end users, integrated with theory and research evidence to create digital health interventions to be used in CAMHS. The intervention then entered the pilot phase aimed at obtaining end-user input for further development, views on acceptability, and an exploration of the feasibility of conducting a randomized controlled trial. The lessons learned from this process may inform the development of other interventions.

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Authors' Contributions

SL and JEC developed initial ideas for the intervention. SL worked with the staff at Create Health (Helen Webber and Rob Matthews) to develop, adapt, and refine Power Up for Parents. SL drafted the manuscript, and both authors revised the manuscript and read and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Logic model outlining the intervention process. CAMHS: child and adolescent mental health services; NHS: National Health Service; SDM: shared decision making.
[PDF File (Adobe PDF File), 894 KB - formative_v5i6e24896_app1.pdf]

Multimedia Appendix 2
User manual.
[PDF File (Adobe PDF File), 472 KB - formative_v5i6e24896_app2.pdf]

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Abbreviations

CAMHS: child and adolescent mental health services
MRC: Medical Research Council
PPI: patient and public involvement
SDM: shared decision making

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Original Paper

An mHealth Physical Activity Intervention for Latina Adolescents: Iterative Design of the Chicas Fuertes Study

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Abstract

Background: Only 3% of Latina teens meet the national physical activity (PA) guidelines, and these habits appear to persist into adulthood. Developing effective interventions to increase PA in Latina teens is necessary to prevent disease and reduce disparities. Mobile technologies may be especially appropriate for this population, but mobile health (mHealth) intervention content must be designed in collaboration with the target population.

Objective: This study aims to develop an mHealth PA intervention for Latina adolescents using a multistage iterative process based on the principles of human-centered design and multiple iterations of the design phase of the IDEAS (Integrate, Design, Assess, Share) framework.

Methods: On the basis of the feedback from a previous pilot study, the planned intervention included visual social media posts and text messaging, a commercial wearable tracker, and a primarily visual website. The development of the requested mHealth intervention components was accomplished through the following 2 phases: conducting focus groups with the target population and testing the usability of the final materials with a youth advisory board (YAB) comprising Latina adolescents. Participants for focus groups (N=50) were girls aged 13-18 years who could speak and read in English and who were recruited from local high schools and after-school programs serving a high proportion of Latinos. Facilitated discussions focused on experience with PA and social media apps and specific feedback on intervention material prototypes and possible names and logos. Viable products were designed based on their feedback and then tested for usability by the YAB. YAB members (n=4) were Latinas aged 13-18 years who were not regularly active and were recruited via word of mouth and selected through an application process.

Results: The focus group discussions yielded the following findings: PA preferences included walking, running, and group fitness classes, whereas the least popular activities were running, swimming, and biking. Most participants (n=48, 96%) used some form of social media, with Instagram being the most favored. Participants preferred text messages to be sent no more than once per day, be personalized, and be positively worded. The focus group participants preferred an intervention directly targeting Latinas and social media posts that were brightly colored, included girls of all body types, and provided specific tips and information. Modified intervention materials were generally perceived favorably by the YAB members, who provided suggestions for further refinement, including the shortening of texts and the incorporation of some Spanish phrases.

Conclusions: Latina teens were generally enthusiastic about an mHealth PA intervention, provided that the materials were targeted specifically to them and their preferences. Through multiple iterations of development and feedback from the target population, we gained insight into the needs of Latina teens and joined with industry partners to build a viable final product.

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KEYWORDS

mobile health; human-centered design; qualitative research; adolescent health; health disparities; mobile phone

Introduction

Adolescent Girls' Physical Activity

Adolescent girls report the lowest levels of regular physical activity (PA), particularly girls from racial and ethnic minority backgrounds [1]. Although only 8% of adolescents meet the national guidelines of 60 minutes of moderate-to-vigorous physical activity (MVPA) per day [2], the number is even worse when examined by gender and ethnicity, with only 2.9% of Mexican American adolescent girls meeting the guidelines (compared with 17.9% of Mexican American boys) [1]. These disparities in adolescents are paralleled by disparities in adulthood, with Latina women reporting less MVPA than non-Latino White and non-Latino Black women and higher rates of lifestyle-related chronic diseases, including overweight or obesity and diabetes [3-5]. Developing interventions to increase MVPA in Latina adolescents could not only improve their physical, psychosocial, and cognitive health during childhood [6] but also promote lifelong health habits that can reduce growing health disparities [7,8].

Theory-Based Interventions to Improve PA in Latina Adults

One approach is to use theory-based interventions shown to be effective in Latina adults and adapt them to an adolescent population. We previously developed and tested the efficacy of a 6-month, culturally adapted, individually tailored, Spanish web-based PA intervention called *Pasos Hacia La Salud* [9] for Latina women based on the principles of social cognitive theory (SCT) [10,11] and the transtheoretical model (TTM) [12]. The results showed that MVPA was significantly higher in the intervention group than in the control group over the 6-month intervention [13], and the increase was maintained 6 months later [14]. In addition, the intervention group was approximately 3 times more likely to meet the national guidelines than the control group [13].

Pilot Study to Increase PA in Latina Adolescents

On the basis of this success, we adapted the web-based intervention through formative research to make it appropriate for Latina adolescents and then conducted a 12-week single-arm pilot study (called *Niñas Saludables)* to examine the feasibility, acceptability, and potential efficacy of the adapted intervention [15]. The results of this study were promising, with 90% (19/21) of Latina girls returning for follow-up measures at the end of 12 weeks, and self-reported PA increased by 58.8 (SD 11.33) minutes per week (*P*<.001) [15]. However, acceptability was only moderate, with girls in closeout interviews expressing a desire for an intervention that was primarily delivered via mobile technologies, including social media, wearables, apps, and text messaging.

Developing a Mobile Health Intervention

On the basis of the findings from the pilot study, a new study was launched to develop a mobile health (mHealth) multiplatform and multitechnology intervention to increase MVPA in Latina adolescents. The development of mHealth interventions requires the assimilation of user-friendly platforms and theoretical constructs in addition to technical and practical considerations and user feedback. Although mobile technologies are increasingly being incorporated into behavioral health interventions, the design of such interventions is not always guided by end users' experience with technology [16,17]. The successful integration of technology components is most likely to occur when interventions are cocreated with behavioral scientists and stakeholders, such as members of the target population and technology industry partners. Human-centered and user-centered design emphasizes understanding the needs of a target population and developing solutions through multiple iterations of design, testing, and feedback from end users [18]; these steps have been integrated into sequential frameworks, such as IDEAS (Integrate, Design, Assess, Share) [19,20], which grounds human-centered design in behavior change theory. To ensure acceptability and usability while maintaining theoretical rigor, we chose to design the new intervention through an iterative process, with the target population guided by principles of human-centered design and the design phase of the IDEAS framework. Our ultimate goal was to work with Latina teens and tech partners to co-design mHealth intervention content that would meet the needs and preferences of the target population while being based in behavior change theory.

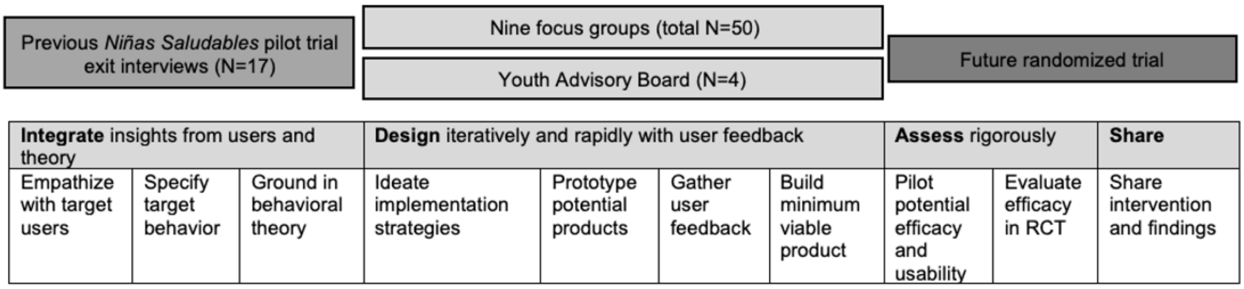
Methods and Results

Study Overview

We conducted multiple iterations of formative research partnering with Latina adolescents to co-design intervention materials for a 6-month mHealth MVPA intervention. The focus was on the design of the content and protocols rather than ideating approaches or testing efficacy; thus, the process was guided by design frameworks, including human- and user-centered design [17,18] and the four phases of the design topic area of the IDEAS framework [19].

The IDEAS framework [19] comprises 10 phases organized into 4 larger topic areas (integrate, design, assess, and share; Figure 1). The first area, integrate, centers on broader processes of empathizing with the target population, specifying a target behavior, and grounding in behavior change theory. This was largely addressed by the *Niñas Saludables* pilot study [15], including initial formative interviews, a single-arm pilot study, and exit interviews with participants, all of which highlighted the need for an mHealth MVPA intervention for Latina adolescents further grounded in the TTM and SCT. IDEAS is meant to act as a flexible framework and toolbox rather than a rigid structure; thus, rather than moving sequentially through all phases, we chose to conduct multiple iterations of the design phase: ideate implementation strategies, prototype potential products, gather user feedback, and build a viable minimum product. Consistent with human-centered design, we conducted multiple iterations of these four steps in collaboration with the target population. Given the novelty of this intervention approach with this population, rather than moving on to testing the new materials in a pilot trial, we chose to confirm the acceptability of the intervention materials by asking members of the target population to perform a usability test of the intervention components through an additional iteration of design feedback [17].

Figure 1. Study iterations addressing the phases of the IDEAS (Integrate, Design, Assess, Share) framework. RCT: randomized controlled trial.



Planned Intervention

The planned intervention included multiple components—an initial goal-setting session based on motivational interviewing and teaching behavior change techniques and theoretical constructs (eg, goal setting, self-monitoring, behavioral capability, and self-efficacy), followed by a 6-month intervention delivered via multiple mobile technology channels. The approach was chosen in response to feedback from the pilot study, in which girls requested more use of mobile technology; frequent, short doses of intervention (vs weekly or monthly); greater accountability and real-time feedback; and primarily visual content [15]. On the basis of this feedback, the following changes were planned for the new intervention's content and delivery, following step 4 (ideate potential implementation strategies) of the design category:

- Theory-based behavior change tips previously posted on the website would be converted into Instagram posts.
- A commercial activity tracker (Fitbit) would be introduced to reinforce key elements of behavior change (eg, goal setting, self-monitoring, and reinforcement).
- Automated text messages would provide reminders, support, and accountability.
- The website would be redesigned to reduce text, focus on visuals, and integrate data from activity trackers.
- The study would adopt a new name, as participants felt that the name *Niñas Saluables* was more appropriate for younger girls.

The intervention content was developed through 2 phases: (1) conducting focus groups with the target population (first iteration of design) and (2) vetting the modified materials for usability with a youth advisory board (YAB) comprising Latina adolescents (second iteration). The procedure and findings are described here. As each process informed the next, the methods and results from each phase were presented contiguously.

Focus Groups

Participants

Inclusion criteria for the focus groups required participants to identify as females aged between 13 and 18 years who reside in San Diego County and spoke English. We chose to develop an English intervention because the majority (88%) of Latino children in the United States speak only English or very good English, with only 1% speaking no English [21]. No interested participants were excluded because they did not speak English. Participants were recruited through in-person presentations at local middle and high schools with a high percentage of Latina students. Recruitment was also conducted through community partnerships and after-school teen programs, such as the Young Men's Christian Association and college-readiness programs, focused on Latinas. The focus groups were described as seeking insight and feedback from teenage Latinas regarding PA and social media as a means to develop a more age-relevant and culturally relevant digital media intervention. Ultimately, the final sample of participants included 9 focus groups of 2-8 girls in each (total: N=50), aged between 13 and 18 years, with 94% (47/50) of participants identifying as Latina. Focus groups took place across San Diego County between September 19, 2019, and October 29, 2019. All study procedures and data collection materials were reviewed and approved by the University of California San Diego institutional review board, and all participants provided written informed assent or parental consent. Parental consents were available in either English or Spanish.

Procedures

The focus groups were structured to capture information using 2 different methods. The first portion of the focus group was formatted as a semistructured group discussion, during which the focus group moderator posed questions regarding PA likes, dislikes, barriers, and motivators as well as questions about social media apps and use.

The second portion of the focus group adopted a market research approach to assess the intervention content. Each focus group viewed 16 sample Instagram posts intended to motivate teenage girls to become more physically active, each based on a behavioral change technique [19] or SCT or TTM theoretical constructs, such as goal setting, self-monitoring, outcome expectancy, social support, or environment [10-12], and modeled off of popular Latina, fitness-focused Instagram accounts. Participants were provided with prepared notepads in which they could record their personal thoughts and reactions to each one. They were then asked to provide written feedback on 12 sample text messages based on similar constructs that included either general information (eg, "remember to schedule your activity for the week!") or personalized information (eg, "call [friend's name] and see if she can exercise today"). Finally, participants viewed potential study logos and potential names for the study and ranked their favorites.

Consistent with user-centered design [17], modifications were made to the content throughout the process. After 2 focus groups, staff members reviewed the feedback and eliminated posts or text messages that received consistently negative feedback. These were replaced by new samples that incorporated the suggestions.

Focus Group Data Synthesis

Audio-recorded data from the group discussions were transcribed and examined to identify trends in PA and social media preferences. Responses to questions regarding preferences for PA and social media were tallied to determine the most common responses. Feedback on social media posts and text messages were generally short (eg, “like it,” and “not my favorite”) and did not lend themselves to formal qualitative analysis; however, our ultimate goal was assessing end users’ experience with the intervention products, particularly whether they were perceived positively or negatively and why. Therefore, written responses to sample Instagram posts and text messages were compiled and grouped based on the nature of the feedback, with 2 staff members determining which examples were viewed positively and negatively and whether there were specific suggestions for improvement.

Focus Group Findings

Focus group discussions yielded trends regarding PA preferences, barriers, and motivators among the participants. When asked which activities they enjoyed the most, the top 3 responses were walking (n=11), running (n=8), and going to the gym or group fitness classes (n=7). Regarding activities they disliked, running (n=10), swimming (n=7), and biking (n=7) were the least popular. Homework (n=17) and feeling lazy or tired (n=14) were the top 2 barriers to being physically active, and family support (n=10) and supportive friends or teammates (n=9) were the most common motivators across the focus groups.

Discussions of social media use showed that a large majority of the participants favored Instagram, Snapchat, and TikTok. For Instagram, participants expressed a preference for regular posts rather than using only Instagram stories (which expire after 24 hours) because they wanted to have access to all posts on the account. Feedback on the Instagram posts revealed several patterns regarding their preferences, with the most popular posts incorporating (1) brightly colored images and limited, succinct text; (2) specific tips and applicable information on PA; (3) Latina cultural themes and Spanish phrases; (4) images of relatable and ethnically diverse models of all body types engaging in PA; (5) images promoting social support; and (6) videos demonstrating specific exercises that they could try at home. They did not like posts with darker colors, with less specific suggestions or phrases, or with images of girls with extremely thin body types.

For feedback on text messages, participants indicated the types of texts that would be most helpful and motivating as well as how frequently they should be sent. When assessing the preferences expressed by participants, there were 3 notable patterns across the focus groups. The first was a preference for messages to be sent at a rate of no more than 1 message per day. Second, on reviewing samples of both personalized and generic text messages, there was a strong preference for personalized texts that included their own name, the name of a friend, and a familiar location and a particular preference for feedback and reminders based on their own current PA rather than generic reminders. Finally, feedback revealed that texts should be casually worded with positive messages. Participants expressed antipathy toward language they perceived as “negative,” “annoying,” or “nagging,” with a particular aversion to any message that “sounds like something my mom would say.”

Finally, participants were presented 8 eight potential study names and 5 potential logo styles, and they indicated which ones they felt were most appealing and appropriate for their demographic. Then, they ranked their top 3 choices for each, with the option of creating their own idea for a study name. The most popular choice was *Chicas Fuertes*, which was selected as the new study name. Participants also expressed enthusiasm for one particular logo’s esthetic, which was chosen as the new study logo (Figure 2). Participants were also asked whether they would prefer an intervention that was only for Latinas or whether they would prefer a program targeted at adolescent girls in general that any of their friends could participate in. Participants expressed a desire for an intervention that was specifically built for and only included Latinas.

Figure 2. Chicas Fuertes study logo.

Incorporating Focus Group Feedback

Following the last stage of the design phase, feedback from the focus groups was used to develop a minimum viable intervention product. On the basis of the findings from the focus groups, the study adopted a new name and logo, and staff developed new materials and protocols. The new study name, *Chicas Fuertes*, and the new logo framed the study branding and were incorporated into all study and recruitment materials. Feedback on PA preferences, motivators, and barriers was factored into the development of Instagram posts and text messages to feature topics and themes that proved relevant to the study population while still being based on SCT and TTM theoretical principles.

To provide personalized text messages, we engaged tech industry partners (Fitabase, Small Steps Lab LLC) to develop and implement an algorithm to provide automated texts based on real-time data from Fitbit activity and incorporate names of family and friends the participant identified as key supporters. A text messaging schedule was developed to reflect the preferences of the participants, with messages sent 4 days per week, and the language of all text messages was worded succinctly and positively regardless of whether the message was framed to praise, reinforce, or encourage PA. For the midweek feedback text, participants who had achieved ≥45% of their weekly goal received reinforcing messages informing them that they were on track to meet their goal. Those achieving <45% of their goal received an encouraging message along with specific suggestions of behavior change techniques, social support sources, and personalized locations where they could get the rest of their activity minutes for the week. Those already meeting goals received praise and were encouraged to set a higher goal for the following week. Table 1 provides the text messaging schedule and a sample of each type of text.

Table 1. Sample text messages.

Day	Type of text	Example
Thursday	Midweek physical activity feedback	“So far, you’ve logged ## active minutes. Schedule time this weekend to get in some exercise with [social support #1] so you can meet this week’s goal of ## minutes by Sunday!”
Saturday	Weekly quiz reminder	“Take a 60 second break from your day and answer the weekly quiz question here! chicasfeurtessd.com”
Sunday	End of week physical activity feedback	“Here’s some good news for you! You completed your goal last week and got in ## active minutes! How many minutes will you get next week?”
Sunday	Plan activity reminder	“The best way to meet your activity goals is to plan ahead. Hop onto the website and plan your daily activity for the week! chicasfeurtessd.com”

When developing Instagram posts, the focus group participants’ preferences coupled with evidence-based behavior change techniques and theoretical constructs determined the nature of the content, resulting in an Instagram posting schedule of 1 post per day (Textbox 1). Each day featured a different theoretical construct or behavior change technique, including goal setting, self-monitoring, accountability, avoiding boredom, and finding time to exercise (Figure 3). Some images incorporated Spanish words or phrases, and all captions were written in English.

Textbox 1. Instagram posting schedule (day and behavior change construct).

Sunday

- Behavior change technique

Monday

- Weekly challenge

Tuesday

- Self-efficacy

Wednesday

- Built environment

Thursday

- Modeling

Friday

- Benefits and outcome expectancies

Saturday

- Social support

Figure 3. Sample Instagram posts demonstrating (A) self-efficacy and (B) social support and accountability.

Instagram story posts were also created using the polling feature for additional reminders to exercise and sync Fitbits. A study hashtag was also created to allow participants to tag their own posts if they wanted to share them with the study team or other participants.

Youth Advisory Board

Participants

Following the focus groups, iterative intervention development continued with the establishment of the YAB. The purpose of the YAB was to complete another iteration of the design phase by beta testing each of the newly developed intervention components to assess usability and by providing additional ongoing feedback on the finer details of the study design to develop the final version of the intervention materials to be used in a larger trial. Recruitment for the YAB took place across local high schools and after-school programs, with teachers and leaders helping to promote the position by distributing application forms to Latina teenagers. To be eligible, participants had to self-identify as Latina, be aged between 13 and 17 years, not engage in regular PA (<150 min per week of MVPA), and express an interest in public health research and promoting health in their community. Over the course of 2 weeks, the study team received applications from 10 candidates and ultimately selected 5 based on their application responses. The 5 members came from 3 different San Diego high schools and were aged between 15 and 17 years. After 1 week, 1 member notified the study team that she was unable to fulfill her commitment, resulting in a final YAB of 4 members.

Procedures

The YAB members agreed to a minimum 6-month commitment, in which they would beta test intervention materials and provide honest and timely feedback on a regular basis. During months 1 to 2, the YAB was invited to follow the *Chicas Fuertes* Instagram account and provide feedback on posts developed based on the focus group feedback. Through email, the YAB provided commentary on a weekly basis on each post from the past week regarding what they liked about each post, what they did not like, and what changes they would suggest for improvement. During this time, the YAB also received sample text messages intended to provide individualized PA information and motivation and responded to each of these text messages with a detailed report of their reactions.

Beyond the scope of the focus groups, the YAB members were each given a test account for the *Chicas Fuertes* website and asked to test out all the website features during months 3 to 4. They used emails to provide comments on their experience with the website and report any bugs or confusing elements. The study website was adapted from the version used in the *Niñas Saludables* pilot study through collaboration with industry partners (Illumina Inc, Fitabase) and included resources for motivating behavior change, planning activity, and connecting with other participants. The site included a calendar for planning out weekly activity, which was overlaid with real-time activity data from Fitbits. Other features included a weekly leader board showing the 2 participants with the most active minutes that week, a message board between participants, maps of the city with links to places to be active, and tips for overcoming common barriers. Finally, the website included questionnaires used in previous trials [9] about theoretical constructs (eg, social support, self-efficacy, and processes of change) that participants would fill out monthly, also indicating their stage of change regarding PA (ie, contemplation, preparation, and action) per the TTM. On the basis of their questionnaire responses, participants received individually tailored reports on their current activity, which included their progress to date, praise for behavioral and cognitive strategies of change they used, and suggestions for areas to improve (eg, identifying sources of social support and ways to enhance self-efficacy). To keep participants engaged in the features of the website, they received points for engaging in certain activities (eg, logging in, planning their activity, and writing on the message board), and they could redeem points for prizes.

Finally, in months 5 to 6, the YAB provided feedback on finer details of the intervention and research protocols, such as the types of study participation incentives (eg, cash and gift cards) they believed would be most appealing to Latina teenagers for research participant compensation. As intervention materials and procedures continued to evolve, the YAB provided ongoing feedback. As the YAB was small (only 4 members), data were not compiled across them; rather, we focused on their individual experiences as end users of the minimum viable products.

YAB Findings

Intervention materials were generally perceived favorably by the YAB members, who also provided suggestions for further improvements (Table 2). Consistent with the feedback from the focus groups, YAB members enjoyed Instagram posts that were colorful and positive and particularly liked having specific suggestions or demonstrations of activity:

> *I liked the inspirational aspect to the post i know a lot of times when I'm on instagram and have nothing else to do and I see post with quotes that really inspire me I get up and do something active so it really helps.* [YAB member 1]
>
> *I looked through the Instagram feed and like it so far. The ideas that are given to encourage are actually helpful in my opinion, for instance, the post that suggests to have friends join or to dance, these I consider helpful because it's not just hardcore Exercise like other accounts describe it to be. The videos that show certain exercises that would be easy to do at home or at a closed environment, for those who aren't comfortable doing so outside, are also very helpful. The stories are useful, reminding to check their sync because most of people have a busy schedule so they can often forget.* [YAB member 2]
>
> *The post where the woman is running I didn't like. The words were motivating yes but the color of the picture was very dark and it didn't bring that enthusiasm for me to go for a run or something. I would have made it more clear and more.* [YAB member 3]

Table 2. Findings from the focus groups and youth advisory board.

Steps in the design phase	Findings	
	Focus groups	Youth advisory board
Prototype potential products	• Built sample Instagram posts incorporating theoretical constructs • Wrote sample text messages prompting goal setting and providing progress feedback • Redeveloped website to be primarily visual and incorporate real-time data from wearable trackers • Developed possible study logos and study names	• N/A[a]
Gather user feedback	• Desire for positive media; bright colors, positive wording, and encouragement versus nagging • Preference for personalized (vs generic) text messages, at most 1 per day • Preference for intervention exclusively for Latinas, with the incorporation of cultural themes and Spanish phrases • Preference for Chicas Fuertes study name	• Largely positive response to all social media posts; appreciation for mix of cognitive and behavioral strategies for behavior change; and suggestions for even more bright colors, varied body types, and Spanish phrases • Positive response to text messages, suggestions to make them shorter, and appreciation for positive language • Positive response to website design and content • Positive response to study name and logo • Preference for cash incentives and identified prizes for engagement
Build minimum viable product	• Built texting algorithm for automatic goal setting and real-time feedback based on Fitbit • Wrote text messages in a casual language and positive tone • Developed new Instagram posts with bright colors and with models with a broad array of body types and incorporated cultural themes and Spanish phrases • Developed Instagram posting schedule of 1 post per day, which were mapped onto theoretical constructs and BCTs[b] • Branded all study materials with the new study name and logo	• Final schedule and content of text messages and social media posts developed and mapped onto behavior change theory constructs • Bank of 120 Instagram posts developed featuring bright colors, motivational quotes, specific strategies for change, and Spanish phrases • Website content finalized • Text message algorithm finalized with positive, succinct text messages • Prize and payment schedule finalized

[a] N/A: not applicable.

[b] BCT: behavior change technique.

As for text messages, the YAB also provided feedback on the wording, length, and content of each. For the text message “You’ve completed 38 minutes out of your goal of 100 active minutes for the week. Use the weekend to reach your goal by getting active with a friend! You can do it!!!,” YAB members provided the following feedback:

> *I like this message a lot actually. It’s a useful reminder and not too long and doesn’t sound like nagging.* [YAB member 1 feedback]
>
> *I think it might be a little wordy in the beginning but overall I think it’s pretty good. Maybe try “You’ve completed 38 out of 100 minutes for your goal this week.”* [YAB member 2 feedback]

For the text message “Hey girl! Got a minute? Click on chicasfuertessd.com to answer the weekly quiz question,” a YAB member provided the following feedback:

> *Sounds good to me! I especially like the “Got a minute” part lol.* [YAB member 1 feedback]

Finally, for the website, the YAB reported on the website’s esthetics, functionality, and content. Feedback was largely positive:

> *I really liked how everything was really accessible. Everything was really clear and aesthetically cute. I could tell on the home page that there are more things coming up since there are empty spaces. I really liked the leader board, I am the type of person that likes comparing progress and knows my level of how active I’ve been, so the leader board would really be of motivation for me. Likewise, the instagram link seems very encouraging since there is a certain display of what is in the social media page. My favorite part is that in all it seems like it’s a very supporting group to be more active, with many different ways to move along your day while being active.* [YAB member 1]

Some critical feedback included the 15-minute monthly questionnaire, which was too lengthy. However, the study team ultimately decided to leave this feature, as the individual tailoring of the website was based on the questionnaire responses.

The YAB also provided feedback on which prizes to offer to study participants as incentives to complete website activities. Consistently favored prizes include logo-branded items, such as a cell phone power bank, plastic tumbler, aluminum water bottle, and a Bluetooth speaker. Finally, when asked which incentives they believed would be most appealing to participants in exchange for participating in study activities (eg, attending baseline visits and completing 6-month assessments), YAB members unanimously expressed that cash or checks would be more appealing than gift cards. Findings from the focus groups and YAB are summarized in Table 2.

Discussion

Partnering With Stakeholders to Design Intervention Content

This paper focused on ways to address the challenges encountered by both academia and industry when creating effective, user-friendly, and culturally adapted mHealth interventions with high retention rates. The first step in developing and implementing a successful mHealth intervention is to engage a multidisciplinary leadership team comprising researchers in public health, industry partners, and the target population. For this study, we included behavioral researchers, mHealth technology partners (web developers and programmers), and multiple groups of Latina adolescents and used the principles of human-centered design and the design phase of the IDEAS framework to integrate expertise from each party.

Our previous research highlighted Latina teens' desire for an MVPA intervention that was primarily delivered via mobile technologies. The research team ideated implementation strategies to incorporate text messaging, social media, a wearable tracker, and a redesigned website and then developed prototypes by collaborating with industry partners, including programmers and web developers. The design iterations in this study confirmed the acceptability of this approach, and preferences expressed by the target population guided the deep and surface features of the prototypes, which were mapped onto behavior change constructs from SCT and TTM. Further assessment of these prototypes through beta testing with a YAB allowed for further refinement and confirmation that the end product was viable and acceptable to the target population.

Mobile Technology and Adolescents

Digital technologies are an attractive component of behavioral interventions because of their low cost and broad reach in both adult and pediatric populations. Access to smartphones is now nearly universal in teens (95%) and eclipses computer access (88%), and nearly all teens (91%) reported using social media [22]. However, incorporating mobile technologies into interventions has achieved mixed success [23,24]. As more digital technologies emerge, frameworks guiding the incorporation of these technologies into behavioral interventions are increasingly needed [25]. Technology will improve efficacy and reach only if it is used as a tool to meet the needs of target populations and strategically designed to facilitate, rather than compete with, elements of behavior change theory [25].

Cocreating With Participants

Human-centered design emphasizes enlisting members of a target population as cocreators of interventions, along with refining interventions through multiple iterations of design, testing, and feedback [18]. Importantly, the IDEAS framework expands this process to center it in sound behavioral theory, along with outlining a clear sequence of steps from ideating to disseminating solutions [20]. It was developed in the process of building an app-based intervention to increase vegetable consumption in overweight adults [19], and it has also been used to develop a mobile app to reduce problem drinking among college students [26] and to build a nutrition education mobile app for families [27]. No studies have previously used it to design content for a PA intervention or an intervention specifically targeting a racial and ethnic minority population.

As previously mentioned, the framework is meant to be flexible to allow for adaptation to populations and interventions. We felt it was most important to focus on multiple iterations of the design phase of the framework rather than moving on to a pilot trial for several reasons, as follows: (1) we targeted the intervention to a niche population with unique needs and preferences based on age and ethnicity, (2) no previous MVPA interventions had specifically targeted Latina teens using digital technologies, and (3) our intervention design focused on integrating multiple technologies rather than developing a single technology channel. By cocreating the intervention content with a large sample of the target population through multiple iterations of focus groups and a YAB, we developed intervention content with high acceptability, which is ready for testing in a trial.

Strengths

This study had several strengths. The proposed intervention focused on a key preventive health behavior (MVPA) in an at-risk, underserved population (Latina teens) and thus will fill a critical gap in public health literature. The intervention development was guided by a framework that included elements of human-centered design and behavior change theory. To ensure the production of a viable product that met the needs of the target population, we engaged in multiple iterations of feedback and design, each with a new sample from the target population. In addition, the focus groups had a large sample size (N=50).

Limitations

Despite its notable strengths, this study had several limitations. Owing to the guidelines at schools where focus group participants were recruited from, we did not exclude non-Latina girls from participating in the focus groups. However, very few (n=3) non-Latina girls participated; thus, it is not likely that this influenced the results in any meaningful way. In addition, although the short, written feedback from participants in a market research format met the overall needs of the study, it did not allow for a more thorough qualitative analysis, which may have provided further insight into the needs and preferences of the target population. Finally, the intervention incorporated elements of SCT and the TTM because the original intervention was designed around these theories; however, other theories of behavior could have also been appropriate.

Conclusions

We sought to design an mHealth MVPA intervention for Latina adolescents that not only incorporated digital technologies but did so in a way that was theory based and addressed the needs and preferences of our target population. Latinas were enthusiastic about a multitechnology intervention, particularly if it felt relatable, positive, and encouraging. Through multiple iterations of development and feedback, we gained insight into the needs of Latina teens and joined with industry partners to build a viable final product that is now being tested in a randomized controlled trial.

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Conflicts of Interest

None declared.

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Abbreviations

IDEAS: Integrate, Design, Assess, Share
mHealth: mobile health
MVPA: moderate-to-vigorous physical activity
PA: physical activity
SCT: social cognitive theory
TTM: transtheoretical model
YAB: youth advisory board

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Original Paper

Comparing Two Commercially Available Diabetes Apps to Explore Challenges in User Engagement: Randomized Controlled Feasibility Study

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Abstract

Background: Diabetes apps represent a promising addition to face-to-face self-management interventions, which can be time and resource intensive. However, few randomized controlled trials have evaluated the efficacy of diabetes apps, in particular as a stand-alone intervention without additional clinical support.

Objective: We used a feasibility randomized trial design to investigate differences in user engagement between 2 commercially available apps (free versions of Glucose Buddy and mySugr) over 2 weeks in adults with type 2 diabetes. Feasibility was assessed based on recruitment uptake, adherence to the diabetes apps, and follow-up rates. We also hypothesized that the diabetes app mySugr would demonstrate higher user engagement at follow-up due to its use of gamification. We also predicted higher user engagement would be associated with improved self-care behaviors and illness beliefs.

Methods: Adults with type 2 diabetes attending outpatient diabetes clinics in Auckland were recruited and randomized (1:1 without blinding) to use either the Glucose Buddy or mySugr diabetes apps. User engagement, self-care behaviors, and illness beliefs were measured 2 weeks after baseline. Spearman rank correlations, Mann-Whitney tests, and Wilcoxon signed-rank tests were used to explore associations between the outcome measures and to investigate possible changes between and within groups. Six participants were interviewed to further explore acceptability and usability.

Results: In total, 58 participants (29 per group) completed the 2-week follow-up, of whom only 38 reported using the apps (Glucose Buddy: n=20; mySugr: n=18). Both groups reported low engagement (Glucose Buddy: median 4 days; mySugr: median 6.5 days; *P*=.06; use for both groups: median 10 minutes). No changes were observed in self-care or illness beliefs in either group. Out of the self-care behaviors, only blood glucose testing was significantly associated with minutes of app use (*P*=.02). The interviews suggested that although both apps were deemed acceptable, they were generally viewed as time-consuming and too complicated to use.

Conclusions: Low engagement with both Glucose Buddy and mySugr reflect the challenges associated with engaging users with diabetes apps. Due to low engagement and loss to follow-up, the changes in outcome measures should be interpreted with caution. The results highlight the need for more clinical support as well as involvement from end users and behavior change specialists in order to incorporate evidence-based behavior change techniques to motivate and provide value to users.

Trial Registration: Australia New Zealand Clinical Trials Registry ACTRN12618000424202; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=374671

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KEYWORDS

type 2 diabetes; mobile apps; diabetes; self-management; user engagement; app; mHealth; randomized controlled trial; intervention; efficacy

Introduction

The World Health Organization (WHO) estimates that diabetes affects over 400 million people [1]. Of all people with diabetes, an estimated 90% have type 2 diabetes (T2D) [2]. Treatment for T2D is multifaceted and includes modifying health behaviors, such as diet and physical activity, checking blood glucose levels, and adhering to medication. In New Zealand, diabetes affects approximately 241,000 people, with the majority having T2D [3]. T2D disproportionately affects people of Māori, Pasifika, and South Asian descent and is also more common among people residing in more socioeconomically disadvantaged regions in the country [4].

Several factors influence an individual's adherence to a diabetes treatment regimen, including economic and sociocultural factors as well as beliefs and cognitions regarding their illness [5-7]. For example, several studies have found that illness perceptions (ie, the cognitive and emotional representations that people have of their illness) influence how people with T2D cope with their illness and the degree to which they adhere to their treatment regimen [8,9]. Unlike sociocultural factors, illness beliefs are modifiable [10] and may therefore represent a promising approach for improving self-care behaviors and glycemic control in diabetes [11].

Self-management education for T2D generally involves face-to-face interactions between individuals and health care professionals, who provide instructions and limited cognitive and behavioral strategies (within the resource limitations of the health care environment) to help people to manage their diabetes [12,13]. Mobile technologies, including commercially available diabetes apps, represent a more scalable and potentially more cost effective alternative to traditional interventions, offering a means of improving T2D management by expanding the reach of health care services and improving individuals' access to health-related information and interventions [14,15].

Commercially available diabetes apps vary in the number and type of self-management behaviors they support [16]. The most commonly found features include logging of health information—including blood glucose levels, weight, physical activity, blood pressure, and dietary intake—educational modules, and insulin bolus calculators [16-18]. A large number of apps also provide some form of feedback to the user, most commonly as a graphical summary of their data or as a phone notification [17,18]. Some apps may also integrate directly with select blood glucose monitoring devices, allow data to be exported in various formats to be shared with third parties, or connect users directly with health care providers (HCPs) for feedback [16,18].

Reviews have increasingly suggested that diabetes apps may improve glycemic control and self-care behaviors in people with diabetes [17,18], possibly by facilitating the monitoring of self-care behaviors (eg, blood glucose monitoring) [19]. However, the findings of such reviews have several limitations that make it difficult to generalize to the wider T2D population. For example, detailed analyses of efficacy in the context of ethnicity, gender, and disparity in health literacy remain limited [20,21]. In addition, despite commercially available apps having arguably the largest user base, there is still a lack of studies that measure user engagement of commercially available diabetes apps [16,22-24]. "User engagement" comprises both frequency and duration of technology use, along with the users' overall experience of the technology [25]. It is therefore not surprising that user engagement is thought to be integral to whether or not a digital intervention is effective [26]. Furthermore, there is a lack of theoretical input into the development of health apps aimed at changing health-related behavior. The vast majority of health-related apps are not theory-based, and their efficacy for improving health-related outcomes has not been sufficiently tested [27-31]. Finally, despite the large number of commercially available diabetes apps, there are few randomized controlled trials investigating the efficacy of these apps, especially studies which explore the efficacy of the app without additional clinical support [32-34].

A promising approach for increasing user engagement is gamification [35-37]. The concept of gamification is arguably context specific but is generally defined as the use of elements (eg, score systems, avatars, challenges, awards) commonly linked with video games in a nongaming setting [38,39]. It is suggested that when integrated into digital health interventions, these elements may increase motivation and learning [35,36,40] (see Landers et al [40] for an overview of the psychological theories behind gamification). However, evidence for the effectiveness of gamification in digital health interventions is mixed [36], particularly as it concerns whether gamification can improve health or psychological outcomes [35].

This study aimed to address these gaps in the literature by conducting a randomized controlled feasibility study to explore user engagement of 2, free, commercially available diabetes apps (Glucose Buddy and mySugr) that function without additional clinical support. We were specifically interested in whether the aspect of gamification (present in the mySugr app) could increase user engagement and thereby influence self-care behaviors. We also wanted to explore whether there was a relationship between user engagement and adherence to self-care behaviors. These apps were chosen, as they are both popular, have high user ratings on both iOS and Android [41,42], and contain functions deemed most useful by users of diabetes apps [43], with 1 app being explicitly based on gamification [44]. We hypothesized that mySugr, by virtue of its use of gamification, would be rated as more engaging than would Glucose Buddy and would demonstrate between-group improvements in self-care behaviors. We also hypothesized that higher user engagement would be associated with improved self-care behaviors at follow-up.

Methods

Participants

Participants were recruited from Auckland diabetes outpatient clinics between April 24, 2018, and July 24, 2018, and were randomized to trial 1 of 2 free apps (Glucose Buddy or mySugr), with follow-up after a 2-week trial period. Eighty-nine patients with T2D consented to participate and provided baseline data. This sample size was considered adequate to assess feasibility and conduct a preliminary evaluation of differences in user engagement between the 2 diabetes apps. Ethics approval for the study was obtained from the Health and Disability Ethics Committee on February 26, 2018 (reference #18/STH/43), and the study was prospectively registered with the Australia New Zealand Clinical Trials Registry on March 23, 2018 (ACTRN12618000424202). Inclusion criteria required that participants were 18 years or older; had a diagnosis of T2D; had the ability to speak, read, and write in English, and provide informed consent; and owned an iOS or Android smartphone capable of downloading apps.

Procedure and Randomization

After completing baseline questionnaires, participants were randomly assigned 1:1 to parallel groups (Glucose Buddy or mySugr) using a computer-based random number generator. Blinding was not used. Randomization was done using sealed envelopes labeled with sequential study numbers. After randomization, AM helped the participants download the app onto their phone to use for 2 weeks. After the 2-week trial, participants were asked to complete a set of follow-up questionnaires online or were posted a hard copy of the questionnaires. Participants who completed the follow-up questionnaires received a NZ $20 (US $14.48) voucher to thank them for their time.

Intervention Groups

Glucose Buddy

The diabetes app, Glucose Buddy, is a commercially available app developed by Azumio Inc. The free version of the app was used. The app facilitates the manual entry of information pertaining to various self-care behaviors and other health parameters, including exercise, diet, blood glucose, medications, blood pressure, and glycated hemoglobin (HbA_{1c}). Users can track trends in these behaviors over time. The glucose tab allows users to log blood glucose levels, carbohydrates and food, and medication in 1 entry. Colour-coded graphs assist with monitoring blood sugar levels and medication. The app also has a large food database, and users can manually enter or scan the barcode of food items to record calorie and nutrition information. Participants were asked to use the app at their own pace, with no minimum or maximum requirements for usage time or features used.

mySugr

mySugr is a diabetes app developed by mySugr GmbH (acquired by Roche in 2017). The free version of the app was used. The mySugr app facilitates the manual input of information relating to self-care behaviors and other health parameters, including exercise, diet, medications, blood glucose, HbA_{1c}, and blood pressure. Users can also track trends in these behaviors over time and set a target range for their blood glucose levels. A traffic light system facilitates monitoring of blood sugar levels, whereby entries falling within the target range are green and entries falling outside this range are red or orange depending on the values set by the user. A graph at the top of the home screen shows diet, exercise, medication, and blood glucose levels. Additionally, gamification is incorporated into all the key features of the app through the virtual avatar called the “diabetes monster.” Users can “tame” their diabetes monster based on their entries, which earns them points. Again, there were no minimum or maximum requirements for usage time or features used.

Measures

Demographic details of age, sex, ethnicity, education, and employment status were collected at baseline through self-report. Other relevant information, including diabetes duration, HbA_{1c} levels at baseline (time of recruitment), and current diabetes treatments (including for comorbid conditions), was also obtained from patient medical records.

We used self-report questionnaires to examine user engagement, adherence to the diabetes apps, and changes in self-care behaviors and illness beliefs. To determine feasibility, we examined recruitment uptake, self-reported adherence to the diabetes apps, and follow-up rates. Due to the feasibility trial design, we did not specify primary or secondary outcomes.

User Engagement

User engagement was measured using an adapted form of the Mobile Application Rating Scale [45]. The original instrument was created for researchers, app developers, and health professionals to rate the quality of health apps. The current study used a simplified, user version of the Mobile Application Rating Scale (uMARS), which was designed for app users to complete [46]. The uMARS comprises 4 subscales: engagement, functionality, aesthetics, and information quality. In total, these subscales include 16 items. All items are rated on a 5-point Likert scale, where 1 indicates the app is unsatisfactory in that area and 5 indicates the app is excellent in that area. Mean scores are calculated for each subscale, and a total uMARS mean score is calculated by adding the mean scores for each of the subscales and dividing the total by 4. The uMARS demonstrates good internal reliability for both the whole instrument and for the individual subscales within the instrument [46]. The Cronbach α for the instrument in the present sample was .95.

Two additional questions were also included to measure users’ level of adherence with the apps. These were as follows: “In the last 14 days, on how many days did you use the app?” and “On the days that you used the app, approximately how many minutes did you spend using the app?”

Self-Care Behaviors

Self-care behaviors were assessed using a modified form of the Summary of Diabetes Self-Care Activities (SDSCA) [47]. This scale measures many facets of diabetes self-management: blood glucose testing, exercise, foot care, smoking, and general and specific diet and medication-taking behaviors. As diabetes self-management is multifaceted, this instrument allows scores for each component to be calculated individually. This study focused on self-care behaviors, and so to minimize participant burden, the 14 extra items from the expanded version of the SDSCA were omitted and only the first 7 subscales pertaining to self-care behaviors were included.

All 7 subscales were scored as the number of days per week participants engaged in a particular self-care behavior (eg, followed a healthy eating plan) on a scale of 0 to 7 days. Medication adherence was assessed with 1 item: “On how many of the last seven days did you take your recommended diabetes medication?”; the total number of days was then used to indicate participants’ medication adherence behavior. The general diet, exercise, blood glucose testing, and foot care subscales all contained 2 items each. Means for each of the subscales were calculated with higher numbers signifying better adherence to the behavior in the previous 7 days. The specific diet subscale was also made up of 2 items; however, the authors of the scale advised that these items be scored individually due to the low interitem correlations for the subscale [47]. Additionally, the specific diet item, “On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products?” was reverse coded in scoring, as it indexed less healthy dietary behavior. Finally, smoking status was scored as a yes or no response to the question, “Have you smoked a cigarette—even one puff—during the past seven days?” This section further asked participants that responded yes to specify how many cigarettes they smoked on an average day. The SDSCA demonstrates adequate reliability and validity across T2D populations [48,49].

Illness Beliefs

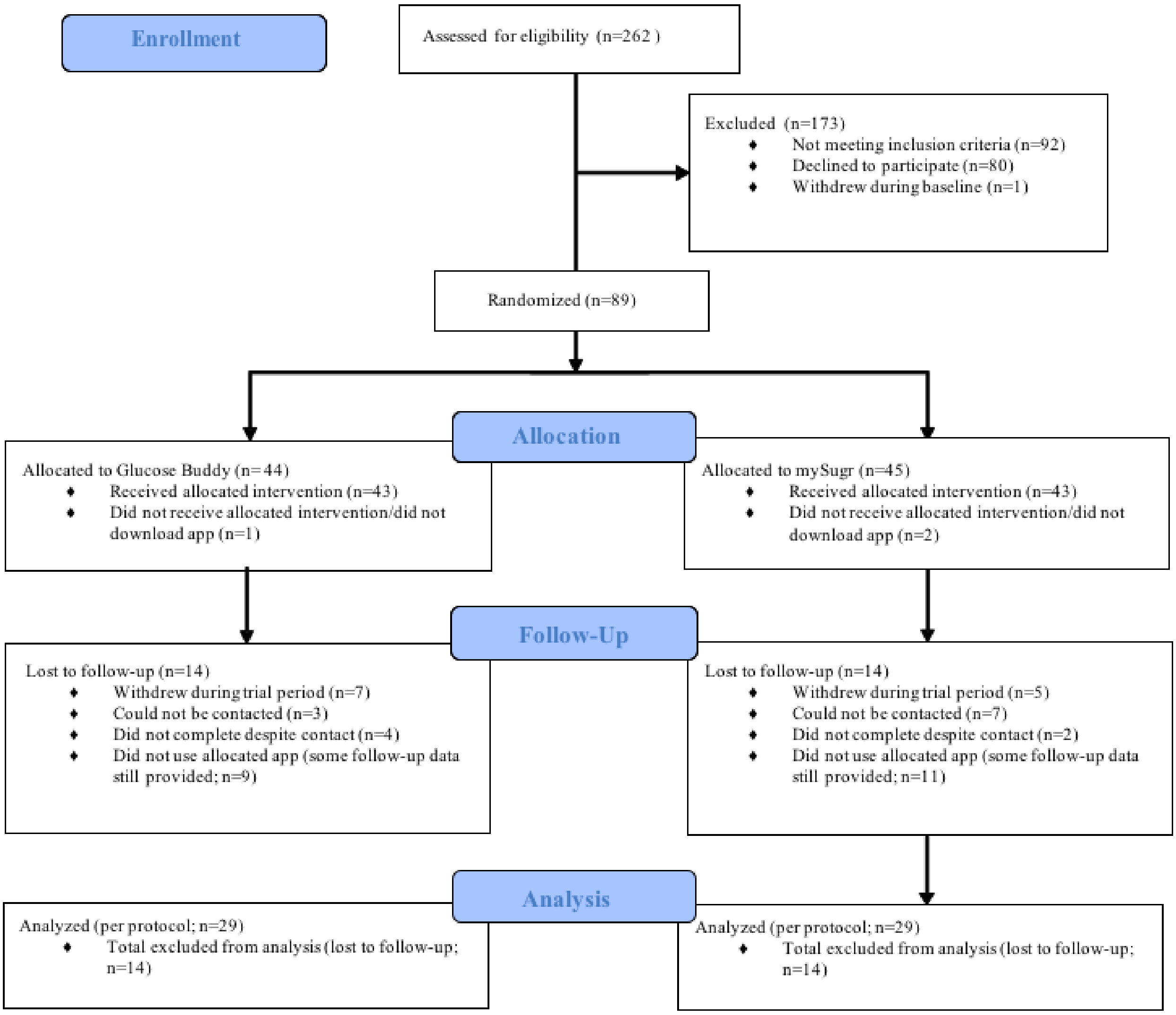
Illness beliefs were measured using the Brief Illness Perceptions Questionnaire [50]. This scale has 9 items that assess cognitive and affective beliefs about illness. The cognitive items assess individuals’ beliefs relating to the timeline, identity, controllability, consequences, and causes of the illness. The remaining items assess individuals’ concern, understanding, and emotional representations of their condition. Furthermore, 8 of the 9 items are rated on a 0 to 10-Likert scale, where 0 represents the lowest score and 10 represents the highest score. The instrument shows satisfactory reliability and validity across a range of chronic conditions, including T2D [51].

Statistical Analyses

The study was designed to explore the feasibility, acceptability, and possible differences in user engagement, self-care behaviors, and illness beliefs between the 2 app groups. Preliminary analyses were conducted to examine whether the data complied with parametric assumptions. The key outcome variables were not normally distributed; therefore, Mann-Whitney tests were used to examine differences between the 2 groups in user engagement, self-care behaviors, and illness beliefs at follow-up. Wilcoxon signed-rank tests were also used to check for changes in participants’ self-care behaviors and illness beliefs from baseline to follow-up in each group. Spearman rank correlations were conducted to explore the relationships between user engagement and self-care behaviors at follow-up. Due to significant loss to follow-up (Figure 1), missing data were not included in the analyses and per protocol analyses were conducted.

The qualitative data obtained from the interviews were assessed using quantitative content analysis. Quantitative content analysis involves assessing how participants use language to describe their experiences and includes systematically allocating content into numerical categories [52]. In this study, quantitative content analysis was used to further explore participants’ experiences of using the apps, which included assessing the acceptability and usability of the apps and exploring views on how the apps could be improved.

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) diagram of participant involvement.



Results

Overall, 89 patients agreed to participate and provided baseline data. Of these, 31 were lost to follow-up and did not complete any of the follow-up questionnaires. Ultimately, 58 participants (29 per treatment arm) completed all assessments and were included in the final analyses (Figure 1).

Baseline Characteristics

The sample at baseline (N=89) was mostly male (58/89, 65%), ranging in age from 28 years to 80 years with a mean age of 53 years (SD 11.99). The majority identified as Indian (30/89, 34%) or Pasifika (22/89, 25%), had done some tertiary level study (42/78, 54%), were married (60/88, 68%), and were employed (69/89, 78%; Table 1).

With regard to clinical characteristics, the mean age at which participants were diagnosed with T2D was 43 years (SD 11.28). On average, participants had been diagnosed with T2D for 9.9 years (SD 6.93) and had a mean BMI of 33.8 kg/m^2. HbA$_{1c}$ levels for participants at the time of recruitment ranged from 39 mmol/mol (5.7%) to 111 mmol/mol (12.3%), with a mean HbA$_{1c}$ level of 68.4 mmol/mol (8.4%). Approximately half the sample consumed alcohol (47/88, 53%), while a considerably smaller percentage of participants smoked (9/88, 10%). Most participants had other long-term illnesses together with their T2D (70/89, 79%), with hypertension (63/89, 71 %) being the most commonly reported comorbid condition. Metformin was the medication participants were predominantly using to manage their T2D (80/88, 91%).

Equal numbers of participants owned an iPhone (38/87, 44%) or Samsung (38/87, 44%) smartphone, while the remaining participants (11/87, 13%) owned other Android smartphones, such as Sony, Huawei, or Oppo. Most participants (82/89, 92%) reported using apps on their phone and slightly more than one-third of the sample (33/89, 37%) reported using health apps.

Table 1. Baseline characteristics of participants (N=89).

Characteristic	Glucose buddy (n=44)	mySugr (n=45)	*P* value
Age (years), mean (SD)	53.15 (11.06)	52.59 (12.96)	.83
Sex, n (%)			.46
Male	27 (61.4)	31 (68.9)	
Female	17 (38.6)	14 (31.1)	
Ethnicity, n (%)			.90
New Zealand European	6 (13.6)	9 (20)	
Māori	4 (9.1)	5 (11.1)	
Pasifika	12 (27.3)	10 (22.2)	
Indian	16 (36.4)	14 (31.1)	
Other	6 (13.6)	7 (15.6)	
Relationship status[a], n (%)			.17
Single	7 (15.9)	11 (25)	
In a relationship	3 (6.8)	7 (15.9)	
Married	34 (77.3)	26 (59.1)	
Education[b], n (%)			.16
Secondary education	14 (37.8)	22 (53.7)	
Tertiary education	23 (62.2)	19 (46.3)	
Employment status, n (%)			.95
Employed	34 (77.3)	35 (77.8)	
Unemployed	10 (22.7)	10 (22.2)	

[a] Missing data for 1 participant (n=88).

[b] Missing data for 11 participants (n=78).

Feasibility and Attrition to the Intervention

It took 2 months to recruit 89 participants: 31 participants were lost to follow-up after completing the baseline questionnaires, and 20 participants did not use their allocated app but completed the self-care behaviors and illness beliefs measures at follow-up and were included in the final analyses. There were significant differences between individuals who completed the study (n=58) and those lost to follow-up (n=31) for sex (χ^2_1=4.59; *P*=.03), with the proportion of men not using their allocated app (38/51, 75%) being greater than the proportion of women (13/51, 26%). There were also significant differences for ethnicity (χ^2_1=11.43; *P*=.02), with European New Zealanders more likely to complete the study compared to the other ethnic groups. Of those participants who dropped out, a greater proportion identified as Indian (24/51, 47%) compared with other ethnicities.

User Engagement and Self-Care Behaviors

Out of the 58 participants who completed the study, only 20 participants in the Glucose Buddy group and 18 participants in the mySugr group reported using the apps during the trial (Table 2). Self-reported user engagement was low in both groups (Glucose Buddy: median 4 days; mySugr: median 6.5 days; *P*=.06; use for both groups: median 10 minutes). The median uMARS score was 3.37 for Glucose Buddy and 3.36 for mySugr (uMARS scale 1-5).

There was little evidence to suggest any between-group differences in self-reported user engagement scores between the 2 app groups or in self-reported adherence to the diabetes apps (Table 2). No improvements were found in self-care behaviors or illness beliefs from baseline to follow-up in either group (Table S1, Multimedia Appendix 1).

In regard to associations between user engagement and self-care behaviors, no significant relationships were found between number of days of app use and any of the self-care behaviors at follow-up (Table 3). Blood glucose testing was positively and moderately related to minutes of app use (Spearman ρ=0.37; *P*=.02). There were no significant relationships found between total uMARS scores and self-care behaviors (Table 3).

Table 2. Self-reported user engagement of the 2 apps.

Measure	Glucose Buddy, median (n=20)	mySugr, median (n=18)	*P* value
Days used	4.00	6.50	.06
Minutes used	10.00	10.00	.43
Engagement	3.20	3.30	.39
Functionality	3.25	3.63	.16
Aesthetics	3.33	3.50	.58
Information	3.50	3.75	.47
Total uMARS[a] score	3.37	3.36	.89

[a] uMARS: user version of the Mobile Application Rating Scale.

Table 3. Spearman rank correlations between user engagement (days used, minutes used, total uMARS[a] score) and self-care behaviors at follow-up.

Measures	Days used	Minutes used	Total uMARS score
General diet	–0.04	0.21	–0.04
Fruit and vegetable consumption	–0.14	0.27	0.09
High-fat foods consumption	–0.03	0.02	–0.18
Exercise	–0.15	–0.06	0.17
Blood glucose testing	–0.07	*0.37* [b]	0.34
Foot care	0.004	0.04	0.07
Medication adherence	–0.08	0.16	0.16

[a] uMARS: user version of the Mobile Application Rating Scale.

[b] Italics indicate *P*<.05.

Interviews

After the 2-week trial, 6 participants (3 from each app group) were interviewed over the phone after about their experience of using the diabetes app (Table 4). A diverse group of participants who reported having used the apps were selected for the interviews in order to obtain a variety of viewpoints. Of the interviewees, 3 were female and 3 were male and aged between 29 and 58 years; 1 participant was New Zealand European, 2 participants were of Pasifika descent, 2 were of Indian descent, and 1 was of Chinese descent. Regarding medication use, 1 participant's regimen included both oral diabetes medication and insulin, and the remaining 5 participants reported taking oral medication only. Additionally, 4 of the 6 participants reported being advised to test their blood sugar regularly, and the remaining 2 participants reported not being required to test their blood sugar regularly as part of their T2D self-management. Feedback was grouped into positive experiences, negative experiences, most frequently used functions, and suggestions for improvement (see Table 5 for a summary of the participants' feedback).

Table 4. Illustrative interviewee responses.

Feedback category by respondent	Illustrative quote
Positive experiences using the app	
Male, 30 years, mySugr app	“I was curious and excited during the demonstration…good initial impression.”
Female, 50 years, Glucose Buddy app	“Looked great when going through initially.”
Male, 49 years, mySugr app	“Yes, certainly I would download such an app…Could be subsidized? I am willing to pay if it’s worthwhile.”
Female, 50 years, mySugr app	“Keeping track of glucose testing, keeping track of medication.”
Female, 29 years, mySugr app	“Liked the diabetes monster.”
Negative experiences using the app	
Female, 58 years, Glucose Buddy app	“Diet and calories is good and what I found most useful and necessary, but I don’t know how to calculate, for example, how many calories in a piece of meat or a bowl of rice?”
Female, 29 years, mySugr app	“A bit confusing sometimes, don’t understand all of it. Carbs a bit confusing.”
Male, 49 years, mySugr app	“Converting carbs challenging. Food descriptions take a lot of time.”
Female, 50 years, Glucose Buddy app	“I wanted to use it and tried to use it a few times, but I kept getting stuck on the medication page. I often couldn’t navigate to other pages.”
Male, 30 years, mySugr app	“Occasionally froze, a bit slow.”
Female, 58 years, Glucose Buddy app	“So many features. Lots of things I need to know before I can use it. I have well-controlled diabetes, so only need simple monitoring functions.”
Male, 49 years, mySugr app	“I want to do it quite quickly, but this app has too many things…too much information and too many questions. Could be simplified.”
Male, 45 years, Glucose Buddy app	“Recording what I was already doing, so wasn’t super useful. Became too much of a chore. Not interesting enough. No motivation.”
Male, 49 years, mySugr app	“Current app is too much like a log book and not engaging enough.”
Most frequently used functions	
Male, 30 years, mySugr app	“Blood glucose result most useful. Logging everything...Keeping track of numbers.”
Female, 29 years, mySugr app	“I liked putting my blood glucose test in. Blood glucose test was the most useful feature.”
Female 58 years, Glucose Buddy app	“Advice on diet—sample advice. You should be eating this sized bowl of carbs, this amount of fruit and vegetables, this much butter and fats. Videos. Suggestions of age-appropriate activities and how to do it safely.”
Female, 29 years, mySugr app	“Tips on exercise and food and nutrition. Good meals, new workouts would help a lot. Things you can do at home if you don’t have time to go out.”
Suggestions for improvement	
Female, 58 years, Glucose Buddy app	“Measure food and activities more regularly. See pattern between things, like food and activity and how it affected my blood sugar.”
Male, 49 years, mySugr app	“Should be able to set goals, for example, identify how many carbs you can eat per day and note down how much you’ve consumed at breakfast and how much you could still consume throughout the rest of the day. Same for activity—record steps taken so far and how many more to take to meet goals. Goals per day or per week.”
Male, 45 years, Glucose Buddy app	“People that have had diabetes for two or three years, we know about eating and testing blood sugars, but you have so many things going on you forget, so it would be helpful to have regular reminders that are relevant.”
Male, 49 years, mySugr app	“Something user-friendly and quick to enter. Simplify the current app and make it easier to navigate.”
Male, 45 years, Glucose Buddy app	“Way that smartphone can talk directly to glucose meter. Glucose meter only remembers one month’s readings and then records over, so would like to have it send readings directly to smartphone. Communication between existing apps, for example this app and Google Fit.”

Table 5. Summary of participants' feedback and suggestions for improvement (n=6).

Feedback category	mySugr	Glucose Buddy
Positive experiences	Graphs, colorful images, good interface, easy to read, glucose log, diabetes monster	Graphs, glucose log, medication log, food log
Negative experiences	Commercial emails, confusing, time-consuming, carb calculator hard to use	Hard to use, advertisements to upgrade to paid version, calorie calculator hard to use
Most frequently used functions	Glucose log	Glucose log, medication log
Suggestions for improvement	Provide fun and relevant reminders, allow the ability to set goals, simplify the app, provide dietary advice, make it quicker to enter information	Provide dietary advice, provide exercise advice, give relevant reminders, add more visual content, provide feedback based on blood sugar levels, use more videos

Positive Experiences of Using the App

All participants reported positive initial impressions of their respective app and reported a willingness to download a T2D smartphone app in the future and to pay for the app if they deemed the app to be valuable to them.

All participants reported finding both apps visually appealing. Four participants reported that they found the ability to monitor and log their blood sugar levels and produce graphs useful, and two participants also reported finding the medication and food logs useful. One participant also reported that they enjoyed the gamification aspect of mySugr.

Negative Experiences Using the App

All participants reported finding some aspect of the app confusing to use, with 3 of the 6 participants expressing that they found calculating calories and carbohydrates to be particularly challenging. Half of the participants also reported experiencing some technical obstacles like difficulty navigating the app. One of the main drawbacks reported by 3 participants was the large amount of information that was required to be entered into the app to use it. Participants found this to be time-consuming and complicated to use.

Some participants also felt that the apps did not engage or motivate them enough. Five of the six participants mentioned that they had not learnt any new information, for instance, about diabetes or how to improve their self-care behaviors, and two participants also mentioned that they forgot about the app sometimes.

Most Frequently Used Functions

Four of the six participants reported that logging blood glucose was one of the most useful features of the apps. Two participants reported that they used the medication tracker.

Suggestions for Improvement

Four of the six participants expressed a desire for more education and advice around nutrition and physical activity. With regard to diet, participants reported being interested in receiving advice on the types and quantities of the various food groups that they should be consuming. Similarly, for exercise, participants wanted suggestions of new exercises that they could do, along with advice and encouragement.

A desire for other features, in particular feedback and goal setting, were also mentioned. Three participants talked about wanting to receive feedback based on the information they entered, and two participants discussed the importance of being able to set goals and see how they are progressing towards achieving their goals.

Another feature that all 6 participants mentioned was tailored reminders and notifications. Participants stated that having reminders relating to their self-care behaviors, such as a reminder to check their blood glucose levels or take their medication, would be useful, as would be reminders relating to their goals.

Three of the six participants also reported wanting an app that allowed for easy monitoring of their self-care behaviors and that was not too time-consuming. One participant reported that having a diabetes app that communicated with their glucose meter or existing apps would be helpful.

Discussion

To our knowledge, this is the first study to compare user engagement and associated changes in self-care behaviors in 2 popular, commercially available diabetes apps as stand-alone interventions without additional clinical support. The results suggested that over a period of 2 weeks, participants spent a limited amount of time using the apps, only using the apps for a median of 4 days for Glucose Buddy and 6.5 days for mySugr. There was little evidence to suggest that participants found one of the apps to be more engaging than the other despite mySugr's use of gamification. There were also no improvements in self-care behaviors or illness beliefs from baseline to follow-up in either group. Indicators of feasibility (including adherence to the diabetes apps and follow-up rates) suggest that expecting participants to engage daily with a diabetes app without additional clinical support may be unrealistic.

Regarding the qualitative data, although the apps were considered to be acceptable to participants based on favorable initial impressions of the apps and a willingness to download diabetes apps in the future, they also reported facing various challenges in terms of usability. Two main reported shortcomings were the time-consuming nature and complexity of the apps. Participants also reported wanting apps to include more education and advice about diabetes self-care behaviors like diet and exercise. Participants also reported wanting tailored reminders or notifications relating to T2D self-care behaviors in general and to their specific diabetes-related goals.

The quantitative results from this study contradict with many other recent trials of diabetes apps, which have demonstrated efficacy in improving self-care behaviors or glycemic control in patients with type 1 diabetes (T1D) or T2D [18]. For example, Kirwan and colleagues [53] tested Glucose Buddy (coupled with weekly text messages from a diabetes nurse educator) in adults with T1D and found significant improvements in glycemic control from baseline to 9 months compared to standard care but no changes in self-care behaviors. In contrast to our study, their study included weekly clinical support from a certified diabetes educator over the duration of the intervention. Other differences included their intervention being significantly longer (6 months), the inclusion of a standard care control group, and testing of the app in adults with T1D. It is likely that all these differences played a role in improving glycemic control, particularly the additional clinical support, which has been argued to be the deciding factor for whether diabetes apps are effective in improving diabetes management outcomes. This makes it difficult to untangle whether intervention effects are due to the app or the increased clinical contact [54].

In contrast, the qualitative findings regarding the reported challenges and complexity of information in both apps are consistent with previous findings, in particular for older adults living with diabetes who are likely to benefit from a smaller range of functions [55]. Usability is a key factor influencing whether users engage with apps or not, and in the this study, all 6 participants who were interviewed reported finding some aspect of the app confusing, which included difficulties with calculating calories and carbohydrates and issues navigating the app. In a survey of more than 900 individuals who had downloaded a health app, just under half of these people reported discontinuing use of the app, with one of the main reasons being that they felt the app was not easy to use [56]. Other research also suggests that users fail to engage at all or stop engaging with technology once they consider it to be too hard to use [25]. These findings highlight the importance of having user input during the design and development of health apps [57], as something that seems intuitive to app developers or researchers may not feel straightforward to users, particularly if they are not confident or are new to using apps.

Research on user engagement and design indicates that several elements influence engagement with technology, like gamification, interactivity, feedback, challenge, and novelty [23,58], yet commercially available diabetes apps do not seem to fully leverage these features. The principal behavior change technique used in both free versions of the apps was self-monitoring, with the primary function being the recording of diabetes-related self-care behaviors. Thus, it seems that neither gamification nor self-monitoring alone may be sufficient to engage users, and greater inclusion of other evidence-based behavior change strategies (eg, goal setting) and fully exploiting the unique functions of smartphone technology (eg, the ability to provide personalized feedback through real-time reminders) are needed to successfully increase engagement, modify illness beliefs, and improve self-care behavior.

The glucose log feature was reported by all 6 participants to be one of the most useful—if not the most useful—feature of the apps. This is in line with other research that also found the glucose log to be the most frequently used diabetes app feature in a sample of patients with T2D who reported using apps [43]. Of the self-care behaviors, only blood glucose monitoring was significantly associated with minutes of app use and also demonstrated a trend towards a significant association with overall user engagement. This suggests that individuals who used the app for longer also tested their blood glucose more regularly. This may also indicate that more adherent patients are more likely to use diabetes technology in general [59], including diabetes apps. This is worth exploring in future studies to determine how we can improve engagement of diabetes technology for people who are currently struggling with diabetes self-management. In addition, despite the increased use of commercially available health apps by HCPs, there is relatively little evidence or guidance available for HCPs to evaluate their quality and efficacy [22,60]. Future studies should also incorporate interviews with HCPs to gather their feedback on the clinical usefulness of diabetes apps in diabetes self-management.

Several limitations of this study should be noted, including the short follow-up period, lack of blinding, and the high levels of attrition. We also tested the free versions of the Glucose Buddy and mySugr apps instead of the pro or paid versions, with the latter being more likely to incorporate more features that enhance user engagement, like real-time feedback and reminders. However, we deliberately chose the free versions of each app, as people living with T2D in New Zealand often come from lower socioeconomic status backgrounds. We also did not include regular clinical support to help patients use and engage with the apps, as the focal point of the study was to explore how patients use and engage with diabetes apps without additional support from HCPs. Another limitation was the reliance on self-reported user engagement. Ideally, user engagement should include a range of user engagement metrics, including app analytics, which was not possible in this study. Furthermore, the qualitative data collected from 6 participants may not be representative of the study cohort and cannot be generalized to the wider T2D population. Another limitation is the lack of intention-to-treat analyses, which we were unable to conduct due to the missing data.

The strengths of this study include the randomized controlled design, the testing of 2 popular apps that are commercially available and free to use, and the recruiting of a diverse sample of people living with T2D. Future research comprising larger samples and higher rates of user engagement and interaction with apps would offer greater power for detecting possible between-group differences. Longer follow-up would also be beneficial in ascertaining whether diabetes apps could successfully encourage long-term behavior change. Finally, studies examining whether clinical support from HCPs leads to better outcomes compared with unsupported use of diabetes apps are needed. It remains to be seen whether larger trials testing diabetes apps without additional clinical support can sufficiently engage patients.

In conclusion, there was little evidence of between-group differences in user engagement, and neither app group showed improvements in self-care behaviors or illness beliefs after a median of 6.5 days and 4 days of use over 2 weeks for mySugr and Glucose Buddy, respectively. However, our findings suggest that individuals who used the apps for longer periods per day also tested their blood glucose more frequently. Overall, the results of this feasibility trial demonstrate how difficult it is for individuals with long-term conditions to engage with diabetes apps without additional clinical support. It also highlights the importance of having both patients' and HCPs' input during the app development process to ensure the app meets patients' needs, both in terms of being user-friendly and engaging as well as targeting all self-care behaviors with appropriate behavior change techniques to support behavior change.

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Authors' Contributions

AS and RM designed the study, assisted with the analysis and interpretation of the data, and drafted and approved the final version of the manuscript. AM collected the data, conducted the initial analyses and interpretation of the data, wrote the first draft of the manuscript, and approved the final version of the manuscript. DL assisted with the analysis and interpretation of the data, assisted with drafting the manuscript, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Median scores of self-care behaviours and illness beliefs by app group at follow-up.
[DOCX File , 16 KB - formative_v5i6e25151_app1.docx]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 11577 KB - formative_v5i6e25151_app2.pdf]

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Abbreviations

HbA_{1c}: glycated hemoglobin
HCP: health care provider
SDSCA: Summary of Diabetes Self-Care Activities
T1D: type 1 diabetes
T2D: type 2 diabetes
uMARS: user version of the Mobile Application Rating Scale
WHO: World Health Organization

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Original Paper

Inpatient Telemedicine Implementation as an Infection Control Response to COVID-19: Qualitative Process Evaluation Study

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Abstract

Background: The COVID-19 pandemic created new challenges to delivering safe and effective health care while minimizing virus exposure among staff and patients without COVID-19. Health systems worldwide have moved quickly to implement telemedicine in diverse settings to reduce infection, but little is understood about how best to connect patients who are acutely ill with nearby clinical team members, even in the next room.

Objective: To inform these efforts, this paper aims to provide an early example of inpatient telemedicine implementation and its perceived acceptability and effectiveness.

Methods: Using purposive sampling, this study conducted 15 semistructured interviews with nurses (5/15, 33%), attending physicians (5/15, 33%), and resident physicians (5/15, 33%) on a single COVID-19 unit within Stanford Health Care to evaluate implementation outcomes and perceived effectiveness of inpatient telemedicine. Semistructured interview protocols and qualitative analysis were framed around the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework, and key themes were identified using a rapid analytic process and consensus approach.

Results: All clinical team members reported wide reach of inpatient telemedicine, with some use for almost all patients with COVID-19. Inpatient telemedicine was perceived to be effective in reducing COVID-19 exposure and use of personal protective equipment (PPE) without significantly compromising quality of care. Physician workflows remained relatively stable, as most standard clinical activities were conducted via telemedicine following the initial intake examination, though resident physicians reported reduced educational opportunities given limited opportunities to conduct physical exams. Nurse workflows required significant adaptations to cover nonnursing duties, such as food delivery and facilitating technology connections for patients and physicians alike. Perceived patient impact included consistent care quality, with some considerations around privacy. Reported challenges included patient–clinical team communication and personal connection with the patient, perceptions of patient isolation, ongoing technical challenges, and certain aspects of the physical exam.

Conclusions: Clinical team members reported inpatient telemedicine encounters to be acceptable and effective in reducing COVID-19 exposure and PPE use. Nurses adapted their workflows more than physicians in order to implement the new technology and bore a higher burden of in-person care and technical support. Recommendations for improved inpatient telemedicine use include information technology support and training, increased technical functionality, and remote access for the clinical team.

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KEYWORDS

telemedicine; inpatient; COVID-19; qualitative; RE-AIM; infection control; personal protective equipment; implementation science; quality improvement

Introduction

The COVID-19 pandemic created new challenges to delivering safe and effective health care while minimizing virus exposure among staff and patients without COVID-19. Telemedicine has long been recognized as a potential solution to these challenges and was deployed in response to the Ebola, SARS, and H1N1 outbreaks [1], and now the COVID-19 pandemic [2,3]. Health systems worldwide have moved quickly to implement telemedicine in diverse settings [4-8], drawing on existing best practices for implementing telemedicine to increase remote access [9]. Much less is understood about how best to connect patients who are acutely ill with nearby clinical team members, even in the next room. To guide this widespread deployment, a deeper understanding of inpatient telemedicine's current use and potential impact on quality of care and team dynamics is needed.

Inpatient telemedicine adoption is also useful for personal protective equipment (PPE) conservation. For inpatients with known infections, the clinical team must don one-time-use PPE each time they enter the patients' rooms to safely provide care and help prevent transmission. Increased demand for PPE has led to intermittent regional supply shortages that place millions of health workers at risk [10,11]. Inpatient telemedicine allows health workers to address patient needs without physically entering the room, thereby reducing exposure and preserving scarce PPE resources [2,12]. These consults occur on the same unit, making them qualitatively different from other telemedicine in that the clinical team is able to convert an initial virtual encounter to an in-person one should the need arise.

Health systems hoping to incorporate telemedicine must overcome several recognized barriers, including costs, training, resistance to change by clinical team members and staff, and patient characteristics associated with reduced comfort in using technology, such as older age or lower level of education [13,14]. The COVID-19 pandemic has helped facilitate the removal of some of these barriers, as the United States moved to relax regulations on interstate licensing and offered parity in reimbursement in many telemedicine settings [15]. Examples of this adoption by hospitalists to deliver inpatient care include system-wide deployment of an in-room video intercom system [16] and tablet-based web-conferencing systems [17]. Specialty care via telemedicine has also been explored in palliative medicine [18], urological care [19,20], and dermatology [21]. The United States is not alone, as telemedicine programs have been developed in other infection hot spot countries, such as China, Spain, and Italy, to minimize virus transmission [5,22,23].

Despite the growing implementation of inpatient telemedicine, formal evaluations are limited. Telemedicine used to deliver care remotely has been shown to be effective in many clinical settings [24]. In the more novel use of infection control, Borchert et al demonstrated that a portion of inpatient telemedicine urological consults were safely directed through a triage protocol that included a pathway exclusively for inpatient telemedicine care [20]. Given the nascent use of inpatient telemedicine, an exploratory understanding of how clinical teams are using inpatient telemedicine and the challenges they face is needed. Qualitative approaches are best suited for exploratory, ground-up understanding of emerging issues and situations within health services research [25]. In evaluating inpatient telemedicine, for example, qualitative methods have afforded us insights around how the technology is implemented and why it is or is not adopted. This paper is one of the first to seek frontline clinical team voices to understand how inpatient telemedicine is being implemented and its downstream effects on patient care, team dynamics, and perceived quality.

Methods

Overview

This study conducted 15 semistructured interviews with attending (5/15, 33%) and resident (5/15, 33%) physicians and nurses (5/15, 33%) on a designated COVID-19 unit at Stanford Health Care as part of a qualitative process evaluation. To clarify, attending physicians (eg, consultants) have completed all medical training and oversee resident physicians (eg, house officers) who have recently graduated from medical school and are in years 1 to 3 of their hospital training. This evaluation sought to understand the implementation and perceived effectiveness of an inpatient telemedicine solution across multiple domains, including patient care, clinical workflow, and clinical team satisfaction.

Setting

Beginning in March 2020, a large academic health center—Stanford Health Care, Palo Alto, California, USA—designated a single inpatient nonintensive care unit to treat all potential and confirmed patients with COVID-19 admitted to their hospital. To reduce clinical team and staff pathogen exposure and to conserve PPE, each patient received an iPad tablet (Apple Inc) with the ability to receive web-conference calls from computers in two private conference rooms on the unit. A patient's unique web-conferencing link and a password were required to enter the privacy-compliant system; this information was available to any clinical team members on the unit. Each tablet in the patient rooms had the web-based teleconferencing software Zoom (Zoom Video Communications, Inc) installed in a "hub-and-spoke" configuration, such that a call from the "hub" tablet on the unit floor would trigger the "spoke" patient tablet to automatically turn on its audio and video functions. The inpatient telemedicine intervention aimed to reduce clinical team in-person encounters and allowed the primary and specialist physician team, nurses, and extended care team members (ie, dietitians, respiratory therapists, physical therapists, social workers, and others) to provide patient care remotely in the on-unit conference rooms throughout the day.

Instrument and Population

Semistructured interview protocols explored the implementation and perceived effectiveness of inpatient telemedicine in reducing pathogen exposure and PPE use. The interviews also captured perceptions of the appropriateness of inpatient telemedicine use in various settings and its impact on clinical team satisfaction. Interview protocols were developed using RE-AIM (reach, effectiveness, adoption, implementation, and maintenance), an implementation science framework most commonly used to support effective implementation of interventions, but that is also valuable in structuring the evaluation of key implementation outcomes [26-28]. Interview questions were open-ended and organized into themes around individual experience with the intervention, perceived patient and clinical team outcomes, changes to clinical team workflow, and anticipated future use cases of inpatient telemedicine beyond the COVID-19 pandemic. Interviews lasted approximately 30 minutes and took place by phone, except in the case of two interviews that were conducted in person in a private location on the COVID-19 unit. Though the team would have preferred to conduct all interviews in person, access to the unit was rightfully highly restricted requiring use of phone interviews.

The target population for interviews included nurses and resident and attending physicians who were part of the clinical team and had used telemedicine since its launch within the organization in March 2020. The evaluation team contacted the medical director and nursing manager on the COVID-19 unit and received a list of clinical team member names from which to contact potential participants and request an interview. Interviews were conducted between May and June 2020 and reflect technical capabilities and workflows used during this period. Purposive sampling methods were used to recruit participants until thematic saturation was reached. Recruitment was challenging due to the small pool of clinical team members working on the COVID-19 unit and their demanding responsibilities in the context of the pandemic. Saturation was reached, by role, when new themes no longer emerged during interviews [29].

Analysis

Interviews were audio recorded and transcribed verbatim using Rev (Rev.com Inc). A qualitative health services researcher (NS) and a physician health services researcher (SV) independently reviewed and summarized key themes across all interview transcripts using a rapid analytic process structured around *a priori* categories informed by interview question categories (eg, structure, process, and patient outcomes) and RE-AIM constructs (Multimedia Appendix 1) [30]. Key themes and any inductive categories that emerged from this preliminary round of analysis were then validated using a consensus approach including an additional qualitative health services researcher on the evaluation team (CBJ) and two research assistants (EW and ZZ) who were also closely familiar with the data [31]. Each member of the team provided feedback on the others' key themes, highlighted similarities and differences, and surfaced relevant participant quotes. Differences in data interpretation were reviewed and resolved only once a majority of the team came to consensus. The Stanford Institutional Review Board determined that this project did not qualify as human subjects research (Protocol 55927). As such, informed consent for participation was not required. However, each participant received a verbal description of the evaluation and was informed that their participation was voluntary and confidential.

Results

Overview

Using RE-AIM, as defined above, and categories drawn from the semistructured interview guide as an *a priori* coding framework for analysis, the following themes emerged: (1) implementation setting and climate, (2) clinical team workflows around inpatient telemedicine, (3) clinical team satisfaction with inpatient telemedicine, (4) perceived impacts on patients, (5) limitations of inpatient telemedicine, and (6) anticipated future uses of inpatient telemedicine. Table 1 describes the qualitative findings by theme and subtheme.

Table 1. Qualitative results by theme and subtheme and example quotes.

Theme and subtheme	Quote
Implementation setting and climate	
Adoption	“Great. And who’s using this video chat option? Which types of roles are using it? Is it just attendings? Are residents involved? Nursing? Who else?” (Interviewer) “Yeah, I think everybody is, and I know nurses go in and out of the room too when I’m using it. So, everybody, essentially.” (Attending physician #2)
Information sharing and training	“I believe I was told about it at a division meeting and I didn’t receive any formal training in it, but it was easy enough to use without having to go through a training session.” (Attending physician #3)
Information sharing and training	“What information were you given when this all first launched about how to use the technology?” (Interviewer) “Not a lot. I was told it was available and that most patients with COVID had it as long as they were on the right units. And then that it was allowed in lieu of the physical exam now. So that was sort of the information that we were given.” (Resident physician #2)
Clinical team workflows	
Physician workflow	“Typically what we do is as a team, we’ll go into one of the Zoom rooms and we will call the patient using the video chat. We’ll call in an interpreter if we need, and we’ll do the history taking and a visual physical exam over Zoom. And if the patient is new to me or had a clinical change that requires a physical exam, then after we do the rounding over the video chat, then I’ll go into the room and do any parts of the physical exam that require me to be physically in the room.” (Attending physician #4)
Nurse workflow	“The organization is really depending on nurses to be solely, I guess the person who’s doing direct patient care most of the time in COVID rooms. Before this there were very few barriers to having physical therapy in the room or consulting teams doing their assessment and chatting with the patient, having housekeeping come in, right? But now we’ve taken over some of respiratory therapy’s responsibilities just to decrease exposure for them and to conserve PPE [personal protective equipment], so we’re doing metered-dose inhalers, et cetera, for them. Housekeeping isn’t allowed into the room except to do discharge. So we’re doing trash and linen for the moment. I mean, physicians will come in if it’s emergent and there are definitely different teams that come in to do their daily assessments, but for the most part it’s solely nursing doing physical assessments and they’re really relying on us to see the changes and advocate for the patients if something is new or if they’re deteriorating, et cetera.” (Nurse #5)
Nurse workflow	“...in the beginning when the nurse comes in, before she goes in the room, she’ll do a teleconference with the patient to check on them, see if they’re awake, if they’re ready to order breakfast. What do they need before we come into the room, because we’re trying to compile care, kind of do as much as possible when we enter, so we’ll do it in the morning. We’ll bring them the breakfast tray, we’ll get them fresh linen, we’ll get them the morning medicine. So, we’re doing as much as possible when we go in the patient’s room.” (Nurse #3)
Extended care team workflow	“...You have to first log in with the patient and then you say, ‘Hey.’ I speak Spanglish. I’m like, ‘Hola. Un minuto.’ And then I get the information for the chat, the number and the password, and I text it to the interpreter and then they hop in and some are between five and 10 minutes.” (Attending physician #2) “So in that five- to ten-minute gap, what happens?” (Interviewer) “Yeah, that’s awkward. And if you leave the room then the password changes. So, you have to stay there. I say in my Spanglish, ‘A person’s coming,’ and then we just kind of hang out. But actually, today the patient fell asleep, literally while we were sitting there because I think it took like nine minutes.” (Attending physician #2)
Technology support workflow	“You mentioned a few things that weren’t going well already, but what else with the Zoom technology isn’t working well?” (Interviewer) “I think those were the main things. Like there were a couple times when it just like, was on pause or out of batteries or something...” (Resident physician #3) “Okay. And who’s actually responsible for maintaining the iPads? Like charging them?” (Interviewer) “I don’t know.” (Resident physician #3)
Clinical team satisfaction	
Physician satisfaction	“For me, it helps the anxiety a lot. I have a young child at home, so related to that, I was really extra worried about becoming sick myself. Once I was actually in the hospital for the first time during COVID and seeing how smoothly things were going with the PPE and everything, I felt a little better already. But then just knowing that I didn’t need to be exposed any more than absolutely necessary. That was very helpful.” (Attending physician #5)
Physician satisfaction	“So when I was on wards, I never went physically in the room with any of these [COVID-19] patients and in that way I think it’s detrimental...you don't get a lot of the teaching about the physical exam that you probably wanted.” (Resident physician #3)

Theme and subtheme	Quote
Nurse satisfaction	“It’s a little time consuming to be able to coordinate [calls]. [Physicians ask] ‘Oh, can you show me how to Zoom? Can you show me?’, even though we have clear instructions in each of those Zoom rooms, each of the conference rooms on how to set it up, everyone’s like, ‘Oh, can you show me how to do it?’ So, we have to kind of stop what we’re doing if it’s nothing too important and we have to go.” (Nurse #1)
Perceived impacts on patients	
Quality of care	“I think from a like, is the patient getting the care that they need and are they getting better standpoint? The answer is yes, but I do think you lose something by not being able to be physically present next [to] your patient. And that might be something that’s like a, it’s like an intangible, but it’s kind of just like the, having the proximity of being a physician next to you to comfort you or reassure you, which is just different when you’re doing things remotely.” (Attending physician #3)
Quality of care	“I think it puts a lot of onus on the nursing staff, which is okay because there is clinically a really strong staff, but I just wonder if that is the safest quality of care...That is why I don’t know if it really is good. I mean, yeah. I’m a little bit indifferent about it...I think in certain scenarios, it is really important and probably others, it is probably not. I do think there is potential for something to be missed. I worry, I guess.” (Nurse #4)
Patient privacy considerations	“Sometimes we would try calling first to ask on the room phone and to ask if it was a good time. Another thing is [the tablet] was angled such that it was at their faces, not anywhere else, and so we felt like it was unlikely that they were going to be kind of like exposing that much of themselves. That was a challenge I don’t think I’ve fully solved.” (Attending physician #5)
Patient privacy considerations	“I don’t think [privacy]’s an issue at all, and I could see how it’d be a question, but...to be honest with you, if you had to wait for the patient to answer, it just wouldn’t work. Most of the time they’re sleeping, even the middle of day, or they just don’t hear it...So if you needed them to answer the call, then it would only work 50 percent of the time.” (Attending physician #2)
Limitations of inpatient telemedicine	
Communication	“[Researchers] were consenting [the patient] for remdesivir and they used an interpreter. They didn’t go into the room and they used an interpreter via phone and there was still a language barrier where the patient didn’t understand what they were consenting him on. So, he said no to remdesivir... I speak Spanish, so the next day I went into the room and I said, ‘Just a question. Why did you say no to the remdesivir trial?’ And he’s like, ‘I don’t know. I couldn’t really understand what they were saying over the phone, so I just said no.’” (Nurse #1)
Patient–clinical team connection	“I had one COVID patient where I needed to have a goals of care conversation that really didn’t feel like it was working well over the Zoom, and so I did that in the room. I think I worry a little bit sometimes that if we only see patients over the Zoom, that it increases their sense of isolation and their feeling of fear and feeling... Yeah, their feelings of isolation and fear. And that there’s something to be said for the emotional connection and support that comes from physically being in the room.” (Attending physician #4)
Anticipated future uses of inpatient telemedicine	
N/A[a]	“I do think that especially if it were something that we could access from all over the hospital...now that we have a new hospital and our patients are not well co-localized, people spend so much time just walking from place to place. I could see it really being helpful. Of course you want, under normal circumstances, to see every patient in person at least once a day, but if you’re literally a mile away in the hospital and a patient just has a question, it does feel more personal to Zoom in and be able to talk to them where they can see your face...Of course you get more information too, you can see, are they having trouble breathing? Do they look sicker than when you saw them earlier? That kind of thing.” (Attending physician #5)

[a] N/A: not applicable; there were no subthemes for this theme.

Implementation Setting and Climate

Implementation setting and climate subthemes addressed adoption, information sharing, and training.

Adoption

Adoption of inpatient telemedicine was reported to be near universal across attending and resident physicians and nurses who cared for patients on the COVID-19 designated inpatient unit. Web-conferencing was also used to replace morning rounds for patients with COVID-19, which would otherwise take place with the full physician team (both residents and attendings) and nurses, when available.

Information Sharing and Training

Information sharing and training about the intervention were reported to be informal. The novelty of the inpatient telemedicine system also led to variations in the terminology used to describe it. Clinical team members called it “video visits,” “virtual rounding,” “inpatient telemedicine,” “telemedicine,” “video chat,” “Zoom visits,” or “Zoom.” There were no consistent terms used within interviewee roles, and no miscommunications resulting from variation in terminology were reported.

Most clinical team members learned about the inpatient telemedicine system through word of mouth, though some did participate in a technical training session, and instructions for initiating inpatient telemedicine visits were posted on the computers in the designated web-conferencing rooms. Most physicians reported learning about the technology from either the nursing team or from a physician coming off a previous shift. Most nurses also reported learning about inpatient telemedicine through their peers, though one had received training from an information technology (IT) representative. Though instructions were posted, nurses shared that they regularly received an influx of questions and requests for help initiating visits from physician team members and others. Nurses reported that these questions and requests did not seem to diminish in the months following implementation.

Clinical Team Workflows Around Inpatient Telemedicine

Overview

Clinical team workflow subthemes addressed the relative stability of physician workflows compared to the period before the COVID-19 pandemic, the significant adaptations of nurse workflows to account for additional responsibilities associated with COVID-19 restrictions and inpatient telemedicine, workflows for extended care team members hinging on call coordination and availability of translators, and a need for improved technology support workflows.

Physician Workflow

Attending physicians and senior residents shared that they entered patient rooms less frequently due to the availability of inpatient telemedicine and, as a result, they reduced their PPE use and exposure to COVID-19. Junior residents did not enter the rooms at all per trainee program guidelines.

Clinical team members reported that a baseline physical exam was typically conducted in person by the senior resident or attending physician. Any additional in-room examinations were conducted by the nurse, senior resident, or attending and took place anywhere from daily to every few days, depending on the patient's clinical needs. When asked how they decided whether or not to enter a room for an in-person assessment, physicians considered patient acuity of illness, opting to forgo low-value in-person encounters that could otherwise be addressed via video. Any decrement in clinical status also triggered an in-person exam. Rounding activities typically included daily telemedicine conversations between the patient and the physician team (ie, attendings and residents), as long as patients were clinically stable.

Nurse Workflow

Patients continued to receive regular, in-room nursing care multiple times each day. In addition to their usual responsibilities, nurses reported being tasked with additional responsibilities outside their standard work. These included delivering food multiple times per day, changing linens, and disinfecting patient rooms due to room entry restrictions barring housekeeping and cafeteria staff from entering the rooms of patients with COVID-19. Nurses reported "batching" their entrances to complete several tasks at once to reduce PPE use, and they used inpatient telemedicine when they wanted to check on patients but deemed an in-room encounter unnecessary. Nurses shared that inpatient telemedicine was primarily used for hourly assessments of each inpatient, which is considered best practice in nursing care, and was often a satisfactory alternate to an in-person encounter.

Most notably, nurses reported expending significant time to facilitate team use of inpatient telemedicine, including scheduling the virtual meetings and circulating web-conferencing links and passwords to all participants (eg, clinical team, interpreters, family members, and extended care team members). The coordination of a single call was reported to take up to 20 minutes of a nurse's time to complete. While some attendings and residents reported setting up calls themselves, some corroborated their ongoing reliance on nursing support to facilitate calls.

Nurses also reported being asked to don PPE and enter patient rooms during inpatient telemedicine visits to turn the tablet screen or increase tablet volume to optimize the interaction with the physician or extended team member in the conference, as patients frequently moved the tablet or adjusted its settings between visits. These situations negated any reduction in PPE consumption that the inpatient telemedicine system may have facilitated and transferred potential exposure from the caller to the nurse. While nurses did not express dissatisfaction with these changes directly, some nurses shared concern that time spent facilitating telemedicine encounters for other team members pulled them away from their own patient care responsibilities.

Nurse-led adaptations of the technology that supported patient care included the following: (1) acquiring an extra tablet at the nursing station through IT to be able to monitor and provide 24/7 visualization of a delirious patient with dementia who was a fall risk and (2) facilitating communication between patients and family members, particularly in acute care situations, if they had time to coordinate the conference room and the family member and patient schedules.

Extended Care Team Workflow

On-site extended care team members, such as respiratory therapists, dietitians, psychiatrists, social workers, research coordinators, and other team members, were not physically permitted on the unit and could, therefore, not initiate inpatient telemedicine visits through on-site conference rooms. Given these limitations, nurses were also sometimes asked to conduct respiratory therapy activities or fulfill other clinical needs on behalf of their remote care team members.

Call coordination via inpatient telemedicine was reported to rely on nurses to coordinate and required each relevant team member to be available simultaneously in their own confidential setting for the telemedicine visit to take place effectively. Many patients with COVID-19 did not speak English as their first language, and it was particularly challenging to schedule remote interpreters on telemedicine visits. Interpreters worked virtually in multiple settings using multiple technical platforms, often producing a 5- to 10-minute delay while the physician and patient waited in the teleconference room.

Technology Support Workflow

The logistics of using and maintaining tablets in patient rooms created new workflows for the clinical team. Each tablet was mounted on a cart to the side of the patient bed and nurses mentioned that the placement of the tablet sometimes interfered in patient care, specifically in conducting physical exams or providing treatment that required access to that side of the bed. Additionally, tablet maintenance meant that updates automatically pushed by the technology companies or a dead battery could put a tablet out of commission, without reported backup machines available on the inpatient unit that could immediately address the issue.

Clinical Team Satisfaction With Inpatient Telemedicine

Satisfaction subthemes highlighted high attending and resident physician satisfaction specific to reduced infection exposure and improved efficiency in daily workflows, resident physician concerns with reduced educational opportunities, and no stated change in satisfaction for nurses.

Physician Satisfaction

Most physicians perceived inpatient telemedicine to have a positive impact on their daily work and reported that the platform was intuitive to use, given their experience with the technology in nonclinical settings. Physicians also perceived having additional time to check in on patients given the reduction in time spent walking between patient rooms. These factors, in addition to reduced PPE use and in-room COVID-19 exposure, were reported to contribute to improved job satisfaction and reduce feelings of anxiety around infection among attending and resident physicians.

In-room physical exams prior to the pandemic typically included attending physicians and senior and junior residents; however, during the pandemic, attending physicians and senior residents primarily conducted in-room physical exams with patients with COVID-19 alone. Junior residents mentioned missing educational aspects of the physical exam due to this reduction in training at the bedside, though they appeared to accept the small trade-off on education to prioritize their safety and were still able to engage with patients through inpatient telemedicine.

Nursing Satisfaction

Nurses did not report a change in job satisfaction or anxiety, as they perceived that their in-room exposure stayed at similar, if not increased, levels following the implementation of inpatient telemedicine due to the increased housekeeping and care responsibilities described above. As fewer members of the primary physician team and extended care team were allowed to enter patient rooms, these additional tasks fell on the nursing team to complete.

Perceived Impacts on Patients

Perceived patient impact subthemes included consistent quality of care, privacy considerations, and limitations of inpatient telemedicine, particularly with respect to communication, physical exams, and patient–clinical team connection.

Quality of Care

Overall, inpatient telemedicine was perceived to be effective in reducing COVID-19 exposure and PPE use without significantly compromising quality of care. Patient outcomes, specifically around quality of care, were perceived to be of similar quality to in-person visits. Physicians and nurses reported that inpatient telemedicine facilitated improved care by allowing the clinical team to "eyeball" a patient's physical status remotely throughout the day without donning PPE. Additionally, all physicians reported that the inpatient telemedicine system allowed for higher-quality care than care delivered via phones available at the patient's bedside, as physicians were able to assess patients' physical statuses and capture facial expressions otherwise missed through audio alone.

Patient Privacy Considerations

Physicians and nurses felt that patient privacy was protected, as calls could only be made in the designated conferencing rooms through the secure system. Some clinical team members mentioned feeling concerned about the auto-activation of video in the patient's room and would call the patient by phone just before initiating a web-conferencing visit to alert the patient. However, some physicians felt the auto-accept feature was critical to provide timely care if patients were unable to activate video by themselves.

The clinical team reported that patients sometimes turned the tablet screen away from themselves for privacy reasons and reduced the volume, especially at nighttime when the screen brightness and sound might interrupt their sleep. This allowed patients to rotate the screen toward themselves when they were ready for the visit, but it also meant that sometimes calls from the clinical team were missed, as the patient did not notice or could not hear the team initiating the call. It was at these points that a physician might ask a nurse to don PPE and enter the room to turn the tablet screen toward the patient and increase the audio volume.

Limitations of Inpatient Telemedicine

Some residents acknowledged concern that the lack of physical presence may compromise care, particularly for vulnerable patients with an altered mental status and hearing challenges as well as for non-English speakers. At the same time, a resident also acknowledged that telemedicine opened up new care possibilities for a deaf patient who was admitted with COVID-19 and could only read lips. Whereas PPE would have covered the resident's mouth during an in-person exam, telemedicine allowed a conversation to take place.

Additional use cases where inpatient telemedicine was thought to be inappropriate around prognosis included when sharing bad news or communicating complex information in another language. Several nurses reported concerns of less appropriate use by the extended care team, such as a psychiatric evaluation completed over telemedicine for a patient with known dementia or a physical therapy evaluation for a patient who had trouble standing. Other adaptations made to adjust to virtual patient care were also reported as less ideal, such as directing patients to identify complex medical instruments or asking nurses to conduct exams typically done by a resident. Some physicians and nurses also noted the loss of in-person connection, worrying that it may inadvertently lead to worse outcomes or at least reduce patient satisfaction. One nurse felt that this loss of interpersonal connection went against her training.

Loss of connection was reported to be felt by the patients as well. The clinical team reported that few patients had commented on their inpatient telemedicine experience, though those who had received feedback shared that some patients were confused as to why physicians and nurses were not entering the room as often. Some clinical team members perceived that inpatient telemedicine made their patients feel more isolated.

Anticipated Future Uses of Inpatient Telemedicine

Clinical team members agreed that inpatient telemedicine might expand beyond use in patients with COVID-19 in future use cases. Contexts favorable to telemedicine use included those with patients who were comfortable with the technology and were clinically stable and mentally coherent. When asked what percentage of daily encounters they prefer to conduct via inpatient telemedicine in the future, clinical team members shared preferences ranging from 0% to 80%. Suggested uses included leveraging inpatient telemedicine to allow remote (ie, off-unit) access to patients throughout the day and to connect patients with remote visitors.

Discussion

Principal Findings

This is the first qualitative analysis of inpatient telemedicine used to improve infection control using established implementation science frameworks that the authors are aware of. Findings suggest that telemedicine used as an infection control tool in a nonintensive care inpatient setting was generally accepted and adopted among attending physicians, resident physicians, and nurses. Clinical team members agreed that quality of patient care remained largely unchanged, particularly given the ever-present option to convert a telemedicine assessment to an in-person exam if clinical deterioration was suspected. Recognized limitations included challenges around clinical team communication and personal connection with the patient, perceptions of patient isolation, ongoing technical challenges, and certain aspects of the physical exam. Such barriers have been previously reflected in the literature alongside concerns of technical costs and unfavorable reimbursement [13,32,33]. However, this work goes further to suggest that telemedicine *used in the context of an infectious disease* may be uniquely more favored by the clinical team than its past uses, which predominantly focused on connecting patients to remote providers. In the infectious disease setting, inpatient telemedicine provides both an additional layer of defense against an infectious pathogen and an opportunity to visually connect “face-to-face” (ie, without a mask) with vulnerable patients in need of care.

Inpatient Telemedicine Improvements Underway

Investigations to augment key aspects of the physical exam and others with a “remote hospital system,” such as a connected stethoscope, are ongoing in the institution. In addition, the institution is implementing solutions to the challenges around the patient–clinical team connection; ease of communication, particularly with the timeliness of incorporating interpreters, is in the process of being improved, following rapid feedback of these findings. These findings also point to the possibility of incorporating a calendar system for patients who are hospitalized who may see their schedules filled with procedures, specialist consults, and family conference calls. A series of remote but human connections throughout the day may ease reported feelings of patient isolation and simplify challenges related to multi-party scheduling.

Variance in Level of COVID-19 Exposure, by Role

While stakeholders perceived that inpatient telemedicine is effective in preventing COVID-19 exposure and reducing PPE use for most clinical team members, perceptions varied by role. Physicians, especially junior residents, reported having the lowest degree of in-room exposure, as attendings and senior residents conducted the majority of in-person assessments. In-room exposure was reportedly highest among the bedside nursing team who spent more time in the room, as their responsibilities shifted to include ancillary duties (eg, food delivery, linen changes, and respiratory care) that would have otherwise been conducted by the extended care team; their experience is consistent with those in other health systems and countries that have highlighted the critical roles nurses have played in the COVID-19 response [34]. The overall impact that telemedicine availability had on the number of times nurses entered a room was not clear from interviews: while nurses adapted to increased responsibilities, they also reported “batching” these activities to reduce PPE use. This shift in behavior is consistent with previously documented nursing responses in infection settings [35]. Overall, telemedicine seemed to magnify pre-existing discrepancies of time spent at the bedside between roles [36], with physicians spending less time at the bedside and nurses spending the same or more time at the bedside.

Literature suggests this major shift in clinical workflow may not be without cost. Nursing interruptions are dangerous and have been shown to compromise patient safety and quality of care, particularly around wrong medication or wrong dose [37-39]. In this academic setting, early learnings have facilitated conversations with operational, IT, and nursing leadership, and solutions to minimize nursing interruptions are actively being investigated. Any such solution must also consider nursing goals to optimize patient care and experience, as literature suggests that nurses may prefer to oversee who enters the patient room, even if virtually, to avoid disrupting the patient’s sleep or to optimize coordinated communication with family [40-42].

Need for Rapid Evaluation of Information Technology

Many have pointed out that for health care institutions to become learning health care systems, they must pair rapid innovation with rapid evaluation [43]. Perhaps this is nowhere more important than in the adaptation of IT during a pandemic. Stanford Health Care had previously developed a system for such rapid evaluation [44] and deployed it in real time as the system struggled to adapt to the strain of the influx of new COVID-19 cases. This allowed clinical managers to draw lessons quickly and fine-tune the socio-technological system to maximize patient quality and minimize infection risk. Other health care systems might employ similar techniques in implementing IT solutions.

These interviews with clinical stakeholders point to a set of key opportunities to improve inpatient telemedicine, including clinical team education, IT support and training during the transition phase, technical functionality around audio volume and video privacy, and remote access for staff. Recommendations for improved inpatient telemedicine use are outlined in Table 2.

Table 2. Recommendations for improved inpatient telemedicine use.

Opportunity for improvement	Recommendations
Information technology (IT) support and training	• Robust and locally available IT support staff to manage tablet maintenance, including charging and updating software, and to support the education of key end users • Technological onboarding for the extended care team should go beyond written instructions and include videos and real-time support
Increased technical functionality	• Camera and microphone functionalities in the patient room may be further optimized by relocating devices to the ceiling or wall, out of the way of bedside care • Remote direction change, zoom, and volume functionalities may reduce the currently reported need for nursing staff to enter the room to reposition and change tablet settings • Additional functionality focused on patient privacy may include a camera that clearly points away from the patient when it is not in use and incorporates a “knock knock” feature prior to automatic answer
Remote access for staff	• Remote inpatient telemedicine can increase patient-team connections and leverage a partially remote workforce by enabling the clinical team to check on patients from remote settings outside of the COVID-19 designated unit • National policies surrounding parity in reimbursement for telemedicine services and privacy laws that are still under debate in the United States will determine the feasibility of this recommendation

Limitations

This study was conducted within a single academic medical center undergoing operational changes in response to the COVID-19 pandemic, and learnings are, therefore, not generalizable to other institutions or time periods. The use of qualitative methods provided a more nuanced assessment of facilitators and barriers to inpatient telemedicine implementation and adoption; however, this study was limited by a small sample size representing each role, as the hospital appropriately restricted nonclinical staff on the COVID-19 unit of interest. While the evaluation team felt that thematic saturation for each population was attained, unexpected viewpoints from a broader population may have been missed. Additionally, though efforts were made to include patient voices in this evaluation, the authors were unable to complete a sufficient number of patient interviews to draw meaningful conclusions from this perspective. An exploration of the patient perspective and a quantitative analysis of inpatient telemedicine’s impact on patient outcomes are important areas of future work.

Conclusions

In this evaluation of an inpatient telemedicine system deployed as an infection control measure, attending and resident physicians and nurses reported virtual encounters as acceptable and effective in reducing COVID-19 exposure and PPE use for certain clinical team members. Additionally, the clinical team perceived quality of patient care to remain unchanged, though challenges were identified around the following: increased burden of technical implementation borne disproportionately by nurses, technology support, integration of remote extended care team members, patient–clinical team communication and connection, and conducting physical exams. Ongoing optimization of the technical and team workflow aspects of inpatient telemedicine is needed to deliver safe, effective care during the current and future pandemics.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured interview protocol.
[PDF File (Adobe PDF File), 47 KB - formative_v5i6e26452_app1.pdf]

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Abbreviations

IT: information technology
PPE: personal protective equipment
RE-AIM: reach, effectiveness, adoption, implementation, and maintenance

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Original Paper

Professionals' and Students' Perceived Needs for an Online Supportive Application for Reducing School Absence and Stimulating Reintegration: Concept Mapping Study

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Abstract

Background: To limit students' medical absenteeism and premature school dropout in the Netherlands, the Medical Advice for Sick-reported Students (MASS) intervention was developed to enhance collaboration between students, parents, school, and health care professionals. MASS reduces medical absenteeism. However, it does not yet optimally support professionals in monitoring students nor automatically stimulating students' autonomy regarding their situation.

Objective: This study aimed to identify professionals' and students' perceived need for an online supportive application to monitor and reduce absenteeism and stimulate student autonomy and school reintegration.

Methods: Concept mapping sessions were held with professionals (n=23) and secondary school students (n=27) in group meetings or online to identify their perspectives and needs. Multidimensional scaling and hierarchical clustering were done with Ariadne 3.0 software. The resulting concept maps were reclustered and interpreted by 4 researchers.

Results: Three heterogeneous groups of professionals generated 17 clusters (135 unique statements), with a mean importance rating ranging from 2.9 to 4.6 on a Likert scale with scores ranging from 1 to 5. Three heterogeneous groups of secondary school students generated 18 clusters (95 unique statements), with a mean importance rating ranging from 3.2 to 4.6. Professionals considered as most important the following: easily accessible contact with students; supporting, motivating, and rewarding students; monitoring absent students; providing information to students and their parents; exchanging information between professionals. Students considered as most important the following: better teacher-student communication and respect; communication between school professionals on the one hand and parents, other professionals, and students on the other hand; guidance in missed learning materials and tests. Students perceived an online format for support as the obvious option.

Conclusions: Both professionals and students were positive about an online application to support students in dealing with medical absenteeism, especially considering the need for better and easily accessible contact between students and professionals. An eHealth or mobile health (mHealth) application addressing these aspects could stimulate student autonomy and have positive effects on medical absenteeism.

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KEYWORDS

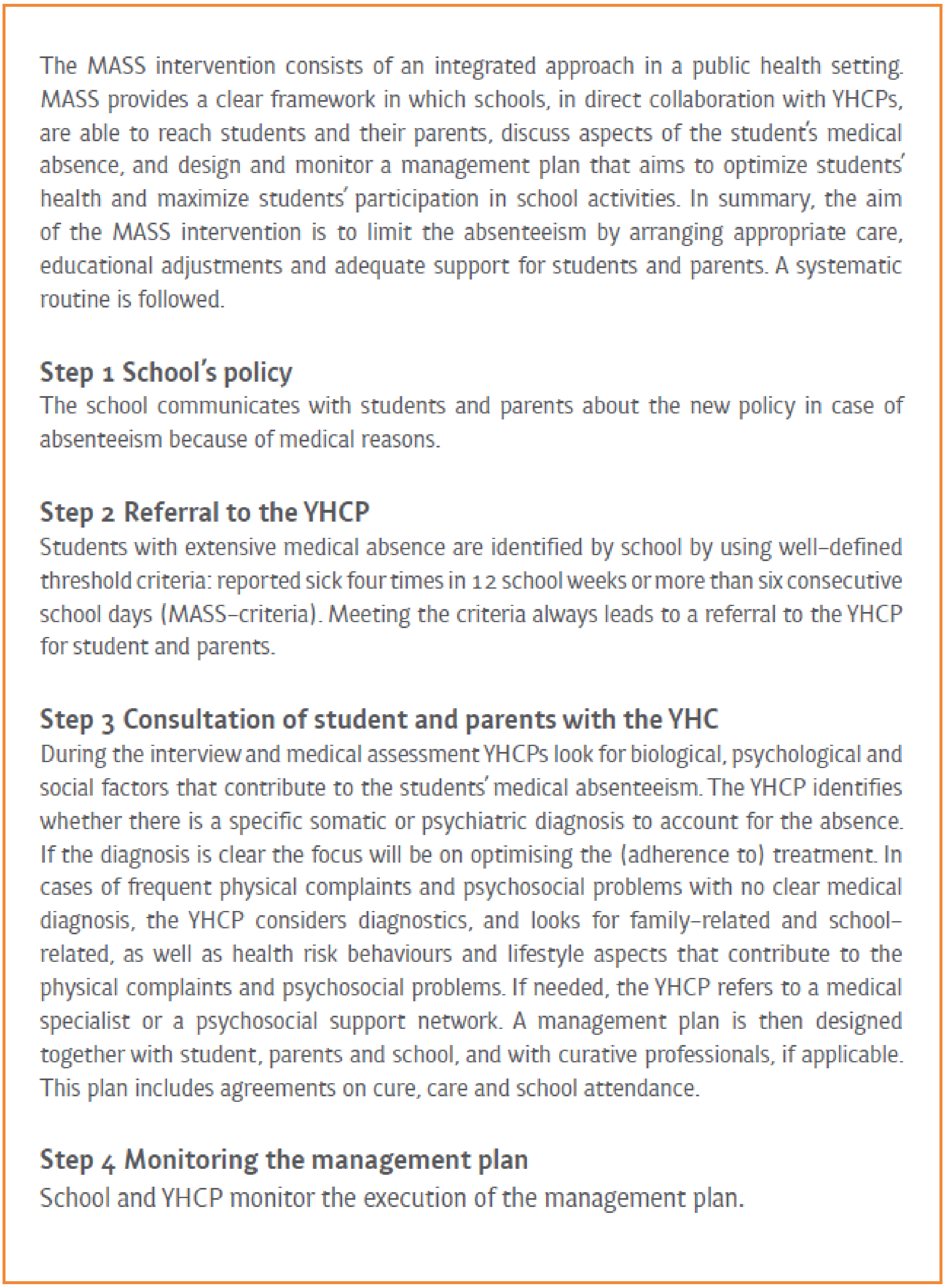
medical absenteeism; secondary education; eHealth; mHealth; mobile health; students; schools, health occupations; youth health physicians; concept mapping

Introduction

School absenteeism is a serious problem in many countries worldwide [1-3], including the Netherlands. Recent numbers show that, for example, in the United States, at least 13% of all students (5-18 years old) are chronically absent from school, involving both excused and unexcused absences as well as suspensions. In the Netherlands, no clear-cut definition of chronic absenteeism exists. Problematic absenteeism is defined as being absent from school for a minimum of 16 hours during a consecutive period of 4 weeks [4]. Recent numbers show that at least 5% of all students aged 5 to 18 years old is problematically absent from school [5,6]. However, this only involves unexcused absences and not absences because of illness or problems. Although Dutch schools are required to register both unexcused and excused absences, they only need to report chronic unexcused absences to the authorities [4]. Frequent and prolonged school absenteeism due to either unexcused or excused absences can have a significant impact on a student's life, for example leading to stagnation of a student's (learning) development, a lower education level, and even school dropout [7-10]. In the Netherlands, 2% of students attending secondary or vocational schools (12-23 years old) drop out prematurely, a number that is slowly increasing [5,6,11]. Successfully completing school and having a degree is important, as it will provide better employment opportunities, contributing to a better financial and living situation. Furthermore, people with a school diploma are less likely to exhibit delinquent behavior and more likely to continue studying and to live healthier and longer lives [12-18]. Subsequently, health outcomes can be improved by early diagnosis and management of specific physical and mental health problems associated with school absence [19] and by optimizing educational opportunities [20]. Therefore, school absenteeism and school dropout should be considered public health problems [13,15,16,18].

Behind excused school absenteeism there may be many reasons, medical absenteeism being one of them. Medical absenteeism refers to students reporting absent from school because of (a wide range of) health-related problems [1,12]. Exact numbers relating to medical absenteeism are unclear, as schools are not required to report these to the Dutch authorities. Multiple factors are involved in chronic absenteeism, and schools may differ in how they report absence [4,6,12]. However, a World Health Organization report from 2002 [21] showed that, in half of the school absenteeism cases in Dutch secondary schools, being ill was reported as the cause. Additionally, a national health monitor study with students in the second and fourth grades of secondary school showed that in 40% of absentee cases, students reported that this was because of illness, while truancy was reported in 11% of the cases [22]. This indicates that, in secondary school, medical absenteeism is a significant and prevalent type of absenteeism. However, in most countries, the approach to reducing school absenteeism primarily focuses on truancy. Nonetheless, integrated solutions are being developed such as the involvement of physicians and (public) health services [1,7,12]. In the Netherlands, an integrated approach to addressing medical absenteeism has been developed, namely the Medical Advice for Sick-reported Students (MASS) intervention [23,24] (see Figure 1 by Vanneste et al [25]). This intervention, as well as other school health care activities, is coordinated by the youth health care section of regional Public Health Services. The MASS intervention has dual purposes: (1) stimulating collaboration between professionals involved in the care of a medically absent student, in particular schools, youth health care, and the school attendance service, and (2) optimizing students' health, maximizing students' participation in school activities, and limiting school absenteeism for medical reasons [17,18,24,25].

Figure 1. Description of the Dutch intervention “Medical Advice for Sick-reported Students” (MASS) by Vanneste et al [25]. YHCP: youth health care provider.



The MASS intervention consists of an integrated approach in a public health setting. MASS provides a clear framework in which schools, in direct collaboration with YHCPs, are able to reach students and their parents, discuss aspects of the student's medical absence, and design and monitor a management plan that aims to optimize students' health and maximize students' participation in school activities. In summary, the aim of the MASS intervention is to limit the absenteeism by arranging appropriate care, educational adjustments and adequate support for students and parents. A systematic routine is followed.

Step 1 School's policy

The school communicates with students and parents about the new policy in case of absenteeism because of medical reasons.

Step 2 Referral to the YHCP

Students with extensive medical absence are identified by school by using well-defined threshold criteria: reported sick four times in 12 school weeks or more than six consecutive school days (MASS-criteria). Meeting the criteria always leads to a referral to the YHCP for student and parents.

Step 3 Consultation of student and parents with the YHC

During the interview and medical assessment YHCPs look for biological, psychological and social factors that contribute to the students' medical absenteeism. The YHCP identifies whether there is a specific somatic or psychiatric diagnosis to account for the absence. If the diagnosis is clear the focus will be on optimising the (adherence to) treatment. In cases of frequent physical complaints and psychosocial problems with no clear medical diagnosis, the YHCP considers diagnostics, and looks for family-related and school-related, as well as health risk behaviours and lifestyle aspects that contribute to the physical complaints and psychosocial problems. If needed, the YHCP refers to a medical specialist or a psychosocial support network. A management plan is then designed together with student, parents and school, and with curative professionals, if applicable. This plan includes agreements on cure, care and school attendance.

Step 4 Monitoring the management plan

School and YHCP monitor the execution of the management plan.

The MASS intervention shows promising effects regarding the reduction of absenteeism in secondary schools for medical reasons [25-27]. However, certain aspects of the intervention could still be further improved, for example, regarding the monitoring of students and stimulating students’ autonomy regarding their situation, as well as regarding the collaboration between professionals [28]. Many different professionals are involved in the MASS intervention and the care and support of students frequently absent from school. This makes collaboration and the alignment of efforts more complex, but also more necessary [29]. eHealth and particularly mobile health (mHealth) could be used to support communication and collaboration between all professionals involved [30,31]. Additionally, it could have beneficial effects for students. According to the European Commission, mHealth has a preventive function and adds value to patient-focused care [32]. mHealth has a broad reach, can be tailored, is easily accessible, appeals to a person's autonomy, and is relatively low in cost [28,30,33]. Furthermore, mHealth is considered a low threshold tool to access information, change behavior, and monitor and guide a person from a distance [28]. All these aspects would make eHealth or mHealth an appealing tool for both professionals and students to use as support in reducing school absenteeism and stimulating student autonomy, especially in the Netherlands, where over 93% of students use the internet daily [34]. Therefore, a supportive online application might be a helpful tool to complement the MASS intervention and enhance its effects regarding the reduction of school absenteeism and school dropout.

To develop a relevant and effective online application to complement the MASS intervention, it is key to first explore and take into account the perspectives and needs of the target population [35,36]: professionals in the field of school absenteeism and students. Therefore, our study focused on the following research questions:

1. What are the perspectives and needs of professionals involved in the care of an absent student concerning an online application aimed at reducing school absenteeism, stimulating student autonomy, and stimulating school reintegration?
2. What are the perspectives and needs of students concerning an online application aimed at reducing school absenteeism, stimulating student autonomy, and stimulating school reintegration?

Methods

Design

This study followed an exploratory descriptive design. To examine the perceptions of relevant stakeholders, the participatory research method of concept mapping was used [37,38]. Concept mapping has been widely applied in health care–related research for this purpose [39]. Concept mapping consists of 6 steps: (1) preparation, (2) generation of statements, (3) structuring of statements, (4) analysis and representation of statements in the form of a concept map, (5) interpretation of the maps, (6) utilization of maps. A qualitative method is used to collect group data (ie, perspectives/statements from the group) following an inductive and structured approach. Quantitative analysis is then used to generate a representation of the collected statements in the form of a concept map. To interpret the generated concept maps, qualitative analysis is used.

Recruitment of Participants

For our study, we recruited professionals involved in the care or support of absent students, as well as students currently attending secondary school. Concept mapping sessions were conducted with both target groups independently from each other to ensure that they could speak freely, as the hierarchy between students and professionals may affect the group dynamics and responses given. All concept mapping sessions were facilitated by CE and RB. Regarding both target groups, we aimed for a heterogeneous group of participants, to stimulate discussion and provide a more comprehensive and diverse range of perspectives. Participants for both target groups were recruited in the period of February 2018 and March 2018.

With the Public Health Service Flevoland (GGD Flevoland) as our base, we recruited professionals and students from the 2 largest cities in the Flevoland province: Almere (205,000 inhabitants) and Lelystad (77,000 inhabitants) [40].

Professionals

The professionals were selected through purposive sampling, aiming to include 30 professionals with diverse job functions from various organizations relevant to (medical) school absenteeism or the MASS intervention (eg, youth health care physicians, teachers, school care coordinators, remedial educationalists, other health professionals, and school attendance officers). All professionals were recruited by email. Follow-up telephone calls were conducted with those who were nonresponsive to the initial email.

Students

To recruit students, we first contacted secondary schools—varying in educational levels—located in Almere and Lelystad by email. Follow-up telephone calls were conducted with those that were nonresponsive to the initial email. Eventually, 3 secondary schools were willing to participate. Once a school agreed to participate, the school sent their students a pamphlet and information letter concerning our study. Participants were promised a gift voucher of €10 after completion of the data collection.

Ethics Approval

The study protocol did not need approval by a Medical Ethics Review Committee because it did not fall within the legal scope of medical research involving human subjects. All students received an informational letter, and written informed consent was obtained before participation. If a student was under the age of 16 years, a parent or caregiver received an informational letter concerning our study as well and had to cosign the informed consent form.

To ensure anonymity and privacy of the participants, personal data and informed consent forms were stored in a secured file only accessible by the researchers. Other data such as fieldnotes and online input per email during the concept mapping were de-identified, removing names and other identifying data if necessary. All data were stored and processed on a secured network drive at the university.

Concept Mapping Sessions

All sessions followed a similar structure, using the 6 steps involved in concept mapping. We organized 3 concept mapping sessions with professionals (maximum of 2 hours). The first 2 sessions were physical meetings, and the third one was conducted online. We also conducted 3 concept mapping sessions with students at the 3 school locations. However, with Hidding et al [41] as an example, the concept mapping sessions conducted with the students were split into 2 parts because their attention spans can be more limited than that of adults. The first part (1 hour) consisted of the generation of statements (step 2 of concept mapping). The second part (1 hour) consisted of the structuring of statements (step 3). Between the first and second part was an intermission of 1-3 weeks.

Step 1: Preparation

Participants were selected, and the focus statement was formulated. A focus statement is used as a starting point in order to stimulate participants to "free associate" and to generate as many perspectives or statements as possible. The focus statement for the professional sessions was: "How can you support young people who are frequently or long-term (medically) absent from school with the help of a digital tool?"

The focus statement for the student sessions was intentionally formulated more broadly in order to explore their overall supportive needs and not only their need for an online application. Additionally, to enhance the understanding of the student participants, the same focus statement was formulated in 2 ways: (1) "How do I want school to help me when I am frequently or long-term ill?" and (2) "When I am frequently or long-term ill, I want school to help me with …"

Step 2: Generation of Statements

Each concept mapping session started with an introduction to the topic and concept mapping. Then, participants were asked to respond to the focus statement and to generate as many statements as possible. Participants started with an individual brainstorm of approximately 10 minutes, after which they shared their responses in a group brainstorm. Participants were asked to share 1 statement at a time, after which the other participants could add something to this statement. In the online session (only with professionals), all the statements of the individual brainstorm were sent by email to the facilitators, who merged all the statements and subsequently shared all the statements with the group. Then, via email, participants could respond to the given statements and add new ones. Regarding all sessions, the final list of generated statements was reformulated, where necessary, by the session facilitators (CE and RB and discussed with MH and FS until consensus was reached) to keep the meaning of the statements clear and understandable for every participant.

Step 3: Structuring of Statements

The structuring of statements was conducted using the concept mapping software Ariadne 3.0 [42]. Participants first individually organized all statements generated in their session according to content, grouping statements into clusters of related statements. Subsequently, they each ranked the importance of all statements according to a 5-point Likert scale, where 1 represented "not important at all" and 5 represented "very important."

Step 4: Representation of Statements in the Form of a Concept Map

Using Ariadne 3.0, a graphical representation of the statements was created in the form of a concept map [39]. All statements are presented as separate points in the visual representation/concept map. Statements that are frequently placed together are similar in content and presented more closely together on the concept map, resulting in clusters. Statements that are seldomly placed together by the participants are placed on the map opposite from each other. The analyses were conducted separately for each concept mapping session.

Step 5: Interpretation of the Maps

The interpretation of the final concept maps, in which the clusters (ie, themes) are named and discussed, was done by 4 researchers (CE, RB, FS, and MH). Similarities between statements in every cluster were identified. The researchers named each cluster in the final concept maps by the overarching theme that it represented. Subsequently, the researchers critically contemplated the clusters generated by the software Ariadne 3.0, because some of the statements did not optimally suit a particular cluster. After deliberation and when consensus between the researchers was reached, some of the statements were moved to other clusters nearby, or new clusters were formed. Finally, using Ariadne 3.0, the average importance rates of the clusters were calculated to rank them from high to low.

Step 6: Utilization of Maps

The sixth and final concept mapping step, utilization of the maps, involves the identification of determinants that could be used for the development of a supportive mobile online application to complement the MASS intervention (see Discussion).

Statistical Analysis

The data from each concept mapping session were analyzed with the software program Ariadne 3.0 [42], which uses multivariate statistical techniques (multidimensional scaling and hierarchical clustering) to visually present statements generated in the group sessions. The analyses resulted in 1 concept map per session.

Results

Participants

Professionals

Overall, 23 professionals participated in our concept mapping sessions (Table 1). For the first session, 28 professionals were invited, of which 5 were able to participate. For the second session, 17 professionals were invited, of which 10 were able to participate. The third (online) session consisted of 8 professionals who were initially invited for the first or second session but could not participate earlier because of a busy work schedule. In this session, only 6 participants were involved with the clustering and prioritizing of the statements (step three of concept mapping), again because of a busy work schedule. The majority of our sample was female (n=21), ranging from 27 to 60 years old and with an average work experience with school absenteeism of 9 (SD 6.4) years. The participants were professionals with diverse functions in 7 organizations and 6 schools (see Multimedia Appendix 1 for an overview of the professionals' job functions).

Table 1. Sample characteristics of professionals (n=23).

Characteristic	n (%)
Gender	
Male	2 (9)
Female	21 (91)
Age group (years)	
21-30	4 (17)
31-40	6 (26)
41-50	8 (35)
51-60	5 (22)
Work experience with school absenteeism (years)	
<5	8 (35)
5-10	6 (26)
11-20	8 (35)
>20	1 (4)

Students

Overall, 27 students participated in our study (Table 2), ranging in age from 13 to 18 years old, with the majority being female (n=16). They attended 1 of the 3 participating secondary schools: (1) a special education school teaching at the general secondary level (n=7); (2) a regular school teaching at various educational levels (n=11); (3) a regular school teaching at the prevocational secondary level (n=9). The MASS criteria were met by 8 participants (see Figure 1, Step 2 [24,25]) of school absenteeism for medical reasons. Although 4 participants, of which 3 met the MASS criteria, were not able to attend the second part of the concept mapping session, 1 of them completed the session online.

Table 2. Sample characteristics of students (n=27).

Characteristic	n (%)
Gender	
Male	11 (40)
Female	16 (60)
Age (years)	
13	5 (18)
14	3 (11)
15	1 (4)
16	10 (37)
17	7 (26)
18	1 (4)
Educational level	
Pre-vocational secondary (Dutch: vmbo)	16 (59)
Higher general secondary (Dutch: havo)	7 (26)
Pre-university (Dutch: vwo)	3 (11)
Unknown	1 (4)
Special education (yes)	7 (26)
Meeting MASS[a] criteria (yes)	8 (30)

[a] MASS: Medical Advice for Sick-reported Students.

Concept Maps and Clusters

Professionals

Three heterogeneous groups of professionals generated 135 unique statements, with an importance rating ranging from 1.6 to 4.8 on the Likert scale with scores ranging from 1 to 5. These statements were combined into 17 clusters, with a mean importance rating ranging from 2.9 to 4.6 on the Likert scale with scores ranging from 1 to 5 (see Multimedia Appendix 2 for the corresponding concept maps). Table 3 presents the clusters relating to the perspectives and needs for a supportive tool in reducing school absenteeism mentioned by professionals. Important aspects as considered by professionals were (1) easily accessible contact with students; (2) supporting, motivating, and rewarding students; (3) monitoring absent students; (4) providing information to students and their parents; and (5) exchanging information between professionals.

Table 3. Clusters, associated example statements, and mean importance ratings per group concerning the perspectives and needs of professionals for a supportive tool in reducing school absenteeism.

Cluster name	Example statement	Mean importance[a]
Group 1		
1. Contact from (school) professional to student	An extra function for mentors to get in contact with the students	4.6
2. Reward system	A reward system when showing desired behavior	4.2
3. Contact from student to (school) professional	The possibility for students to have easily accessible contact with the outside world	3.8
4. Characteristics and functions of the application	User-friendly for all school levels	3.7
5. Exchange information between professionals	An overview of concerned parties to improve the collaboration between professionals	3.5
6. Responsibilities of involved youth health care professionals	Help from the youth health care nurse during start-up for students to use the application	3.2
7. Inform students and parents about school absenteeism	To provide information about the consequences of school absenteeism, including appropriate tools	3.2
Group 2		
1. Dossier access for professionals	Access to the student's dossier so all involved parties can add supplemental information	4.1
2. Contact with students and other features of the application	Direct lines with the students to make them feel noticed	3.7
3. Monitor absent students	A system to map the (absenteeism) developments of the students	3.7
4. A separate account for parents	A notification for parents about their child's school absenteeism	3.2
5. Provide information and an overview of professionals involved	An overview for students to understand precisely what is and is not a legitimate reason for school absenteeism	2.9
Group 3		
1. Contact between (school) professionals and students	Daily or more frequent contact with students who are absent	4.3
2. Support and motivate students	Inclusion of self-set goals by the students in the tool, with indicators if they are achieved or not	3.7
3. Responsibilities of schools and other professionals	Prevent students from long-term absenteeism by supporting them in formulating their action plan and goals	3.5
4. Provide information and monitor absenteeism	To provide students with advice, tailored to their problems, such as problems with eating, sleeping, gaming, or mood swings	3.5
5. Involve parents and professionals	Support and unburden parents using the tool	3.1

[a] Rated on a 5-point Likert scale with higher scores indicating higher importance.

The first aspect, easily accessible contact with students, refers to the professionals' reported need for a supportive online tool to be able to communicate and stay in contact with absent students in an easy and low-threshold way. Professionals expressed the belief that students should receive attention and support in an approachable and informal manner. Additionally, the application design should be appealing for and tailored to the target group of students.

The second, third, and fourth aspects (supporting, motivating, and rewarding students; monitoring absent students; and providing information to students and their parents, respectively) were closely related to each other, with all emphasizing the importance of adequately supporting, motivating, and monitoring students. Professionals expressed the importance of working with personal goals and a reward system when students show the behavior that brings them closer to their personal goals, for example, when they are present at school or doing schoolwork at home. Additionally, suggestions were made to add a game or reward element to motivate students to work on their goals and to continue using the tool. The ability to monitor students using a supportive tool would provide professionals with more insight into the frequency of school absenteeism and to what extent absent students experience physical and psychological symptoms. In addition, professionals mentioned a preference for a separate account for parents, enabling them to support their child with working on their goals, after their child gave permission. Furthermore, professionals expressed a need to provide information to both students and parents through an online tool, especially about the causes and consequences of school absenteeism and how to deal with common health and learning issues in general.

The fifth aspect, exchanging information between professionals, refers to professionals wanting to know which other care organizations or professionals are involved with a student and to be able to share relevant information with them—in a secure manner and with the student’s informed consent—in order to improve collaboration and support for the student. The suggestion was to use the online tool to provide an overview and contact details of the professionals involved.

Students

Three heterogeneous groups of secondary school students generated 95 unique statements, with an importance rating ranging from 2.2 to 4.9 on the Likert scale with scores ranging from 1 to 5. These statements were combined into 18 clusters, with a mean importance rating ranging from 3.2 to 4.6 on the Likert scale with scores ranging from 1 to 5 (see Multimedia Appendix 3 for the corresponding concept maps). Table 4 presents the clusters relating to the perspectives and needs for a supportive tool in reducing school absenteeism mentioned by students. Important aspects as considered by students were (1) respect and better teacher-student communication; (2) communication between school on the one hand and parents, professionals, and students on the other hand; and (3) guidance for missed learning materials and tests. They perceived an online format as a supportive tool as undoubtedly the obvious option.

Table 4. Clusters, associated example statements, and mean importance ratings per group concerning the perspectives and needs of students for a supportive tool in reducing school absenteeism.

Cluster name	Example statement	Mean importance[a]
Group 1		
1. Training teachers	Training teachers to support students in returning to school	4.2
2. Counsellor	You should get along with your counsellor	3.8
3. Information for parents	Overview for parents of when their child has to go and does not have to go to school	3.6
4. Dossier	Information in the dossier is confidential and well-protected	3.6
5. Missed learning materials and tests	Review of missed learning materials provided by school	3.4
6. Contact between teachers and students	Teachers are better informed on what is going on with the student	3.2
7. Independent case management	Improve and expedite the communication between school and attendance officer	3.2
Group 2		
1. Communication and respect	Equal rights and rules for students and teachers	4.6
2. Registration of medical absence	Easier logging in and out	4.4
3. Schedule	Access to correct school schedule	4.4
4. Overview of missed learning materials	Online summary of missed learning materials available	4.2
5. Alleviating the rules on absenteeism	Maintaining the opportunity to do a makeup test when you missed a test due to illness	4.1
6. Preparations for a test	Having the option to review a test before the next one to be able to prepare better	3.9
7. Communication during absenteeism	Weekly check-in by school how the absent student is doing	3.6
Group 3		
1. Keeping up with learning materials and more fun classes	More fun classes help to pay attention and to return to school	4.0
2. Respect and rules on absenteeism	Teachers have to treat students respectfully	3.8
3. Online features	One working app that displays the schedule, homework, grades, and missed information	3.6
4. Makeup tests	Offering makeup tests for a longer period of time	3.2

[a] Rated on a 5-point Likert scale with higher scores indicating higher importance.

The first 2 aspects (respect and better teacher-student communication; communication between school on the one hand and parents, professionals, and students on the other hand) refer to students' reported need for teachers to be better informed about a student's situation and well-being and to improve communication between all parties involved (ie, school, students, parents, other professionals). Students expressed a desire for equal rights, rules, and respect between teachers and themselves and a preference to be able to ask their teacher questions through an easily accessible (online) tool. Students also believed that schools should ask in-depth questions about their reason for their absence and expressed a need for earlier communication by the school regarding a possible change in their schedule.

The third aspect (guidance for missed learning materials and tests) refers to students' expressed need for an overview of the missed learning materials and a main contact person from which to receive relevant notes, learning materials, and homework. Additionally, students expressed a desire for take-home tests and an extension of the period to take tests that they missed. The fourth aspect (online support as obvious) refers to the students' preferred supporting format, namely online. Students mentioned that one comprehensive application is necessary, providing them access to their schedule, homework, grades, and (missed) learning materials. They also discussed the need for a forum where they can post questions to their peers and teachers.

Discussion

Principal Findings

Both professionals and students expressed positive perceptions and identified added value regarding an online application to support students in dealing with school absenteeism for medical reasons and to stimulate student autonomy and return to school. The most important aspects of a supportive eHealth or mHealth application as considered by professionals were easily accessible contact with students; supporting, motivating, and rewarding students; monitoring absent students; providing information to students and their parents; and exchanging information between professionals. The most important aspects as considered by students were better teacher-student communication and respect; communication between school on the one hand and parents, professionals, and students on the other hand; and guidance for missed learning materials and tests. Furthermore, students perceived an online format as a supportive tool as undoubtedly the obvious and self-evident option.

A shared need among professionals and students in our study was the fostering of better and easily accessible contact between students, parents, and professionals involved, preferably using online facilities. Previous research on the needs of health care professionals relating to patient care and the use of eHealth or mHealth also found easily accessible contact to be an important need [35,43]. Additionally, studies reviewing the impact of mHealth interventions worldwide reported that the use of mHealth can improve communication with and between health care professionals [30,44]. Furthermore, previous research within the context of school absenteeism and dropout also confirms the importance of easily accessible contact between students, parents, and professionals. Positive teacher-student contact contributes to students feeling supported, empowered, and engaged in school, as well as a reduction of school absenteeism [45-48]. e-Learning and other online tools can facilitate establishing this contact and related benefits [49,50]. In addition, better communication between schools and parents contributes to parental involvement, which has shown to be beneficial to students' school engagement and reduced absenteeism [46,51,52]. The benefits of better and easily accessible contact between all parties involved relate to the monitoring, supporting, motivating, and guiding of students in general, which are all aspects of a supportive online application considered important by professionals and or students in our study.

The importance of easily accessible contact is also supported by research on occupational health [53-55], which appears to have relevant similarities to the context of school absenteeism. From the occupational health research, it is known that keeping in touch with medically absent workers on a regular basis and providing supervisor or co-worker support helps with the return to work or being able to continue working when chronically ill [53]. Additionally, these studies have shown that it is beneficial for the absent worker to discuss returning to work with their employer and to receive information on the recovery process as well as on sick leave procedures. Also, if necessary, an occupational health physician will be involved [54,55]. For an absent worker, it is just as essential as it is for students that contact and communication between all parties involved is done with respect, taking the perspective of the absentee as a starting point [53,55].

The perceptions and needs expressed by professionals and students in our study relate to key elements of the MASS intervention, particularly communication, motivation, individual monitoring/guidance, early detection of absence, and professional collaboration [24-27], with the addition of incorporating online facilities. The MASS intervention is promising in reducing medical absenteeism in secondary schools [25-27], but aspects such as the monitoring of students, stimulating students' autonomy, and collaboration between professionals could be further improved [28]. The findings from our study indicate that these specific aspects could be addressed with the use of an online application, which is supported by many previous studies showing eHealth or mHealth and online tools to have an empowering and facilitating effect [28,30-33,50,56-59]. Therefore, developing an online application complementary to the MASS intervention could potentially stimulate and enhance the intervention's positive effects on school absenteeism, especially when the online application can be tailored to students' unique sets of reasons behind their absenteeism and their individual needs [45].

Strengths and Limitations

To our knowledge, this is the first study to apply concept mapping to examine professionals' and students' perspectives regarding (medical) school absenteeism as well as the use of an online tool. Our study has several strengths. First, our study samples of professionals and students were relatively heterogeneous (differing in age, education level, experience with school absenteeism, school location, organization, job function, and work experience), increasing the generalizability of our findings. Second, combining individual generation of ideas with a group discussion of these ideas, as well as the context of heterogeneous groups, results in an ample and diverse selection of ideas, thoughts, and perceptions. Third, the concept mapping method has the added value of structuring qualitative data in a quantitative manner and visualizing the results.

Our study also has some limitations. First, generalizability could be affected because we only included participants from 1 of 12 Dutch provinces and most student participants were not randomly selected by their school. Also, professionals with—or experiencing—a heavier workload may have been underrepresented, as a busy work schedule was the most common reason not to participate. Additionally, the sample sizes of 2 of the professional concept mapping sessions were smaller than the recommended minimum number of 8 participants [42]. However, other studies using smaller sample sizes have been successful in applying the concept mapping method [60,61]. Furthermore, the online format used with the third group of professionals resulted in less interaction between professionals compared to the physical group meetings, potentially restricting the generation of new ideas. Nevertheless, this online concept mapping session generated the most statements of all sessions with professionals. It is possible data saturation regarding the professionals' perspectives has not been reached, although the themes generated in both the online and physical sessions were similar to each other. Due to time restrictions as well as the busy schedules of professionals, an additional concept mapping session was not feasible within our current study. Data saturation regarding the students' perspectives does appear to have been reached, as only one new theme emerged during the third concept mapping session with students.

Future Activities

The sixth and final concept mapping step, utilization of the maps, was not conducted in this study. However, the development of an actual online application, in which the perspectives of both professionals and students will be included, was already planned. The interpretation of clusters and concept maps generated in our current study proved helpful in deciding which statements or themes to include in the development of the online application. A selection of these themes will be translated into functionalities for a pilot version of the application that will be tested and evaluated with professionals and students from more cities and provinces than in our current study. We consider the online application development a co-creation process, collaborating with relevant stakeholders from needs assessment to development, testing, and (effect) evaluation [62,63].

Conclusion

Both professionals and students were positive about an online application to support students in dealing with school absenteeism for medical reasons and to stimulate student autonomy and return to school. Better and easily accessible contact between students, parents, and professionals was a shared need for which an online tool is highly suited. Developing an online application to be used complementary to the MASS intervention could potentially stimulate and enhance the intervention's positive effects on school absenteeism.

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Authors' Contributions

MH conceptualized the study, with the assistance of FS. RB and CE executed the concept mapping study, under the supervision of MH and FS. RB, CE, MH, and FS analyzed and interpreted the data. LD and MH wrote the first draft of the paper. All authors critically reviewed the manuscript and provided suggestions. MH finalized the manuscript. All authors have read and approved the final version of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Overview of professionals' job functions (total N=23).
[DOCX File , 15 KB - formative_v5i6e24659_app1.docx]

Multimedia Appendix 2
Concept maps of the sessions with professionals.
[DOCX File , 1112 KB - formative_v5i6e24659_app2.docx]

Multimedia Appendix 3
Concept maps of the sessions with students.
[DOCX File , 154 KB - formative_v5i6e24659_app3.docx]

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Abbreviations

MASS: Medical Advice for Sick-reported Students
mHealth: mobile health

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Original Paper

Modeling the Implementation Context of a Telemedicine Service: Work Domain Analysis in a Surgical Setting

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Abstract

Background: A telemedicine service enabling remote surgical consultation had shown promising results. When the service was to be scaled up, it was unclear how contextual variations among different clinical sites could affect the clinical outcomes and implementation of the service. It is generally recognized that contextual factors and work system complexities affect the implementation and outcomes of telemedicine. However, it is methodologically challenging to account for context in complex health care settings. We conducted a work domain analysis (WDA), an engineering method for modeling and analyzing complex work environments, to investigate and represent contextual influences when a telemedicine service was to be scaled up to multiple hospitals.

Objective: We wanted to systematically characterize the implementation contexts at the clinics participating in the scale-up process. Conducting a WDA would allow us to identify, in a systematic manner, the functional constraints that shape clinical work at the implementation sites and set the sites apart. The findings could then be valuable for informed implementation and assessment of the telemedicine service.

Methods: We conducted observations and semistructured interviews with a variety of stakeholders. Thematic analysis was guided by concepts derived from the WDA framework. We identified objects, functions, priorities, and values that shape clinical procedures. An iterative "discovery and modeling" approach allowed us to first focus on one clinic and then readjust the scope as our understanding of the work systems deepened.

Results: We characterized three sets of constraints (ie, facets) in the domain: the treatment facet, administrative facet (providing resources for procedures), and development facet (training, quality improvement, and research). The constraints included medical equipment affecting treatment options; administrative processes affecting access to staff and facilities; values and priorities affecting assessments during endoscopic retrograde cholangiopancreatography; and resources for conducting the procedure.

Conclusions: The surgical work system is embedded in multiple sets of constraints that can be modeled as facets of the system. We found variations between the implementation sites that might interact negatively with the telemedicine service. However, there may be enough motivation and resources to overcome these initial disruptions given that values and priorities are shared across the sites. Contrasting the development facets at different sites highlighted the differences in resources for training and research. In some cases, this could indicate a risk that organizational demands for efficiency and effectiveness might be prioritized over the long-term outcomes provided by the telemedicine service, or a reduced willingness or ability to accept a service that is not yet fully developed or adapted. WDA proved effective in representing and analyzing these complex clinical contexts in the face of technological change. The models serve as examples of how to analyze and represent a complex sociotechnical context during telemedicine design, implementation, and assessment.

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KEYWORDS

telemedicine; telementoring; implementation context; surgical guidance; health technology; usability; work domain analysis; cognitive work analysis

Introduction

This paper focuses on a successfully trialed telemedicine service for remote surgical guidance [1] that was to be scaled up to four additional hospitals and clinically evaluated. However, there were many technical, social, and organizational differences between the participating clinics, and indications that the acceptance of teleguidance varied [2]. We wanted to account for the implementation context by conducting a work domain analysis (WDA) to systematically investigate what set the sites apart and identify the factors that might come to affect the implementation and clinical outcomes of the telemedicine service [3-5].

Background

Health technology innovations that appear successful in one setting can produce different outcomes in another context. This may contribute to variability in clinical outcomes and cause failure to scale. There is growing recognition that the complexity of health care presents challenges for evaluating new health information technology (IT) [6] and that high-quality design and evaluation requires considering the context in which new technologies will be used. This paper focuses on systematically charting the implementation context for a telemedicine service for surgical consultation.

The telemedicine service was a practitioner-to-practitioner videoconferencing system designed to enable remote surgical guidance in endoscopic retrograde cholangiopancreatography (ERCP), a technically advanced procedure for biliary and pancreatic disease. The telemedicine innovation, called teleguidance, was successfully trialed through collaboration between a high-volume clinic at a university hospital and a low-volume regional clinic, and health economic modeling demonstrated positive quality impacts [7]. Teleguidance was subsequently scaled up to four additional hospitals and clinically evaluated.

However, there were many technical, social, and organizational differences between the clinics participating in the scale-up process, along with indications that acceptance toward telemedicine services varied among practitioners [2]. This raised concerns about how to successfully implement the service and understand the outcomes. It was unknown if and how contextual variations might affect clinical outcomes or whether telemedicine might interact with daily ERCP work in ways that might affect the implementation and use of teleguidance over time.

Therefore, we wanted to identify important contextual issues to be considered when evaluating the implementation and clinical outcomes by first focusing on factors that shape regular ERCP “work as done” [8] at the teleguidance implementation sites. This required a method that could accommodate the complexity of the clinical work systems [9,10]. Methodological concerns about the implementation context, complexity, and the scope of the analysis are discussed in detail in a related paper [11].

Cognitive Systems Engineering

Cognitive systems engineering [3,12,13] is a systems design discipline for complex settings; it emphasizes that the design and evaluation of technologies must be based on knowledge about the real-world context of their use [14]. Cognitive work analysis (CWA) [3,4] is a set of methods driven by systems theory, where work systems are viewed as fields of practice in which the agents, artifacts, and external world interact to produce outcomes [15]. This set of methods has been used for design and evaluation in a range of sociotechnical systems, including health care [16].

WDA Method

The first level of analysis in CWA is WDA. WDA is typically performed to provide representations of a complex work setting in the face of technological change (eg, during the design requirements and specification phase, or acquisition evaluation) [5]. This method has proved valuable in the design and evaluation of health technology [17], in the definition of health care team requirements [18,19], and in patient safety work [20].

WDA explicitly focuses on contextual factors by modeling the terms and conditions that shape work in functional terms. WDA provides compact representations that can support systematic investigations of how new technology impacts the overall domain purposes [21] in settings with large variability in behaviors and events as well as during system change [22].

Objectives

Our aim was to identify intrinsic constraints that shape ERCP work from a clinician’s perspective, ranging from physical objects to processes and priorities that affect regular work. A broad WDA would provide a systematic description of the factors shaping regular ERCP work at one hospital, including the macroscopic, mesoscopic, and microscopic levels of the system [23], which are commonly analyzed and represented separately [24]. The graphical format would be useful to contrast the work systems where teleguidance is to be implemented and proactively identify how the telemedicine service might interact with work at the different sites.

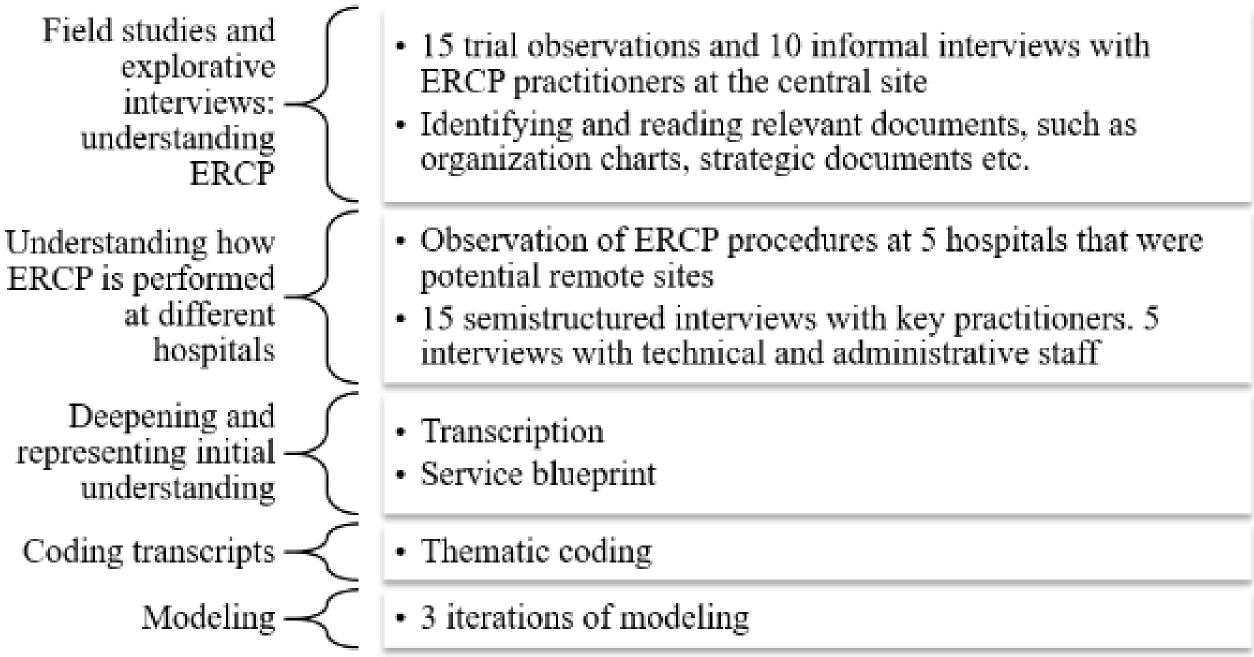
The *Methods* section describes how we modeled daily ERCP work as a work system involving physical components, processes, and goals and intentions, and how this allowed us to contrast the implementation contexts at the hospitals involved and reflect upon how teleguidance might interact with the work systems.

Methods

Data Collection

An ethnographical approach was used, with extensive field work conducted to collect data and generate a deep understanding of the context in a work system [25]. This included three iterations of data collection using a sequence of techniques, moving from a general “rough” level of description to a finer understanding, as Figure 1 shows.

Figure 1. Phases in data collection, analysis, and modeling.



The focus during the first round of observations and interviews was on the practical aspects of ERCP work, namely identifying everyday work practices, including tradeoffs and challenges encountered by the staff. The aim was to understand the ERCP procedure itself, roles of different stakeholders, and details about the clinical work from the perspective of the ERCP staff. We also read the clinical decision support and strategic documents and spoke to practitioners with administrative and management roles to gain an understanding of the organizational issues shaping the clinical work.

After these steps, a service blueprint [26] was developed as an intermediate, shared representation to externalize our understanding of the different phases of regular work practices and tasks during each phase (see Multimedia Appendix 1, which is in Swedish). The service blueprints were used as a resource to support discussions with practitioners and help compare work practices at the different hospitals.

The second phase of data collection included designing a protocol for semistructured interviews focusing on the details of regular ERCP practices (see Multimedia Appendix 2) and conducting a series of interviews with physicians, nurses, and technical and administrative staff at each of the four remote participant sites. Observations of the work practices, such as how surgery was prepared and conducted at each site, were documented as field notes, and the surgical facilities at the remote sites were documented as images to obtain details regarding the layout and medical equipment available in the operating theaters.

Analysis

All interviews were recorded and transcribed. The coding work was mainly performed by the first author, with support from the second author. We conducted thematic analyses [27] to identify the constraints mentioned in the interviews; the initial codes were generated by grouping and naming interesting or repeated findings, such as the patterns of activities or the mention of challenges in the work environment or during ERCP. We used the prompts derived from the WDA framework to link our findings to a priori identified themes in line with the abstraction levels suggested by Naikar [5](see Multimedia Appendix 3).

Modeling

One of the common WDA representations is the abstraction hierarchy (AH). The AH matrix is a way of modeling the work domain, and it shows means-ends relationships among constraints (eg, how a physical object serves or interferes with system objectives).

The AH can be used as a tool to trace how introducing new technologies and work processes can interact with numerous aspects of work [28]. The AH was constructed using Naikar’s method [5] as the main resource, together with feedback from three domain experts, two ERCP surgeons and one project manager.

The modeling focused on the ERCP team subsystem, and these cells were populated at the highest level of detail in the AH matrices.

Suggestions regarding system decomposition and populating the cells of the AH were developed through multiple iterations, and the details are available elsewhere [11].

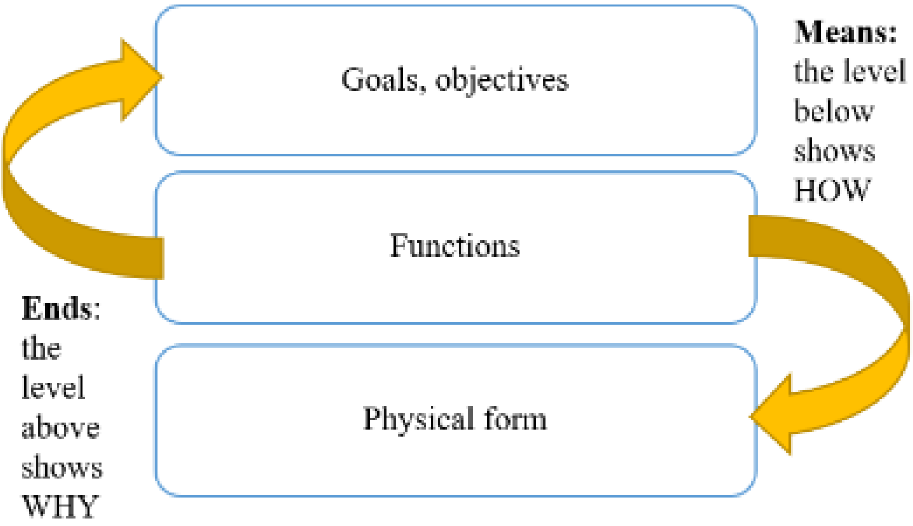
We worked through several versions of the work system decomposition, identifying systems and subsystems within the hospital organization. We found that the open nature of the hospital systems and constant reorganization made it difficult to define a detailed hierarchical decomposition that would contribute to the analysis. Moreover, after three modeling iterations, we found a satisfactory way to represent the domain as three functional facets: treatment, development, and administration.

These facets are sets of constraints distinguished by the nature of the tasks, competencies, and roles. Individuals can have multiple roles and be involved with several facets, as is the case with senior physicians and nurses who may perform clinical, managerial, research, or teaching/mentoring functions.

Exploring Interactions Among Constraints

Considering the individual nodes in the AH and tracing the means-ends links to the levels above and below (Figure 2), the models were used as a tool to verify our understanding of how ERCP is currently performed and further explore possible interactions and system changes when teleguidance is introduced.

Figure 2. How the means-ends structure of an abstraction hierarchy can support the investigation of interactions in a work system.



The purpose of these exercises was to elicit new insights about the implementation of teleguidance and determine whether the models provided a representation that different stakeholders could relate to.

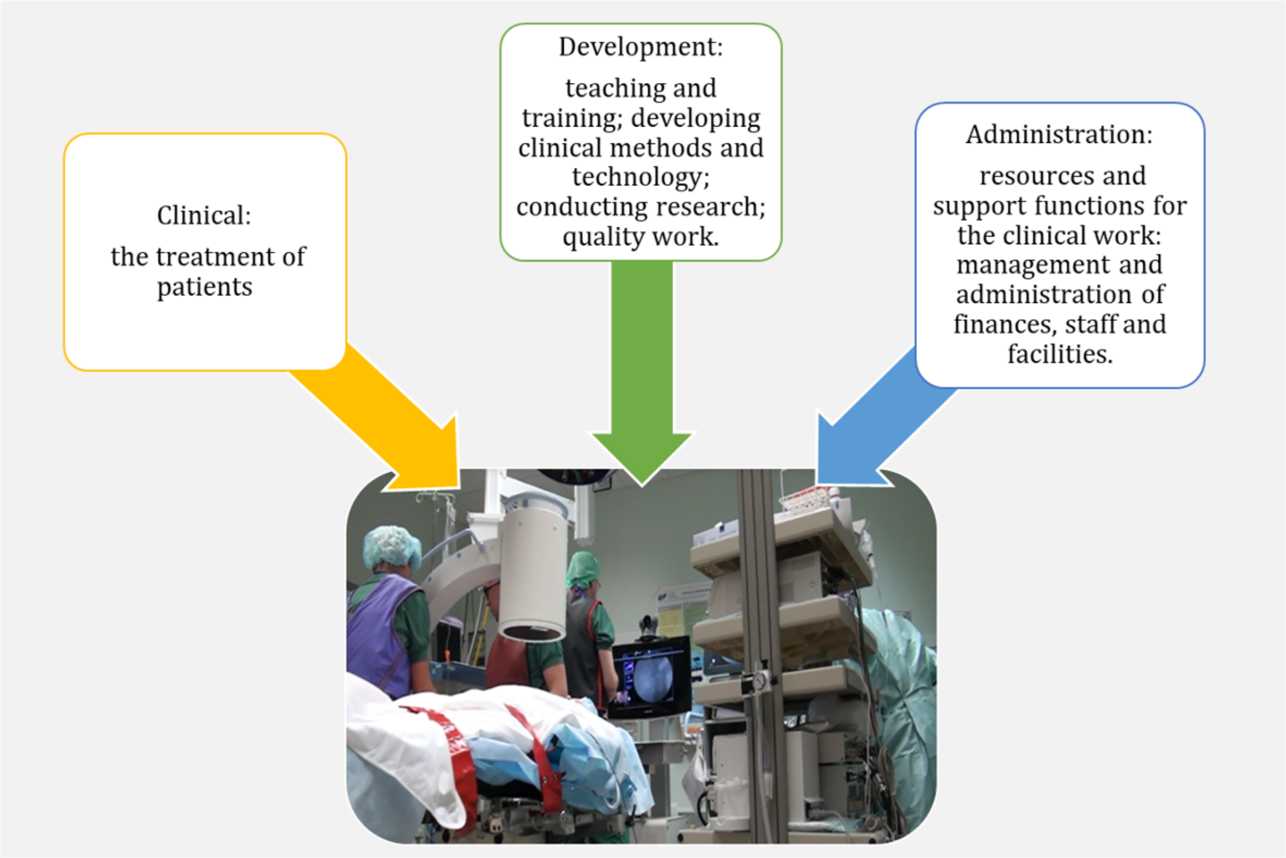
Results

Multiple Models

Owing to the open nature of the work systems, the scope of our analysis was very wide and deep; we identified many causal (physical) and intentional constraints (goals, priorities, etc). Some constraints were conflicting, such as policies that might cause tradeoffs between clinical performance and economic efficiency.

The complexity of the context was difficult to incorporate within a single AH, and we resolved this by modeling three sets of constraints affecting ERCP procedures, namely the clinical, administrative, and development facets of the domain, as Figure 3 shows.

Figure 3. Three sets of constraints shaping daily endoscopic retrograde cholangiopancreatography work.

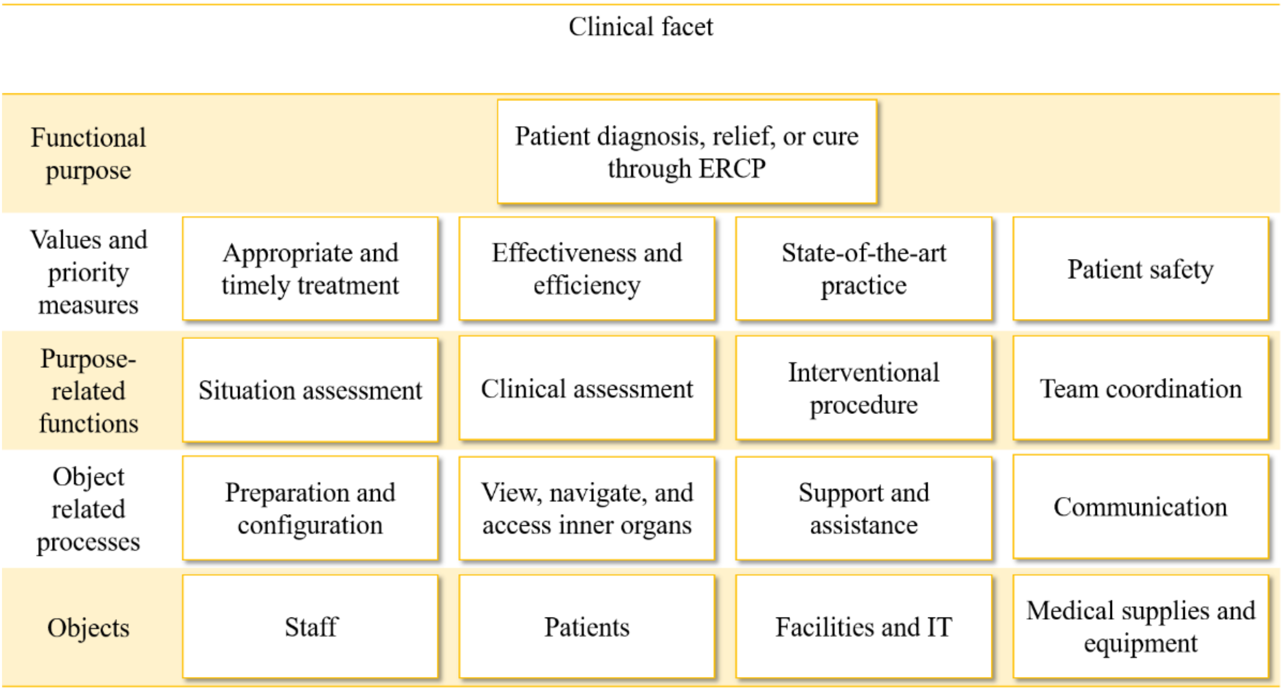


In the following sections, we present the AHs, which were aggregated to increase legibility, and representative examples of constraints; we describe how these can vary between the implementation sites and how the constraints may interact with teleguidance. The clinical facet is described in greater detail than the development and administration facets.

The Clinical Facet

The clinical facet (Figure 4) represents the constraints that shape the ERCP team's work in terms of the functional purpose, namely "patient diagnosis, relief, or cure through ERCP." The physical entities are the ERCP team members, patients, medical facilities, and medical equipment.

Figure 4. Abstraction hierarchy, clinical facet.



Clinical facet

Functional purpose	Patient diagnosis, relief, or cure through ERCP			
Values and priority measures	Appropriate and timely treatment	Effectiveness and efficiency	State-of-the-art practice	Patient safety
Purpose-related functions	Situation assessment	Clinical assessment	Interventional procedure	Team coordination
Object related processes	Preparation and configuration	View, navigate, and access inner organs	Support and assistance	Communication
Objects	Staff	Patients	Facilities and IT	Medical supplies and equipment

The set of possible clinical actions during an ERCP session is largely determined by causal constraints such as the patient's condition, staff competencies, and capabilities and limitations of the available technology and devices. Teleguidance introduced new physical equipment and staff to the ERCP team, providing new affordances and constraints that propagate throughout the clinical facet.

Constraints were represented in considerably higher detail during modeling. Multimedia Appendix 4 shows a cropped image of a detailed model of the clinical facet.

Values and Priority Measures

The values and priority measures show the criteria that must be respected for the clinical facet to achieve its functional purposes and those guiding decision-making and tradeoffs during procedures (eg, between patient safety and quality on the one hand, and efficiency on the other hand).

We visualized four values and priority measures: appropriate and timely treatment; effectiveness and efficiency; state-of-the-art practice; and patient safety (see Multimedia Appendix 5).

Multimedia Appendix 6 shows an example of how "appropriateness," a value/priority constraint, differs among hospitals, and how this might interact with teleguidance. Textbox 1 shows an example transcript regarding findings linked to the abstracted constraint "appropriateness."

Textbox 1. Sample transcript showing value and priority measures: appropriate treatment.

Appropriate treatment

"Yes, it is more dangerous with PTC* than ERCP, even though ERCP can be dangerous and risky. But I have noticed it all over the country so there are still ideas about PTC and if you are not as skilled at ERCP then it often happens that you do them."

"We have shown it, the more skilled we become at ERCP the fewer the PTCs will be. Provided the indications are the same. But in the past people were allowed to die in icterus. And that's not so very long ago. And it may not be so... if you have a huge spread of cancer, then maybe you should ask yourself how far to drive this? The oncologists are happy to push for it only if there is a small snippet left to live, to try an option. But we still have to consider, I want to do that, what do we want, what is the goal of this activity? After all, the person will die within a month or so anyhow… maybe it's not that bad to die of icterus instead of drying out emaciation, pain everywhere."

*Percutaneous transhepatic cholangiography and drainage

Purpose-Related Functions

The purpose-related functions represent the general functions that the ERCP work system must fulfill to achieve its functional purpose.

We defined four main functions: situation assessment, clinical assessment, interventional procedure, and team coordination (see Multimedia Appendix 7).

Multimedia Appendix 8 illustrates how this constraint shapes work, how it can vary between sites, and how it might interact with teleguidance.

Object-Related Processes

The object-related processes level represents the functional capabilities of physical objects, namely the use of physical objects, and their properties and affordances.

We defined four main object-related processes: preparation and configuration; view, navigate, and access inner organs; support and assistance; and communication (see Multimedia Appendix 9).

Multimedia Appendix 10 provides an example of the constraint "preparation and configuration."

Physical Objects

The physical objects level shows objects that afford functional capabilities to the system. Causal constraints such as patient conditions, staff availability and competencies, and the capabilities and limitations of the technology and devices in an ERCP clinic constrain the set of possible clinical actions during an ERCP session.

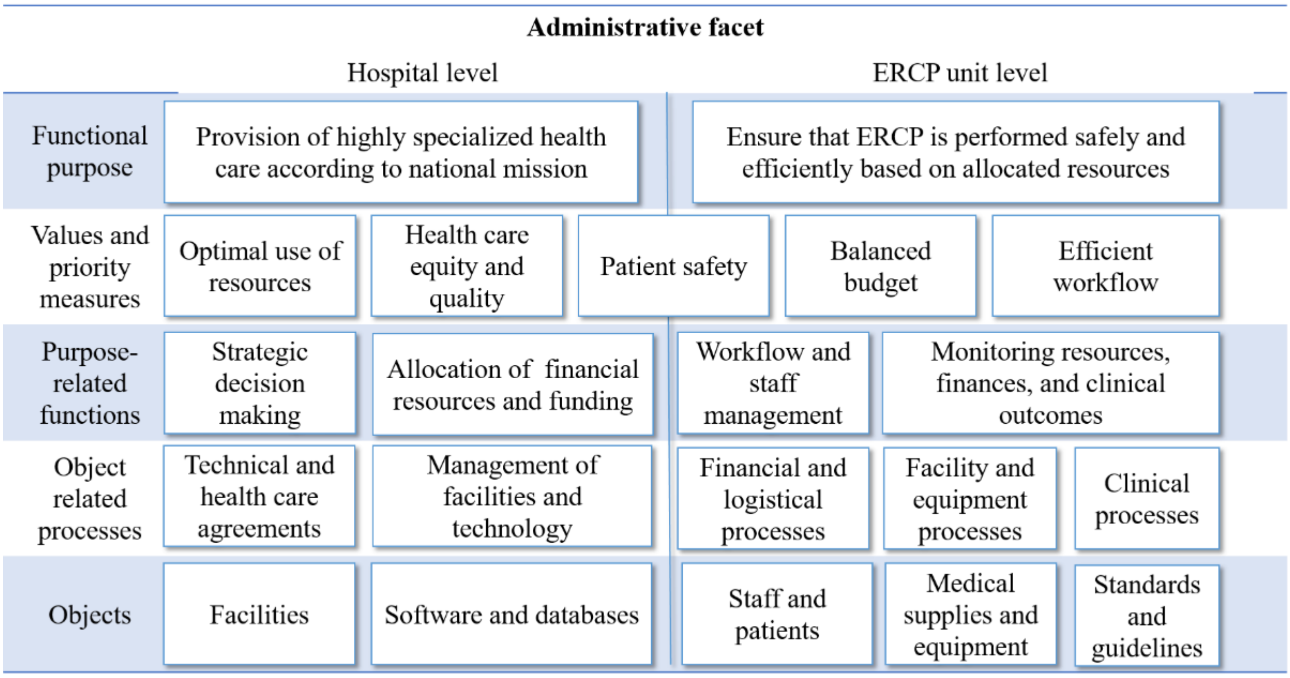
We grouped the large number of physical objects required during ERCP procedures into four main categories: staff; patients; facilities and IT; and medical supplies and equipment (Multimedia Appendix 11).

Multimedia Appendix 12 provides an example of the constraint "facilities and IT."

The Administrative Facet

The administrative facet (Figure 5) was conceptualized as part of the domain that provides the resources for "primary" clinical work.

Figure 5. Abstraction hierarchy, administrative facet.



Administrative facet

	Hospital level	ERCP unit level
Functional purpose	Provision of highly specialized health care according to national mission	Ensure that ERCP is performed safely and efficiently based on allocated resources
Values and priority measures	Optimal use of resources Health care equity and quality Patient safety	Balanced budget Efficient workflow
Purpose-related functions	Strategic decision making Allocation of financial resources and funding	Workflow and staff management Monitoring resources, finances, and clinical outcomes
Object related processes	Technical and health care agreements Management of facilities and technology	Financial and logistical processes Facility and equipment processes Clinical processes
Objects	Facilities Software and databases	Staff and patients Medical supplies and equipment Standards and guidelines

This facet is largely shaped by intentional constraints such as institutional objectives, organizational and management policies, legislations, and regulations. The administrative facet also places demands on work performance, such as efficiency. Although efficiency demands are considered even during surgery, these demands are largely controlled from outside the clinical facet, which is emphasized in our model.

Individuals can play multiple roles and be involved with several facets, as is the case with senior physicians and nurses who may be directly involved in an ERCP procedure (clinical facet) while also executing managerial, research, and teaching/mentoring functions.

We arrived at two levels of decomposition when we modeled the university hospital, one at the hospital level and the other involving the subsystem "ERCP unit." Although the administrative facet largely set intentional constraints on ERCP work, there were also causal constraints that might affect teleguidance.

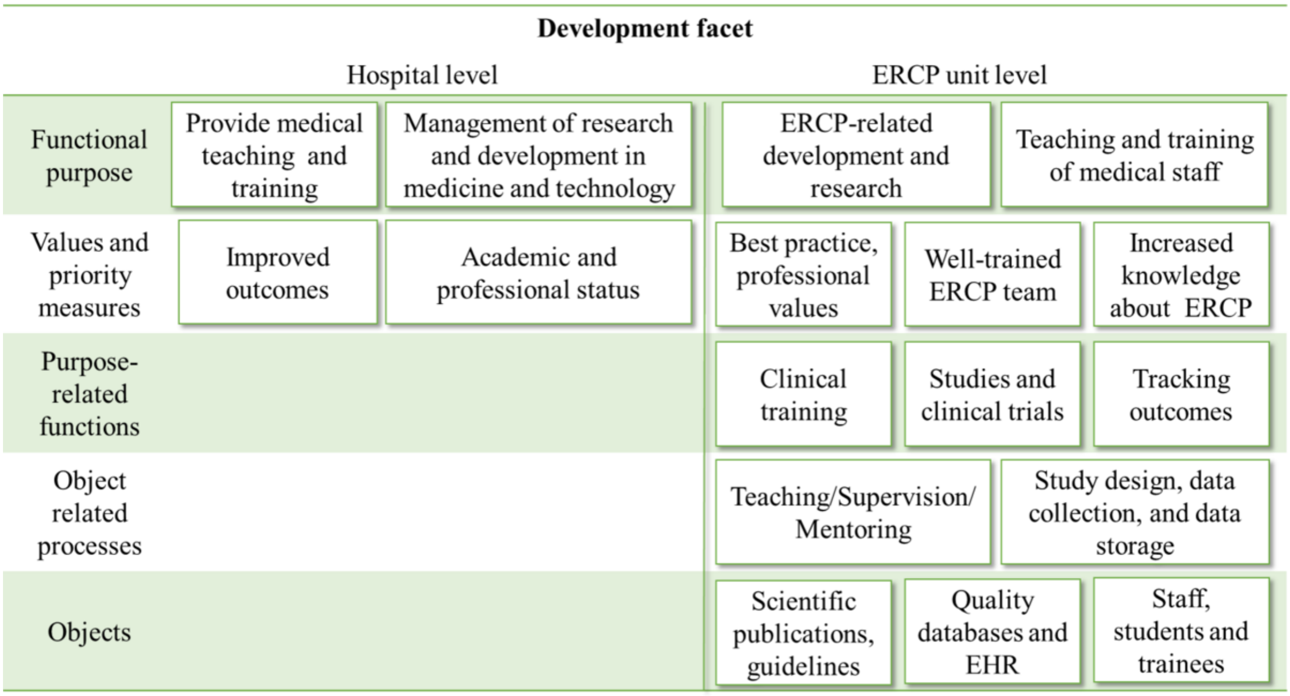
All hospitals were under considerable pressure for increasing their efficiency and undergoing constant reorganization. At the hospital level, this was represented as the values and priority measure "optimal use of resources," and at the unit level, it was represented as "balanced budget" and "efficient workflow."

Multimedia Appendix 13 shows an example of how the purpose-related function "strategic decision-making" in the administrative facet might affect teleguidance. More examples are presented in Multimedia Appendix 14.

The Development Facet

The development facet (Figure 6) is distinguished from the administrative facet owing to its focus on training, research, and quality management, which are the characteristics of advanced clinical practices. In many cases, funding and accountability for these activities are external to the ERCP work system; clinical education and training are often linked to an educational facility; research funding is external; and clinical quality and patient safety criteria are set according to standards and regulations. However, many development activities take place during procedures, such as research activities (eg, documenting unusual physiological features) or teaching and training activities (eg, taking extra time for instruction or allowing a less experienced practitioner operate equipment under supervision).

Figure 6. Abstraction hierarchy, development facet.



Development facet

	Hospital level		ERCP unit level		
Functional purpose	Provide medical teaching and training	Management of research and development in medicine and technology	ERCP-related development and research	Teaching and training of medical staff	
Values and priority measures	Improved outcomes	Academic and professional status	Best practice, professional values	Well-trained ERCP team	Increased knowledge about ERCP
Purpose-related functions			Clinical training	Studies and clinical trials	Tracking outcomes
Object related processes			Teaching/Supervision/Mentoring	Study design, data collection, and data storage	
Objects			Scientific publications, guidelines	Quality databases and EHR	Staff, students and trainees

The development facet is accorded higher priority at the university hospital, where part of the functional purpose includes a mission to provide development, education, and training at the national level.

Many aspects of the development facet appeared to motivate the staff we interviewed, and academic and professional statuses were important aspects for being regarded as trustworthy team members. At the regional hospitals, there were expectations that teleguidance would strengthen the development facet by not only increasing opportunities for training but also for participating in research activities.

Multimedia Appendix 15 provides an example of how a constraint in the development facet might affect teleguidance.

Discussion

Principal Results

The ERCP work system is an open system as there are factors beyond the control of the clinical team, which influence how ERCP procedures are conducted. The high number of factors that could potentially affect each procedure led us to characterize the ERCP work context as having three facets, representing clinical work as the primary field of interest, and administration and development as complementary fields of the domain, which provide resources for clinical work.

Each facet served as a "dimension" along which we could reason about the differences between the implementation sites and how the different sets of constraints affecting ERCP could impact the implementation of teleguidance.

Although the clinical and administrative facets in some aspects reflected organizational partitions, the development facet was clearly not reflected within the organizational structures. However, development is an important aspect of the work domain, which motivates staff and shapes daily clinical work in the highly specialized and constantly evolving field of ERCP, where quality work, training, research, and design of medical equipment are pervasive.

Specific Findings

The implementation sites could be described with the same AHs and compared by contrasting how specific constraints were instantiated.

The functional purposes of the clinical facet show the ERCP team's primary objectives, namely "patient diagnosis, relief, or cure through ERCP." Teleguidance will not change the functional purpose, but it will affect the constraints through which this purpose is achieved.

During procedures, we expect teleguidance to mainly support the purpose-related functions of clinical assessment and interventional procedures by advising how to interpret imagery or providing specific suggestions for handling a certain instrument.

Teleguidance may create challenges in the functions of "situation assessment" and "team coordination." Situation assessment will change in some ways during teleguidance sessions because team members will be in different locations, and there are risks that the remote surgeon and on-site team might perceive the situation differently (eg, the guiding surgeon may miss information that is apparent to the on-site team).

Team coordination may be affected in ways we do not yet understand as the guiding surgeon becomes part of a geographically and organizationally distributed clinical team that requires cognitive, practical, and administrative coordination.

Teleguidance may also cause differences in the values and priorities among clinical practitioners to surface during teleguidance sessions, as shown by the example of appropriateness.

The broad definition of the ERCP work system allowed us to identify constraints that shape events during procedures, along with the object-related processes included in in the work prior to the clinical procedure, such as preparation and configuration. An example is how handling the telemedicine equipment can affect the workload of the assisting staff; at two of the hospitals, the staff would need to spend additional time for preparation and configuration as they must fetch and set up the teleguidance cart, as well as establish a functioning video link. In an already strained work setting, this inconvenience may very well lead to negative experiences with teleguidance over time.

Regarding the “secondary” facets of the domain, the AHs provide some indications of how technical and administrative issues may play out more significantly over time, such as technical responsibility for service and reimbursement issues. We expect that the initial mismatches between the administrative facets can be overcome if the priorities and responsibilities for development work are clear.

If development activities are not a priority, then there is a risk that users will not have the time and resources necessary to handle the awkwardness of work process adaptations.

Comparison With Prior Work

There are prior examples of WDA that distinguish primary operations and resource management through multiple models, showing the different stakeholder perspectives or facets of a problem [5]. There are also examples of behavioral studies involving health care work systems, which differentiate clinical work and the infrastructure and resources for this work, conceptualizing health care work in terms of primary (clinical) and secondary (billing, audit, and management) work activities [29].

In our case, a third facet, development, is relevant, and this highlights that teleguidance is an effort to facilitate training and quality assurance in routine clinical ERCP practices and the control and constraints for these aspects appear different from the clinical and administration facets.

Limitations

There are many ways to construct AHs, and the answer to the question of whether it is well done in this study lies in issues such as the boundary definition and conceptualization of abstraction levels, goals, and objects. These aspects were continually addressed during the numerous iterations for creating the AHs.

Owing to the broad system definition and the open nature of the work system, it was not easy to achieve a hierarchical decomposition, and we initially struggled to represent the wide array of constraints. The facets presented a solution to this dilemma.

WDA is developed for complex settings that are resistant to deterministic analysis because of their nature. Therefore, AHs cannot be objectively correct or complete; the highlight of this study is that the models provide a structured and accountable way to reason flexibly and imaginatively on how constraints from multiple system levels interact.

Conclusions

According to numerous reviews and policy documents, system dynamics and complexity should be considered during the design and evaluation of technological change in health care [30]. This includes the contextual factors constituting “the normal conditions of practice,” thus contributing to the implementation outcomes [31]. Our WDA serves as an example of how a complex clinical implementation context can be analyzed and represented in a in a granular yet structured manner while also showing the interactions among the system elements.

We identified clinical, development, and administrative facets of the work domain. These facets represent the general aspects of clinical work systems as sets of contextual factors that should be factored in during the design and implementation of any telemedicine service.

Future Work

The AHs can serve as artifacts to support the shared understanding required for multidisciplinary collaboration, which is a prerequisite for successful human-system integration [32] (eg, by increasing project managers’ understanding of project complexities). This may be extremely valuable in participatory development processes such as contextual inquiries and value specifications, which are important for developing a holistic implementation approach [33].

The models may also be valuable for providing the necessary insights regarding proactive project risks and patient safety management during implementation [34] as well as for guiding clinical and project evaluations [11].

Conflicts of Interest

None declared.

Multimedia Appendix 1

Service blueprint showing the processes involved prior to, during, and after endoscopic retrograde cholangiopancreatography (in Swedish).

[PNG File , 319 KB - formative_v5i6e26505_app1.png]

Multimedia Appendix 2

Protocol for semistructured interviews. ERCP: endoscopic retrograde cholangiopancreatography.

[PNG File , 61 KB - formative_v5i6e26505_app2.png]

Multimedia Appendix 3
Coding categories and criteria for qualitative data analysis. ERCP: endoscopic retrograde cholangiopancreatography.
[PNG File , 28 KB - formative_v5i6e26505_app3.png]

Multimedia Appendix 4
Partial view of a detailed model of the clinical facet. This image shows the high level of detail in which we modeled the domain, prior to aggregating the abstraction hierarchies.
[PNG File , 89 KB - formative_v5i6e26505_app4.png]

Multimedia Appendix 5
Values and priority measures.
[PNG File , 39 KB - formative_v5i6e26505_app5.png]

Multimedia Appendix 6
Example of the value/priority constraint “appropriateness” showing how it diverged among hospitals and how this might interact with teleguidance. ERCP: endoscopic retrograde cholangiopancreatography.
[PNG File , 73 KB - formative_v5i6e26505_app6.png]

Multimedia Appendix 7
Purpose-related functions.
[PNG File , 40 KB - formative_v5i6e26505_app7.png]

Multimedia Appendix 8
Example of purpose-related function: team coordination. ERCP: endoscopic retrograde cholangiopancreatography.
[PNG File , 67 KB - formative_v5i6e26505_app8.png]

Multimedia Appendix 9
Object-related processes. ERCP: endoscopic retrograde cholangiopancreatography.
[PNG File , 38 KB - formative_v5i6e26505_app9.png]

Multimedia Appendix 10
Example of object-related processes: preparation and configuration. ERCP: endoscopic retrograde cholangiopancreatography.
[PNG File , 57 KB - formative_v5i6e26505_app10.png]

Multimedia Appendix 11
Physical objects (aggregated). ERCP: endoscopic retrograde cholangiopancreatography; IT: information technology.
[PNG File , 30 KB - formative_v5i6e26505_app11.png]

Multimedia Appendix 12
Example of physical objects: facilities and information technology.
[PNG File , 36 KB - formative_v5i6e26505_app12.png]

Multimedia Appendix 13
Example of how the purpose-related function “strategic decision-making” might interact with teleguidance. ERCP: endoscopic retrograde cholangiopancreatography.
[PNG File , 22 KB - formative_v5i6e26505_app13.png]

Multimedia Appendix 14
Examples of constraints in the administrative facet that might affect teleguidance. ERCP: endoscopic retrograde cholangiopancreatography; IT: information technology.
[PNG File , 62 KB - formative_v5i6e26505_app14.png]

Multimedia Appendix 15

Example of how a constraint in the development facet might affect teleguidance. ERCP: endoscopic retrograde cholangiopancreatography.
[PNG File , 50 KB - formative_v5i6e26505_app15.png]

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Abbreviations

AH: abstraction hierarchy
CWA: cognitive work analysis
ERCP: endoscopic retrograde cholangiopancreatography
IT: information technology
WDA: work domain analysis

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Original Paper

Usability Analysis of a Health Sciences Digital Library by Medical Residents: Cross-sectional Survey

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Abstract

Background: The usability of a digital library depends on a myriad of factors ranging from the end users' ability to website complexity. Although digital libraries provide instant access to online content, offering an efficient reference platform, their usability is highly variable.

Objective: The aim of this study was to measure users' perspectives and usability of the digital library of the Saudi Commission for Health Specialties (SCFHS).

Methods: A web-based questionnaire survey was conducted using a validated System Usability Scale (SUS) containing 5 positive and 5 negative items on the usability of the digital library. The SUS standard cut-off score of 68 was considered for interpretation.

Results: The overall mean SUS score of digital library usability was 52.9 (SD 15.2) with a grade "D" categorization, indicating low usability. The perceived measures of attributes of the 10 SUS items of findability, complexity, consistency, and confidence obtained below average scores. Only item 1 relating to perceived willingness to use the digital library frequently obtained a score above the targeted benchmark score (mean score 3.6). Higher SUS scores were associated with training (*P*=.02). Men felt the digital library to be more complex (*P*=.04) and board-certified physicians perceived a greater need for training on digital library use (*P*=.05). Only the UpToDate database was widely used (72/90, 80%).

Conclusions: These findings demonstrate the low usability of the extensive facilities offered by the SCFHS digital library. It is pivotal to improve awareness of the availability of the digital library and popularize the databases. There is also a need for improved user training to enhance the accessibility and usability of the multiple databases.

(JMIR Form Res 2021;5(6):e23293) doi:10.2196/23293

KEYWORDS

digital library usability; medical education; system usability scale; medical residents; Saudi Arabia

Introduction

The transition of conventional print materials to electronic formats has revolutionized the use of libraries. Digital libraries are a result of the marvelous technological advancements of the 21st century. The availability of extensive online literature has curtailed the classic style of print-based articles and photocopying, resulting in diminished usage over the last decade [1]. Digital libraries provide comprehensive databases containing electronic books, journals, online gray literature, web publishing, and evidence-based guidelines and literature, with additional benefits of animation, audio-visual aids, and mobile apps with scientific content. Institutional libraries are an invaluable asset in making users competent in terms of scientific knowledge, research skills, and keeping pace with the most updated information [2]. As early as the second half of the 1990s, when internet technology was still in a nascent stage, Morse and Clintworth [3] compared the usage of a traditional library with the then-novel electronic library (e-Library) and found an astoundingly high predominance of electronic usage among health science students of an academic library in California. Recent studies have demonstrated that the worldwide web has made traditional libraries obsolete, forcing students to rely entirely on digital libraries even in low- and middle-income countries [4,5]. Given that the economics of establishing and running a digital library costs millions of dollars, its quality of services and effectiveness should be decisive and significant.

The Saudi Commission for Health Specialties (SCFHS), which was established in 1983, is the regulatory body in Saudi Arabia that is responsible for the country’s health care workforce in aspects related to licensing, training, and continuous professional development. The SCFHS has been commissioned as the Kingdom’s largest and most competent digital library service, facilitating the work of health care practitioners and trainees from all specialties, thereby empowering continuing medical education [6]. The SCFHS extensively partners with international institutions, and subscribes to leading medical and health care journals and online databases. Residents are given free access to the digital library by registering with a valid residency ID. The provision of such extensive facilities and universal access to online literature necessitates the end users’ usability description. The term “usability” has varied definitions since this multidimensional construct can be evaluated from different perspectives. Some authors have linked usability to ease of use, considering the effectiveness of human-computer interaction [7], while others prefer the usability definition highlighted by Brinck et al [8] “as the degree to which people (users) can perform a set of required tasks.” The perceived usability of interactive systems is evaluated to identify usability issues, improve the usability of the design, and to encourage recommendations [9].

Although a library is a platform that offers access to a variety of databases and applications, the library portal itself consists of many features and services that warrant assessment of their usability measures. The user experience includes the start of accessing the digital library portal until acquiring the needed information. This journey involves many interactions with the portal, such as the universal search, finding the right database/journal/book, authenticating access to third-party portals, technical and librarian support, and integration with other systems. All of these user-portal interactions are related to the library itself and warrant usability assessment. This study was performed with the objective of assessing the usability of the digital health sciences library provided by the SCFHS among trainees, including their information-seeking behavior and perceptions in the usability of the digital library. The findings may point toward the generic deficiencies in any digital library, which, if rectified, may enhance the user interface and increase the usability of the digital library for professional development in research to ameliorate evidence-based practice.

Methods

Study Design and Sampling

A quantitative cross-sectional study design was applied to assess the usability of the digital library of the SCFHS. The study participants included the trainee residents from all specialties with valid registration at the SCFHS. A list containing the registered names of 3455 professionals was obtained from the SCFHS, which constituted the sample frame. Assuming that 50% of the population conveys positive perceptions of digital library usability, with a 95% CI and a precision of 5%, the estimated sample size using the single proportion formula was calculated to be 384. This study was performed over a period of 2 months, in March and April of 2018. The study tool was constructed using the SurveyMonkey platform. The tool was sent online to all registered email IDs listed in the sample frame. Two reminder emails were sent after 2 weeks to increase the response rate.

Description of the Questionnaire

This study adopted the validated questionnaire of the System Usability Scale (SUS) developed by John Brooke in 1996 [10]. The SUS system is a robust, reliable, and valid tool, which has been extensively used by researchers. It has also shown a high degree efficiency in testing library systems, repositories, and websites [11]. The first section comprises 10 questions measuring the system usability of various hardware, software, websites, and applications, with scaled responses on a 5-point Likert scale ranging from strongly disagree to strongly agree. The SUS is considered to be an easy-to-use tool with simple and straightforward statements arranged as odd numbers (1, 3, 5, 7, 9) that are positively expressed and statements with even numbers (2, 4, 6, 8, 10) that are negatively expressed.

The 10 items on the SUS are as follows: (1) I think that I would like to use this system frequently, (2) I found the system unnecessarily complex, (3) I thought the system was easy to use, (4) I think that I would need the support of a technical person to be able to use this system, (5) I found the various functions in this system to be well-integrated, (6) I thought there was too much inconsistency in this system, (7) I would imagine that most people would learn to use this system very quickly, (8) I found the system very cumbersome to use, (9) I felt very confident using the system, and (10) I needed to learn a lot of things before I could get going with this system.

The sequence of the statements was created so as to reduce concurrence and extreme bias. The second section comprised questions on demographic characteristics, accessibility, training and experiences in using databases, and suggestions to improve the digital library. A pilot study was performed with 12 participants to ensure reliability and validity of the questions in section 2, and these responses were not included in the main analysis.

Scoring SUS Responses

The SUS scores were calculated with reference to the guidance outlined by Jeff Sauro [12]. The scores for each question were converted to a new number, summed, and then multiplied by 2.5 to convert the original scores ranging from 0 to 40 to a range of 0 to 100. The SUS scores were interpreted with a cutoff of 68. A score above 68 indicates average performance, whereas a score below 68 is considered to be below average. Furthermore, comparison and easy reference of individual items of findability, complexity, consistency, and confidence can be achieved using targeted benchmark scores that make the responses more meaningful [12].

Data Analysis

The data were analyzed using the IBM software Statistical Package for Social Sciences version 22.0. Descriptive statistics (frequencies, percentages, mode, and mean and SD) were used to describe the categorical and quantitative variables. Testing of associations between categorical and continuous variables was performed by the Student *t* test and analysis of variance, respectively. A *P* value less than .05 was judged to indicate statistical significance.

Ethical Considerations

The study was reviewed and approved by the Institutional Review Board Committee of College of Medicine, with reference number CMED 305-F8-2018-18. All participants were informed about the purpose of the study and electronic informed consent was obtained on the first page of the survey tool. The study ensured that the participants' data will be confidential, private, and used for research purposes only.

Results

Ninety completed questionnaires were received at the end of the study period. The majority of the respondents were men with a mean age of 29.3 years (SD 4.2). The distribution of demographic characteristics is provided in Table 1.

The study participants' overall average SUS score was 52.9. The average mean score in comparison with benchmark scores for the 10 SUS items are presented in Table 2. Item 1, which states "I think that I would like to use the digital library frequently," was the only SUS item that obtained a score above the targeted average benchmark.

The participants' experience with the SCFHS digital library is shown in Table 3. The most successful method of spreading awareness of the SCFHS digital library was email. However, communication through colleagues was also popular. UpToDate was the most predominantly used database, whereas Cochrane and DynaMed showed low utilization. The most frequently stated purpose for use of the SCFHS digital library was preparation for presentations, closely followed by patient care-seeking information. The use of the digital library for research and teaching support ranked in the third and fourth priority, respectively. The other popular alternatives to the SCFHS digital library were the participants' respective institutions' libraries, followed by the Saudi Digital Library.

The associations between demographic and other variables with the total score are presented in Table 4. The results showed that training on how to access databases was significantly associated with a higher total score (*P*=.02). Although not significant, female gender, non-Saudi nationality, and senior residency levels obtained higher SUS scores. However, the analysis of individual SUS items with different study variables showed two items with a significant association. The score for item 2, which states "I found the digital library to be unnecessarily complex," was significantly higher in men than in women (*P*=.04) and among board-certified physicians (*P*=.01). The score for item 4, which states "I think that I would need the support of a technical person to be able to use this digital library," was significantly higher among board-certified physicians (*P*=.05).

Table 1. Demographic characteristics and System Usability Scale (SUS) scores of Saudi Commission for Health Specialties digital library users (N=90).

Variable	Value
Gender, n (%)	
Male	53 (59)
Female	37 (41)
Nationality, n (%)	
Saudi	83 (92)
Non-Saudi	7 (8)
Age (years), n (%)	
20-25	8 (9)
26-30	57 (63)
31-35	20 (22)
>35	5 (6)
Residency level, n (%)	
R1	17 (19)
R2	27 (30)
R3	14 (16)
R4	11 (12)
Fellowship	6 (7)
Board-certified	3 (3)
Medical specialty, n (%)	
Family medicine	16 (18)
Internal medicine	17 (19)
Pediatrics: general	11 (12)
Surgery	9 (10)
Psychiatry	3 (3)
Radiology	4 (5)
Emergency medicine	3 (3)
Community medicine/public health	3 (3)
Critical care medicine (intensive care unit)	3 (3)
Other	9 (10)
SUS score	
Mean (SD)	52.9 (15.2)
Range	25-100

Table 2. Comparison of the mean scores with benchmark targets for average scores of the 10 System Usability Scale items.

Item	Benchmark target mean score	Obtained mean score
1: I think that I would like to use digital library frequently	≥3.39	3.6
2: I found the digital library to be unnecessarily complex	≤2.44	2.8
3: I thought the digital library was easy to use	≥3.67	3.3
4: I think that I would need the support of a technical person to be able to use the digital library	≤1.85	3.1
5: I found the various functions in the digital library to be well-integrated	≥3.55	2.9
6: I thought there was too much inconsistency in the digital library	≤2.20	2.9
7: I would imagine that most people would learn to use the digital library very quickly	≥3.71	3.3
8: I found the digital library to be very cumbersome to use	≤2.25	3.0
9: I felt very confident using the digital library	≥3.72	3.1
10: I needed to learn a lot of things before I could get going with the digital library	≤2.09	3.2

Table 3. Participants' experience with the Saudi Commission for Health Specialties (SCFHS) digital library (N=90).

Question	Participants, n (%)
How did you learn about the SCFHS digital library?	
Colleagues	21 (23)
Email	59 (66)
Trainers	7 (8)
Twitter	5 (6)
WhatsApp	7 (8)
SCFHS website	4 (4)
Others	5 (6)
What are the databases that you used within the digital library?	
UpToDate	72 (80)
Cochrane	14 (16)
Clinical evidence	17 (19)
Best evidence	14 (16)
DynaMed Plus	19 (21)
Others	13 (14)
Purpose (s) for use of the SCFHS digital library?	
Research	62 (69)
Support teaching activities	55 (61)
Patient care	68 (76)
Preparation for presentation	70 (78)
Preparation for examination	46 (51)
Continuing medical examination	35 (39)
Others	2 (2)
What other electronic library/libraries do you have access to?	
None	32 (36)
Saudi Digital Library	37 (41)
My institute/hospital/center library	43 (48)
Others	10 (11)

Table 4. Association of questionnaire responses with System Usability Scale (SUS) scores (N=90).

Question	Response, n (%)	Total SUS score, mean (SD)	*P* value
Do you pay to use any other databases or electronic libraries?			.40
Yes	18 (20)	50.2 (15.8)	
No	72 (80)	53.5 (15.0)	
Did you have previous experience with electronic libraries before the SCFHS[a] digital library?			.94
Yes	61 (68)	52.8 (16.6)	
No	29 (32)	53.1 (12.3)	
Have you ever received training on how to access and use health information databases/libraries?			.02
Yes	20 (22)	59.5 (14.5)	
No	70 (88)	51.1 (14.5)	
Gender			.35
Male	53 (59)	51.8 (13.8)	
Female	37 (41)	54.9 (17.3)	
Nationality			.51
Saudi	83 (92)	52.8 (14.5)	
Non-Saudi	7 (8)	56.7 (25.5)	
Residency level			.08
R1	17 (22)	53.2 (8.7)	
R2	27 (35)	51.1 (17.4)	
R3	14 (18)	59.4 (14.2)	
R4	11 (14)	51.5 (17.4)	
Fellowship	6 (8)	66.6 (17.7)	
Board-certified	3 (4)	39.1 (10.1)	
Residency category			.28
Junior (R1 and R2)	44 (49)	51.9 (14.6)	
Senior (R3 and R4)	25 (28)	56.0 (15.8)	
Age group (years)			.99
20-25	8 (9)	51.5 (9.8)	
26-30	57 (63)	53.2 (15.7)	
31-35	20 (22)	53.3 (16.9)	
>36	5 (6)	53.0 (17.6)	

[a] SCFHS: Saudi Commission for Health Specialties.

Discussion

Principal Findings

This study focusing on the usability of the SCFHS digital library by registered trainee health practitioners is the first of its kind in Saudi Arabia. Some of the main findings indicate that digital library use in terms of perceived complexity, consistency, and confidence is below average among the trainees. Since the overall SUS score obtained in this study was 52.9, a grade D categorization may be given, denoting low usability [13]. Benchmarking of the scores of individual SUS items provides useful interpretation [14]. In this study, item 1 that reflects the digital library's frequent use was the sole item that obtained a score above the benchmark score. This finding suggests the participants' increased perceived usability toward using the digital library, whereas the rest of the SUS items obtained low scores, suggesting difficulty in all attributes of measures of complexity, consistency, and confidence.

Nevertheless, on a positive note, the SUS score showed a significant increase among those who attended a voluntary introductory training session on an ad hoc basis that was provided either by the individual databases or by their affiliated institutions through webinars and YouTube sessions. However, it must be emphasized that no formal training sessions were organized facilitating use of the digital library. These key findings may draw attention. Research studies have linked high computer literacy and social media to increased digital library usability among users. Umukoro et al [15] examined the factors associated with increased digital library use among university students by performing a mixed methods study in Nigeria, and established three major predictors among the users. They linked high system and service quality, computer skills, and level of satisfaction with electronic services to increased e-Library use, whereas the determinants of not using the digital library were primarily lack of awareness of services, inadequate computer skills, and absence of user-training facilities. These results are highly consistent with our findings, which could indicate the chief reasons for low usability. Similarly, Piccoli et al [16] built a conceptual framework of contributing factors for effective electronic learning (e-Learning) that depends on the interface between human and design factors. Human factors constitute the instructors' and students' roles such as motivation, learning, and training, whereas design factors include technology, course contents, and an interactive environment that have a direct effect on the level of use. A qualitative analysis demonstrated incomprehensible website design and content as some of the major themes for low usability of a digital library, which suggested that the search protocol should be established in accordance with the end users' expectations to improve website usefulness [17]. Since some users may demonstrate computer literacy, the reasons for low usability remain ambiguous. In-depth qualitative research is required to comprehend the factors associated with low SUS scores. The poor system usability may reflect a combination of factors or attributes that regulate actual usability.

The other main finding of training-assisted improvement in digital library usability suggests that the respondents may enhance usability with essential training skills and operative assistance. These findings are in accordance with similar studies from Nigeria and Zimbabwe, where lack of training and awareness were identified as principal barriers for poor electronic resource utilization [4,5,18]. These findings are further supported by a study that demonstrated improved e-Learning behavior after implementation of a successful end-user internet literacy training program for university students [19]. Our study thereby suggests the definite need for training measures to be reinstated by the SCFHS for the effective use of digital library facilities. Future studies obtaining pre and post evaluation measures of efficacy of training programs are highly recommended.

Another issue of concern is the lack of awareness of digital library facilities. The finding that only 3.7% of the participants knew about the digital library facility through the SCFHS website is alarming. The content display on the website plays a constructive role in spreading awareness about the digital library. There is an immediate need to exemplify content guidance to improve awareness and accessibility of the digital library in the SCFHS website. Hinchliffe and Mummery [20] elucidated the significance of the involvement of intended audience and end users in designing websites through usability testing to improve and optimize user experiences. Likewise, we recommend performing similar research to obtain users' suggestions for content directions of the SCFHS website highlighting the digital library facilities, which can result in increased usability.

Furthermore, the library usage patterns demonstrate that preparation for presentations and obtaining information on routine patient care are the two most common reasons for use. Although these results are reasonably expected from the trainees, the suboptimal usage for other relevant purposes warrants further clarification. The use of a digital library during examinations and for research and additional support materials was found to be low. However, the use of alternate sources such as institutional libraries and the Saudi Digital Library may account for the probable low use. These findings are strong indicators of the suboptimal awareness of available online databases. A similar study performed at a university library in the United States showed that 94.5% of residents accessed the resources for patient care, 92% of nursing professionals accessed the library for class preparations, and 76% accessed the library for research purposes [1]. There is great potential for research to further discover the reasons for low usage among the participants. Library orientation for residents and fellows, web helpdesk service, training on online database searching skills, and web-based notification systems are some of the suggested methods to improve usability [21].

This study found an inclined preponderance toward the use of UpToDate as the most popular online database. This is also reflected in the lower utilization of other multiple databases. Provision of training facilities ought to incorporate content description and specifications of other online databases such as Cochrane, Best evidence, and DynaMed to maximize benefits. These three evidence-based medicine databases containing full free texts and voluminous literature on clinical trials with a level of evidence and recommendations based on established guidelines serve as priceless assets for both research and clinical practice. The reported low use of these resources raises concerns. Moreover, this may lead to concealing a significant amount of variance in perceived usability scores. These findings point toward the need for further exploratory research to identify the determinants and reasons for low usage, which can inform exhaustive measures to be taken to improve awareness and usability.

Limitations

This study has certain limitations. The relatively small sample size restricts the generalizability of the findings. Furthermore, the sample included only trainees, and other health care providers who could have served as potential resource participants were not included, which again may lead to limited generalizability. However, the strength of this study is that it is the first such investigation in the region of Saudi Arabia, and the multiple findings generated can be considered as a vital basis for future research. Another relevant point is the ambiguity in the usability of each of the multiple online databases. This study assessed the overall usability of the digital library; however, details of the usability of individual databases were not explored, which can be a subject of future research.

Conclusion

The concept of digital libraries has revolutionized the usability of libraries by providing instant and simplified access. The digital library of the SCFHS is a major source of referencing for health professionals in Saudi Arabia. This study is the first to evaluate the usability of the digital library of SCFHS.

Lower usability scores were obtained, demonstrating the below-average utilization of resources. The participants demonstrated low confidence in accessing the digital library, and needed technical support, guidance, and training programs for efficient access and use of the contents. The online database UpToDate was the most popular database accessed for clinical support decisions, whereas the remaining databases showed limited usability. However, training and orientation were associated with higher usability scores, suggesting a promising solution to improve usage. A well-structured training program facilitating simplified and efficient navigation of the digital library contents is the need of the hour. In addition, the SCFHS website should consider increasing awareness through innovative methods to increase the potential use of multiple databases. There is a great potential for modification in website design to increase awareness and improve digital library usability.

Recommendations to Improve e-Library Usability

This research may highlight certain general recommendations to improve the usability of the SCFHS digital library based on the identified findings in two major contexts: personnel and technical. Primarily, at the outset, we highly recommend facilitating an end-user training program as a mandatory apprenticeship featuring the navigatory steps in addition to the introduction of the available online databases and their specifications for wider use.

Next, the focus of recommendations may include the technicality and design of the website. Accessibility can be markedly improved by direction and guidance in a user-friendly mode. In addition, the design should facilitate categorization and description of the digital library contents. The homepage of the website must contain a downloadable user-friendly guide as an overview of digital library orientation. Furthermore, the trainees must be assisted with provision of helpdesk facilities, online chats, and regular notifications on digital library updates.

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Authors' Contributions

AJ and HA conceived and designed the study. BSJ, DAA, NSA, OMA, and RHA acquired the data and performed the analysis. ST wrote the manuscript. All authors contributed to the interpretation of the data and critically revised the manuscript for important intellectual content.

Conflicts of Interest

None declared.

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Abbreviations

e-Learning: electronic learning
e-Library: electronic library
SCFHS: Saudi Commission for Health Specialties
SUS: System Usability Scale

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Original Paper

Virtual Engagement in a Social Media Community of Mothers With Substance Use Disorders: Content Analysis

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Abstract

Background: Co-occurring substance use disorder is common among pregnant and parenting women with mental illness, but their engagement with and utilization of relevant services and treatment is low. Social media has the potential to convey benefits and facilitate engagement among this target group.

Objective: This study aimed to explore the reach and engagement of specific social media posts among pregnant women and mothers with substance use disorders.

Methods: Eighteen posts providing content related to substance use (cannabis, opioids, or alcohol), varying in type of content (informational or experiential) and target (policy-, practice-, or perception-related), were posted in a closed Facebook community page comprising over 33,000 pregnant women and mothers between May 2019 and October 2019.

Results: The overall level of reach of these Facebook posts ranged from 453 to 3045 community members. Engagement levels, measured via the number of likes, comments, or posts shared, varied based on the type of post content (ie, informational or experiential).

Conclusions: Participation in a virtual community via social media platforms can facilitate engagement among pregnant women and mothers with mental illness by communicating relevant information about substance use, as well as potentially promoting awareness of, access to, and engagement with treatment services.

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KEYWORDS

virtual engagement; virtual community participation; social media; mental health; opioids; substance use

Introduction

During the perinatal period, women are vulnerable to a variety of life stressors and are at a higher risk of experiencing depressive symptoms [1,2]. Many find themselves at an increased risk for using substances [3-5]. Yet, women's needs for mental health services are often unmet [6], and those who are vulnerable and at high risk often disengage from mental health services and substance use treatment [7,8]. Several factors contribute to such high levels of disengagement from services and treatment among high-risk women, including stigma, fear of losing the child's custody, or fear of legal consequences of substance use [3,9-14]. The postpartum period itself presents additional stressors such as childcare responsibilities, work-life balance, and physical and emotional recovery, which may interfere with the utilization of mental health and/or substance use services [15,16].

Social media communities have become a central platform for individuals seeking emotional support, especially during the COVID-19 pandemic [17,18]. Social media communities are web-based platforms wherein members with common experiences and interests share real-time information and offer support [19-22]. Social media offers anonymity, reduces perceptions of stigma, and helps eliminate geographic barriers [20,23]. Therefore, by providing relevant information and support, social media has the potential to overcome barriers to facilitate engagement among women during pregnancy and in the postpartum period [24,25].

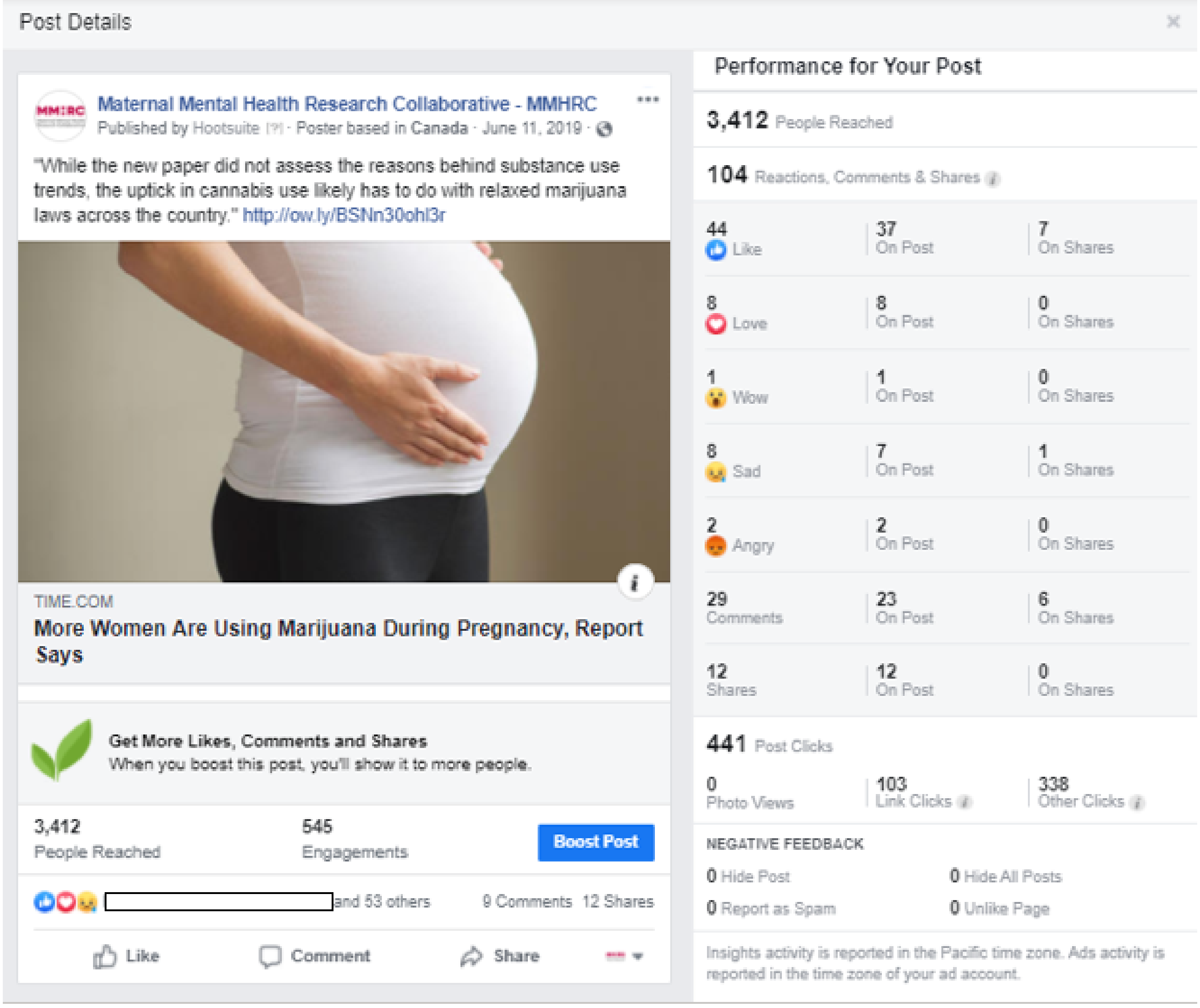
Recent surveys indicate that individuals experiencing bipolar disorder, major depressive disorder, anxiety, or schizophrenia spectrum disorder are inclined to using Facebook [26]. However, little is known about the willingness of social media users and online community members to engage interactively in substance use–related topics on social media platforms. Furthermore, limited information is available about the potential of those online communities for engaging pregnant and parenting women with mental illness who are at risk for using substances. The purpose of this exploratory study is to fill a gap in the literature by investigating, for the first time, the extent to which social media posts can be used to increase outreach to high-risk, vulnerable women. We also investigated how social media posts can increase awareness and sense of support among women and facilitate engagement in managing their mental health. Specifically, this study focuses on the level of *reach* of social media posts, impact of the post content, and relevance of the target of content to the *engagement* within an online community.

Methods

Study Design

This exploratory, descriptive study assessed responses to Facebook posts pertaining to substance use (N=18) on the Maternal Mental Health Research Collaborative (MMHRC) Facebook page [27] between May and October 2019. Data were obtained from the MMHRC Facebook page by using Facebook Insights data in response to the purposefully selected sample of posts regarding substance, type, and target of content. Examples of published posts can be seen in Figures 1 and 2. This study was deemed exempt by the Brandies University Institutional Review Board.

Figure 1. An example of a cannabis-related Facebook post on the Maternal Mental Health Research Collaborative Facebook page.



Maternal Mental Health Research Collaborative - MMHRC
Published by Hootsuite [?] · Poster based in Canada · June 11, 2019 ·

"While the new paper did not assess the reasons behind substance use trends, the uptick in cannabis use likely has to do with relaxed marijuana laws across the country." http://ow.ly/BSNn30ohl3r

TIME.COM

More Women Are Using Marijuana During Pregnancy, Report Says

Get More Likes, Comments and Shares
When you boost this post, you'll show it to more people.

3,412 People Reached
545 Engagements

[redacted] and 53 others
9 Comments 12 Shares

Performance for Your Post

3,412 People Reached

104 Reactions, Comments & Shares

44 Like	37 On Post	7 On Shares
8 Love	8 On Post	0 On Shares
1 Wow	1 On Post	0 On Shares
8 Sad	7 On Post	1 On Shares
2 Angry	2 On Post	0 On Shares
29 Comments	23 On Post	6 On Shares
12 Shares	12 On Post	0 On Shares

441 Post Clicks

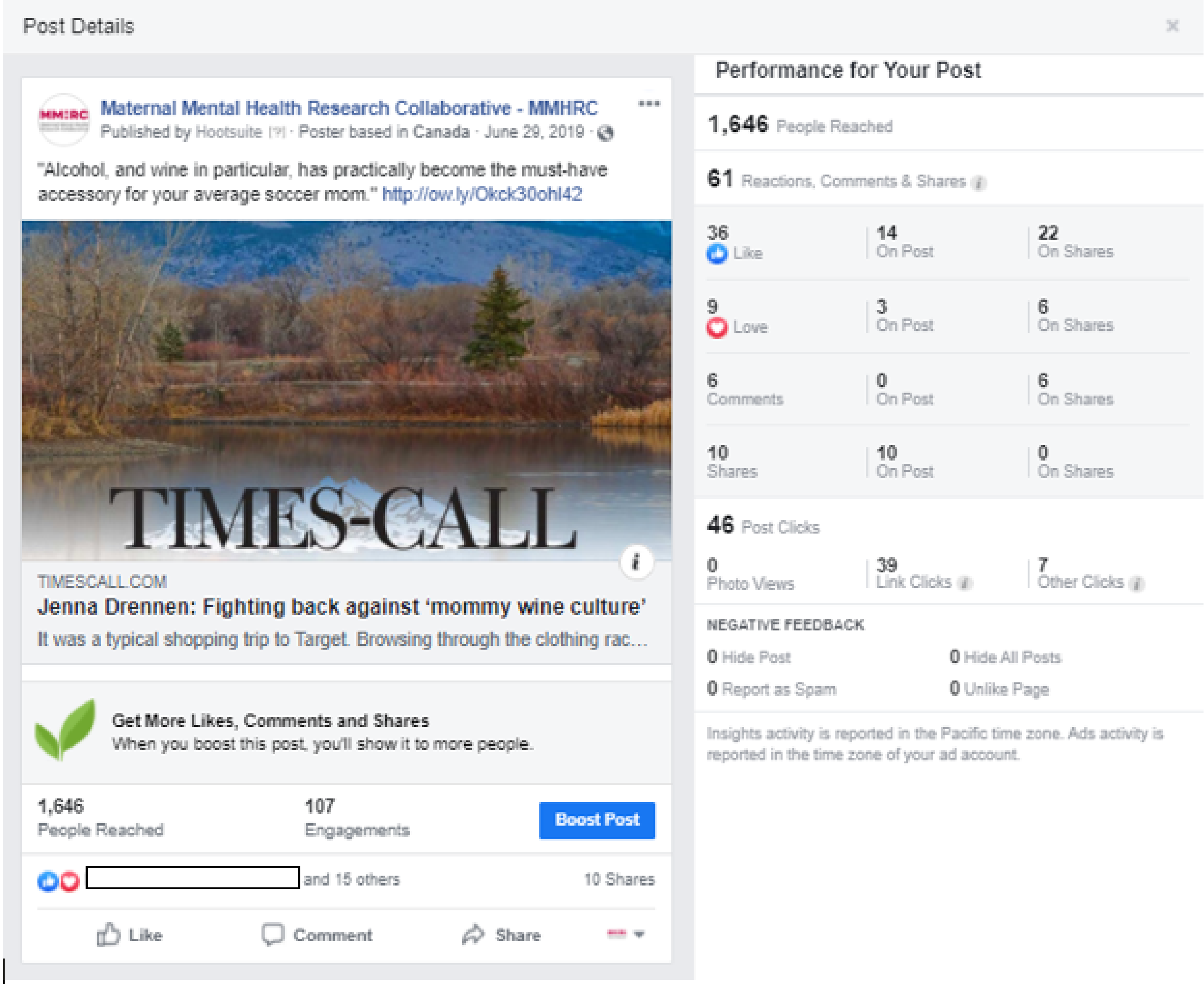
0 Photo Views	103 Link Clicks	338 Other Clicks

NEGATIVE FEEDBACK

0 Hide Post	0 Hide All Posts
0 Report as Spam	0 Unlike Page

Insights activity is reported in the Pacific time zone. Ads activity is reported in the time zone of your ad account.

Figure 2. An example of an alcohol-related Facebook post on the Maternal Mental Health Research Collaborative Facebook page.



Post Details

Maternal Mental Health Research Collaborative - MMHRC
Published by Hootsuite [?] · Poster based in Canada · June 29, 2019 ·

"Alcohol, and wine in particular, has practically become the must-have accessory for your average soccer mom." http://ow.ly/Okck30ohl42

TIMESCALL.COM
Jenna Drennen: Fighting back against 'mommy wine culture'
It was a typical shopping trip to Target. Browsing through the clothing rac…

Get More Likes, Comments and Shares
When you boost this post, you'll show it to more people.

1,646 People Reached
107 Engagements

[redacted] and 15 others · 10 Shares

Performance for Your Post

1,646 People Reached

61 Reactions, Comments & Shares

36 Like	14 On Post	22 On Shares
9 Love	3 On Post	6 On Shares
6 Comments	0 On Post	6 On Shares
10 Shares	10 On Post	0 On Shares

46 Post Clicks

0 Photo Views	39 Link Clicks	7 Other Clicks

NEGATIVE FEEDBACK

0 Hide Post	0 Hide All Posts
0 Report as Spam	0 Unlike Page

Insights activity is reported in the Pacific time zone. Ads activity is reported in the time zone of your ad account.

Setting

MMHRC is a peer-led, patient-centered online community dedicated to linking pregnant and parenting women with mental health conditions with information and support, providers, and researchers [28]. Currently funded by the Patient Centered Outcomes Research Institute (PCORI), the MMHRC was created in 2016 to provide opportunities for mothers, researchers, providers, and other stakeholders to cocreate research; amplify the voices of women who have experienced a perinatal mood or anxiety disorder; and foster strength, advice, and support within a community of others with shared experiences. MMHRC is an active group in many social media networks, including Facebook, Twitter, Instagram, and Pinterest, and it utilizes social media best practices to expand its reach.

The MMHRC Facebook page has an international base of followers or Facebook users who choose to receive updates from the MMHRC Facebook page. Ninety percent of MMHRC's followers are from the United States and Canada, with additional followers living in Australia, the United Kingdom, South Africa, India, Philippines, New Zealand, Ireland, and Mexico. During the time of the study (May 2019 to October 2019), the MMHRC Facebook page following rose to 32,410 followers, and it currently exceeds 33,000 followers. The vast majority are women (99%). Of those identifying as women, 92% were of childbearing age (18-44 years old) at the time they joined the community. Followers of the MMHRC Facebook page do not need to self-identify as having a mental illness in order to view page content. We posit that these followers are users who are interested in or may have a lived experience of mental illness. Because extensive research in the literature underscores the high prevalence of co-occurring mental health and substance use disorders, we conjecture that many women with mental illness may have experience with substance use issues as well [29-32].

Study Sample: Facebook Posts

In this study, the analytic sample comprised 18 Facebook posts selected by the researchers to allow exploration of the relationship between the post's characteristics and potential reach and engagement. A Facebook post was defined as content that is inserted and appears on a Facebook newsfeed. For the MMHRC Facebook page, posting is managed by the page administrator—the MMHRC Program Director. Most posts are accompanied by a caption, also inserted by the page administrator, as an introduction to or an explanation of the content posted (eg, a web link to an article, photo, or graphic). Content on the MMHRC Facebook page is posted approximately four times a day—at 7:00 am, 9:00 am, 12:00 pm, and 2:00 pm

Mountain Time (MT). The study content was posted on the MMHRC Facebook page on randomly selected days and times during the study months. The purposefully selected sample of substance use–related posts were considered independent variables in this study. These posts included content selected by members of the research team from the scientific literature, gray literature, and popular press, during the study months. To help generate interest in the content among Facebook users, all content was purposely designed to be relatively current, with most posts from content that was recently published. Each post was categorized in three ways: (1) by specific substance (opioids, cannabis, or alcohol), (2) the type of information delivered (informational or experiential), and (3) the target of the post (policy-, practice-, or perception-related). Informational posts included content that educates and informs. Examples of informational posts included a research article providing statistics about opioid use among pregnant women or information pertaining to a recently opened recreational cannabis facility. Experiential posts included content that was designed to conjure sensory and behavioral reactions or material that may be relatable to followers' experiences with substances [33]. Examples of experiential posts included a woman's blog post about her experience in recovery from using opioids or a link to popular media article about a celebrity's story of alcohol use while they were pregnant. Policy-related posts reflected aspects of local, state, or federal policy pertaining to substance use. Practice-related posts referred to an individual's actual use of opioids, cannabis, or alcohol (ie, a person's behavior or habits). Perception-related posts referred to individual, organizational, or societal beliefs, awareness, or judgement about opioid, cannabis, or alcohol use, treatment, and recovery. Members of the research team identified and discussed each post and achieved consensus regarding the categorization of post characteristics. It is important to note that the titles of posts do not fully reflect their content; content was reviewed as part of the categorization process (Table 1).

Table 1. Characteristics of Facebook posts classified by substance.

Substance type and post title	Date posted (2019)	Type	Target
Opioids			
Insurance and pregnancy are barriers to opioid treatment	June 1	Informational	Policy
Opioids increasingly tied to deaths of pregnant women	May 14	Informational	Practice
Embracing the needs of pregnant women and infants in our nation's battle against the opioid crisis	May 24	Informational	Perceptions
Most physician health plans don't allow medical professionals access to the same treatment as patients	September 30	Experiential	Policy
The dangerous stigma against pregnant women addicted to opioids	July 10	Experiential	Practice
How the opioid epidemic affects women differently	June 13	Experiential	Perceptions
Cannabis			
Is cannabis safe during pregnancy? More expecting mothers are wondering	August 7	Informational	Policy
Pregnant women in the US are giving up major vices—except one	May 15	Informational	Practice
Marijuana use doubles in U.S. pregnant women, especially during first trimester	August 9	Informational	Perceptions
More women are using marijuana during pregnancy, report says	June 11	Experiential	Policy
Why some mothers keep using cannabis during pregnancy and breastfeeding	June 19	Experiential	Practice
Good Chemistry, Worcester's first marijuana dispensary, is open for recreational sales	May 5	Experiential	Perceptions
Alcohol			
Conversational approach most successful way of encouraging drinking habit disclosure	October 1	Informational	Policy
Study tracks drinking habits of new parents	June 4	Informational	Practice
Mixed messages about safe consumption during pregnancy	September 30	Informational	Perceptions
Drinking during pregnancy: is a little alcohol ever okay?	June 6	Experiential	Policy
Jenna Drennen: fighting back against 'mommy wine culture'	June 29	Experiential	Practice
Does pregnant Gretchen Rossi drink a little wine?	June 7	Experiential	Perceptions

Measures

Organic Reach

Organic reach was defined as the number of unique Facebook users who viewed an MMHRC post as indicated by Facebook Analytics. Users can view a post that is pushed to their newsfeed or find Facebook content via word of mouth, online or offline referrals, and from targeted web searches of the Facebook page. Organic reach metrics were used in this study rather than total reach metrics that include paid reach, to reflect the number of unique users reached by each piece of content. Although organic and paid reach data together indicate the number of Facebook users who saw or engaged with a post and both metrics are a result of Facebook-created search algorithms, organic reach considered is a better indicator of the number of users who may have specifically sought out MMHRC-related content. In contrast, paid reach includes the number of Facebook users who may have seen MMHRC content because it was provided to them by paid Facebook advertising. Facebook does not publish information regarding how they operationalize their algorithms.

Engagement

Engagement was measured in terms of actions taken by the Facebook user in response to viewing content—an original post, a shared post, or another user's comment regarding a post. Engagement data, also obtained via Facebook Analytics, included the following:

- The number of *clicks* was defined as the total number of times people click on a post content.
- The number of *likes* was defined as the total number of times people like either an original post content or a comment by another user.
- The number of *comments* was defined as the total number of times users respond to posts by entering text into a post's comment box, including emojis, tags, or hashtags (eg, @JohnDoe or #PMAD).
- The number of *shares* was defined as the total number of times users share content on their personal timeline; a Facebook friend's timeline; in a Facebook group; in an event page; in a page managed by the user; or in a private message to a friend, group, or page.

Facebook provides a dashboard of quantitative information regarding user views or the number of users reached by each Facebook post, as well as the number of times content was reshared by users. User views are only viewable by the administrators of the Facebook account, whereas the volume of engagement for each post (ie, clicks, likes, comments, and shares) are public.

Facebook discloses the number of *likes* garnered from each post, as well as emoji-based *reactions*. These reactions include the number of positive reactions as well as negative reactions to the post (eg, sad or angry emojis) to the posts. These data provide insight into the level of engagement elicited by each Facebook post.

Procedures and Analyses

Members of the research team extracted data using Facebook Analytics, compiling responses to post information into a standard spreadsheet format. Responses to Facebook content were deidentified as data were extracted, to ensure anonymity of Facebook users who view the MMHRC Facebook page was maintained. Data were extracted at least one month after substance use content was posted, as Facebook uses that timeframe when sharing information about reach. Descriptive counts were compiled and tabulated according to substance (cannabis, opioids, or alcohol), content type (informational or experiential), and target (policy-, practice-, or perception-related) to facilitate review by the research team over the course of the study and to report findings.

Results

Reach and Engagement Classified by Substance Featured in Post Content

Posts related to cannabis generated the largest reach on Facebook, followed by alcohol- and opioid-related content (Table 2). User reactions to content had a similar ranking; cannabis-related content generated the most reactions, followed by opioid- and alcohol-related content. The level of engagement paralleled the level of reach. Cannabis-related content generated the highest levels of engagement, followed by alcohol- and opioid-related content.

Table 2. Levels of reach and engagement per Facebook post classified by substance.

Substance type and post title	Organic reach, n	Clicks, n	Likes, n	Comments, n	Shares, n
Opioids					
Insurance and pregnancy are barriers to opioid treatment	530	3	4	0	2
Opioids increasingly tied to deaths of pregnant women	688	17	8	0	3
Embracing the needs of pregnant women and infants in our nation's battle against the opioid crisis	491	10	3	0	1
Most physician health plans don't allow medical professionals access to the same treatment as patients	461	4	0	0	0
The dangerous stigma against pregnant women addicted to opioids	1117	24	8	1	2
How the opioid epidemic affects women differently	833	18	3	2	3
Cannabis					
Is cannabis safe during pregnancy? More expecting mothers are wondering	1242	125	12	3	3
Pregnant women in the US are giving up major vices—except one	1076	56	5	1	1
Marijuana use doubles in U.S. pregnant women, especially during first trimester	1990	59	17	0	10
More women are using marijuana during pregnancy, report says	3045	441	44	29	12
Why some mothers keep using cannabis during pregnancy and breastfeeding	1256	67	9	1	5
Good Chemistry, Worcester’s first marijuana dispensary, is open for recreational sales	654	8	5	0	2
Alcohol					
Conversational approach most successful way of encouraging drinking habit disclosure	453	13	0	0	0
Study tracks drinking habits of new parents	2291	249	17	11	12
Mixed messages about safe consumption during pregnancy	1086	204	9	0	3
Drinking during pregnancy: is a little alcohol ever okay?	754	30	6	0	1
Jenna Drennen: fighting back against ‘mommy wine culture’	1642	46	36	6	10
Does pregnant Gretchen Rossi drink a little wine?	534	22	2	0	0

Reach and Engagement Classified by Type of Post Content

Experiential posts reached more Facebook users than informational posts for cannabis- and opioid-related content, whereas informational posts reached more Facebook users than experiential posts for alcohol-related content (see Tables 1 and 2). A similar trend was observed for the number of likes, comments, and shares; there were more likes, comments, and shares for experiential posts than informational posts for cannabis- and opioid-related content, whereas there were more likes, comments, and shares for informational posts than experiential posts for alcohol-related content.

For cannabis-related content, experiential posts reached and engaged more Facebook users than informational content. For opioid-related content, experiential posts reached more Facebook users and had slightly higher levels of engagement than informational posts. For alcohol-related content, informational posts both reached and engaged more Facebook users than did experiential posts.

Reach and Engagement Classified by Target of Post Content

For cannabis-related content, policy-targeted posts reached and engaged almost double the number of Facebook users than perception- and practice-targeted posts. Although the levels of reach were similar for practice- and perception-targeted posts, practice-targeted posts had almost double the number of clicks yet half the number of shares and similar numbers of likes as compared to perception-targeted posts. For opioid-related content, practice-targeted posts reached the most Facebook users (n=1805), followed by perception-targeted posts (n=1324) and policy-targeted posts (n=991). Practice-targeted posts had almost double the number of clicks as perception-targeted posts and more than five times the number of clicks as policy-targeted posts. Practice-targeted posts also had more likes, comments, and shares than perception- and policy-targeted posts. For alcohol-related content, practice-targeted posts reached the most

Facebook users (n=3933), followed by policy-targeted posts (n=1840) and perception-targeted posts (n=987). Although policy-targeted posts had less than half the level of reach compared to practice-targeted posts, both post types had similar numbers of clicks (n=234 and n=295, respectively). Perception-targeted posts had a much lower number of clicks (n=35). Practice-targeted posts also had more likes and shares than policy- and perceptions-targeted posts.

Discussion

Principal Findings

The purpose of this study was to explore, for the first time, the level of engagement with social media posts in an online community for mothers with mental health and substance use disorders. The study supports the potential benefit of social media in reaching mothers and conveying information about substance use, potentially serving as an avenue to treatment access and engagement. Our findings highlight the potential benefits of using social media to provide preventive messaging about substance use during or after pregnancy and opportunities to provide information to women about what is safe and unsafe and how to anonymously ask these questions.

Social media posts through the MMHRC Facebook page reached approximately 3000 members of the online community. Although previous studies have not explored whether different substances or content characteristics elicit different levels of reach and engagement, our results suggest that social media users who viewed the posts may have been more interested in engaging with content related to cannabis use than alcohol or opioid use at the time of the study. It is possible that cannabis elicited more reach and engagement among these women because cannabis use has increased among women and pregnant women in recent years [34] and because, at the time of the study, additional states decriminalized cannabis, possibly resulting in additional media coverage and awareness. With a focus on cannabis-related content, policy-targeted posts garnered more reach and engagement than practice- and perception-targeted posts. For opioid- and alcohol-related content, however, posts that were targeted toward practice generally garnered more reach, clicks, likes, comments, and shares than those targeted toward policy or perceptions. Cannabis- and opioid-related experiential posts also generated more reach and engagement than informational posts, as compared to alcohol-related content (which generated more reach and engagement from informational posts). These results have implications for which types of content may be best shared in a social media setting. Perhaps it would behoove individuals looking to share substance use content to tailor posting language in accordance with these findings, acknowledging that women may be more likely to engage with content that pertains to more widely used substances (eg, cannabis). At the same time, these findings suggest that women are interested in information pertaining to alcohol use and perhaps would further engage with informational social media posts.

Limitations

There are a few notable limitations to this exploratory study. First, this study refers to substance use or misuse as a continuum of substance use problems. We have not made a distinction between substance use or misuse and substance use disorders, such as meeting the Diagnostic and Statistical Manual of Mental Disorders criteria (which is less common than use or misuse), although using or misusing substances during pregnancy requires different strategies (ie, preventative messaging) as opposed to substance use disorders (which implies chaotic or uncontrolled use despite consequences). This study also presents the results of online engagement with one social media–based community; therefore, the findings may not be generalizable to other online communities and to the general population of Facebook users. As the MMHRC’s mission is to connect mothers with researchers and other stakeholders in the cocreation of research, it is possible that MMHRC followers are more willing to be engaged in content than similar online communities and social media–based peer support networks. At the same time, MMHRC followers do not need to self-identify with a mental illness or have experience with substance use or substance use disorder in order to view or engage with the Facebook community posts. Hence, viewing or engaging with the posts does not necessarily suggest that a person is actively engaged in substance use, meets the criteria for a substance use disorder, or is interested in treatment or other health services.

Second, only one piece of content was posted for each intersection of substance type, type of post, and target of post. Since only 18 pieces of content were posted in total, the generalizability of findings is further limited, as one piece of substance use content cannot fully represent all of its intersections. Moreover, although the time of posting was randomized, each piece of content was not posted more than once. Therefore, the day and time of posting could have impacted the levels of reach and engagement for each post.

Third, it is unknown whether the reach and engagement was due to the content itself or the caption used when posting the content piece on the Facebook page. Because the post caption precedes the post content, the caption has the potential to either encourage or dissuade the Facebook user from engaging with the content.

Fourth, organic reach includes Facebook users who may not be followers of the MMHRC page, so it is possible that individuals other than women with mental health conditions who follow the MMHRC Facebook page were reached and that they engaged with the social media content.

Despite these limitations, this exploratory study is a step toward identifying and framing substance use content in a way that is accessible and available to women with mental health conditions and substance use disorders. Future studies could include additional postings to increase generalizability and perhaps repeat posting content on additional days and times to ensure all MMHRC followers can view the content.

Conclusions and Implications

Policymakers and providers are challenged to develop effective ways to reach women with substance use disorders and engage them in services, treatment, and support that will ultimately benefit them as well as their children. Although some states offer priority treatment for this vulnerable population [35], barriers to accessing treatment persist. The COVID-19 pandemic has intensified the need for digital and, potentially, social media solutions to mitigate logistical barriers and act as an extender of the system of care to help pregnant women and mothers engage in the substance use treatment system. Although the pandemic makes it difficult for women to access in-person treatment and services due to safety concerns, online peer support, perhaps navigated via social media platforms, could reduce social isolation and result in enhanced treatment access, engagement, and outcomes for women with substance use disorders.

Social media has the potential to be an important avenue for reaching Facebook users and engaging them with substance use content, making them aware of health consequences for both the mother and baby and available treatment options. This is especially useful for engaging individuals with co-occurring mental health conditions, who can be a difficult-to-reach population for the substance use treatment system. Given the additional challenges that the COVID-19 pandemic poses in terms of the limitations of in-person treatment services and the increasing the number of individuals who may be in need of treatment for substance use disorders, these findings suggest that providers and policymakers incorporate social media in their plans to mitigate these barriers. Additional research is needed to determine why certain substances garnered more engagement than others; nevertheless, this study suggests that social media has the potential to be an equal player in the treatment system.

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The statements presented in this article are solely the responsibility of the authors and do not necessarily represent the views of PCORI, its Board of Governors, or Methodology Committee.

Conflicts of Interest

None declared.

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Abbreviations

MMHRC: Maternal Mental Health Research Collaborative
NIAAA: National Institute on Alcohol Abuse and Alcoholism
PCORI: Patient-Centered Outcomes Research Institute

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Original Paper

Effects of Mobile App–Based Intervention for Depression in Middle-Aged and Older Adults: Mixed Methods Feasibility Study

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Abstract

Background: Digital mental health interventions may help middle-aged and older adults with depression overcome barriers to accessing traditional care, but few studies have investigated their use in this population.

Objective: This pilot study examines the feasibility, acceptability, and potential efficacy of the Meru Health Program, an 8-week mobile app–delivered intervention.

Methods: A total of 20 community-dwelling middle-aged and older adults (age: mean 61.7 years, SD 11.3) with elevated depressive symptoms participated in a single-arm pilot study investigating the Meru Health Program, an app-delivered intervention supported by remote therapists. The program primarily uses mindfulness and cognitive behavioral skills to target depressive symptoms. A semistructured interview was completed at the baseline to establish current psychiatric diagnoses. Depressive symptoms were measured using the Patient Health Questionnaire and Patient-Reported Outcomes Measurement Information System (PROMIS) depression measures. Anxiety symptoms were measured using the Generalized Anxiety Disorder Scale and the PROMIS Anxiety measure. User experience and acceptability were examined through surveys and qualitative interviews.

Results: In total, 90% (18/20) of the participants completed the program, with 75% (15/20) completing at least 7 of the 8 introductory weekly lessons. On average, participants completed 60 minutes of practice and exchanged 5 messages with their therapists every week. The app was rated as helpful by 89% (17/19) participants. Significant decreases in depressive (P=.03) and anxiety symptom measures (P=.01) were found; 45% (9/20) of participants showed clinically significant improvement in either depressive symptoms or anxiety symptoms.

Conclusions: The findings suggest that the commercially available Meru Health Program may be feasible, acceptable, and potentially beneficial to middle-aged and older adults. Although larger controlled trials are needed to demonstrate efficacy, these findings suggest that digital health interventions may benefit adults of all ages.

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KEYWORDS

aging; depression; digital health; digital therapeutics; mHealth; mobile phone

Introduction

Background

Major depressive disorder (MDD) is among the foremost causes of disability worldwide among older adults [1-3]. In adults aged 55 years and older in the United States, 5.6% experienced MDD within a 1-year period [4]. Two nonpharmacological interventions, cognitive behavioral therapy (CBT) and mindfulness-based interventions have been efficacious in reducing late-life depressive symptoms [5-7]. However, high rates of depression persist because of undertreatment [8,9].

Older adults face multiple barriers in accessing mental health interventions, including limited transportation and mobility, living distally from treatment settings, and high health care costs, which could be addressed with digital health interventions [10,11]. As smartphone use grows, interest in using mobile apps to deliver therapeutic interventions has proliferated [12]. A meta-analysis [13] of randomized controlled trials of mobile apps for depression in adults found a moderate effect size than in inactive controls and a small effect size than in active controls. The applicability of these findings to older adults is unknown because the majority (65%) of randomized controlled trials in the meta-analysis included younger participants (age: mean ≤30 years). Trends in smartphone ownership suggest that older adults, particularly baby boomers, are rapidly adopting mobile devices [14], yet many older adults have not yet used mental health–related mobile apps, despite reported interest and openness to these interventions [15,16].

Few studies have examined mental health–related mobile apps among older users. One group tested an adapted app-based intervention to promote the self-management of chronic conditions alongside peer coaching among middle-aged and older adults with serious mental illness and found it to be feasible, acceptable, and potentially helpful in improving outcomes among the 8 study completers [17]. Another small study examining an app targeting mental wellness in a group-based treatment setting yielded positive feedback about the app from older users, but the findings were limited by substantial attrition [18]. These small studies suggest the acceptability of mental health apps among older users when used alongside in-person support (ie, peer coaches and group-based support). Given the barriers to care faced by older adults, there is a need to examine app-based interventions that do not include extensive in-person support.

Objectives

This study investigates the use of an 8-week mobile app–based intervention with remote therapist support called the Meru Health Program (version 2.0), a commercially available digital health program. The Meru app contains video instructional content and guided practices delivered to a group of 5 to 10 individuals who work through the program as a cohort. Videos and practices teach CBT and mindfulness techniques to manage depressive and related symptoms, such as worry. Patients have access to a dedicated therapist via asynchronous within-app messaging or, if needed, a phone call. The therapist provides guidance by (1) responding to patients' messages, (2) sending unprompted messages to patients and encouraging program adherence, and (3) reviewing responses to practice exercises. The app also includes a moderated discussion where group members can share thoughts and experiences with practices and support other patients by providing limited feedback on their posts.

An uncontrolled study of the Meru Health Program in young adults demonstrated feasibility and reduced depressive symptoms [19]. Similarly, a second uncontrolled study found that 60% exhibited clinically significant improvement in depressive symptoms at the 12-month follow-up [20]. This study extends to an understudied age group of middle-aged and older adults. It examined the feasibility, acceptability, and preliminary efficacy of the Meru Health Program among middle-aged and older adults using a mixed methods approach.

Methods

Participants

Participants were recruited through various announcements describing a mobile app intervention for depression using (1) flyers posted at medical offices and on community boards (eg, at libraries and coffee shops), (2) web-based advertisements (Craigslist and Facebook), (3) word of mouth, and (4) invitations to previous research participants interested in future research opportunities.

The inclusion and exclusion criteria were assessed during the telephone screening. Inclusion criteria were age ≥40 years, elevated depressive symptoms, owning a smartphone, and residing in California because of telehealth laws regarding practicing across state lines. Exclusion criteria included cognitive impairment, suicidal ideation, current participation in psychotherapy, problematic drinking, and psychotic symptoms. Participants taking psychotropic medications must have been on a stable dose (>1 month) to be included.

Measures

Demographic and Health Questionnaire

Demographic information and health status, presence of eight major health conditions (arthritis, asthma or bronchitis, cancer, diabetes, epilepsy, heart disease, hypertension, and stroke), and vision and hearing impairment were gathered at baseline via questionnaires.

The Mobile Device Proficiency Questionnaire

The Mobile Device Proficiency Questionnaire (MDPQ) [21] examines experience with and aptitude for using mobile devices across eight domains: mobile device basics, communication, data and file storage, internet, calendar, entertainment, privacy, troubleshooting, and software management. Each of the 46 items is rated using a 5-point scale with an option for "never tried" (1) and then ratings for ease of completion from "not at all" (2) to "very easily" (5). The total score ranges from 8 to 40, with higher scores reflecting greater proficiency. Internal consistency was excellent (Cronbach α=.96). The MDPQ was completed at the baseline.

Patient Health Questionnaire 9-Item

The Patient Health Questionnaire 9-item (PHQ-9) [22] measures the frequency of depression symptoms over the last 2 weeks. Total scores range from 0 to 27, with higher scores reflecting increased depressive symptom severity. Internal consistency varied across timepoints (baseline α=.60; week 5 α=.82; posttreatment α=.77). The PHQ-9 was completed at the telephone screen, baseline, week 5, and week 8 (posttreatment). Within the app, the PHQ-9 was completed during weeks 1, 3, 5, 7, and 8.

Generalized Anxiety Disorder 7-Item Scale

The Generalized Anxiety Disorder 7-item (GAD-7) scale [23] measures anxiety symptoms characterizing Generalized Anxiety Disorder. Total scores range from 0 to 21, with higher scores reflecting increased anxiety symptom severity. Internal consistency was acceptable to good across timepoints (baseline α=.77; week 5 α=.83; posttreatment α=.86). The GAD-7 was completed at baseline, week 5, and posttreatment. Within the app, the GAD-7 was completed during weeks 1, 5, and 8.

Patient-Reported Outcomes Measurement Information System Depression and Anxiety Measures

The Patient-Reported Outcomes Measurement Information System (PROMIS) Depression (short form 8a) and Anxiety (short form 8) scales were used as secondary measures [24]. Total scores ranged from 8 to 40 on the PROMIS Depression and from 7 to 35 on the PROMIS Anxiety, with higher scores reflecting increased symptom severity. The PROMIS Depression and Anxiety scores had good-to-excellent internal consistency at baseline (α=.90 and .89, respectively) and posttreatment (α=.97 and .95, respectively). The PROMIS measures were completed at baseline and at weeks 5 and 8.

Mini International Neuropsychiatric Interview

The Mini International Neuropsychiatric Interview (MINI 7.0.2) [25] is a semistructured interview that assesses psychiatric disorders using the Diagnostic and Statistical Manual of Mental Disorders 5th Edition [26] criteria. The MINI psychotic screen was administered during the telephone screen; the remainder was administered at baseline to assess current major depression and other comorbid psychiatric disorders. For diagnostic accuracy and supervision purposes, the principal investigator conducted live or audio-recorded observations for half of the interviews conducted by the research staff.

App Use

The app use data collected included the number of messages sent, duration of use, lessons completed, and the number and types of practices completed.

User Experience Survey

At posttreatment, participants completed a 6-item self-report measure about their experiences and impressions of the program (Multimedia Appendix 1). Participants ranked the four components of the app (information, practices, therapist chat, and group support) from most to least helpful. Participants then responded to five statements about the ease of use of the app, helpfulness of the app, helpfulness of the emails, frequency of the emails, and duration of the program using a 5-point Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree).

Qualitative Interview

After treatment, participants completed a semistructured qualitative interview about the program (Multimedia Appendix 1). They were asked about helpful and unhelpful aspects of the program, technical or navigational issues, program benefits, and suggested improvements. The interviews were audio-recorded, transcribed, and reviewed for transcription accuracy.

Procedures

Initial Screening and Baseline Assessment

The study was approved by the Stanford University School of Medicine Institutional Review Board and registered at ClinicalTrials.gov (NCT03652948). The study was conducted between July 2018 and May 2019.

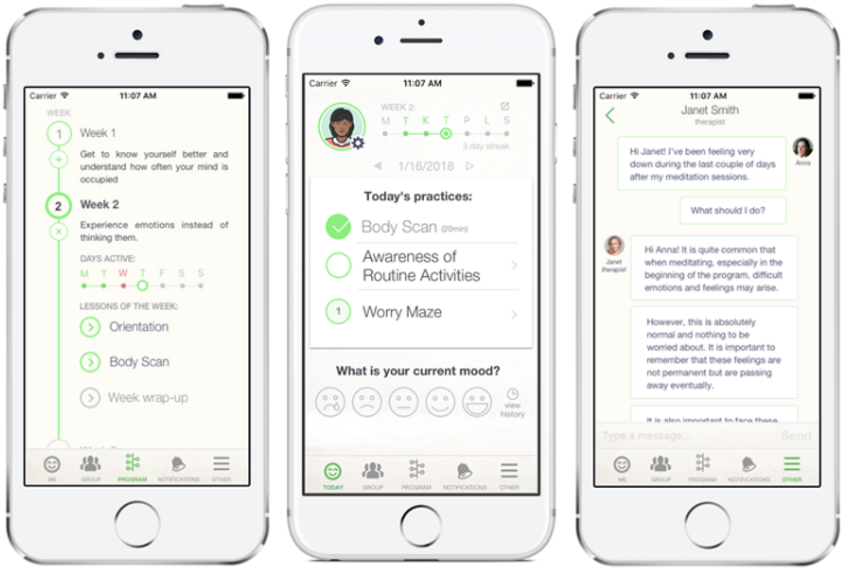
Potential participants completed a telephone screen to assess the inclusion and exclusion criteria. The PHQ-9 [22] determined the presence of elevated depressive symptoms (≥10) [27]. If PHQ-9 item 9 (death or suicide ideation) was endorsed as *several days* or more, then the P4 Suicide Risk Screener [28] was administered to assess active suicidal ideation and, if present, individuals were excluded and referred for treatment. Questions about current mental health treatment assessed for current psychotherapy and use of medications. The Short Blessed Test [29] identified possible cognitive impairments (≥6). The Alcohol Use Disorders Identification Test (AUDIT-C) [30] was used to identify problematic drinking (≥5). Finally, possible psychotic disorders were identified using a psychotic screen from the MINI [25].

Eligible participants were invited to an in-person visit, during which the research staff obtained informed consent, followed by administration of the complete MINI and self-report assessments. Participants then received a handout explaining the steps to begin the Meru Health Program. First, study referrals were sent directly to the Meru therapist, who scheduled an introductory call with the participant. Five days before the start of the program, participants received an email with instructions on downloading and logging into the app on their own smartphone.

Meru Health Program

Meru Health is a registered health care provider in multiple states in the United States and Finland. Individuals primarily access the Meru Health Program by selecting health and employee plans. The app is available for download via the App Store (iOS) or Play Store (Android), but patients require a referral and eligibility screen to access the app after download. As described earlier, the program consists of an app, therapist support (via app and weekly emails), and group discussion. The app has five menu options: (1) "today screen" with informational videos and practices to be completed, (2) group discussion page, (3) program timeline, (4) notifications, and (5) asynchronous within-app messaging with the therapist (Figure 1). Participants can review previous days' content through the program timeline screen and are advised of missed content through notifications. The interactive aspects of the program include the group-based discussion feature wherein participants can share their thoughts, and other members can respond with either a heart icon or one of four supportive statements.

Figure 1. Meru Health Program version 2.0 screenshots.



Week 1

Get to know yourself better and understand how often your mind is occupied

Week 2

Experience emotions instead of thinking them.

Today's practices:

Body Scan (20min)

Awareness of Routine Activities

Worry Maze

What is your current mood?

Janet Smith

therapist

Hi Janet! I've been feeling very down during the last couple of days after my meditation sessions.

What should I do?

Hi Anna! It is quite common that when meditating, especially in the beginning of the program, difficult emotions and feelings may arise.

However, this is absolutely normal and nothing to be worried about. It is important to remember that these feelings are not permanent but are passing away eventually.

Meru Health therapists are licensed practitioners with doctoral or master’s degrees in psychology, counseling, social work, marriage and family therapy, or other related fields. Therapists have formal training in mindfulness, CBT, and manual training (>30 hours), which includes an assessment of skill acquisition to deliver the Meru Health Program. Therapists send weekly emails introducing new content (ie, CBT or mindfulness skills) to be learned within the app each week. Therapists monitor practice completion; send messages to encourage adherence; and review participants’ messages and group discussion posts for possible suicide or homicidal ideation, active substance use, or the presence of psychotic symptoms. The therapist responded to participants exhibiting these symptoms or those who had evidence of worsening mental health within 12 hours. In addition, posts deemed inappropriate or potentially harmful to other group members (ie, triggering) were removed.

5- and 8-Week (Posttreatment) Assessments

Participants were contacted by researchers during week 5 to complete questionnaires assessing depressive and anxiety symptoms. At the posttreatment assessment, participants completed these questionnaires again and provided feedback about the program via a user experience survey and qualitative interview. Participants received payment only for completion of assessments administered by the research team at baseline, week 5, and week 8/posttreatment (total compensation=US $80; US $40 for baseline and posttreatment assessment). No other payment was provided.

Statistical Analysis

To assess the feasibility of the program, we summarized participant flow, inspected retention rates, and calculated the mean use of different app components using the app use data. Acceptability was examined by summarizing responses to the user experience survey.

The qualitative interview transcripts were excerpted by the first author (CEG) using Dedoose 8.2.14 (SocioCultural Research Consultants) web-based software [31]. A codebook was developed using inductive (ie, review of transcripts) and deductive methods. Excerpts were independently coded by the 2 coders. The codebook was revised and adjudicated three times to reach a prespecified reliability of $\kappa>0.70$ (final pooled $\kappa=0.81$). Excerpts were discussed among 3 authors (CEG, CC, and FM), and matrices were created to examine variations in patterns or themes by quantitative ratings consistent with a mixed methods approach [32].

Intervention effects on depressive and anxiety symptoms were estimated using linear mixed effects models using SPSS version 24 (IBM) [33]. All participants were included in the analyses, which used intention-to-treat principles. The models included random intercepts and slopes and used residual maximum likelihood estimation owing to the small sample size [34]; 5% of the data points on dependent variables were missing because of dropouts. Improvement in symptoms indicative of response was defined as having equal to or surpassing the minimally clinically important difference of five points or more [35] on the PHQ-9 or 4 points or more [36] on the GAD-7.

Data Availability

A limited data set that supports the findings of this study is available from the corresponding author upon reasonable request.

Results

Participant Characteristics

Participants (N=20) had a mean age of 61.65 years (SD 11.32; range 42-81 years), and most were women (14/20, 70%) and White and non-Hispanic (12/20, 60%; Table 1). In total, 60%

(12/20) participants were aged 60 years or older; 70% (14/20) met the criteria for the current MDD.

Table 1. Participant characteristics (N=20).

Participant characteristics	Values
Age (years), mean (SD)	61.65 (11.32)
Education (years), mean (SD)	16.60 (2.46)
Sex, n (%)	
Female	14 (70)
Male	6 (30)
Race and ethnicity, n (%)	
White, non-Hispanic	12 (60)
Any race, Hispanic	2 (10)
Asian	3 (15)
Multiracial	3 (15)
Marital status, n (%)	
Single	10 (50)
Married	3 (15)
Separated or divorced	6 (30)
Widowed	1 (5)
Current living situation[a], n (%)	
Alone	9 (45)
With spouse or partner	7 (35)
With relative or roommate	3 (15)
Employment, n (%)	
Full-time	6 (30)
Part-time	2 (10)
Unemployed	7 (35)
Retired	5 (25)
Taking psychotropic medications, n (%)	10 (50)
Self-rated health, n (%)	
Excellent	1 (5)
Good	11 (55)
Fair	6 (30)
Poor	2 (10)
Current medical conditions, n (%)	
Arthritis	10 (50)
Asthma or bronchitis	7 (35)
Cancer	1 (5)
Diabetes	2 (10)
Heart disease	2 (10)
Hypertension	7 (35)
Sensory difficulties, n (%)	
Use eyeglasses	18 (90)
Hearing loss (both ears)	7 (35)
Use hearing aids	3 (15)

Participant characteristics	Values
Prevalence of current psychiatric diagnoses (MINI[b]), n (%)	
Major depressive disorder	14 (70)
Anxiety disorders	12 (60)
Posttraumatic stress disorder	3 (15)
Other disorders[c]	5 (20)
MDPQ[d], mean (SD)	34.68 (4.62)

[a] N=19. Percentages of medical conditions, sensory difficulties, and psychiatric diagnoses do not add up to 100% because participants may have had more than 1 condition.

[b] MINI: Mini International Neuropsychiatric Interview.

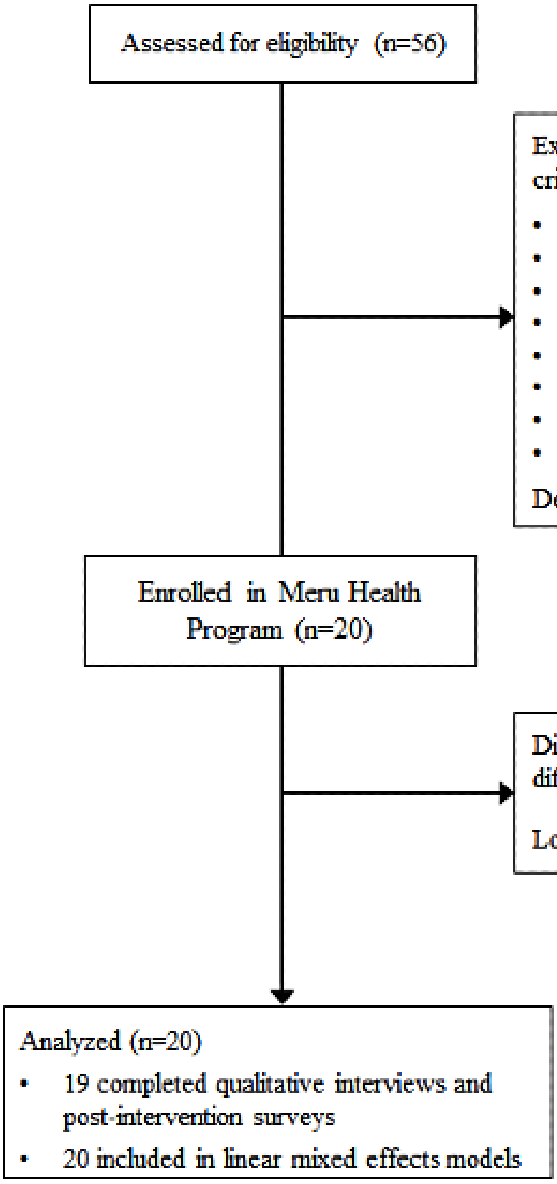
[c] Other disorders include alcohol use (early remission), obsessive-compulsive disorder, and binge eating disorder.

[d] MDPQ: Mobile Device Proficiency Questionnaire.

Feasibility, User Experience, and Acceptability

As displayed in Figure 2, 90% (18/20) participants completed the program, and 2 discontinued the program. One individual (aged >60 years) discontinued the program because of technical challenges with using the app on an older smartphone but completed the postassessment; the other (aged <60 years) discontinued the program because of spontaneous symptom improvement and activities conflicting with app use and did not complete the postassessment. Of the 4 groups conducted during the study, 3 included some Meru Health Program nonstudy patients; one group (n=5) included only study participants. The groups' sizes ranged from 5 to 9 participants. In the mixed groups of study and nonstudy participants, the nonstudy patients comprised half (3/6, 50%) of the participants in one group or a smaller minority (1/9, 11% and 2/6, 33%) in the other two groups. Each group was led by 1 of 2 therapists. No qualitative differences emerged based on which therapist led the groups or whether the groups consisted of study participants only or study and nonstudy participants. Per the app use data (N=20), all participants downloaded the app, logged on, messaged with their therapist, and practiced at least once. The mean duration of time spent on practices throughout the program was 9.07 hours (SD 6.67), which averaged out to approximately 68 minutes each week. Participants sent 13.4 (SD 10.89) messages to their therapist, with a range spanning 2 to 38 messages. Most (15/20, 75%) completed at least 7 of the 8 weekly introductory lessons.

Figure 2. Flow of participants through the study. PHQ-9: Patient Health Questionnaire 9-item.



The user experience survey results displayed in Table 2 highlight that the program was deemed usable by most with some nuances identified during the qualitative interview. Most participants (15/19, 79%) indicated that the program somewhat or completely met their expectations, and 89% (17/19) believed the app was helpful. Examinations of the core program components revealed that the practices were deemed most helpful, and group discussion was the least helpful (Table 3). The inclusion of a therapist proved very important, as highlighted by one participant:

> *Having the therapist there for me was great in the fact that I felt like it wasn't just a computer that I was interacting with in the program. She provided a personal touch which was very important in the program. Because I think we all, at least me, like to be validated by a human, it makes it [the program] more real to me...I had her in case the app was bothering me, I needed a connection to someone that I can talk to about, or if I didn't understand something, I had her to be there for me.*

Another program component, the group discussion component, was deemed the least helpful. However, some participants appreciated reading what others posted (Table 2).

Table 2. User experience survey and qualitative interview findings.

Item	Responses, n (%)	Qualitative interview findings	Example quotes
App usability: the Meru Health app was easy to use.[a]	5 (25): strongly agree; 12 (60): agree 0 (0): neutral 2 (10): disagree 0 (0): strongly disagree	Challenges included difficulty reviewing previous content, typing long answers in response to questions after practices, progress not being saved, crashing, or freezing.	"On some of them [practices] I could pause and rewind and play again, but some of them I could only pause and play." "I'm a typer as opposed to a tapper. I'm much more able to ramble like I'd like to if I had a keyboard in front of me...I seem to have a better hand at expressing my thoughts when I can go back and quickly edit."
Communication: the emails from Meru Health were helpful to me.[b]	9 (45): strongly agree 4 (20): agree 4 (20): neutral 1 (5): disagree 0 (0): strongly disagree	Some expected more communication directly with the therapist. Three were unaware that they would be receiving emails.	"I occasionally got confused whether messages would show up in my email inbox or whether they would show up on the app." "[emails] would break down the topics, and I think that was fabulous, that was very informative. Without that information, it would have been difficult because it was not really explained, I went back and read the emails a few times, so it would make some sense."
Communication frequency: the emails from Meru Health were frequent enough.[b]	11 (55): strongly agree 6 (30): agree 0 (0): neutral 1 (5): disagree 0 (0): strongly disagree	Weekly emails were frequent enough for most participants. Most comments reflected a desire for more personalized communication.	"I thought there would be a little more of the individual therapist or individual communication between the therapist and myself, just a little more of that, a lot more..."
Program length: the Meru Health Program was the right length of time.[a]	9 (45): strongly agree 4 (20): agree 2 (10): neutral 3 (15): disagree 1 (5): strongly disagree	Six participants recommended that it could be longer (9 to 24 weeks). One recommended it be shorter (4 weeks).	"I think it would be great if the app gives [the] participant a time to choose from, for me 3 months would have been ideal."

[a] n=19.

[b] n=18.

Table 3. Mixed methods evaluation of program components (n=19).

Component	Most helpful[a], n (%)	Least helpful, n (%)	Helpful aspects	Areas to improve
Practices	12 (63)	0 (0)	• Having narrator-guided practices • Specific practices, spanning CBT[b] and mindfulness deemed helpful • Included 3-minute reset, breathing, mindfulness, self-compassion, establishing boundaries, and thought record	• Usability issues such as loss of progress if interrupted (or exiting app) while practicing • Desire for chimes or signals when practices end (too much silence) • Need for more introductory practices for certain components (eg, self-compassion) • Clearer option to skip reflection questions after practices
Therapist Support	7 (37)	2 (11)	• Therapist was caring, thoughtful, genuine, and supportive • Provided helpful feedback and comments on participant entries • Helped personalize the program by providing additional information and resources when necessary	• Unclear how frequently to interact with therapist • Unclear how much information to share with therapist
Information Provided	4 (21)	2 (11)	• Education and information about mood and thinking patterns • Provides underlying rationale for CBT and mindfulness practices	• One participant requested practices to help differentiate rumination from reflection concerning thought boundaries.
Group	0 (0)	15 (79)	• Reading others' responses helped people feel less alone and feel validated in their struggles.	• Confusion about how to use the group and need for guidelines • Low rates of participants using group • Limited response options (preprogrammed drop-down) to other members' comments

[a] Three individuals ranked more than 1 component as most helpful; 1 person did not select the most helpful component.

[b] CBT: cognitive behavioral therapy.

Qualitative findings highlighted the aspects of each component that were confusing or would benefit from improvement. Specifically, participants wanted more guidance about how best to use aspects of the program, ranging from questions about the interface to the need for some guidelines in using the therapist and group support. Regarding group support, participants expected to have more flexibility in responding to other group members:

> *A couple of things I read that other people [posted], I wanted to give a comment on, but you were limited to 4 choices...it didn't give you the opportunity to say anything personal, positive, in your own words.*

Other suggestions pertained to having an improved orientation to the app and guidance on how frequently they communicate with the therapist.

Preliminary Effects of the Program on Mental Health Symptoms

Figure 3 displays the mean PHQ-9 and GAD-7 mean scores across timepoints. Table 4 presents the results of the linear mixed effects model. Time was significant (P=.03-.001) in all 4 linear mixed models, which demonstrated that both depressive and anxiety symptoms reduced across the 8-week program (Table 4). The (uncontrolled) effect sizes ranged from medium to large (Hedges *g* values=.41-.94). Regarding clinically significant improvement, 30% (6/20) participants had improvements in depressive symptoms and 45% (9/20) in anxiety symptoms. All 6 who experienced improvement in depression also showed improvement in anxiety. Age and mobile device proficiency were not significantly associated with change in scores on any outcome measures, but older age was associated with lower mobile device proficiency (*r*=−0.60; P=.005). Mobile device proficiency total scores ranged from 26.47 to 40, which falls above the average for older adults (mean 19.2, SD 10.5) in the initial MDPQ validation paper [21].

Figure 3. Mean depression and anxiety symptoms measured within the app and by paper or phone assessments. GAD-7: Generalized Anxiety Disorder 7-item; PHQ-9: Patient Health Questionnaire 9-item.

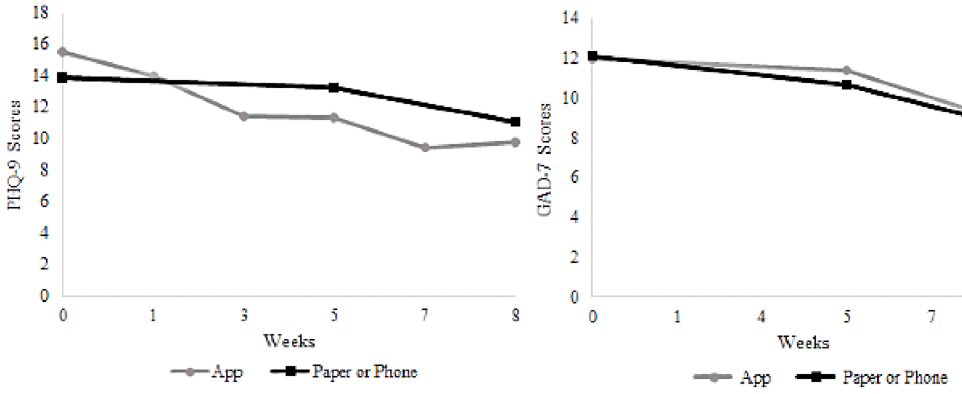


Table 4. Mean assessment scores across timepoints and linear mixed effects models.

Measure	Baseline, mean (SD)	5 weeks, mean (SD)	8 weeks[a], mean (SD)	Parameter estimate (SE)	*t* value (*df*)	P value	Hedges g
PHQ-9[b]	13.90 (4.25)	12.95 (5.86)	10.95 (5.77)	−1.36 (0.58)	−2.33 (19.63)	.03	0.53
GAD-7[c]	12.10 (4.24)	10.33 (5.42)	8.53 (5.18)	−1.74 (0.65)	−2.67 (23.09)	.01	0.69
PROMIS Depression	29.05 (6.96)	24.89 (7.64)	21.21 (8.18)	−3.84 (1.03)	−3.72 (20.32)	<.001	0.94
PROMIS Anxiety	25.25 (6.47)	23.11 (5.92)	21.32 (10.32)	−2.01 (0.83)	−2.40 (20.88)	.03	0.41

[a] N=19 for week 8. Parameter estimates for main effects (time) correspond to changes across each time point (baseline, midpoint, and end of program).

[b] PHQ-9: Patient Health Questionnaire 9-item.

[c] GAD-7: Generalized Anxiety Disorder 7-item.

Discussion

Principal Findings

Our findings suggest the feasibility and acceptability of an 8-week mobile app–based intervention for depressive and anxiety symptoms in a sample of middle-aged and older adults approximately 30 years older than samples in most mobile intervention research. The low dropout rate (10%) and robust engagement with the app mirrors findings with the Meru Health Program in younger adults [19,20] and with an average dropout rate of 17% for internet or mobile interventions [37]. Similarly, the high satisfaction with the app, good ratings of usability, and overall perception that the program was helpful by most participants underscores the acceptability of this intervention in older age groups.

Older adults with depression may benefit from mobile interventions, such as the Meru Health Program, based on significant reductions in depression and anxiety outcomes. This and the finding that 45% (9/20) of individuals achieved a clinically significant reduction in symptoms suggest that the program may be beneficial to some middle-aged and older users. The uncontrolled effect sizes were slightly larger than, but comparable with, those found in a meta-analysis of mobile interventions for depression [13]. Larger controlled studies are needed to replicate our findings and to explore the moderators of treatment outcomes, such as cognition in older adults with depressive symptoms.

The qualitative findings provide an important context to help elucidate specific aspects of the feasibility and acceptability of the program. As expected, the practices were found to be the most helpful component, which is consistent with previous findings regarding guided self-management programs in older adults [38]. The therapist was a critical aspect of the program, particularly for participants who desired human contact, support, and encouragement or struggled with the practices or the app itself. The support model mostly used *pull* support where users reach out for help but also incorporated some *push*-based support (eg, feedback on practice reflections or weekly messages). According to the Efficiency Model of Support, the limitations of pull support include underutilization because of concerns about burdening the supporter [39]. Our findings corroborate this with participants describing uncertainty about how often to communicate with the therapist and warrant further consideration for program refinement.

Group support was a unique, yet underutilized, program component. Being part of a group facing similar struggles was helpful to some in promoting understanding and a sense of not being alone. Unfortunately, the limited response options for communicating with other members undermined the use of and interest in this feature. Thus, this component should be considered for modification to increase its utilization. Such future enhancements will need to balance the risks of providing open-ended interactions, including potential breaches in confidentiality.

Another potential refinement to the program that might especially benefit older adults is an enhanced program orientation, including an in-person or preview of the app, a handout, instructional videos, or a combination of these. Such an orientation may encourage greater exploration of the app, as older users tend to be hesitant about making errors or pressing incorrect buttons, resulting in less app exploration compared with younger users. Other suggestions for program improvements included greater control over video-delivered information (eg, ability to rewind videos to review content). Program compatibility with tablets could help older users experience dexterity and vision challenges. Including older users in usability testing and research on digital health interventions would ensure that these interventions are optimized for all users. Furthermore, ensuring universal design is an important step before dissemination in health care settings, such as primary care that serves patients across the life span.

Limitations

Conclusions from our findings must consider the limitations of the study. Foremost among these was the lack of a control condition, leaving open the question of whether the intervention was responsible for symptom improvement. Second, most of our sample had at least 16 years of education, which may limit the generalizability of the findings to those with less education. Third, our sample for the pilot study was quite small, with 90% (18/20) of participants completing the intervention. Although the sample included 40% (8/20) non-White individuals, because of the small overall sample size, further research is needed to evaluate the efficacy of this intervention in larger and even more racially and ethnically diverse samples. Fourth, a standardized mobile app rating scale or evidence-based usability measure was not used to assess the acceptability or usability of the Meru Health app. Fifth, mobile device proficiency for the sample was substantially higher than that evidenced in the initial study of the MDPQ [21]; thus, the findings may not generalize to individuals less proficient with mobile devices.

Conclusions

In summary, this study found evidence of feasibility and acceptability of a commercially available app, the Meru Health Program, in a small sample of middle-aged and older users. Furthermore, the findings show that some participants experienced reduced psychiatric symptoms. Although larger, controlled trials are needed to demonstrate efficacy, our findings align with research with younger adults and suggest that digital health interventions may benefit and should be offered to adults of all ages. If future research validates these preliminary findings, mobile mental health interventions could be a valuable tool in addressing unmet treatment needs and reducing the burden of depression among older adults.

Acknowledgments

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Conflicts of Interest

CEG, CC, FM, and EK have no conflicts of interest to report. VFH is employed as the Head of Research at Meru Health, Inc, receives a salary from the company, and owns the options of the company. KR serves as the Chief Executive Officer of Meru Health, Inc and owns a large share of the company's stocks.

Multimedia Appendix 1
Meru Health Program study user experience and interview.
[DOC File , 56 KB - formative_v5i6e25808_app1.doc]

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Abbreviations

AUDIT-C: Alcohol Use Disorders Identification Test
CBT: cognitive behavioral therapy
GAD-7: Generalized Anxiety Disorder 7-item
MDD: major depressive disorder
MDPQ: Mobile Device Proficiency Questionnaire
MINI: Mini International Neuropsychiatric Interview
PHQ-9: Patient Health Questionnaire 9-item
PROMIS: Patient-Reported Outcomes Measurement Information System

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Original Paper

Transforming Health and Resiliency Through Integration of Values-based Experiences: Implementation of an Electronic Evidence-based Whole Health Clinical Program

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Abstract

Background: Complementary and integrative health (CIH) is the foundation of the Department of Veterans Affairs (VA) Whole Health System program (WH), including Transforming Health and Resiliency through Integration of Values-based Experiences (THRIVE). The global COVID-19 pandemic prompted an urgent need to provide services such as THRIVE while following guidelines for social distancing.

Objective: The objective of this paper was to describe the systematic implementation of THRIVE using an electronic delivery model.

Methods: The study involved an observational clinical program implementation project using the RE-AIM framework to contextualize the implementation strategies and results, and then the implementation of an electronically delivered CIH group medical appointment program (eTHRIVE).

Results: Clinical staff transitioned to 100% electronic delivery of the THRIVE curriculum using the new eTHRIVE delivery model. The current electronic delivery model, eTHRIVE, has effectively enrolled 10-12 veterans per cohort, with 8 cohorts, totaling 87 veterans to date. eTHRIVE attrition has been 6% (5/87) since initiation.

Conclusions: The current climate of the VA WH programmatic initiative combined with the public health needs during a global pandemic prompted the move of THRIVE program into an electronic format to broaden scalability and reach.

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KEYWORDS

virtual care; group medical appointment; complementary and integrative health; veteran; implementation

Introduction

Opioid reduction, mental health management, and suicide prevention are named priorities for the Department of Veterans Affairs (VA) and the nation. Chronic pain conditions are often not responsive to pharmacological treatment long term [1], yet opioid agents have been the mainstay of treatment. Mental health conditions are often complex, requiring difficult work from patients and are responsive to an integrated approach of medication, lifestyle, and psychological counseling when patients complete treatment programs [2-5]. The urgent need for improved pain and mental health management coupled with veteran demand resulted in the VA Complementary and Integrative Health (CIH) mandate in Subtitle C of the Comprehensive Addiction and Recovery Act (CARA) [6]. In a strategic responsive effort, the VA has implemented a systematic effort to promote patient-centered care through the implementation of a Whole Health System program (WH) of care [7].

The WH integrates allopathic and CIH care, focusing on patients' goals and priorities, with peer-led support, personalized health planning, WH coaches, and well-being classes. There are 3 major components of the WH: (1) the pathway, (2) well-being programs, and (3) whole health clinical care. The pathway introduces veterans to the concepts of WH and helps them identify their health goals and develop their personal health plan. Through the pathway, veterans are introduced to the components of Proactive Health & Well-Being Programs to support their personal health, including health coaching and CIH services, such as acupuncture, chiropractic care, meditation, therapeutic massage, biofeedback, clinical hypnosis, guided imagery, yoga, and Tai Chi. Finally, the third and final component is whole health clinical care, which is a clinical care model that includes use of a WH paradigm for providing a higher level of care in both allopathic and CIH settings, delivered by a multidisciplinary team of clinical providers (eg, physician, social worker, psychologist, pharmacist). Although this third component is critical for combining the delivery of CIH and clinical care, a standardized evidence-based program has not yet been adopted by VA. Standardization of content and delivery of a program supports broader program fidelity efforts (ie, evaluation, treatment effectiveness research, and service administration) [8]. Basing clinical programs on evidence in published literature assures program effectiveness for targeted outcomes (ie, informed clinical decisions, patient outcomes) [9]. Without standardized evidence-based clinical programs, health care programs may stagnate to the status quo, providers and facilities cannot anticipate fidelity, and veterans cannot all access the same quality programs across facilities. There is a need for a standardized evidence-based WH Proactive Health & Well-Being Programs. In addition, group medical appointments provide a sustainable model, to meet the demand of the Proactive Health & Well-Being Programs.

Transforming Health and Resiliency through Integration of Values-based Experiences, more commonly known as THRIVE, based on evidence-based principles of whole health/integrative medicine [10-12], positive psychology [13,14], and acceptance and commitment therapy [15,16], is a clinical program to improve access to CIH modalities for chronic pain, mental health, and suicide prevention services. THRIVE has been implemented in multiple VA regions and is gaining attention as a potential opportunity to fill the need for the WH Proactive Health & Well-Being Programs component. THRIVE is a 14-week curriculum-based group medical appointment for veterans, facilitated by an interdisciplinary team of clinicians. Each weekly group medical appointment focuses on a different component of wellness (eg, financial, spiritual, physical) and is led by a knowledgeable clinician (eg, social worker, chaplain, physical therapist). THRIVE is currently the only evidence-based clinical program in practice that fulfills the 3 components of WH, namely, the pathway, well-being programs, and clinical care, and is identified a best practice by the VA Office of Patient Centered Care and Cultural Transformation (OPCCCT). Although this program was developed for face-to-face delivery, it was adapted for the remote electronic delivery format during the COVID pandemic due to the suspension of face-to-face group medical appointments.

The purpose of this paper is to describe the systematic, rapid implementation of THRIVE using an electronic delivery model. Our intention is to provide a practical example that may be applied to other CIH and group medical appointments as they transition to electronic delivery while maintaining integrity and quality. Evaluation of this implementation is ongoing.

Methods

Overview

RE-AIM is an ideal evidence-based framework for contextualizing the implementation of THRIVE [17]. RE-AIM's 5 elements (*reach the target population, effectiveness, adoption, implementation*, and *maintenance*) provide a systematic framework for planning and implementing programs from the initial efforts of reaching audiences, to establishing effectiveness, then on to promoting adoption, implementation, and ultimately sustaining maintenance over time [18-20]. It is also noteworthy that RE-AIM is a commonly used framework for implementing evidence-based programs in large health care systems, such as the VA, making it a popular and practical framework for such implementation efforts as the THRIVE program. The RE-AIM model has been the guiding framework throughout the development and implementation of THRIVE; however, the pandemic required a real-time adaptation that was expeditious in nature. Through an ongoing development and quality improvement between the clinical team and the implementation team, RE-AIM has been used to provide a framework to contextualize and guide eTHRIVE implementation. Planning and implementation of THRIVE are described using the 5 elements.

Reach the Target Population

THRIVE was developed by a female veteran physician for female veterans. The program was provided within VA women's health care clinics, using a clinician-informed referral process to ensure the program was aligned and appropriate for the *target population* (female veterans with chronic conditions). Subsequently, based on patient outcomes and feedback, the THRIVE program was expanded and modified for male veterans. The program moved from women's health to the larger WH service to ensure access and integration throughout the health care system to reach all veterans in need of access to CIH modalities in managing not only chronic conditions but also living a values-based life.

Effectiveness

Effectiveness can be measured in many ways (eg, clinical outcomes, organizational outcomes). A recent evaluation of 201 female veteran participants in THRIVE demonstrated the *effectiveness* of this program at improving self-reported mental health outcomes, such as depression, anxiety, psychological inflexibility, and experiential avoidance, as well as improvements in life satisfaction and work pain interference [21]. Organizational outcomes such as cost-effectiveness are currently under review.

Adoption

An organizational cultural transformation is imperative for adoption of innovative programs such as THRIVE [7,22,23]. THRIVE gained popular support and *adoption* by clinical teams, administration, and veterans. Once adopted at the originating veterans' hospital, implementation efforts expanded to facilities within the Veterans Integrated Service Network (VISN) followed by spread to neighboring VISNs.

Implementation and Maintenance

The VA is an established leader in implementation science. The *implementation* of eTHRIVE was subsequent to many implementation efforts to the original THRIVE program. Implementation strategies [24] facilitated the strategic steps used to reach the population (ie, veterans) with an effective program (ie, THRIVE) through a new service delivery (ie, electronic). This rapid practical application of implementation strategies was based on best practices [24], literature [24], experience of the implementation team [25,26], and the needs of the program in the real-time implementation. [*Implementation strategies are hereafter presented in parenthesis in the following sections.]*

Results

eTHRIVE Overview

The eTHRIVE process resulted in 14 strategic steps and implementation strategies, and data on program uptake and attrition. In its initial development, to support fidelity, scalability, and maintenance of THRIVE, an implementation manual and a train-the-trainer program (*use train-the-trainer strategies, make training dynamic*), THRIVE Immersion, were developed for VA staff to facilitate and sustain the THRIVE program within various clinical settings.

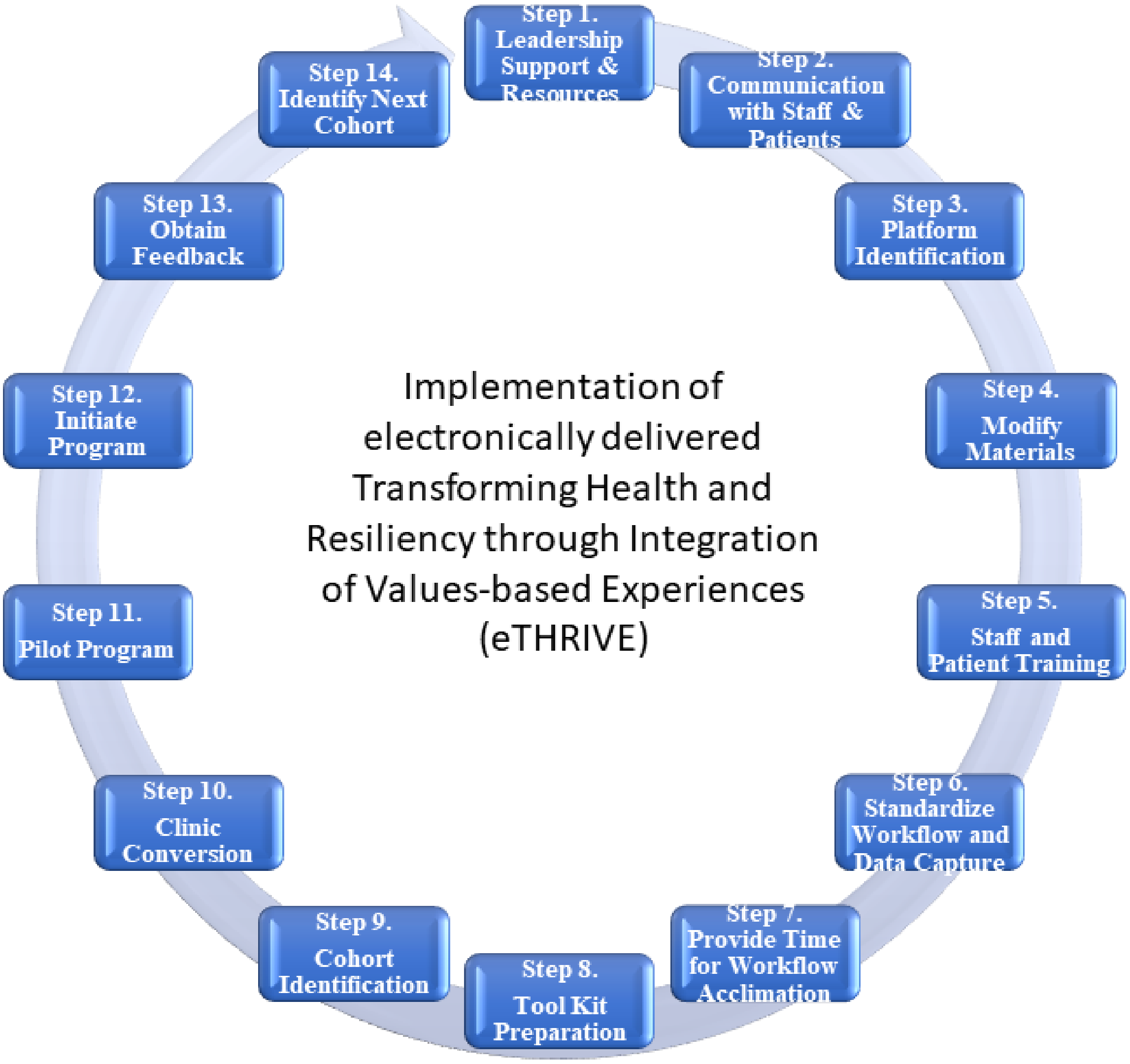
As THRIVE moved into its fourth year of implementation in 2020, a growing waitlist and limited resources posed challenges for access and hopes for establishing the scalability of this clinical program. As with most programs, staffing, space, and other resources that are often in high demand illustrate the limitations of scaling up access to the program. Transferring the earlier in-person THRIVE program to a standardized electronic format for delivery creates an exponential opportunity for scalability, mobility, and control. For example, in the face-to-face delivery model, 10 veterans per cohort, averaging 13 cohorts per year, totaled 400 veterans to date. Whereas with an electronic version (*stage implementation scale up*) processes allow approximately 10 veterans per cohort (to maintain a small, yet high-quality dynamic group), with 50 cohorts per year, resulting in 500 veterans served per year, exponentially increasing the number of veterans served annually. The eTHRIVE program not only creates an opportunity to broaden reach through scalability, but also presents benefit through resource conservation, cutting costs in materials, and space. For example, some of the in-person materials were modified to electronic materials (eg, presentations converted to video), thus eliminating the need for staff to be present for those segments of the program, creating more time to serve additional cohorts. It is critical to understand there is an issue with supply and demand when considering meeting space within most medical centers. With competing interests and high demand, remote delivery becomes the most economical strategy to broaden reach to veterans. Although the program creator and early adopting providers saw the potential of delivering the program as an electronically delivered service, VA policies and infrastructure did not support the opportunity for eTHRIVE in the current system. However, recent COVID-19 pandemic events have thrust the VA into a new era of policy and opportunity for innovating in the delivery of care using electronic resources while reducing contact. As such, providers must now deliver services virtually, including WH care. This presents a timely opportunity for implementing the THRIVE program in the broader VA system.

Implementation and Maintenance of eTHRIVE

Overview of Steps

Implementation of eTHRIVE was a clinical care process that required clear communication and quick response to ever evolving public health pandemic crisis. During this unprecedented public health emergency, WH providers, staff, and clients acted together to support continuity of care through electronically delivered services. The 14-step process is shown in Figure 1.

Figure 1. 14-step process for implementation of electronically delivered Transforming Health and Resiliency through Integration of Values-based Experiences (eTHRIVE).



Step 1

The first step was to garner leadership support (involve executive boards) and resources (hardware, software, ongoing technical support as staff learned new systems, reallocation of funding from salaries to equipment) for the transfer and implementation of eTHRIVE. This critical step involved establishing stakeholder buy-in and justification of necessary resources to transition to electronic delivery (*change service sites*) of THRIVE in the wake of a larger transition required to maintain continuity and access to care in the wake of establishing new paradigms of remote care in the context of a global pandemic. Staff were organized into small groups (*organize clinician implementation team meetings*) for brain storming implementation (*conduct local consensus discussions*).

Step 2

Communication of transition with staff and veteran patients was imperative. As in-person group medical appointments came to an immediate halt at the onset of the COVID-19 pandemic, the disruption of workflow for staff and potential discontinuation of services to veteran patients presented problems that required immediate attention. As such, communication about the transition of THRIVE to electronic delivery (eTHRIVE) was prioritized as a critical need to establish new workflow patterns and ensure veteran patients continued to have access to care (*promote adaptability*).

Step 3

The THRIVE team leveraged existing resources to identify a platform (*tailor strategies*, *promote adaptability*) to provide electronically delivered services. The platform needed to be accessible to all levels of technology-proficient providers, staff, and clients. Intuitive platforms were most desirable to facilitate platform training (*facilitation*) to all who would access the platform. The platform also needed to include an educational package such as whiteboards, polling, and shared video viewing. After reviewing the locally available platforms, an appropriate platform was selected.

Step 4

eTHRIVE materials were reviewed to determine if they were already in the appropriate electronic format (ie, video, PowerPoint) or if they needed to be revised (*audit and provide feedback*) to an optimal presentation mode for the new platform. Paper-based materials would be delivered in the eTHRIVE tool kit (see Step 5).

Step 5

It was critical to prepare staff with skills and proficiency in using technology to deliver eTHRIVE [in addition to the THRIVE immersion training (train-the-trainer training)]. Most clinic staff worked within the clinic weekdays during regular business hours. They had no need for computer, video, or audio equipment to be assigned to them for use from home. This caused a delay in standing up the eTHRIVE program. Lack of equipment and software for work from home created transition stress for staff and providers. Once individuals had the technical mobility for remote work (*change physical structure and equipment*), training on the new platform began. We ran through scenarios, tested platform functions, and delegated “champions” (*identify and prepare champions*, *provide local technical assistance*) who could be a resource for technical issues. These champions (*identify early adopters*) were instrumental in assisting team members with transitions to the home environment. As staff and providers became familiar with the platform, we began training patients. With each patient training, staff became more familiar with the platform and were able to independently modify trainings (*conduct ongoing training*) to best meet patient needs. Teams met routinely with staff, consultants, and leadership to provide ongoing consultation (*provide ongoing consultation*) and continued education (*conduct educational meetings*).

Step 6

While staff and clients became familiar with the platform and new processes, eTHRIVE leadership, in collaboration with researchers (*use data experts, use an implementation advisor*), identified and developed standardized tools (*develop and implement tools for quality monitoring*) and processes (*develop and organize quality monitoring systems*) to capture patient and workflow data. Data, collected in an organized, standard way across providers and time, was used to identify glitches in the new system. These issues were brought to the attention of leadership (*inform local opinion leaders*) and addressed in a timely fashion to maintain continuity of care, even though this was such a large transition.

Step 7

When transitioning into a remote work environment, it is critical to give staff time and support to acclimate to their new workflow dynamics. WH leadership recognized the stress of these transitions and built time into plans to allow acclamation to this new work environment and all the changes that come with a public health emergency requiring stay at home orders. Most urgent transitions can be burdensome, creating stress not only among clients but also for the staff and providers who provide care. Stay at home orders meant many staff and providers were also juggling personal life demands with new work protocols while finding space and equipment in the home for all household members to continue addressing their responsibilities.

Step 8

The next step was to create eTHRIVE tool kits (*develop educational materials*). Each tool kit contained a THRIVE workbook, THRIVE journal, art supplies, markers, dry erase response paddle, and other supplies used with each of the 14 units. Tool kits were mailed to participants (*distribute educational materials*) in a single package. Materials for each unit were placed in individual envelopes. The tool kit also included additional worksheets, metrics, and packets for clients to complete in specific weeks with a self-addressed stamped envelope to return metrics to the WH team.

Step 9

Although identification of eTHRIVE cohorts was a step in this process, the means for identification did not change from identification of THRIVE cohorts. Each cohort is generated from consults. Consults were typically entered into the VA electronic health record by primary care providers familiar with WH and the benefits of group medical appointments such as THRIVE. WH staff contacted veterans with pending consults and invited them to participate in eTHRIVE. When clients accepted the invitation, staff further verified acceptability and capability with electronically delivered care (*intervene with patients/consumers to enhance uptake and adherence, prepare patients/consumers to be active participants*).

Step 10

Conversion of clinics (*alter incentive/allowance structures*, *change record systems*) from standard to virtual care was conducted to get organizational virtual care credit (*make billing easier*). This conversation required rebuilding every clinic, creating a grid and renaming these clinics, and obtaining time-consuming administration approvals.

Step 11

Pilot an eTHRIVE group medical appointment with veterans (*assess for readiness and identify barriers and facilitators*) to ensure usability. Piloting the eTHRIVE group was an essential component to ensuring the staff and veterans were comfortable using the technology, as well as ensuring the technology and delivery modes were fully functional for eTHRIVE delivery.

Step 12

Conduct an eTHRIVE program with veteran cohorts. Once all systems, processes, and materials were prepared and piloted, the eTHRIVE program was conducted as a fully functioning electronically delivered group medical appointment.

Step 13

As in any implementation of a large-scale process change, rapid feedback on the process (*conduct cyclical small tests of change*) is imperative and a critical aspect of maintaining optimal implementation over time. Hard copy standard metrics were sent to all participants (N=87) with the majority (n=69) returned to the team by postal mail. There is typically a response burden when participants are required to mail (postal) paper data to clinicians or evaluators. Electronic data collection was subsequently implemented to be in alignment with delivery and remote accessibility. Attrition (5/87, 6%) and acceptability were tracked (*purposely reexamine the implementation*) as a marker for the new platform. Additional feedback measures included feedback surveys (*obtain and use patients/consumers and family feedback*) after each episode of care and recap after each session with staff to improve performance. These data (ie, acceptability, feedback surveys) are currently being analyzed.

Step 14

Identify next cohort and repeat delivery of eTHRIVE with integration of feedback and lessons learned to enhance delivery support program implementation maintenance over time. As with all program implementation and evaluation, eTHRIVE used this approach with the first groups to elicit feedback (*involve patients/consumers and family members*) and inform revisions (*capture and share local knowledge*) to improve the program process and delivery to optimize veterans' experience and promote program outcomes.

Uptake and Attrition

Clinical staff have transitioned to 100% electronic delivery of the THRIVE curriculum using the new eTHRIVE delivery model. The current electronic delivery model, eTHRIVE, has effectively enrolled 10-12 veterans per cohort, with 8 cohorts, totaling 87 veterans to date. eTHRIVE attrition has been 6% (5/87) since initiation. As efforts move forward, program content will be fully re-designed for electronic format and program administrators will leverage opportunities, such as the use of tablets, while balancing barriers associated with those same opportunities, including acquisitions.

Discussion

Principal Findings

The Whole Health Program is the VA's systematic response to provide a CIH care approach to help veterans manage their health, particularly mental health and pain conditions associated with opioid use and suicide. THRIVE, an evidence-based clinical CIH program, has been systematically transitioned to an electronic delivery model to ensure continuity and access to care in light of the COVID-19 crisis, and the resultant critical need for remote access of care.

Implementation of eTHRIVE was a clinical care process that transitioned face-to-face group medical appointments to electronic delivery group medical appointments in 14 systematic steps. From garnering stakeholder support and selecting a virtual platform, to implementing, evaluating, and refining the program, the process was systematically conducted to ensure successful delivery of eTHRIVE for targeted veteran patients in need.

eTHRIVE presents a multitude of opportunities, including moving to a more pliable applicable platform that is sustainable and remotely accessible, improving reach to marginalized populations. However, eTHRIVE implementation also presented a multitude of potential challenges. First, government-issued equipment for speed and security is required, and patients require technology such as smart pads and personal computers. In addition to equipment and bandwidth requirements, information technology support, which is often limited, is a critical resource required for implementation. Besides, adequate transition time is required to get staff and patients prepared for electronic delivery. While the challenges and resource limitations pose barriers for any electronically delivered program implementation, the benefits of remote access and patient outcomes associated with CIH in a group medical appointment setting warrant effort and resources.

Because of the urgency for continuity of care during the COVID-19 pandemic, the transition and implementation of THRIVE to eTHRIVE was done with urgency. Some limitations to this rapid implementation include lack of a needs and readiness assessment and co-creation of a stakeholder-invested implementation plan, and solutions (eg, adequate equipment, employee telework protocols, and IT support) had to be developed concurrently and reactively opposed to a proactive strategic process. Although these limitations clearly present challenges to the implementation process, the real-world implementation necessitated by a global pandemic presented a unique opportunity to create a remote delivery option that was previously prohibitive, due to outdated confidentiality and privacy policies that did not reflect modern technological capabilities in an emerging era of remotely delivered health care.

Conclusions

This paper shows the value of outlining the strategic process for adapting a shared medical appointment approach to a remote delivery model while maintaining the integrity of the group medical experience. The current climate of the VA WH programmatic initiative combined with the health care remote access needs due to the current pandemic creates an opportune time to move group medical appointment clinical care programs into an electronic format to broaden scalability and reach. The VA now has the motivation—and need—to leverage infrastructure and resources to implement group medical appointment clinical care programs such as eTHRIVE. The transition from face-to-face to electronic delivery of eTHRIVE occurred in 14 pseudo-simultaneous steps. As implementation of this exemplar group medical appointment clinical care program advances, dissemination of data findings, return on investment, cost-effectiveness, and factors effecting electronic implementation will be critical in moving the science forward as the VA strategizes the electronic delivery of care to all veterans while reducing contact.

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Authors' Contributions

JH, as primary author, consulted on the program implementation, developed this manuscript, participated heavily in drafting all sections, and provided extensive editing. JP spearheaded the implementation of eTHRIVE, provided details on the steps of implementation and oversight to the integrity of this manuscript with implementation of eTHRIVE. CM developed this manuscript, drafted Abstract, Background, Methods, and Discussion. CM was responsible for formatting, editing, and submission of this manuscript. The corresponding author attests that all coauthors have reviewed and approved of the manuscript prior to submission.

Conflicts of Interest

None declared.

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Abbreviations

CARA: Comprehensive Addiction and Recovery Act
CIH: complementary and integrative health
OPCCCT: Office of Patient Centered Care and Cultural Transformation
THRIVE: Transforming Health and Resiliency through Integration of Values-based Experiences
VA: Department of Veterans Affairs
VISN: Veterans Integrated Service Network
WH: Whole Health System program

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Original Paper

Advancing Mental Health and Psychological Support for Health Care Workers Using Digital Technologies and Platforms

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Abstract

Background: The COVID-19 pandemic is a global public health crisis that has not only endangered the lives of patients but also resulted in increased psychological issues among medical professionals, especially frontline health care workers. As the crisis caused by the pandemic shifts from acute to protracted, attention should be paid to the devastating impacts on health care workers' mental health and social well-being. Digital technologies are being harnessed to support the responses to the pandemic, which provide opportunities to advance mental health and psychological support for health care workers.

Objective: The aim of this study is to develop a framework to describe and organize the psychological and mental health issues that health care workers are facing during the COVID-19 pandemic. Based on the framework, this study also proposes interventions from digital health perspectives that health care workers can leverage during and after the pandemic.

Methods: The psychological problems and mental health issues that health care workers have encountered during the COVID-19 pandemic were reviewed and analyzed based on the proposed MEET (Mental Health, Environment, Event, and Technology) framework, which also demonstrated the interactions among mental health, digital interventions, and social support.

Results: Health care workers are facing increased risk of experiencing mental health issues due to the COVID-19 pandemic, including burnout, fear, worry, distress, pressure, anxiety, and depression. These negative emotional stressors may cause psychological problems for health care workers and affect their physical and mental health. Digital technologies and platforms are playing pivotal roles in mitigating psychological issues and providing effective support. The proposed framework enabled a better understanding of how to mitigate the psychological effects during the pandemic, recover from associated experiences, and provide comprehensive institutional and societal infrastructures for the well-being of health care workers.

Conclusions: The COVID-19 pandemic presents unprecedented challenges due to its prolonged uncertainty, immediate threat to patient safety, and evolving professional demands. It is urgent to protect the mental health and strengthen the psychological resilience of health care workers. Given that the pandemic is expected to exist for a long time, caring for mental health has become a "new normal" that needs a strengthened multisector collaboration to facilitate support and reduce health disparities. The proposed MEET framework could provide structured guidelines for further studies on how technology interacts with mental and psychological health for different populations.

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KEYWORDS

mental health; health care workers; health informatics; digital intervention; health technology; mobile health; COVID-19

Introduction

The COVID-19 pandemic, as a prolonged global public health crisis, has heavily burdened health care systems and the health care workers who are the direct responders to safeguard people's health. Positive and optimistic emotional states play important roles in stimulating the human body's immune system, which could enable health care workers to effectively engage in the fight against the pandemic. Excessive pressure, anxiety, and depression can be detrimental to mental health and may prevent health care workers from actively performing their duties in response to the pandemic. The scale, pervasiveness, and complexity of the stressors associated with the ongoing pandemic are unprecedented, despite the fact that some countries have achieved milestones in controlling the pandemic and have moved forward to the initiation of vaccination [1]. With the realization that the end of the pandemic is far from close, the toll of the pandemic on the mental health and well-being of health care workers still requires urgent attention.

Experiencing intense pressure at work for a long time may cause a series of problems that can affect physical and mental health, which can also affect workers' quality of life and work efficiency [2,3]. The threat of being infected by the virus, inability to complete work, emotional impact of patients' deaths, and concerns regarding the safety of family members all increase the emotional pressure on health care workers. Although vaccines have been distributed in some countries, research indicates that vaccine compliance remains variable and inconsistent [4,5]. The existing mental problems in the face of extensive media coverage of the rising numbers of casualties, overburdened health care systems, and psychological issues caused by the COVID-19 pandemic may have fostered health care workers' anxieties and distrust in preventative health care. These fears could also result in vaccine hesitancy [4]. Given that the COVID-19 pandemic is expected to persist for a long time, caring for health care workers' mental health has become a "new normal" that requires strengthened multisector collaboration to facilitate mental health support and reduce health disparities. However, to enhance their psychological preparedness for the new normal of the pandemic, there is a need to integrate resources and provide a more comprehensive and concerted psychological support for health care workers.

Understanding the risks of mental health issues that health care workers have been experiencing, identifying effective interventions to address the adverse effects of the pandemic, and proposing tailored strategies based on digital health will offer valuable support for health care workers. As we look to an uncertain future, a conceptual framework for the development and deployment of support will facilitate well-being endeavors and provide a foundation for addressing long-term mental health needs. The aim of this study is to develop a framework to describe and organize the mental health and psychological problems that health care workers are facing during the pandemic. Based on the framework, this study also proposes potential interventions from digital health perspectives that health care workers could leverage during and after the pandemic.

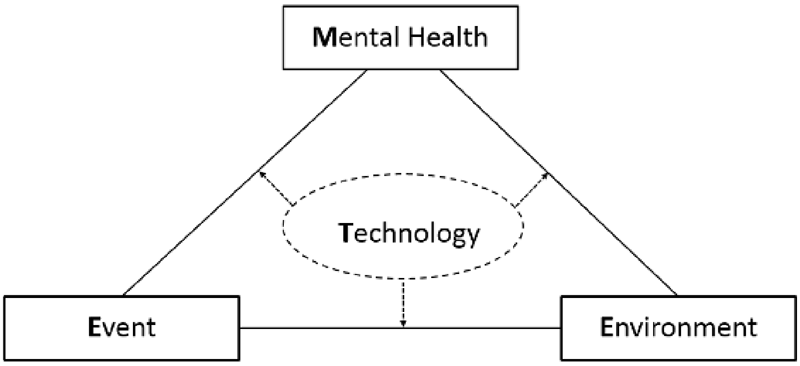
Methods

Conceptual Framework

In this study, we reviewed and analyzed the psychological problems and mental health issues that health care workers have encountered during the COVID-19 pandemic, and we developed the MEET (Mental Health, Environment, Event, and Technology) framework (Figure 1) to demonstrate the interactions of mental health, digital interventions, and social support.

There is a mismatch between the societal and organizational sources of psychological problems, such as lack of personal protective equipment, overwhelming workload, and the attempts by health care systems to address mental health issues at an individual level [6]. In this framework, mental health includes cognitive status, activities of daily living, behaviors, and instrumental activities of daily living. Environment refers to factors that are related to social support, family, and network composition. Events include the COVID-19 pandemic, lockdown, social distancing, and vaccine distribution [7]. Technology includes diverse types of digital interventions and platforms [8], such as online support forums, telehealth platforms, health apps, and wearable devices. Through the MEET framework, it is possible to better understand the interactions between mental health, event, environment, and technology.

Figure 1. The MEET (Mental Health, Environment, Event, and Technology) framework.



Search Strategy

The search strategy and selection criteria were designed to search the PubMed, Health Source: Nursing/Academic Edition, Embase database, and Scopus databases to identify relevant articles published up to the date of the study. Search terms included *COVID-19*, *2019-nCov*, *SARS-CoV-2*, *SARS-CoV*, and *coronavirus* and in combination with *health care worker*, *mental health*, *psychological health*, *technology*, and *digital intervention*. The search strategy also included Medical Subject Headings terms in the search strategy for PubMed and Emtree terms for Embase. The search was not restricted by study design.

Textbox 1 demonstrates the search strategy based on the proposed MEET framework. This framework could also be applied to other populations by replacing section V with the corresponding population, such as older patients, pediatrics, etc [9].

Textbox 1. Search strategy outline based on the proposed MEET (Mental Health, Environment, Event, and Technology) framework.

I: Mental health

1. Mental*

2. Psychol*

3. Psychiatric*

4. Anxiety

5. Depress*

6. Stress*

7. Psychosocial

8. Emotion*

II: Environment

1. COVID-19*

2. SARS-CoV-2*

3. Severe acute respiratory syndrome coronavirus 2

4. 2019-nCoV*

III: Event

1. Pandemic

2. Lockdown

3. Quarantine

4. Social distanc*

5. Infection

6. Vaccin*

IV: Technology

1. Technology

2. Digital intervention

3. Digital health

4. Digital platform

5. Informatic*

6. Health technology

V: Population

1. Health care worker*

2. Health care provider*

3. Health care professional*

Search strategy:

(I1 or I2 or I3 or I4 or I5 or I6 or I7 or I8) AND (II1 or II 2 or II 3 or II 4) AND (III1 or III2 or III3 or III4 or III5 or III6) AND (IV1 or IV2 or IV3 or IV4 or IV5 or IV6) AND (V1 or V2 or V3)

Study Selection and Eligibility Criteria

This study included any type of study about any type of health care worker during the COVID-19 pandemic with outcomes relating to their mental and psychological health, as well as studies about digital health technologies and platforms. The prevalence of mental health issues and effects and the interventions aimed at preventing or reducing negative mental health issues were analyzed and summarized narratively. The search strategy imposed no restrictions on study design, methodology, or language. This study focused on the health care worker population and identified references by searching (title/abstract) using the keywords from the four domains (mental health, environment, event, and technology) that are listed in Textbox 1.

Results

Psychological Problems and Mental Health Issues of Health Care Workers

Anger

The inner sense of security of health care workers has been threatened by the global pandemic. Health care workers may feel helpless and powerless. From the psychological perspective, anger is a type of psychological defense [10]. There are multiple triggers of anger: anger with sudden outbreak, helplessness during the spread of the pandemic, delayed vaccination, etc.

Anxiety

Health care workers have received professional medical training, which can help them address the pandemic objectively and rationally. However, they also have the same emotional responses as the general population, who are experiencing feelings of anxiety and panic. In addition to worrying about themselves and their families being infected with SARS-CoV-2, some health care workers are worried that the pandemic will continue to spread. Some health care workers pay too much attention to negative news and information. When they feel physical discomfort, especially with respiratory symptoms, they often manifest anxiety, nervousness, and restlessness. This sense of losing control will likely result in overthinking, pessimism, loss of appetite, overeating, or weight loss [11].

Obsessive-Compulsive Habits, Traits, and Disorder

Obsessive-compulsive disorder [12] refers to a mental disorder with the main symptoms of repeated compulsive actions or forced thinking. In the current pandemic situation, hand washing, opening windows, and wearing masks are effective means to prevent SARS-CoV-2 infection. However, health care workers may engage in forced actions of excessive disinfection behaviors. They may overthink the negative consequences of the disease, while these abnormal behaviors can cause painful feelings.

Hypochondriasis

Hypochondriasis is a psychopathological status [13] in which a person ascertains that they have a specific disease without clear medical evidence. In the context of the COVID-19 pandemic, health care workers are in close proximity or direct contact with a large number of patients, and the potential risk factors for infection are significantly increased, which can lead to hypochondriasis. When physical discomfort occurs, the health care workers may overthink their symptoms, which may cause unnecessary anxiety and nervousness.

Depression

Pessimistic feelings are likely to trigger negative and hopeless emotions. These emotions are signs of depression. Various factors may contribute to depression, such as grief over the loss of lives, fear of becoming ill, and psychological trauma from the global pandemic [14].

Sleep Issues

Sufficient sleep is essential for health care workers to restore physical strength and improve immunity after high-intensity work. Having a good quality of sleep can reduce the risk of illness. However, during the pandemic, there are multiple barriers to sleep: isolation from society, disordered life rhythm, mental fatigue, depression, loss of interest and joy in life, etc. Health care workers may have difficulty falling asleep even when in an exhausted physical state, or they may experience shortened sleep time, frequent waking and dreaming, and disordered sleep rhythms [15].

Physical Discomfort and Somatization

During the pandemic, some health care workers may feel physical discomfort, which may be caused by physiological or mental health issues. Strong psychological fluctuation will lead to physical discomfort involving organ systems throughout the body. When health care workers are under great pressure, negative emotions tend to be transformed into physical symptoms, which is commonly called somatization [16]. With these symptoms, psychological disorders and pain may not be detected but may be present in the psychopathological process in the forms of physical discomfort or dysfunction. Common types of physical discomfort include palpitations, chest tightness, shortness of breath, airway obstruction, dizziness, bloating, fatigue, decreased appetite, unstable blood pressure, and menstrual disorders [17]. These experiences of physical discomfort tend to increase the tendency toward hypochondriasis and often lead to a sense of panic.

Cognitive Issues in Concentration

The human body will redistribute blood nutrients to the heart, muscles, and other organs when it is under stress. This process will reduce the essential supply to the brain and result in inattention, inability to focus, and decreased ability of judgment and perception. In addition, paranoia may be generated in such situations [18].

Behavioral Issues

In hospitals, when health care workers treat patients who are suspected SARS-CoV-2 carriers, and they are likely to be sensitive to patients' coughing and prone to have conflicts with them. An irregular lifestyle, such as unhealthy diet, poor sleep, and lack of physical activity, will increase the likelihood of infection. Common behavioral problems include performance avoidance, decreased work enthusiasm and physical activity, increased dependence on families, and disorderly lifestyle and self-management. Health care workers may also experience unhealthy lifestyle activities, such as smoking, drinking, staying up late, and overeating; or blind behaviors, such as panic buying and stockpiling of disinfection supplies, food, drugs, etc [19].

Mental Health and Psychological Protection Interventions

The COVID-19 pandemic has resulted in an increase in risk factors for mental health issues, which requires both short-term adaptations and sustained responses. Lack of training, social support, effective communication, and accommodative coping are common factors for developing psychological morbidities and adverse psychiatric outcomes [20]. Comprehensively integrated intervention approaches are often more effective than single treatment methods and have a longer-lasting effect. The emerging health information technologies [21] coupled with recent innovations in digital health could enable health services to offer tailored and proactive mental health care for health care workers.

Digital Communication Platforms

During the COVID-19 pandemic, health care workers are most likely to communicate with colleagues with whom they have been working together closely. This is because these colleagues are empathetic and understand the hardships and difficulties of frontline work, and their mutual consolation will be an effective intervention. Understanding and support from family are also important. However, due to the policy of social distancing, digital platforms may be more accessible during a pandemic [22]. These platforms could enable health care workers to communicate, which is an essential component of any universal, community-led response to the pandemic [23]. Furthermore, the digital communication platforms could provide a peer-support network for health care workers to share their emotional feelings, challenges, and personalized resolutions, which may foster resilience and comradeship.

Telehealth Platforms

Another ideal communication partner is a psychologist. Communicating with psychologists through telehealth or remote platforms can allow health care workers to express negative emotions, actively talk about the difficulties they face, and express personal feelings encountered during the work. Primary mental health care modes such as counseling, psychotherapy, or pharmacological treatment should be provided through the health care workers' local health care system or organization as needed. Professional guidance from psychologists will help health care workers to relieve negative emotions, adjust their negative cognition, and restore a healthy mentality to enable them to better cope with work and interact harmoniously with their families. For those health care workers who are too busy to receive support from local psychologists, resources such as employee assistance programs, [24] crisis hotlines [25], and other institutional resources may be good first steps.

Self-Guided Psychological Interventions

Nonpharmacological interventions, such as cognitive-behavioral therapy, meditation, mindfulness, breathing, and relaxation training through websites or mobile apps, will be suitable for health care workers. Internet-based psychological intervention may be the most convenient, fast, and economical means for health care workers who are currently fighting the novel coronavirus. With the help of information technology, these interventions can be transformed into audiovisual interactions, which enables health care workers to access web-based psychological intervention without being restricted to a particular time and place. This media information can also transmit scientific psychological crisis response strategies to frontline health care workers effectively. In this way, health care workers can improve their mental health protection awareness and take timely action.

Internet-Based Interventions

Regularity, order, and a sense of control are effective means of coping with anxiety and panic. During the pandemic, despite the limited range and number of activities, health care workers are still expected to actively balance work and life. They should not overuse alcohol or tobacco to relieve pressure or negative emotions. Health care workers who have sleep issues need to pay attention to sleep hygiene and decrease their use of caffeine [26]. Studies have shown that evidence-based internet interventions can be helpful to address these issues [27]. For health care institutions that have not implemented internet-based interventions, providing mindfulness education or meditation interventions could significantly reduce stress and other psychological diseases [28,29].

Web-Based Learning Communities

Obtaining mental health knowledge through web-based learning communities is another effective approach. Emotions such as anxiety and fear are normal psychological reactions, and moderate anxiety can help people increase their awareness of prevention [30] and avoid dangerous environments. However, excessive pressure and anxiety will weaken the human body's immune system and damage its protection mechanisms. Receiving mental health education and training enables health care workers to make rapid and scientific judgments about their psychological status and offers them keen insights into abnormal psychological reactions.

This training includes education on the psychosocial impact of high-casualty events in different settings. Health care workers could develop a personalized resilience plan that involves the identification of anticipated responses. Meanwhile, they should also be taught how to use digital and mobile health technologies for delivering care [31,32]. The earlier the intervention, the more likely that negative moods and psychological situations will be adjusted in time. Furthermore, this training will help health care workers understand stress-related obstacles and approaches to adjust their emotions in the face of catastrophic events as well as establish the correct psychological defense mechanism against crises. Although training and education may not generate an immediate effect, these efforts will create an active continuum of improved environment [33], reinforce the capacity to support increased access to care for mental health issues, and strengthen health care workers' readiness for the new normal of the postpandemic era.

Artificial Intelligence in Health Care Systems

The COVID-19 pandemic has increased the stress of health care workers who were already overwhelmed by high workloads. Many health care workers are on the fringe of reaching their physical and psychological limits. High stress and overwork not only damage health care workers' physical and mental health [34] but also affect their decision-making during clinical work [35]. Health care workers should objectively assess their own ability to withstand pressure and stress and measure their ability to devote themselves to effective work. Using artificial intelligence approaches, such as machine learning and deep learning [36], to plan a reasonable schedule of shifts and assist in clinical decision-making [37] may help health care workers avoid physical and mental burnout [38].

Mobile Health

Point-of-care systems such as portable and smart devices [39], home diagnosis technologies based on the Internet of Things [40], and other digital interventions can help health care workers detect potential physical issues at early stages. In addition, these interventions could be tailored to health care workers and fit with their personal needs and lifestyles.

Short Videos

Health care workers are always seeking a transparent understanding of the situation during the pandemic [41]. Short videos provide a panoramic and detailed record of the actual situation. The intuitive ways in which they present information greatly improve the audience's acceptance and understanding [42]. Some short videos could provide advice on ways to stay healthy by teaching health care workers how to include sufficient physical activity in their routine, eat fresh food, and consume natural supplements that can support their immune systems. In addition, the short videos could facilitate wellness therapies to relieve stress, anxiety, and help health care workers maintain a general sense of mental and physical well-being.

New Media

The timely disclosure and dissemination of information could help health care workers and their families understand the course of the incident, the truth, and the real situation [43]. Meanwhile, authoritative information also eliminates rumors and prevents excessive pressure on health care workers. Higher satisfaction with disseminated public information may contribute to lower psychological distress. In the current situation, authoritative news could be quickly and widely disseminated through health communication technologies (ie, social media, short videos) to address public concerns. This information can strengthen the credibility of official departments and help reduce or even eliminate the influence of rumors [44]. New media platforms are also enhancing the affinity and attractiveness of digital approaches.

Social Media

Social media platforms are important sources for supervision of public opinion. During the pandemic, all departments, agencies, and institutions in society have been interlocked in their responses to the emergency, which requires an orderly, accurate, and efficient workflow. Mobile information and health communication technologies play prominent roles in media supervision, investigation, and filling in information gaps. Through mobile communication platforms, health care workers from different departments at the front line could share their perseverance, efforts, and strategies to prevent and control the pandemic situation from multiple perspectives [45].

Through social media, humanistic information and communication can not only calm health care workers and boost their confidence but also positively guide the public and help mitigate negative and anxious environments [46]. Social media is playing a comprehensive role in science popularization, as it is based on modern mobile communication technologies that are conveying scientific knowledge to the public in a fast, timely, and vivid fashion. With multiplatform and multichannel support to achieve rapid information coverage, the public can obtain a scientific understanding of the dynamic situation in a short time and mobilize their subjective initiatives for effective preventive actions, which is more efficient than passive installation [47].

Discussion

Principal Findings

Health care workers and professionals have the critical responsibilities of saving lives and protecting people's health during the COVID-19 pandemic. The pandemic has undoubtedly created universal psychological distress. Efforts to address the problem and to prevent the long-term mental health deterioration of health care workers are paramount in the response to COVID-19. Understanding the risks of mental health issues that health care workers are experiencing, identifying effective interventions to address the adverse effects of the pandemic, and proposing tailored strategies based on digital health will offer valuable support for health care workers. We provide a conceptual framework for allocation of the main sectors (mental health, environment, event, and technology) at the individual, organizational, and societal levels, focusing on addressing health care workers’ well-being needs during and after the pandemic.

To prepare for the long-term fight against the pandemic, these guardians of human life must maintain their physical and mental health to work effectively to take care of more patients. Providing health care workers with positive support will help mobilize their self-psychological protection capabilities, thus allowing them to continue their valuable work. The need for more mental health services will introduce additional burdens to health care systems, and digital health technologies are playing vital roles to relieve these overwhelmed systems. Leveraging hybrid solutions that offer web-based, telehealth-based, or blended face-to-face intervention and treatment may be more accessible and effective [48].

In addition to using digital technologies and platforms, health care workers should avoid information overload. Due to the modernization of communication approaches, the amount of information about the pandemic is overwhelming, which can increase the sense of insecurity and uncertainty. The traditional ways in which people obtain information, such as newspapers, radio, and television, have been transferred to the internet and mobile platforms such as social media, video, or live broadcast platforms. Mobile information and health communication technologies have revolutionized information dissemination, data exchange, media supervision, guidance of public opinion, and health communication [49]. Health care workers should pay more attention to authoritative information, actively avoiding negative news and preventing information from overwhelming them. Meanwhile, health care workers should also keep in regular contact with families and friends, which can not only increase emotional interaction and psychological support but can also increase mutual encouragement.

The pandemic may cause pressure, panic, and psychological trauma to health care workers. Technologies could not solve all the problems. Mild emotional distress can be adjusted by health care workers themselves, while serious panic will seriously impact their daily life. Self-regulation often has a limited effect and requires professional assistance, and it is not suitable for every health care worker, especially young health care providers who have not experienced such a serious crisis. Health care workers with insufficient clinical experience may generate more pressure and experience persistent depression, anxiety, insomnia, and other symptoms. Health care workers should request remote counseling from experts or go to a psychological clinic for consultation when necessary. If their psychological problems cannot be relieved after receiving professional psychological intervention or mental health services, psychiatrists should intervene in time and provide corresponding diagnosis and treatment. Given that the COVID-19 pandemic is expected to continue for a long time, caring for mental health has become a new normal that needs strengthened multisector collaboration to improve social support and reduce health disparities. To enhance the psychological preparedness of health care workers for the new normal of the pandemic, there is a need to integrate resources and provide them with more comprehensive and concerted psychological support.

Conclusion

The COVID-19 pandemic has heavily burdened health care systems throughout the world. It is urgent and critical to protect the mental health and strengthen the psychological resilience of health care workers. The proposed MEET framework could aid understanding of the interactions among the mental health, event, environment, and technology sectors. In addition, this framework may provide structured guidelines for future research on mental and psychological studies for different populations. Long-term, proactive individual, organizational, and societal infrastructures to support health care workers' mental health are needed to mitigate the psychological impact of the COVID-19 pandemic. Embedding these mental health practices as part of the new normal can be a stepping stone to a new future with benefits and implications for other global public health issues far beyond the response to the COVID-19 pandemic.

Authors' Contributions

JY was responsible for the study design, data analysis, interpretation of results for the work, and writing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

MEET: Mental Health, Environment, Event, and Technology

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Original Paper

A Web-Based Intervention to Increase Smokers’ Intentions to Participate in a Cessation Study Offered at the Point of Lung Screening: Factorial Randomized Trial

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Abstract

Background: Screen ASSIST is a cessation trial offered to current smokers at the point of lung cancer screening. Because of the unique position of promoting a prevention behavior (smoking cessation) within the context of a detection behavior (lung cancer screening), this study employed prospect theory to design and formatively evaluate a targeted recruitment video prior to trial launch.

Objective: The aim of this study was to identify which message frames were most effective at promoting intent to participate in a smoking cessation study.

Methods: Participants were recruited from a proprietary opt-in online panel company and randomized to a 2 (benefits of quitting vs risks of continuing to smoke at the time of lung screening; BvR) × 2 (gains of participating vs losses of not participating in a cessation study; GvL) message design experiment (N=314). The primary outcome was self-assessed intent to participate in a smoking cessation study. Message effectiveness and lung cancer risk perception measures were also collected. Analysis of variance examined the main effect of the 2 message factors and a least absolute shrinkage and selection operator (LASSO) approach identified predictors of intent to participate in a multivariable model. A mediation analysis was conducted to determine the direct and indirect effects of message factors on intent to participate in a cessation study.

Results: A total of 296 participants completed the intervention. There were no significant differences in intent to participate in a smoking cessation study between message frames (P=.12 and P=.61). In the multivariable model, quit importance (P<.001), perceived message relevance (P<.001), and affective risk response (ie, worry about developing lung cancer; P<.001) were significant predictors of intent to participate. The benefits of quitting frame significantly increased affective risk response ($\text{Mean}_{\text{benefits}}$ 2.60 vs $\text{Mean}_{\text{risk}}$ 2.40; P=.03), which mediated the relationship between message frame and intent to participate (b=0.24; 95% CI 0.01-0.47; P=.03).

Conclusions: This study provides theoretical and practical guidance on how to design and evaluate proactive recruitment messages for a cessation trial. Based on our findings, we conclude that heavy smokers are more responsive to recruitment messages that frame the benefits of quitting as it increased affective risk response, which predicted greater intention to participate in a smoking cessation study.

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KEYWORDS

clinical trials recruitment; digital outreach; message design experiment; smoking cessation; lung cancer screening; prospect theory

Introduction

Background

In the United States, lung cancer is the leading cause of cancer-related death and accounts for more deaths than breast, prostate, colorectal, and brain cancers combined [1]. The number one risk factor for lung cancer is cigarette smoking, which is linked to 80%-90% of all lung cancer deaths [2]. Despite a substantial decline in smoking prevalence over the past 30 years, approximately 1 in 7 adults still report daily cigarette smoking [3]. To reduce lung cancer mortality, the US Preventative Services Task Force (USPSTF) recommends eligible individuals complete an annual lung cancer screening test to detect cancer early and improve survival outcomes [4]. To maximize the benefit of lung cancer screening, the National Cancer Institute also strongly recommends tobacco cessation services be provided to patients undergoing screening as an adjunct [5].

Annual lung cancer screening is a viable opportunity to integrate smoking cessation interventions, as smokers are more receptive to changing their smoking behaviors when they present for screening. McBride et al [6] propose that undergoing the screening process can act as a “teachable moment,” in which receptivity to cessation services is greater because screening (1) increases perceptions of personal risk and outcome expectancies, (2) prompts strong affective or emotional responses, and (3) can redefine self-concept as a smoker. By not promoting smoking cessation during lung cancer screening, it may also send the message that screening obviates the need to quit. From a clinical standpoint, if screening identifies a malignancy, quitting smoking after diagnosis can decrease treatment complications and improve survival rates. Thus, integrating smoking cessation interventions into the lung cancer screening process remains a key public health priority.

However, there remains uncertainty over which cessation treatments are most effective to provide smokers undergoing lung cancer screening. Screen ASSIST is a multicomponent tobacco cessation trial offered to smokers during the lung cancer screening process. Screen ASSIST examines each component’s effectiveness, cost, and burden to determine an optimal combination of cessation treatments. Yet, approximately 20% of all clinical trials fail to reach their accrual goal [7]. To proactively recruit and engage smokers in cessation treatment, Screen ASSIST employs digital outreach strategies. These strategies include identification of eligible patients scheduled for lung cancer screening and dissemination of a targeted recruitment video prior to a patient’s upcoming lung cancer screening appointment.

This study details a formative message design experiment used to determine the most effective message content to include within a recruitment video prior to trial launch. Because of the unique position of promoting a prevention behavior (smoking cessation) within the context of a detection behavior (lung cancer screening), the study was guided by prospect theory. As such, we investigated how best to frame (1) the importance of cessation at the time of lung cancer screening (benefits of quitting vs risks of continuing to smoke) and (2) information about the study to motivate participation in Screen ASSIST (gains of participating vs losses from not participating).

Formative Message Evaluation of Clinical Trial Recruitment Messages

There is lack of a formal evaluation of recruitment strategies prior to trial launch, with best recruitment practices typically identified as a by-product of conducting a trial [8]. Rigorous evaluation of recruitment messages prior to dissemination may improve accrual rates, but this area is still understudied, often nontheoretical, and methods to empirically select the most effective messages before dissemination are limited [9]. Krieger and Neil [10] detail that when developing digital recruitment strategies for clinical trials, pretesting recruitment messages must go beyond simplistic source, channel, and content considerations. As such, careful manipulations of different theory-driven message strategies must be tested based on the trial’s target population, the requirements of the trial, and the health setting in which the trial is offered, as all have the potential to differentially motivate trial participation.

A limited number of studies have leveraged different communication theories to improve recruitment materials for clinical trials. For patients with low motivation and low ability to comprehend health-related information, animations improve knowledge about and attitudes toward clinical trials [11]. Other studies have demonstrated interactivity in decision aids promote information sharing about clinical trials [12], whereas narrative interventions have been shown effective at conveying complex information through patient storytelling [13]. The use of cultural metaphors can effectively improve comprehension about randomization and intent to participate in a trial [14,15], while visual appeals that reflect social group memberships may increase perceptions of identity with the trial’s purpose [16]. Efforts to tailor recruitment materials for minorities have focused on framing participation as a way to reduce existing racial disparities in research, but have not yet been shown effective [17]. Other strategies specific to cessation trials have integrated information about the genetic basis of nicotine dependence in recruitment messages, and have been found to significantly increase enrollment rates of current smokers [18].

In order to be effective, information processing models suggest recruitment messages must be perceived as personally relevant, credible, clear to understand, and inform decision making about trial participation [19]. Perceived message relevance is the extent to which people view trial information as being relevant to them or applicable to their health needs. Message relevance has been shown to mediate the effect of an intervention on cancer screening [20], smokers' response to antismoking messages [21], and the effectiveness of a tailored cessation program [22]. However, limited inquiry has explored its relationship with research participation [15]. Credibility evaluations of clinical trials comprise how accurate trial information is perceived and how believable or knowledgeable the source communicating the information is appraised [23]. Assessments of credibility have been demonstrated salient when patients review information about clinical trials participation [24]. Informational clarity ensures patients with diverse health literacy demands can feel informed about participating in a clinical trial [25]. Ethically, proactive recruitment messages should inform patient decision making prior to being contacted for consent by study staff. Therefore, it is crucial to determine whether different message strategies negatively impact these measures of message effectiveness. To evaluate the effectiveness of the study's message frames across these dimensions, we propose the following research question:

Research Question (RQ1): *Are there differences in message effectiveness measures (perceived message relevance, message credibility, message clarity, and informed decision making) by message frame: (1) benefits of quitting versus risks of continued smoking or (2) gains of participating in a smoking cessation study versus losses of not participating in a smoking cessation study?*

Prospect Theory

Prospect theory has been extensively studied in the context of health decision making, and offers a framework within which to understand the nonlinear relationship between objective health outcomes and how best to present the likelihood of those outcomes [26]. The theory implies that an individual's response to objectively equivalent health messages is dependent upon how the messages are framed, either highlighting perceived benefits or stressing costs. Gray and Harrington [27] outline that gain-framed messages predominantly present the likelihood of attaining a desirable outcome, whereas loss-framed messages predominantly present the likelihood of avoiding an undesirable outcome. The utility of each message frame often depends upon the type of health decision in which they are presented. For example, gain-framed messages are more successful at encouraging risk-averse choices (eg, engaging in preventive behaviors), whereas loss-framed messages are more successful at motivating choices where the outcome is more uncertain or risky (eg, engaging in detection behaviors).

The "prevention-detection distinction" offers a unique theoretical lens in which to develop messages to promote smoking cessation (prevention) at the time of lung cancer screening (detection). Gain-framed messaging has been shown to be more persuasive in promoting smoking cessation [28]. Toll and colleagues [29] highlight that because cessation is a prevention behavior with little associated risk, it is likely that gain-framed messages are more effective, as the benefits are more salient in the short- (eg, "You will have less shortness of breath within 7 days") and long-term (eg, "You will live longer if you quit smoking"). In comparison, losses of not quitting are most often presented as a long-term risk (eg, "You will die sooner if you do not quit smoking"). For cancer screening, however, the losses from not completing a detection behavior are made more immediately prominent, invoking individuals to be more willing to complete a risk-seeking behavior (eg, "If you do not screen for lung cancer now, you will not find cancer early when it is more treatable"). A meta-analysis by O'Keefe and Jenson [30] found that loss-framed appeals, which emphasized the disadvantages of noncompliance messages, significantly encouraged disease detection behaviors.

For smokers, the risk of noncompliance of a prevention or detection behavior can differ based on smoking history, motivation or confidence to quit, and perceived risk. Light smokers may perceive less harm to smoking and fewer benefits of quitting than heavy smokers [31]. For lung cancer screening, heavy smokers have reported fatalistic attitudes toward a diagnosis, and therefore decreased willingness to want to undergo a screening test [32]. As such, utilizing gain and loss frames within this context may have differential effects based on a smoker's individual perceptions of risk. Past research has demonstrated loss frames can increase fear arousal [33]. Within cessation messages, loss frames may increase risk perception (ie, a smoker's understanding of absolute or comparative risk of lung cancer), as well as affective risk response (ie, worry about developing lung cancer). Therefore, we propose the following hypothesis:

Hypothesis 1 (H1): *The risks of continuing to smoke message frame will lead to greater (1) risk perception of developing lung cancer and (2) affective risk response when compared to benefits of quitting smoking message frame.*

As noted, studies have explored gain versus loss framing to motivate cessation behaviors [29,34-36], but these interventions did not directly promote participation in a cessation trial. To the best of the authors' knowledge, Balls-Berry and colleagues [37] have conducted the only previous study to examine the effectiveness of prospect theory message framing on intent to participate in health research. In a sample of African American women, a loss-framed message was more effective at increasing intent to enroll in a health study than a gain-framed message, but only for women with high self-efficacy in their ability to enroll. While self-efficacy to participate in research has been demonstrated as important in other studies [38], this is the first evidence of loss-framed messages being more effective. Loss-framed messages can engender a deeper processing of message content than gain-framed messages and may be useful within recruitment materials [39].

Little is known about the effect of gain- versus loss-framed recruitment messaging on patient participation in a clinical trial. In part, this is because of the ethical requirements of most consent documents to detail that there are no direct benefits of participating in a trial that tests an unproven treatment or the potential to be randomized to receive a placebo. However, these requirements are not necessarily extended to recruitment materials, nor are they extended to all trial types. For example, Screen ASSIST tests a combination of different evidence-based tobacco treatments, ensuring that all participants (1) receive an active treatment combination (not a placebo) and (2) do have the opportunity to directly benefit through the provision of free cessation resources. Despite the effectiveness of loss framing in other contexts, framing how patients will lose out on the opportunities provided in a cessation trial, rather than the benefits of what they will receive, is still an underinvestigated area. Therefore, we propose the following research hypothesis:

***H2:** The losses of not participating message frame will lead to greater intent to participate in a smoking cessation study compared to gains of the participating message frame.*

Past studies have identified disparate enrollment rates in cessation trials and uptake of cessation services across patient subgroups, including race, age, and gender [40-43]. Another study has identified nicotine dependence, quit motivation, and a previous quit attempt were positively associated with greater enrollment rates [44]. To explore participant characteristics associated with intent to participate, as well as better understand how those characteristics are associated with evaluating and better informing the formative development of the recruitment messages, we propose the following exploratory research questions:

***RQ2:** What participant sociodemographic, smoking characteristics, message effectiveness, and lung cancer perception measures are associated with greater intent to participate in a smoking cessation study?*

***RQ3:** For message effectiveness and lung cancer perception measures that are associated with intent to participate in a cessation study, are there differences in subgroups defined by participant sociodemographic and smoking characteristics?*

Methods

Sample and Procedures

In January 2019, 314 participants were recruited from Qualtrics Panels (Qualtrics), a proprietary opt-in online panel company, to complete a 20-minute survey. Participants received a small compensation for their participation and Institutional Review Board approval was obtained before data collection began (#2018P002035). Eligibility criteria reflected national guidelines for lung cancer screening and inclusion criteria for the parent trial [4]. Participants were required to be aged 55-77 and a current smoker (defined as having a "puff in the past 30 days"), as well as reporting a smoking history of a minimum of 20 years and no diagnosis of cancer within the past 5 years. Massachusetts residents were excluded from the study to prevent against contamination with the parent trial and all participants had to be able to read and write in English.

Participants were randomly assigned to receive 1 of 4 videos as part of a 2 × 2 factorial design. The first factor tested framing on the importance of changing smoking behaviors at the time of lung cancer screening (benefits of quitting vs risks of continued smoking; BvR) and the second factor tested framing motivating participation in Screen ASSIST (gains of participating in a smoking cessation study vs losses of not participating in a smoking cessation study; GvL). All participants completed self-assessment premessage surveys, and after viewing 1 of the 4 videos, participants immediately completed postmessage surveys.

Stimuli

Four videos were created specifically for this study, with the aim of selecting 1 video to use as part of the primary video recruitment strategy in the parent trial, Screen ASSIST. Each video included 2 members of the trial team talking directly into the camera: a primary care physician, who is also a study investigator (NR), and a tobacco treatment specialist (IG), who provides cessation counseling in the parent trial. Each video was segmented into 6 sections, including 4 kernel sections that all videos possessed: (1) introducing the aims of Screen ASSIST; (2) reaffirming the importance of attending the patient's upcoming lung cancer screening appointment; (3) what resources were available through Screen ASSIST (eg, access to remote counselling, nicotine replacement therapy, and a community-based resource); and (4) a call to action to indicate willingness to join the study.

Therefore, within each video there were 2 sections that tested how best to frame: (1) the importance of changing smoking behaviors at the time of lung cancer screening and (2) motivating participation in Screen ASSIST. For changing smoking behaviors, the benefits of quitting message frame included the text: "As you probably know, stopping smoking is the *major action you can take to avoid* lung cancer...Your lung screening appointment can be your *first step to quitting.*" The risks of continued smoking message frame included the text: "As you probably know, smoking is the *major cause* of lung cancer...Your lung screening appointment can be your *first step to reducing your risk from smoking.*"

For motivating study participation, the gain-framed motivation to participate message frame included the text: "The *good* news is that quitting, or even reducing the number of cigarettes you smoke each day, *could be much easier with* the support of our study. In our previous study, *patients who participated were 3 times more likely to quit smoking than the average patient. By* participating, you can *benefit* from learning how to control your cravings and have a better quality of life." The loss-framed motivation to participate message frame included the text: "The *not-so-good* news is that quitting, or even reducing the number of cigarettes you smoke each day, can be *more challenging without* the support of our study. In our previous study, *the average patient was 3 times less likely to stop smoking compared to patients who participated. By not* participating, you can *lose out* on learning how to control your cravings and have a better quality of life." The greater likelihood of quitting was informed by quit rates in a past trial conducted by the study team when compared with national quit rates.

Measures

Predictor Measures

Sociodemographics

The following sociodemographic characteristics were measured: gender (male, female, transgender, gender nonconforming, other); race (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Pacific Islander, White, or Other); ethnicity (Hispanic/Latino, not Hispanic/Latino); age (in years); health insurance (yes, no, unsure); household income (less than US $20,000, US $20,000-US $39,999, US $40,000-US $59,999, US $60,000-US $79,999, US $80,000-US $99,999, US $100,000-US $199,999, US $120,000-US $139,999, or more than US $140,000); and highest level of education (no schooling completed; some school, up to eighth grade; some high school, no diploma; high-school graduate, diploma or the equivalent; some college credit, but less than 1 year; 1 or more years of college, no degree; associate degree, bachelor's degree; master's degree; professional degree; doctoral degree). Participants reported screening history (prostate [eg, prostate-specific antigen], lung [eg, low-dose computed tomography scan], breast [eg, mammogram], pancreas [eg, endoscopic ultrasound], skin [eg, examination by doctor], stomach [eg, endoscopy], gynecological [eg, pap smear], colorectal [eg, home stool test or colonoscopy], other, and never screened for any type of cancer).

Smoking Characteristics

The following smoking characteristics were measured: how long the participant had smoked cigarettes (in years); how many cigarettes the participant smoke per day; how soon after the participant wakes up does he/she smoke (within 5 minutes; 6 to 30 minutes; 31 to 60 minutes; after 60 minutes); how much of the time the participant felt the urge to smoke in the past 24 hours (all the time; almost all the time; a lot of the time; some of the time; a little of the time; not at all). Participants attitudes toward quitting were measured using 4 dimensions previously used by the authors (blinded for review): how important it was that the participant quit smoking, 0 (not important at all) to 10 (very important); how confident the participant was he/she could quit smoking, 0 (not confident at all) to 10 (very confident); how much quitting smoking would reduce the participant's chances of developing cancer, 0 (not at all) to 10 (very much); stage of motivation to quit smoking (I have decided to continue smoking; I do not think about quitting smoking; I rarely think about quitting and have no plans to quit; I sometimes think about quitting but I have no plans yet; I often think about quitting but I have no plans yet; I plan to quit smoking in the next 6 months; I plan to quit smoking in the next 30 days; I have begun to make changes in my smoking; I have made changes in my smoking but I need to keep working at it; I have already quit smoking).

eHealth Literacy

eHealth literacy was measured using the eHealth Literacy Scale (eHEALS), a rating scale that measures patients combined knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems and their ability to make subsequent health decisions [45]. The scale includes 8 items measured on a 5-point Likert-type scale ranging from 1 (strongly disagree) to 5 (strongly agree). A composite score was computed, where a higher score indicates greater perceived eHealth literacy (mean 3.97 [SD 0.63]). The internal consistency of data collected using the eHEALS in this study was high (α=.83).

Manipulation Check Measures

Video Watched

Each video was embedded within the survey software, which was able to provide metadata on whether participants (1) reached the survey question in which video was embedded and (2) how long the participant spent on that question before clicking onto the next question. The investigative team used these metadata as proxies of whether the participant watched the video and the length of time the participant watched the video for. If participants remained on the question for at least the length of the video, they were coded as having watched the video. The 4 videos were all similar in length (mean 3 minutes and 1 second; range 2 minutes and 59 seconds to 3 minutes and 4 seconds).

Message Framing and Tone

Items were adapted from King et al [42] to determine how participants perceived the focus of each video. For the smoking behavior change message frame, responses to the prompt "this video focused heavily on..." were measured on a scale from 1 (strongly disagree) to 5 (strongly agree) for the benefits of quitting smoking and risks of continuing to smoke. For the study participation message frame, responses to the prompt "This video focused heavily on..." were measured on a scale from 1 (strongly disagree) to 5 (strongly agree) for the benefits of participating in the study and the costs of not participating in the study. To determine participant perspectives on the overall tone of the video, responses were measured on a scale from 1 (extremely negative) to 5 (extremely positive).

Outcome Measures: Message Evaluation

Message Credibility

Perceptions of informational credibility were measured using items from Appelman and Sundar [23] and assessed participants' perceptions that the video was accurate, credible, and believable. Three items (eg, "The information discussed in the video is accurate") were rated on a 5-point Likert scale, with responses ranging from "strongly disagree" to "strongly agree" (α=.89; mean 4.23 [SD] 0.78).

Message Clarity

Perceptions of message clarity were adapted from Cacioppo et al [46] and measured the extent to which participants perceived the content of the video to be clear and the people in the video to be understandable. Two items (eg, "The content in the video is clearly explained.") were rated on a 5-point Likert scale, with responses ranging from 1 (strongly disagree) to 5 (strongly agree) (α=.85; mean 4.44 [SD 0.81]).

Message Relevance

Perceived message relevance was measured using 2 items from a perceived message relevance scale [20,47]. Items measured how personalized or customized the stimuli was (eg, "The video seemed to be made personally for me”). Items were measured on a 5-point Likert scale, with response categories ranging from 1 (strongly disagree) to 5 (strongly agree) (α=.83; mean 3.69 [SD 1.05]).

Informed Decision Making

Informed decision making about participation in a smoking cessation study was measured using a 1-item scale on a 5-point Likert scale, with response categories ranging from a scale of 1 (strongly disagree) to 5 (strongly agree). The item stated: “With this video, I believe I can make an informed decision on participation in a smoking cessation study” (mean 4.01 [SD 1.02]).

Lung Cancer Perceptions

Lung cancer risk perception was measured on a 2-item scale used previously by the study authors (blinded by review). The first item measured absolute risk of lung cancer (“How likely do you think it is that you will develop lung cancer in your lifetime?”), with response categories ranging from a scale of 1 (extremely likely) to 5 (extremely unlikely) and was reverse coded. The second item measured comparative risk of lung cancer (“When compared to other smokers, what do you think your chance of getting lung cancer is in your lifetime?”), with response categories ranging from a scale of 1 (much lower) to 5 (much higher) (α=.64; mean 3.25 [SD 0.72]). Affective risk response measured lung cancer worry on a 1-item scale (“How worried are you about getting lung cancer in your lifetime?”), with response categories ranging from 1 (not at all) to 4 (extremely) (mean 2.56 [SD 0.93]).

Behavioral Intent to Enroll

Behavioral intent to enroll in a smoking cessation study was adapted from the authors’ previous work on intention to enroll in a cancer clinical trial (blinded for review). Intention was measured on a 5-item Likert scale, with responses ranging from 1 (strongly disagree) to 7 (strongly agree) (eg, “I intend to talk to my doctor about enrolling in a smoking cessation study”). The scale had a very strong internal consistency (α=.94; mean 4.25 [SD 1.69]).

Statistical Analyses

Summary statistics were reported using mean with SD for continuous variables and frequency (n) with percentage for categorical variables. Chi-square tests were performed to examine the main effect of the 2 message factors on the completion of watching video and a logistic regression model was used to test the interaction between the 2 factors. All other manipulation check outcomes, message effectiveness, lung cancer risk perception, and intent to participate were compared using analysis of variance (ANOVA) to examine the main effect of the 2 message factors and the interaction between the 2 factors. To determine the predictors for intent to participate in a smoking cessation study, univariate analyses were conducted to determine the relationship between participant sociodemographic, smoking characteristics, message effectiveness, lung cancer perception measures, and intent to participate. Candidate variables with *P* values of .1 or less were included in the variable selection process. The least absolute shrinkage and selection operator (LASSO) approach was used for variable selection in the final multivariable model. The LASSO approach identifies candidate variables and corresponding regression coefficients that lead to a model that minimizes (1) overfitting the number of variables and (2) overestimating the overall model performance, thus reducing prediction error. A mediation analysis was conducted to determine the direct and indirect effects of message factors on intent to enroll in a cessation trial, guided by statistical principles detailed by VanderWeele [48]. An ANOVA was used to explore differences between subgroups on message effectiveness and lung cancer risk perception variables, in which continuous measures were bifurcated on a mean split (eg, eHealth literacy) or widely accepted clinical comparisons (eg, first cigarette within 30 minutes of waking up).

An a priori power analysis was conducted to ensure the study was powered to detect a medium effect size (Cohen *d*=0.5) between each message factor level (ie, BvR and GvL). In the case without message factor interaction, a total sample of 256 participants would permit detection of such a main effect size with 80% power with a 2-sided significance level of .05. After data collection, interactions between message factors were conducted for message relevance (*P*=.68), credibility (*P*=.63), clarity (*P*=.26), informed decision making (*P*=.48), lung cancer risk perception (*P*=.82), intent to enroll (*P*=.81), but none were found to be significant and so are not discussed further. All analyses were conducted using SAS software, version 9.4 (SAS Institute).

Results

Participant Characteristics

A total of 314 participants were recruited for the study but 18 participants indicated the video did not display or they were unable to play it; therefore, responses from 296 participants were included in the final analysis. There were no meaningful differences between the 18 participants and the remaining 296 in participant characteristics (see Multimedia Appendix 1). Among the 296, participants had a mean age of 62.9 (SD 5.5), were predominantly female (196/296, 66.2%), White (262/296, 88.5%), had no post–high-school education (102/296, 34.5%), had health insurance (264/296, 89.2%), and approximately half reported a household income below US $40,000 (141/296, 47.6%). Participants reported a lifetime of nicotine dependence through the number of years in which they smoked cigarettes (mean 41.11 [SD 9.56]), as well as a current dependence through cigarettes smoked per day (mean 15.44 [SD 9.24]) and time to first cigarette (less than 30 minutes, 221/296, 74.7%). Over a quarter of participants had previously completed a lung cancer screening (Table 1).

Table 1. Characteristics of study sample by message factor (N=296).

Participant characteristics	Total	Risk × Loss (n=71)	Benefit × Loss (n=82)	Risk × Gain (n=68)	Benefit × Gain (n=75)
Age (years), mean (SD)	62.9 (5.5)	62.5 (5.4)	62.9 (5.8)	63.6 (5.6)	63.0 (5.3)
Gender, n (%)					
Male	97 (32.8)	18 (25.4)	22 (26.8)	27 (39.7)	30 (40.0)
Female	196 (66.2)	52 (73.2)	60 (73.2)	40 (58.8)	44 (58.7)
Other	3 (1.0)	1 (1.4)	0	1 (1.5)	1 (1.3)
Race, n (%)					
White	262 (88.5)	64 (90.1)	71 (86.6)	57 (83.8)	70 (93.3)
Black/African American	18 (6.1)	5 (7.0)	5 (6.1)	7 (10.3)	1 (1.3)
Other	16 (5.4)	2 (2.8)	6 (7.3)	4 (5.9)	4 (5.3)
Ethnicity, n (%)					
Hispanic	12 (4.1)	2 (2.8)	6 (7.3)	2 (2.9)	2 (2.7)
Education, n (%)					
High-school graduate	102 (34.5)	26 (36.6)	28 (34.1)	21 (30.9)	27 (36.0)
Post–high-school education	194 (65.5)	45 (63.4)	54 (65.9)	47 (69.1)	48 (64.0)
Health insurance, n (%)					
Insured	264 (89.2)	66 (93.0)	70 (85.4)	63 (92.6)	65 (86.7)
Not insured/do not know	32 (10.8)	5 (7.0)	12 (14.6)	5 (7.4)	10 (13.3)
Income, n (%)					
Less than US $40k	141 (47.6)	34 (47.9)	41 (50.0)	28 (41.2)	38 (50.7)
US $40k or above	95 (32.1)	37 (52.1)	41 (50.0)	40 (58.8)	37 (49.3)
eHealth literacy, mean (SD); range	3.97 (0.63); 1.5-5	3.96 (0.66); 2-5	4.04 (0.64); 1.5-5	4.01 (0.59); 2.25-5	3.86 (0.61); 2.13-5
Lung screening history, n (%)					
Screened for lung cancer	78 (26.4)	21 (29.6)	15 (18.3)	23 (33.8)	19 (25.3)
Other cancer screening history, n (%)[a]					
Prostate	9 (3.1)	2 (2.9)	3 (3.7)	2 (3.1)	2 (2.8)
Breast	20 (7.0)	4 (5.8)	5 (6.2)	5 (7.7)	6 (8.5)
Pancreatic	1 (0.3)	0 (0.0)	1 (1.2)	0 (0.0)	0 (0.0)
Skin	8 (2.8)	3 (4.3)	1 (1.2)	1 (1.5)	3 (4.2)
Stomach	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.4)
Gynecological	28 (9.8)	5 (7.2)	10 (12.3)	8 (12.3)	5 (7.0)
Colorectal	130 (45.5)	33 (47.8)	35 (43.2)	34 (52.3)	28 (39.4)
Other	2 (0.7)	0 (0.0)	0 (0.0)	1 (1.5)	1 (1.4)
Never screened for any test	87 (30.4)	22 (31.9)	26 (32.1)	14 (21.5)	25 (35.2)
Smoking characteristics, n (%)					
Years smoked, mean (SD); range	41.1 (9.6); 20-65	41.4 (8.5); 20-65	39.0 (9.1); 20-60	43.3 (10.8); 20-60	41.1 (9.5); 20-60
Cigarettes smoked per day, mean (SD); range	15.44 (9.2); 0-66	16.8 (10.8); 4-66	13.8 (8.5); 0-40	17.4 (9.6); 0-50	14.2 (7.6); 1-40
Minutes to first cigarette, n (%)					
Within 5 minutes	80 (27.0)	21 (29.6)	16 (19.5)	23 (33.8)	20 (26.7)
6-30 minutes	141 (47.6)	35 (49.3)	40 (48.8)	32 (47.1)	34 (45.3)

Participant characteristics	Total	Risk × Loss (n=71)	Benefit × Loss (n=82)	Risk × Gain (n=68)	Benefit × Gain (n=75)
31-60 minutes	43 (14.5)	12 (16.9)	15 (18.3)	7 (10.3)	9 (12.0)
After 60 minutes	32 (10.8)	3 (4.2)	11 (13.4)	6 (8.8)	12 (16.0)
Urge to smoke in the past 24 hours, n (%)					
All of the time	33 (11.1)	9 (12.7)	8 (9.8)	10 (14.7)	6 (8.0)
Almost all the time	29 (9.8)	9 (12.7)	9 (11.0)	7 (10.3)	4 (5.3)
A lot of the time	92 (31.1)	17 (23.9)	29 (35.4)	16 (23.5)	30 (40.0)
Some of the time	100 (33.8)	23 (32.4)	23 (28.0)	27 (39.7)	27 (36.0)
A little of the time	40 (13.5)	12 (16.9)	12 (14.6)	8 (11.8)	8 (10.7)
Not at all	2 (0.7)	1 (1.4)	1 (1.2)	0 (0.0)	0 (0.0)
Quit importance, mean (SD); range	6.76 (3.01); 0-10	6.57 (3.13); 0-10	6.73 (2.80); 1-10	6.51 (3.30); 0-10	7.15 (2.90); 0-10
Quit confidence, mean (SD); range	4.72 (2.90); 0-10	4.66 (2.96); 0-10	5.18 (2.92); 0-10	4.76 (2.73); 0-10	4.19 (2.99); 0-10
Benefits of quitting to reduce cancer risk, mean (SD); range	6.75 (2.99); 0-10	7.15 (2.72); 0-10	7.11 (2.87); 0-10	6.25 (3.27); 0-10	7.11 (2.87); 0-10
Intention to quit smoking, mean (SD); range	4.90 (2.39); 1-10	5.15 (2.38); 1-9	4.74 (2.38); 1-10	4.87 (2.42); 1-9	4.96 (2.42); 1-9

[a] 10 responses were not recorded (n=69, 81, 65, and 71 for columns 2-5).

Manipulation Check

Of the 296 participants who did not report problems with the videos, 245 (82.8%) completed watching the whole video. There were no significant differences in the video completion rate by message condition (risk and loss=76.1%; benefits and loss=89.0%; risk and gain=83.8%; benefits and gain=81.3%; χ^2_3 [N=296]=2.84; *P*=.20). For the smoking behavior change frames, there were no significant differences between BvR on perceived benefits of quitting ($\text{Mean}_{\text{benefits}}$ 4.27 vs $\text{Mean}_{\text{risk}}$ 4.16; *P*=.28) or on risks of continued smoking ($\text{Mean}_{\text{benefits}}$ 3.20 vs $\text{Mean}_{\text{risk}}$ 3.08; *P*=.45). For the motivating study participation messages, there was no significant difference between GvL frames on the benefits of participating ($\text{Mean}_{\text{gain}}$ 4.08 vs $\text{Mean}_{\text{loss}}$ 4.17; *P*=.39), but those assigned to the losses frame reported greater perception of costs of not participating in the study ($\text{Mean}_{\text{gain}}$ 3.02 vs $\text{Mean}_{\text{loss}}$ 3.37; *P*=.02). For the assessment of the overall tone of the video, there were no significant differences between the BvR frames on tone ($\text{Mean}_{\text{benefits}}$ 4.13 vs $\text{Mean}_{\text{risk}}$ 4.21; *P*=.46) or between the GvL frames ($\text{Mean}_{\text{gain}}$ 4.14 vs $\text{Mean}_{\text{loss}}$ 4.20; *P*=.59).

Study Outcome: Message Effectiveness (RQ1)

To answer RQ1, message effectiveness was measured across 4 dimensions: perceived message relevance, credibility, clarity, and informed decision making about participating in a smoking cessation study. The pooled mean across conditions indicated that all the videos were perceived to be relevant (mean 3.68 [SD 1.05]), credible (mean 4.23 [SD 0.78]), clear (mean 4.44 [SD 0.81]), and informed decision making about participating in a smoking cessation study (mean 4.01 [SD 1.02]). Across the 4 message effectiveness measures, there were no significant differences between the BvR message frames (message relevance, *P*=.78; message credibility, *P*=.70; message clarity, *P*=.43; informed decision making, *P*=.74), between the GvL message frames (message relevance, *P*=.80; message credibility, *P*=.50; message clarity, *P*=.28; informed decision making, *P*=.72), or among the 4 message conditions (message relevance, *P*=.96; message credibility, *P*=.85; message clarity, *P*=.39; informed decision making, *P*=.86; Table 2).

Table 2. Comparison of message frames on study outcomes.

Study outcomes	Benefits of quitting versus risks of continuing to smoke			Gains of participating versus losses of not participating		
	Benefits, mean (SD)	Risks, mean (SD)	*P* value	Gains, mean (SD)	Losses, mean (SD)	*P* value
Message effectiveness						
Perceived message relevance	3.70 (1.07)	3.66 (1.03)	.78	3.70 (1.05)	3.66 (1.06)	.80
Message credibility	4.24 (0.79)	4.21 (0.77)	.70	4.19 (0.81)	4.26 (0.75)	.50
Message clarity	4.48 (0.86)	4.40 (0.76)	.43	4.39 (0.88)	4.49 (0.74)	.28
Informed decision making	4.03 (1.04)	3.99 (1.00)	.74	4.04 (1.01)	3.99 (1.04)	.72
Lung cancer perceptions						
Combined risk perception	2.86 (0.44)	2.88 (0.43)	.67	2.91 (0.46)	2.84 (0.41)	.13
Affective risk response	2.64 (0.93)	2.42 (0.92)	.04	2.57 (0.95)	2.50 (0.91)	.52
Intention to participate	4.37 (1.64)	4.06 (1.71)	.12	4.17 (1.62)	4.27 (1.73)	.61

Lung Cancer Perception (H1)

There were no differences in the perceived risk of developing lung cancer between the BvR message frames (Mean$_{benefits}$ 2.90 vs Mean$_{risk}$ 2.90; *P*=.67); therefore, *H1a* was not supported. However, the benefits of quitting message frame reported a significantly greater affective risk response (ie, worry about developing lung cancer; Mean$_{benefits}$ 2.60 vs Mean$_{risk}$ 2.40; *P*=.03); therefore, *H1b* was not supported and was, in fact, the inverse of our hypothesis. There was no difference between conditions on lung risk perception or affective risk response.

Intention to Enroll in a Smoking Cessation Study (H2)

There were no differences in intention to enroll in a cessation study between the GvL message frames (Mean$_{gain}$ 4.14 vs Mean$_{loss}$ 4.20; *P*=.61); therefore, *H2* was not supported. Exploratory analyses also identified there were also no significant differences between the BvR message frames or message conditions on intent to enroll (*P*=.12).

Predicting Intention to Enroll in a Smoking Cessation Study (RQ2)

Participant sociodemographic, smoking characteristics, message effectiveness, and lung cancer perception predictors were explored to determine their association with intention to participate in a smoking cessation study. Message frames were not included in the model as there were no significant differences on intention (*H2*). Univariate analyses identified sociodemographic and smoking characteristic predictors (*P*<.1), which included younger age (*P*=.03), female gender (*P*=.05), history of lung cancer screening (*P*=.04), higher eHealth literacy (*P*=.02), fewer years of smoking (*P*=.07), stronger urge to smoke (*P*=.07), higher quit importance (*P*<.001), higher quit confidence (*P*=.004), higher agreement on quitting reduces risk of cancer (*P*<.001), and higher motivation to quit (*P*<.001). In addition, all message effectiveness and lung cancer perception measures were found to be associated with intention to participate and also included in the multivariable model.

In the final multivariable model, 3 candidate variables were identified using a LASSO regression approach and selected as independent predictors: quit importance, perceived message relevance, and affective risk response about developing lung cancer. The overall variance explained by the model was 58% (Table 3). A higher quit importance score was significantly associated with a higher intent to enroll (*b*=0.14; SE=0.02; *P*<.001), as were greater perceptions of message relevance (*b*=0.72; SE=0.07; *P*<.001) and greater extent of worry about developing lung cancer (*b*=0.39; SE=0.09; *P*<.001).

Table 3. Final multivariable model predicting intent to participate in a smoking cessation study.

Predictors[a]	*b*	Standard error	β	*t (df)*	*P* value
Importance of quitting smoking	0.14	0.02	.25	5.69 (1)	<.001
Perceived message relevance	0.72	0.07	.45	9.61 (1)	<.001
Affective risk response	0.39	0.09	.21	4.42 (1)	<.001

[a] List of variables included in the model’s variable selection process: age, gender, history of lung cancer screening, eHealth literacy, years smoking, urge to smoke, importance of quitting smoking, confidence to quit smoking, belief quitting reduces risk of cancer, motivation to quit smoking, perceived message relevance, message credibility, message clarity, informed decision making about participation in a cessation study, combined risk perception, and affective risk response.

Because participants who received the benefits of quitting message frame reported a significantly greater affective risk response (*P*=.04; *H1*), and affective risk response was associated with intent to participate (*P*<.001; *RQ2*), a mediation analysis was conducted to examine whether affective risk was a mediator on intent to participate (ie, message frame → affective risk response → intent to participate; Table 4). As shown in *RQ2*, the total effect of BvR on intent to participate in a smoking cessation study was not significant (*b*=0.30; 95% CI –0.08 to 0.68; *P*=.12). The total effect comprised a nonsignificant direct effect (*b*=0.06; 95% CI –0.25 to 0.37; *P*=.70) but a significant indirect effect, mediated through affective risk response (*b*=0.24;

95% CI 0.01-0.47; *P*=.03). Thus, the indirect effect of affective risk response explained 79.8% of the total effect on increased intent to participate in a cessation study when participants received the benefits of quitting message frame.

Table 4. A mediation analysis estimating the effect of affective risk response on intention to participate in a smoking cessation study.

Summary of effects	*B*	Standard error	Wald 95% CI	*Z*	*P* value
Total effect	0.30	0.19	–0.08 to 0.68	1.56	.12
Direct effect	0.06	0.16	–0.25 to 0.37	0.39	.70
Indirect effect[a]	0.24	0.12	0.01 to 0.47	2.08	.04

[a] Mediation analysis only includes participants who received either the benefits of quitting versus risks of continuing to smoke message frames as it was shown to have a direct effect on affective risk response.

Subgroup Analysis for Perceived Message Relevance and Affective Risk Response (RQ3)

Finally, perceived message relevance and greater affective risk response were identified as being associated with greater intent to participate in a smoking cessation study (*RQ2*). Therefore, for *RQ3*, we explored which sociodemographic or smoking characteristics predicted greater perceptions of message relevance and affective risk response. Participants with higher eHealth literacy were more likely to perceive the message as relevant (*P*=.02). Similarly, participants with greater quit importance (*P*<.001), a greater belief that quitting can reduce their risk of cancer (*P*<.001), and a greater motivation to quit (*P*<.001) all perceived the message as more relevant to them. There were no significant differences by other sociodemographic or smoking characteristics.

Female participants were more likely to report greater affective risk response than male participants (*P*=.003). There were significant differences in affective risk response by nicotine dependence, including those who smoked a greater number of cigarettes per day (*P*=.04) and those who reported a greater urge to smoke in the past 24 hours (*P*=.003). Similar to perceived message relevance, participants with greater quit importance (*P*<.001), greater belief that quitting can reduce the risk of cancer (*P*<.001), and greater motivation to quit (*P*<.001) all reported a greater affective risk response. There were no significant differences by other sociodemographic or smoking characteristics.

Discussion

Principal Findings

Improving participation rates in smoking cessation trials remains a key priority in the delivery of evidence-based tobacco treatment. To ensure more trials meet their accrual goals, outreach strategies must conduct rigorous formative evaluation of recruitment messages. This study adds to the prospect theory literature by developing and testing proactive recruitment messages prior to dissemination in Screen ASSIST, a cessation trial offered at the point of lung screening. Screen ASSIST offers a unique context within which to test recruitment messages that are guided by prospect theory, as it promotes a prevention behavior (smoking cessation) within the context of a detection behavior (lung cancer screening). Therefore, we tested how best to frame the importance of changing smoking behaviors at the time of lung cancer screening. We also tested how best to motivate participation in a smoking cessation study, an area overlooked in the prospect theory literature.

From the message design experiment, the benefits of quitting frame increased affective risk response when compared with participants who received the risks of continuing to smoke frame. Therefore, participants who were told they could take action to avoid lung cancer by quitting reported a greater worry about developing lung cancer. We did not hypothesize this relationship; however, risk communication literature suggests groups who already have high residual perceptions of risk, such as heavy smokers, may be more likely to strongly counterargue messages that incorporate overt risk messaging about a modifiable risk behavior [49]. Other message processing theories (eg, extended parallel processing model) suggest that without sufficient efficacy information to support behavior change, participants will appraise threat-based messages through defensive motivation and fear control processes before rejecting the message [50,51]. It is possible, therefore, that participants who received the benefits frame did not induce psychological reactance, which instead resulted in a greater affective response and internalization of their own risk for lung cancer.

There were no significant differences in intent to participate in a cessation research study by message frame. The manipulation check measures indicated participants randomized to the losses frame reported greater understanding of the costs of not participating in the study. One of the 3 decision-making biases explicated by prospect theory is loss aversion, that is, losses loom larger than commensurate gains, and the pain of losing is psychologically more powerful than the pleasure of gaining [52]. For this reason, we purposefully worded the loss frame message to incorporate a negative valence (not-so-good news) and promote internalization of the short-term (more challenging without) and long-term outcomes (3 times less likely to stop smoking) of not participating. While participants may have identified that quitting would be more difficult if they did not participate in the study, this finding did not affect participation intentions.

Individual predictors in the multivariable model suggest quit importance, perceived message relevance, and affective risk response to developing lung cancer explained the most variance in intention to participate. Past studies have demonstrated baseline cognitive perceptions about quitting as a predictor of enrollment in cessation trials [44,53]. Consistent with the elaboration likelihood model, greater perceptions of message relevance are associated with high-involvement processing and greater motivations to adhere to recommendations made within a message [20,54,55]. Perceived message relevance has been demonstrated to be important at predicting intentions within other smoking behavior contexts, but is a novel finding in predicting research participation. Past studies have found inconsistent association for affective risk response and completion of prevention and detection behaviors. Lung cancer worry has been associated with a greater change in readiness to stop smoking [56], but also reduced intent to want to complete a lung screening test [31]. In the National Lung Screening Trial, worry was strongly associated with greater risk perceptions of the likelihood of developing lung cancer, but qualitatively, smokers reported frequency or intensity of worry was not sufficient to make them want to quit [57,58].

Finally, we explored participant-level predictors of perceived message relevance and affective risk response. Cognitive perceptions about quitting (greater quit importance, greater belief that quitting can reduce their risk of cancer, and a greater motivation to quit) were associated with both message relevance and affective risk. Understandably, participants who were more positively motivated to want to quit felt the message promoting Screen ASSIST was more relevant to them. Participants with greater nicotine dependence were associated with greater affective risk response, which is consistent with previous studies that have demonstrated heavy smokers report greater worry and risk perception for lung cancer [59]. An interesting finding was that participants with higher eHealth literacy found the recruitment messages more relevant. Higher eHealth literacy is associated with greater capacity to not only find online health information but also distinguish credible and trustworthy online health sources [60]. Source credibility and perceived message relevance have been found to constitute second-order determinants that influence decision making about online sources [61]. In the context of clinical trial participation, where medical mistrust remains high [62], it is logical that participants with higher eHealth literacy perceived the recruitment videos to be more credible and to be more relevant to them. Nonetheless, digital recruitment messages should strive to overcome traditional health literacy barriers and not to incur new technological literacy barriers, so as to cater for a diverse eHealth literate population.

Limitations

The study has limitations that warrant attention. First, the recruitment videos promoted a specific cessation trial (Screen ASSIST), which was offered through a health care network in Massachusetts. Past studies have discussed a hypothetical research and provided no geographic cues to deter perceptions of access [17,37]. To try and maintain engagement, participants were told before viewing the video that they had similar characteristics to the patients who would be enrolled in Screen ASSIST and that their feedback would improve the video. Second, there was no control condition, so it is not possible to infer the degree to which the messages increased or decreased, for example, lung cancer risk perceptions. This was a decision by the study team as a scientifically comparable and practical control condition was difficult to create. A generic antismoking message would have been inappropriate as the videos promoted enrollment in a specific study. Further, a kernel message without both smoking and participation frames was also deemed infeasible as content addressing both issues was required in the final recruitment video to fully inform participants about the aim of the trial and outcome expectancies.

Third, we did not separate framing of cessation and lung screening to ascertain if they had synergistic or antagonistic effect on intent to participate. This decision was made with physician partners who expressed concern about framing risks of both continued smoking and not screening, which is too negative for an initial outreach message. It was also deemed not reflective of how lung screening shared decision-making visits are conducted in clinical practice, as well as inconsistent with institutional marketing efforts to promote lung cancer screening. Fourth, the study was powered to identify significant differences between message factors on intent to participate in a cessation trial, not for individual subgroup analyses. However, estimation of heterogenous treatment effects is a widely accepted statistical practice in randomized trials, and identifying subgroups is an important process in formative message design evaluation. Fifth, the sample was predominantly White (262/296, 88.5%), which overlooks the need to proactively improve minority representation in clinical trials and to test recruitment videos with underrepresented groups who report greater medical mistrust and lower enrollment rates [63-65]. To try and address this issue, we are currently co-developing linguistically and culturally sensitive recruitment videos with and for English- and Spanish-speaking Hispanic and Latinx smokers.

Implications and Future Research

As a result of the study’s findings, the recruitment video employed in Screen ASSIST incorporated the benefits of quitting at the time of lung screening and the losses from not participating message frames. Because of the mediated pathway, in which greater affective risk response increased intent to participate, the benefits of quitting frame was preferred to the risks of continuing to smoke. The losses of not participating frame was selected due to participants identifying the costs of not participating in the study in the manipulation check and feedback that the loss aversion framing was attention getting.

When evaluating the implications of these findings, it is important to compare how sample characteristics reflect patient characteristics in other national lung screening programs. This sample was predominantly lower income, with almost 48% (141/296, 47.4%) reporting a household income below US $40,000. Despite heavy smoking disproportionately affecting the health of people from low socioeconomic backgrounds [66], screening programs often overrepresent patients with higher socioeconomic backgrounds [67]. This sample had a comparative level of nicotine dependence in terms of years smoked (mean 41.1 vs 43.4) but lower average number of daily cigarettes smoked (mean 15.4 vs mean 28.4). Compared with the national lung screening eligible population, this sample did report a higher rate of previous lung cancer screening (26.4% [78/296] vs 4.4%-12.5%) [68,69]. It should be acknowledged that there are limitations of convenience samples through Qualtrics, but the sample characteristics of the study align with current USPSTF lung cancer screening guidelines and other heavy smoking patient populations recruited for cessation trials.

To meaningfully improve digital outreach for cessation trials, future research should find innovative ways in which to adapt recruitment materials to address participant-specific concerns about trial enrollment. The participant-level analyses identified heterogeneity in the cognitive and affective predictors associated with greater intention to participate, as well as message relevance and affective risk response. It is current practice to target prospective participants through community-level outreach, but integrating individually tailored study information within recruitment materials may enhance these processes. For example, if a patient reports low self-efficacy to participate in a trial, a recruitment video platform should be adaptive to incorporate specific efficacy-building content on how to participate. Alternatively, if a patient reports high self-efficacy in participating but low confidence in quitting, the message content should prioritize information on the positive outcome expectancies due to the cessation support offered through the trial. In practice, this will likely require a combination of community-, clinic-, or patient portal-driven recruitment strategies that collect patient perspectives on research participation or a specific cessation trial in order to dynamically tailor and display recruitment materials.

Ethical concerns associated with motivating clinical trials participation should be paramount during the outreach and consent process, and investigators must ensure participation is informed and voluntary to prevent manipulation. However, there is scope within certain types of clinical trials to enhance the effectiveness of recruitment efforts by including strategic message appeals and still ensure patient centeredness. For example, describing the benefits of participating in a trial for an investigational new drug is not similar to Screen ASSIST, which tests the best combination of evidence-based tobacco treatments. It is, therefore, important that recruitment materials are theory driven, and when appropriate, lean on strategies that have been successful in other health promotion and behavior change contexts to increase accrual rates. In doing so, patients are provided greater access to the best cessation resources to help them quit smoking.

Conclusion

This study adds to the prospect theory and digital outreach literature. The study provides an overview of the development and a formative evaluation of proactive recruitment messages for a smoking cessation trial offered at the point of lung screening. Based on our findings, we conclude that heavy smokers are more responsive to recruitment messages that frame the benefits of quitting as it increased affective risk response, which predicted greater intention to participate in a smoking cessation study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1117 KB - formative_v5i6e28952_app1.pdf]

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Abbreviations

ANOVA: analysis of variance
eHEALS: eHealth Literacy Scale
LASSO: least absolute shrinkage and selection operator
USPSTF: US Preventative Services Task Force

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Original Paper

Meaning in Life Among Patients With Chronic Pain and Suicidal Ideation: Mixed Methods Study

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Abstract

Background: Patients with chronic pain have elevated risk of suicidal ideation and behavior, including suicide attempts and completed suicides. In most studies, associations between chronic pain and suicidal ideation/suicidal behavior are robust even after adjusting for the effect of sociodemographics and psychiatric comorbidity. However, to refine the risk profile of these patients, further exploration of other possible risk and protective factors is necessary.

Objective: There is a common clinical observation that experiencing chronic pain often requires a revision of life goals and expectations, and hence, it impacts the existential domain including one's perception of the meaning in life (MiL). This study aimed to characterize the main domains that constitute the personal MiL, including the "presence of" and "search for" constructs, in a group of patients with chronic pain and suicidal ideation.

Methods: Seventy participants were enlisted by ongoing recruitment through a larger project anchored in daily clinical practice at the Multidisciplinary Pain Center of the Geneva University Hospitals. It was an observational mixed method study. Data were recorded through both validated quantitative questionnaires and qualitative open-ended questions.

Results: The total sample consisted of 70 patients. Responses to questionnaires showed a depressive episode in 68 (97%) patients and anxious disorders in 25 (36%) patients. With a score threshold for positive MiL of 24, the mean score for the "presence of" construct was 20.13 (SD 8.23), and 63% (44/70) of respondents had a score <24. The mean score for the "search for" construct was lower at 18.14 (SD 8.64), and 70% (49/70) of respondents had a score <24. The "presence of" and "search for" constructs were significantly positively correlated (*R*=0.402; *P*=.001). An open question addressed the "presence of" construct by inviting the respondents to cite domains they consider as providing meaning in their life at the present time. All patients responded to this question, citing one or more domains. The three main dimensions that emerged from content analysis of this qualitative section were as follows: the domain of relationships, the domain of personal activities, and pain and its consequences on MiL.

Conclusions: The study results provide insights into patients with chronic pain and suicidal ideation, including the domains that provide them with meaning in their lives and the impact of pain on these domains with regard to suicidal ideation. The main clinical implications concern both prevention and supportive/psychotherapeutic interventions. They are based on a narrative approach aiming to explore with the patients the content of their suffering and the MiL domains that they could identify to mitigate it, in order to restructure/reinforce these domains and thus possibly reduce suicidal ideation. Specifically, a focus on maintaining the domains of interpersonal relationships and personal activities can allow patients to ultimately escape the biopsychosocial vicious cycle of chronic pain–induced deep moral suffering.

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KEYWORDS

suicide; suicidal behavior; suicidal ideation; suicide attempt; chronic pain; meaning in life; protective factors; risk factors; mental health

Introduction

Patients experiencing chronic pain are at elevated risk of suicidal ideation and behavior, including suicide attempts and completed suicides. It has been reported that there is a 20% to 40% prevalence rate of suicidal ideation, a lifetime prevalence between 5% and 14% of suicide attempts, and a double risk of death by suicide in patients with chronic pain as compared to controls [1-4].

In most studies, associations between chronic pain, suicidal ideation, and suicidal behavior have been demonstrated to be robust, even after adjusting for the effect of sociodemographics and psychiatric comorbidities, particularly depressive conditions [5-9]. A number of specific factors modulating the suicidal ideation and suicidal behavior risk in patients with chronic pain have been investigated (eg, pain characteristics, functional interference, illness beliefs, and access to opioids) [1,3,10]. However, the literature also highlights the need for further exploration of other possible risk and protective factors in order to refine the characterization of the risk profile in these patients [1]. In particular, in patients with chronic pain, protective factors have been less addressed than risk factors [11]. The interest in exploring protective factors in suicidal chronic pain patients arises from the common clinical observation that experiencing chronic pain often requires a revision of one’s life goals and expectations; hence, its impact affects the existential domain [12]. This perspective is of particular interest to provide clinicians the keys to identify relevant elements for the assessment of crisis factors and psychotherapeutic work, which can be important when making the decision to refer a patient to specialized care [13,14].

The historical intuitions of Frankl, who made his initial observations among prisoners of Nazi concentration camps, described the psychological construct of “meaning in life” (MiL) as a potent protective factor against suicide [15-17], with the individual having a “will of meaning” that presented a potent resiliency resource and the best chance to survive [15]. Afterwards, MiL was conceptualized under several theoretical perspectives, which pointed out different aspects of it. Among them, a recent model described MiL as “the web of connections, understandings, and interpretations that help us comprehend our experience and formulate plans directing our energies to the achievement of our desired future” [18]. This model divides MiL into two constructs, specifically “presence of” and “search for” MiL, which are not mutually exclusive [19]. However, somehow paradoxically, few studies have investigated MiL in relation to suicidal ideation and suicidal behavior [20]. Moreover, even fewer studies have addressed the contents of the subjective MiL in those individuals with suicidal ideation, that is, what makes or could have made their existence in some way meaningful [21,22]. Therefore, the aim of this study was to characterize the main domains that constitute the personal MiL in a group of patients with chronic pain and suicidal ideation.

Methods

Setting

This study was part of a larger research project investigating the role of demoralization and MiL in influencing suicidal ideation among patients affected by chronic pain [23]. This observational study was conducted by the Division of Clinical Pharmacology and Toxicology and the Service of Liaison Psychiatry and Crisis Intervention at the Multidisciplinary Pain Centre (MPC) of the Geneva University Hospitals. The MPC is a third-line ambulatory referral center where most patients are referred by their treating physicians for an interdisciplinary clinical evaluation and a review of the treatment proposals (eg, physical treatment, individual or group psychiatric/psychological treatment, and pharmacological proposals). Routinely, self-administered questionnaires were sent out to each participant before their first MPC visit, including the Beck Depression Inventory-II (BDI-II) [24]. Participants were enlisted by ongoing recruitment through a project anchored in daily clinical practice at the MPC.

The study included patients affected by chronic pain referred to the MPC and presenting with suicidal ideation. Patients were identified as having suicidal ideation by their positive response to question 9 of the BDI-II [24] that addresses suicidal thoughts or wishes with the following items: score 0, I don’t have any thoughts of killing myself; score 1, I have thoughts of killing myself, but I would not carry them out; score 2, I would like to kill myself; and score 3, I would kill myself if I had the chance. Patients whose scores ranged from 1 to 3 additionally underwent a clinical evaluation of suicidal ideation by a qualified team member (VC). This clinical interview determined the presence or absence of depression using a structured diagnostic interview to screen psychiatric diagnoses. The French version (5.0.0) of the Mini-International Neuropsychiatric Interview (MINI) [25] was used for DSM-IV disorders. Participants had to be ≥18 years old.

We excluded patients with an insufficient comprehension of the French language and those affected by dementia, psychotic disorders, or borderline personality as documented in the referral letter or as assessed during the first MPC visit.

Statistical Analysis

During the first MPC visit, about 14 days after receiving the self-administered questionnaires at home, all patients who were identified by their positive response to question 9 of the BDI-II received a written communication informing them about the research project and a consent form. Patients were given at least 24 hours to review the written communication. At the subsequent study visit, a qualified team member (VC) further investigated the presence of suicidal ideation and responded to the patients’ questions about this study. Appropriate measures were taken for cases where severe suicidal ideation was identified using clinical evaluation and BDI-II, including accompanying the patient to the psychiatric emergency ward if necessary. All participants who provided written informed consent underwent face-to-face completion of the Meaning in Life Questionnaire (MLQ) [26]. Following the requirements of the observational study protocol [23], 70 patients with suicidal ideation were recruited.

Instruments

The BDI-II and MLQ [26] were used. The MLQ is a self-reported multiple-choice inventory. The first section includes 10 items that measure the “presence of” construct of MiL (five items) and the “search for” construct of MiL (five items). Each item is rated on a 7-point Likert scale from “absolutely true” to “absolutely untrue,” leading to a score ranging from 5 (low MiL) to 35 (high) for each subscale. The MLQ does not have clear cut scores because it is intended to measure MiL across the complete range of human functioning. However, some probabilistic estimates about scores above or below 24 on the “presence of” and “search for” constructs have been provided on a website [27]. The MLQ has been translated into French and is available on this website. The closed section takes about 3 to 5 minutes to complete. The second section includes an open question asking the patient to cite three to seven domains that the patient considers as providing meaning to his or her life at the time being.

Analysis

Descriptive statistical analyses were conducted to compute means and SDs for numerical variables and frequencies (%) for categorical variables. The chi-square test or Fisher exact test was used for categorical variables and checked for matching between groups regarding age, gender, and years of education. The post-hoc Tukey multiple-comparison test was used to find significant differences between means.

Patients’ responses to the open question of the MLQ were recorded and transcribed verbatim. Data analysis was performed by a medical doctor (psychiatrist) and a PhD psychologist (AC and CC) trained in qualitative procedures and with experience in qualitative studies. No prior relationships between data analysts and respondents were established before data collection.

The transcripts were analyzed using a manual data indexing technique to identify the key themes [28]. The qualitative content analysis began with individual close readings by the two researchers, who were working separately. The analysis continued throughout the coding process, using the constant comparative method, which consists of analyzing the responses by comparing one response with earlier observed ones [29]. This process was followed by comparisons of the readings, which were subsequently used to establish analytical categories and dimensions. A consensual process of reconciling differences in individual lists of categories led to an agreed set of categories [30]. These categories served as the basis for a grid that was then used to analyze the transcripts to maximize the theoretical sensitivity and rigor [31,32]. The sample of patients’ responses investigated allowed us to reach a point where no new categories emerged from the analysis. The categories were discussed and refined by consensus between the two researchers. Not unexpectedly, data saturation, defined as the point in data collection and analysis at which new information produces little or no change in the codebook [33], was reached. Data saturation was achieved after analyzing 40 responses. The next 30 responses confirmed data saturation and allowed further refinement of the grid. These categories and dimensions served as the basis for a final grid, which was used independently by the two researchers to analyze the transcripts. This assessment entailed an analysis of the data carried out by investigators with a different background (AC and CC) so that findings emerged from consensus between investigators. Interrater agreement was high ($\kappa>0.92$), and disagreements were solved by consensus. The matter at stake here may not be the degree of concordance between investigators but rather the insights that discussion can provide for refining coding frames [34].

In line with the recommendations for qualitative analysis reported in a language different from the one used for data collection, the interviews and data analysis were conducted in French, and the researchers used fluid descriptions of meanings in their discussions to achieve the best possible understanding of the concepts involved in the research [35].

Ethical Considerations

The Ethics Committee of the Canton of Geneva approved the scientific utilization of collected data (project no. 2017-02138; decision dated January 25, 2018). The research project was carried out in accordance with the research plan and Swiss legal and regulatory requirements, in agreement with the principles stated in the current version of the Declaration of Helsinki and the Essentials of Good Clinical Practice issued by Public Health Switzerland. Written informed consent was obtained from all patients.

Results

Patient Sample Characteristics

Following the requirements of the observational study protocol, 70 patients were included in the study. Among the 70 participants, 42 were women and 28 were men, with a mean age of 54 years (Table 1). As the results of the BDI indicated, the participants experienced moderate to severe depressive symptoms (Table 1). The MINI validated the presence of a depressive episode in 68 out of the 70 patients, as well as the presence of anxious disorders in one-third of the group (25 out of 70 patients).

Table 1. Sociodemographic and clinical characteristics of the participants.

Characteristic	Value
Age (years), mean (SD; range)	54.3 (15.4; 20-85)
Education, n (%)	
Compulsory school	13 (19%)
Professional degree	27 (39%)
High school	21 (30%)
University	9 (13%)
Employment status, n (%)	
Working (part time or full time)	10 (14%)
Retired	6 (9%)
Sick leave or state support	54 (77%)
Living alone, n (%)	26 (37%)
Pain etiology, n (%)	
Neuropathic	44 (63%)
Osteoarticular	22 (32%)
Visceral or other	4 (6%)
Duration of pain (years), mean (SD)	8.06 (8)
Pain intensity (visual analog scale score, range 0-10)	
At present	6.95
At its best	5.33
At its worst	8.91
Beck Depression Inventory (BDI) score, mean (SD)	31.3 (11.4)
Extent of depressive symptoms (BDI), n (%)	
No depressive symptoms (<10)	2 (3%)
Light (11-20)	10 (14%)
Moderate (21-30)	24 (34%)
Severe (>30)	34 (49%)

“Presence of” and “Search for” MiL

As for the first part of the MLQ, the mean score for the “presence of” MiL was 20.13 (SD 8.23), and 63% (44/70) of the respondents had a score <24. The scores for the “search for” MiL were lower (mean score 18.14, SD 8.64), and 70% (49/70) of the respondents had a score <24. The “presence of” and “search for” MiL were significantly positively correlated (*R*=0.402; *P*=.001).

Open Question Inviting Participants Linking MiL to Personal Domains

The second part of the MLQ addresses more specifically the “presence of” MiL as the open question invites the respondent to cite domains that he or she considers as providing meaning to his or her life at the time being, without referring to the constructs of “presence of” or “search for” MiL. It is noteworthy that all participants provided responses to the open question. The total number of responses was well over 70 as only about one-fifth of the patients mentioned ≤3 domains in their responses. Three main dimensions emerged from content analysis, that is, responses pertaining to (1) the domain of relationships, (2) the domain of activities, and (3) pain and its consequences on MiL.

Responses Linking MiL to Relationships

An overwhelming majority of the participants (n=65, 93%) mentioned relationships with the family, spouse, children (and/or grandchildren), and friends as a domain that provides meaning to their life. The idea of sharing (time, activities, and emotions) was in the foreground as in the following response:

> *My family and my friends. Their presence is very important for me, I feel considered… they give me love… Being valued in their eyes is important for me […]. Then the relationship with other people (outside of my family) also gives meaning to my life. Telling funny stories for example… having a good time with my family and friends or colleagues while sharing a meal…* [respondent #29, 20-year-old man]

Another domain was to be useful and thus be valued through the relationships, as the following responses show:

> *First, humanitarian work is very important for me and gives meaning to my life. Then also…contact with the loved ones I still have. I do not want to hurt them or disappoint them…* [respondent #16, 69-year-old woman]

> *My girlfriend who makes me think that I'm not alone… the wish to have children…help the others. I have always helped others, but my present situation does not allow me to do so… This gives me meaning but at the time being, I can no longer take care of myself, so I cannot help others…* [respondent #63, 38-year-old man]

> *Try to be happy and make people around me happy… try to give the best of myself to others… people call me 'Mother Theresa'… sometimes I feel drained. My companion and my daughter also provide meaning to my life. I need to be useful for the others, to be able to help them be well or just be better. It is frustrating but I cannot do so because of my pain.* [respondent #64, 58-year-old woman]

These responses could be either embodied, that is, referring to one or more specified persons as in the examples above, or disembodied, that is, referring to relationships in general or as a general value or concept. An example response of the latter is as follows:

> *Having contacts with other people… sharing provides meaning to my life* [respondent #4, 57-year-old man]

Although the relationship may be something to hold on to, the interference of pain may be too overwhelming, as reflected in the following response:

> *My life has no particular meaning. My wife is the only element that helps me hold on a bit… I feel much more miserable when she is not there. Sadly, I do not talk enough with my wife… because I cannot…I suffer from being completely dependent on her. I try to spend time reading or watching TV, but that does not make sense to me…. I cannot enjoy it… I have no more pleasure… and I have no more hope to get better… I can no longer go out for a walk… I've become a bedridden sick old man.* [respondent #20, 82-year-old man]

Responses Linking MiL to Personal Activities

Personal activities were frequent responses in this group of patients given by about two-thirds of respondents in this category. These activities may serve various purposes, such as to feel better and engage in relationships. One patient made the following statement:

> *Try to improve my condition and do everything I can for that, go out, move, walk… gives meaning to my life… Also meet people, engage in activities with my daughter and friends.* [respondent #12, 58-year-old woman]

They may also represent a wish to change life and escape from pain and its consequences. The responses refer to travel, moving to a warmer place, moving somewhere closer to nature, and moving far from civilization. An example response is as follows:

> *Travel. I need to fly away…it is a kind of flight, a headlong rush.* [respondent #54, 60-year-old woman]

About one-quarter of respondents stressed that these activities have to be pleasant and enjoyable. An example response is as follows:

> *Playing sports that provide me with good sensations… it helps me balance everything that goes through my mind.* [respondent #21, 67-year-old woman]

However, activities may not be an appropriate response to giving meaning to one's life, as one female respondent indicated, after having mentioned her family who provides her a feeling of belonging, and the energizing power of nature. The response was as follows:

> *There are other things that I enjoy such as reading, playing video games or taking pictures, but all this, it does not provide me with a meaning in life.* [respondent #28, 60-year-old woman]

Furthermore, more than one-quarter of respondents indicated that the identification of pleasurable and meaningful activities is often hampered by pain. An example response is as follows:

> *I think that I have understood the meaning of my life. It is my family, my friends and everything that gives me pleasure, eating, drinking, traveling, football… Yet, it is difficult to experience it because of my pain that is so intense.* [respondent #11, 58-year-old man]

Responses Linking MiL to Pain and Its Consequences on MiL

Indeed, as mentioned above, despite the presence of important and meaningful relationships and activities, the interference of pain may be overwhelming, to the point of erasing all other responses. One respondent made the following statement:

> *Nothing has meaning to me. What kind of meaning in life could I have? My pain does not let me enjoy anything for real…* [respondent #32, 67-year-old man]

About half of the respondents mentioned pain and its consequences explicitly. All of these consequences were described as deleterious, spoiling potential good moments and pleasure, and possibly leading to loss of objectives and MiL. An example response is as follows:

> *[…]…Getting better (without pain) and find a job and have a social life may offer me meaning, although I do no longer believe that these objectives can be reached… I am living one day after the other and I avoid making projects for the future. In fact, I am trying to give a meaning to my life, but sometimes I do not know exactly what I should search for…* [respondent #5, 32-year-old woman]

This lack or loss of objectives and meaning can have suicidal ideation as a counterpart as indicated by a patient:

> *There is nothing that really has sense in my life. I have no specific objective in life nor do I have any*

> *pleasure. My quality of life is zero. I keep up only thanks to my grandson because his mother is unable to care properly for him and I do not want to hurt him if I commit suicide… nothing can help me to get better…* [respondent #6, 60-year-old woman]

Finding MiL in spite of pain may be too difficult a task, as a patient responded:

> *My life has absolutely no meaning. I keep going only thanks to my family, but when pain is very intense, I do not think of them. I have no pleasure. My life is not worth living.* [respondent #18, 46-year-old woman]

Yet, when pain recedes, new perspectives seem to open up. An example response is as follows:

> *I have been feeling better since a few days, so meaning is back in my life… receive other people's appreciation and respect… also various sources of pleasure in my life… and my family, but this is not as important as the other two domains…* [respondent #13, 69-year-old man]

The identification of these dimensions was independent of the respondents' gender and age. Furthermore, there were no significant differences between respondents with neuropathic pain and those with osteoarticular pain. Since a substantial proportion of respondents presented with moderate or even severe symptoms of depression (58/70, 83%), the categories and dimensions mentioned above may be more representative of this particular group. Yet, it was mostly patients who were still working, either part time or full time, who mentioned "work" as an important activity. Patients who were still working also presented with lower scores in depression tests. Taken together, the results from this group of patients with chronic pain and suicidal ideation point toward shared rather than divergent views of what makes or could have made the respondents' existence more meaningful.

Discussion

Principal Findings

To the best of our knowledge, this is the first exploration into MiL using a mixed-method approach characterized by the use of both a validated quantitative questionnaire and qualitative open-ended questions, in patients with chronic pain.

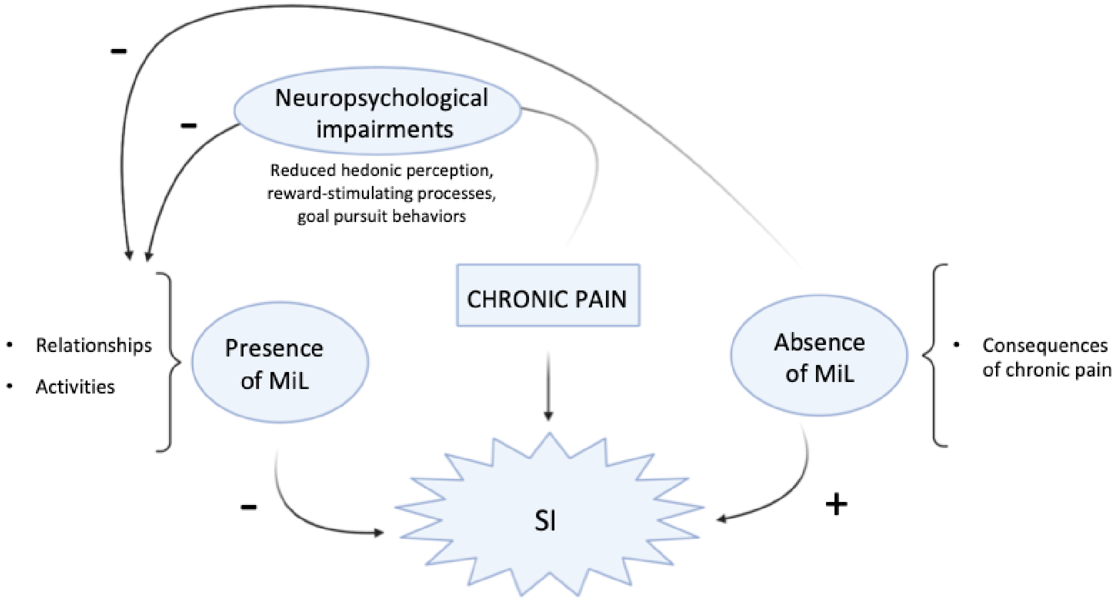
Scores for the first part of the questionnaire were low and did not reach the 24-point cutoff threshold for either the "presence of" or the "search for" MiL constructs [27]. These results are in line with the scores of the BDI that identified a high proportion of moderate to severe depressive symptoms in these patients, thus stressing the link between suicidal ideation and MiL in this group. Findings in the literature are controversial. "Presence of" MiL is rather uniformly thought to be beneficial [36]. By contrast, "search for" MiL appears less consensual, as some authors consider it the essence of human motivation [16] and others consider it a sign that one has lost meaning [37,38] or a feeling like one's life has somewhat less meaning [19,26]. Recently, among patients with chronic pain, different MiL profiles have been characterized by combining various levels of "presence of" and "search for" MiL. Some patients were associated with a unique adjustment outcome. Those having profiles with high scores for "presence of" MiL showed fewer depressive symptoms and greater life satisfaction [37,38]. Both constructs have been found to be highly stable over time by the same authors, suggesting that MiL may reflect more a trait, rather than a state aspect, of individual functioning [38].

When asked to mention domains that provide them MiL by open-ended questions, the typical responses of patients in our study were an illustration of the biopsychosocial model. Indeed, whether short or long, these responses addressed various dimensions. These dimensions included physical, emotional, and social aspects and were embedded in a timeframe where chronicity is central. In this regard, our results identified the following two critical dimensions that define MiL for patients with chronic pain: the presence of supportive interpersonal relationships and meaningful activities. When mentioned, pain was presented as having a major impact on the person's daily life, possibly leading to mood disturbances, social isolation, decrease in activities, fear of the future, and a generalized sense of loss, as well as loss of both objectives and meaning. Pain may thus undermine MiL, directly or by actively limiting the seeking out for the two domains that confer MiL, in a vicious circle that leads to suicidal ideation (Figure 1).

Within this biopsychosocial framework, previous studies have documented the reduction of significant social relationships and personal activities among patients with chronic pain. A large-scale study of more than half a million participants in the United Kingdom showed that chronic pain could be reliably predicted by loneliness (odds ratio [OR] 1.843, 95% CI 1.816-1.870) and social exclusion (OR 2.314, 95% CI 2.249-2.380) [39]. Conversely, a longitudinal study of 1563 adults over the age of 60 years in the United States identified chronic pain as a diagnostic factor for the onset of loneliness as the odds for loneliness onset was 1.58 times higher among participants experiencing pain in comparison with pain-free participants, even after adjustment for other medical and psychosocial covariates [40]. Regarding activities, a community-based study in the United States of 591 patients with chronic pain stressed that this condition interferes significantly with productivity-related societal engagements as work performance in participants with chronic pain was markedly impaired [41]. Similarly, adults with chronic pain, either widespread or localized, showed a lower prevalence of engaging in leisure activities in comparison to those without chronic pain [42].

From a neurological perspective, chronic pain might interfere with the process of rewards, defined as matters that result in positive emotions and feelings. Laboratory studies have shown that acute pain can stimulate reward-related behaviors [43]. In patients with chronic pain, however, reduced hedonic perception in naturally rewarded behaviors has been documented [44]. Such a reduction in the perception of pleasure in patients with chronic pain might be attributed to reduced sensitivity to reward-stimulating processes [45].

Figure 1. Pathways from chronic pain to suicidal ideation (SI): A vicious circle in a biopsychosocial framework. MiL: meaning in life.



Furthermore, goal pursuit behaviors, conceptualized as “internal representations of desired states, where states are broadly construed as outcomes, events, or processes” [46], could also be impacted by chronic pain. A study exploring the presence of daily goal conflicts in patients with fibromyalgia showed that these patients reported more pain-instigated disruption of goal-oriented daily activities (eg, household, social, and interpersonal goals) than healthy control individuals [47]. Collectively, these chronic pain-induced neuropsychological interferences might trigger a gradual loss of social interactions and activities.

The losses in these two domains are particularly salient in our study as patients clearly linked social interactions and activities to MiL, emphasizing that a loss in these domains could lead to a loss in MiL. This is of particular relevance as MiL has a protective role against the development of suicidal ideation and suicidal behavior. Following the pioneering studies of Frankl [15-17], recent studies have proposed this possible function of MiL among heterogeneous populations, including patients with chronic pain [23,48], patients attending a psychiatric emergency department (ED) [21,49,50], and community-dwelling individuals during the COVID-19 pandemic [51]. One of these studies [21] utilized the same qualitative approach as our study, but addressed patients attending a psychiatric ED. The findings of both studies converge. In both populations, relationships and activities were the main domains giving MiL to suicidal patients. These findings are consistent with findings from previous studies in the literature on the impacts of relationships and activities on reducing suicidal ideation and suicidal behavior.

The association between loneliness and suicidality is well documented. A recent extended review of the literature showed that both the objective condition (eg, living alone and social isolation) and the subjective feeling of being alone (ie, loneliness and alienation) were strongly associated with suicidal outcomes, such as suicidal ideation and suicidal behavior [52]. Notably, the subjective feeling had a major impact [52]. Two nationally representative samples (in the United States and in the United Kingdom) showed that social support was associated with a decreased risk of suicide (ORs of 0.7 and 0.9, respectively) [53]. In our study, a particular emphasis was placed on the presence of family members and, among them, of children/grandchildren and spouses. This is concordant with previous studies [21,52].

Our findings regarding the role of activities echo several prior studies suggesting that the lack of professional activities might also result in higher suicide risk [54]. In this regard, the interplay between professional activities and suicide is complex, involving some societal effects, such as the loss of social status, loss of connectedness, and lower income, all or some of which contribute to a higher vulnerability to suicide risk [55]. To the best of our knowledge, only one other study using qualitative data in the literature [21] has mentioned the relevance of other types of activities, although it is more related to personal interests and the intellectual/nonintellectual pleasure sphere, in comparison to our study.

Limitations and Strengths

This study has several limitations. First, the sample size of this study was small, and future large-scale studies are required to substantiate the results regarding the closed-ended portion of the MLQ. However, the sample size allowed us to conduct a thorough analysis of the patients’ responses to the open-ended question investigating the domains that gave them MiL. Currently, we do not know how people with chronic pain but without suicidal ideation would identify the domains that give meaning to their lives. Yet, this study provides further information on the difficulties these patients face when trying to sort out what gives them MiL. Second, we did not analyze our findings in light of the participants’ heterogeneous sociodemographic characteristics. Therefore, it would be important to conduct further investigations to identify whether there are age- and gender-specific perspectives on MiL. We did find, however, that the characteristics of participants enlisted by ongoing recruitment through a project anchored in daily clinical practice at the MPC mirrored those of patients who arrived by referral. Indeed, the research was conducted in a third-line referral consultation. While our results may be transferable to patients having severe chronic pain associated with depressive symptoms, the transferability of our results to other clinical settings might still be difficult. However, the characteristics of our sample provide different perspectives on the issue at stake. Taken together, the results of this study have indicated several avenues that could be pursued by future investigations. For example, the sociodemographic and clinical characteristics of a sample could be used to refine the results presented here and to obtain a better understanding of the role of not only chronic pain and suicidal ideation, but also the various features of pain and its consequences.

It is noteworthy that this study made extensive use of investigator triangulation, with the final thematic analysis discussed within a multidisciplinary group (ie, psychiatry, psychology, clinical pharmacology, and internal medicine) so that findings were confirmed through consensus. Investigator triangulation allowed corroboration of the data, thus contributing to the credibility and validity of the findings [56]. The reliability of the findings was assessed by using patient-generated data via interviews and by verification of interpretation from a multidisciplinary group of researchers [57]. Concerning credibility, confirmability, and transferability of the results, research methods were derived from previous comparable projects, and familiarity with the culture and an adequate understanding of the participants were developed before the first data were collected. A further strength of this study was that its design allowed for an analysis based on two different sets of data investigating MiL, namely closed-ended questions and narrative responses. However, the open question does not specify whether it addresses the “presence of” or the “search for” construct, and this should be specifically investigated in a future study.

Clinical Implications

There are various psychological approaches for chronic pain, but all have the same basic requirements as follows: patient adherence on the one hand and patient-therapist agreement on the definition of objectives that are both realistic and meaningful for the patient on the other hand. It is thus essential to involve the patient in this definition. This in turn implies that the therapist can express empathy and validate the patient’s pain and suffering.

In clinical interviews with patients with chronic pain, pain has to be thoroughly considered along with other aspects, such as activities that may require adaptations, as well as the possible fluctuations in the patient’s perception of MiL. As part of a negotiation process, the clinical interview also has to consider the patient’s resources and how he or she may try to cope with the situation with the clinician’s help, while still avoiding that the psychotherapeutic offer be perceived as a medical desertion. The results of our study stress the benefits of the MLQ as not only an indicator of psychological distress but also a tool that may be used in the patient-therapist discussion about the patient’s goals and sources of meaning. In this regard, such an instrument could help the clinician in the identification of relevant elements for the assessment of crisis factors that may be related to suicidal ideation. It may indeed contribute to the definition of common objectives and expected benefits for the treatment with respect to improvements in the patient’s quality of life and functional capacities.

Conclusions

The results of this study provide the first insights into the views of patients with chronic pain regarding the domains that provide them with meaning in their lives and also into the impact of pain on these domains with regard to suicidal ideation. The main clinical implication concerns prevention and supportive/psychotherapeutic interventions, based on a narrative approach aiming to explore with the patients the contents of their suffering and the MiL domains that they could identify to mitigate them, in order to restructure or reinforce these domains [16,17]. Specifically, any treatment (also involving practical measures) focusing on maintaining the domains of interpersonal relationships and activities can possibly improve MiL and thus reduce suicidal ideation by allowing patients to ultimately escape this biopsychosocial vicious cycle of chronic pain–induced deep moral suffering.

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Conflicts of Interest

None declared.

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Abbreviations

BDI: Beck Depression Inventory
ED: emergency department
MiL: meaning in life
MINI: Mini-International Neuropsychiatric Interview
MLQ: Meaning in Life Questionnaire
MPC: Multidisciplinary Pain Centre
OR: odds ratio

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Original Paper

Patients' and Providers' Needs and Preferences When Considering Fertility Preservation Before Cancer Treatment: Decision-Making Needs Assessment

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Abstract

Background: As cancer treatments continue to improve, it is increasingly important that women of reproductive age have an opportunity to decide whether they want to undergo fertility preservation treatments to try to protect their ability to have a child after cancer. Clinical practice guidelines recommend that providers offer fertility counseling to all young women with cancer; however, as few as 12% of women recall discussing fertility preservation. The long-term goal of this program is to develop an interactive web-based patient decision aid to improve awareness, access, knowledge, and decision making for all young women with cancer. The International Patient Decision Aid Standards collaboration recommends a formal decision-making needs assessment to inform and guide the design of understandable, meaningful, and usable patient decision aid interventions.

Objective: This study aims to assess providers' and survivors' fertility preservation decision-making experiences, unmet needs, and initial design preferences to inform the development of a web-based patient decision aid.

Methods: Semistructured interviews and an ad hoc focus group assessed current decision-making experiences, unmet needs, and recommendations for a patient decision aid. Two researchers coded and analyzed the transcripts using NVivo (QSR International). A stakeholder advisory panel guided the study and interpretation of results.

Results: A total of 51 participants participated in 46 interviews (18 providers and 28 survivors) and 1 ad hoc focus group (7 survivors). The primary themes included the importance of fertility decisions for survivorship, the existence of significant but potentially modifiable barriers to optimal decision making, and a strong support for developing a carefully designed patient decision aid website. Providers reported needing an intervention that could quickly raise awareness and facilitate timely referrals. Survivors reported needing understandable information and help with managing uncertainty, costs, and pressures. Design recommendations included providing tailored information (eg, by age and cancer type), optional interactive features, and multimedia delivery at multiple time points, preferably outside the consultation.

Conclusions: Decision making about fertility preservation is an important step in providing high-quality comprehensive cancer care and a priority for many survivors' optimal quality of life. Decision support interventions are needed to address gaps in care and help women quickly navigate toward an informed, values-congruent decision. Survivors and providers support developing a patient decision aid website to make information directly available to women outside of the consultation and to provide self-tailored content according to women’s clinical characteristics and their information-seeking and deliberative styles.

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KEYWORDS

cancer; decision support techniques; fertility preservation; oncofertility; oncology; needs assessment; patient decision aids; patient needs; shared decision making

Introduction

With cancer survival rates exceeding 75% for young adults, it is increasingly important to minimize the negative effects of treatment, such as infertility, to protect survivors’ long-term quality of life. Infertility ranks fifth on the World Health Organization’s list of serious disabilities, and multiple studies show that cancer-related infertility causes distress and regret that persist long term, even in survivors with otherwise positive mental health status [1-4]. Since 2006, the American Society of Clinical Oncology (ASCO) guidelines have recommended that oncology providers address the risk of treatment-related infertility as early as possible and offer all women a referral for fertility counseling before initiating cancer treatment [5-7]. The decision-making process consists of 2 steps: patients must decide whether to accept or seek a referral to a fertility specialist and then decide whether to undergo fertility preservation and of which type. Referral to a fertility specialist decreases survivors’ long-term regret and distress, whether or not women undergo fertility preservation therapies [2,3]. However, a recent review reported that 25% of physicians, 36% of advanced practice nurses, and 65% of nurses are not aware of the guidelines [8,9]. Only 53% of women of reproductive age recalled having a discussion about the effect of cancer treatments on fertility, and as few as 12.2% women recalled having fertility preservation counseling [2,10].

Several previous studies have explored barriers to fertility preservation discussions, referrals, and treatment [11-15]. Oncology providers report a lack of time for counseling within the consultation and resources to offer patients, particularly those who do not have insurance coverage. Provider education interventions and financial resource programs have been developed to address these barriers. However, gaps remain in helping providers also identify appropriate patients for referral, which necessitates shared decision making to assess patients’ informed personal preferences [8]. For patients, educational booklets have improved awareness and information comprehension; however, gaps remain in providing evidence-based decision support during the brief time (sometimes as little as 24 hours) between diagnosis and cancer treatment initiation [8,16-18]. Interventions are needed that can provide timely information and decision support to women when they need it and can process it, which is often in between clinical consultations.

Patient decision aids are tools that complement clinical consultations by providing up-to-date, plain language descriptions of the options as well as theory- and evidence-based approaches to help patients engage in decision making [19-21]. They are designed for preference-sensitive decisions in which there are 2 or more medically appropriate options, high uncertainty, and trade-offs in risks and benefits [22]. Decision aids may be provided in a variety of formats (eg, booklets, videos, and websites) before, during, or after a clinical consultation. The most recent Cochrane Collaboration review of 89 randomized trials reported that patient decision aids improve patients’ knowledge, realistic expectations of risks, and congruency of treatment choices with their informed *decision-making values* (ie, the factors in the decision that matter most to the patient) [19]. Studies show that patient decision aids improve decision quality (ie, the degree to which decisions are well informed, congruent with what patients value most, and actionable) and reduce decisional conflict (a state of anxiety that blocks action) [19,23,24]. Decisional conflict has been shown to correlate with long-term decisional regret [24]. For every unit increase in decisional conflict, patients are 59 times more likely to change their mind, 23 times more likely to delay, 3 times more likely to fail knowledge tests, and 19% more likely to blame the doctor for bad outcomes [24-26].

In Australia [27], the Netherlands [28], Germany [29], and the United Kingdom [30], fertility preservation patient decision aids have been developed, with positive results on knowledge, decisional conflict, and decisional regret. However, at the time of this study, these decision aids were only available for women with breast cancer. Furthermore, many women in the United States face an additional financial barrier—as of August 2020, only 19 states mandate insurance coverage for fertility counseling or care (with only 10 states covering iatrogenic fertility loss), and few women are aware of available financial resources such Walgreens Heartbeat and LIVESTRONG Fertility [10,16,31]. The long-term goal of this program of research studies is to develop a patient decision aid [32] that provides information tailored for a variety of cancer types and time points and that specifically addresses women’s decision-making, financial, and referral and navigation needs.

As a key step in the systematic development of a patient decision aid, the International Patient Decision Aid Standards (IPDAS) Collaboration recommends a formal assessment of all stakeholders’ decision-making needs and perspectives to ensure that the decision aid will be effective, meaningful, usable, and sustainable [33-36].

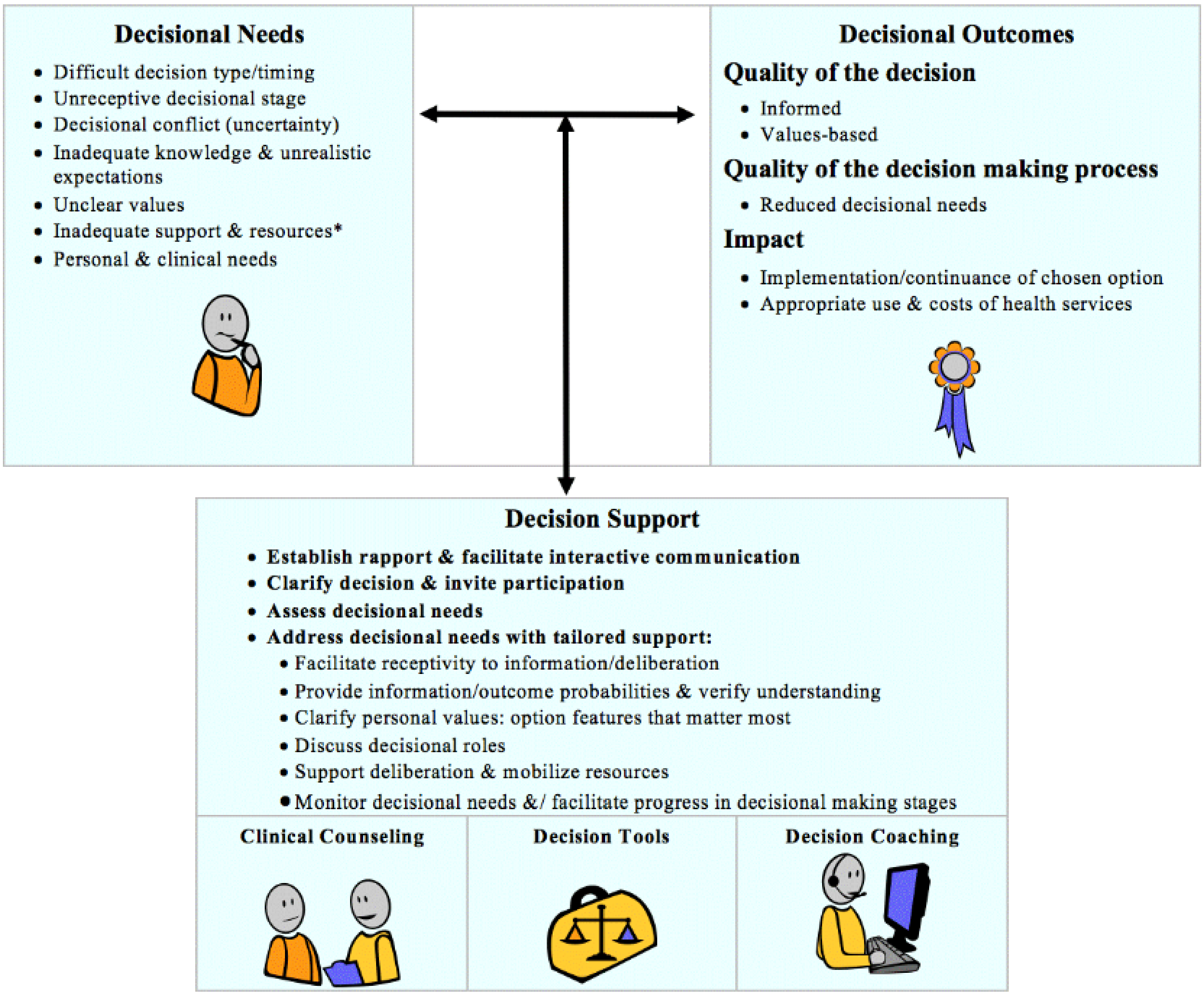
Following the Decisional Needs Assessment approach [37], the specific aims of this study are to assess the decision-making needs of oncology providers and female cancer survivors in terms of their (1) current experiences and key decision-making factors, (2) unmet decision-making needs, and (3) recommendations for the content and design of a fertility preservation patient decision aid website.

Methods

Conceptual Framework

The Ottawa Decision Support Framework (Figure 1) [38] has been used to develop decision support interventions in more than 100 studies across 18 countries. This framework applies behavioral economic [39,40] and cognitive [39,41-43] theories to preference-sensitive health care decisions. For example, it postulates several modifiable decision support needs, such as lack of awareness, knowledge, clarity, or support, which may be addressed to ensure a high-quality decision-making process. The framework was operationalized in 1999 in the Decisional Needs Assessment Workbook (updated in 2013 [37]), which details a series of 10 steps to define and select the appropriate objective(s), participants (key informants), rationale, methods, data collection tools, sample size, sampling procedure, analytic methods, and presentation of findings. The research team completed these steps, resulting in the approach described here in the *Methods* section.

Figure 1. The Ottawa Decision Support Framework.

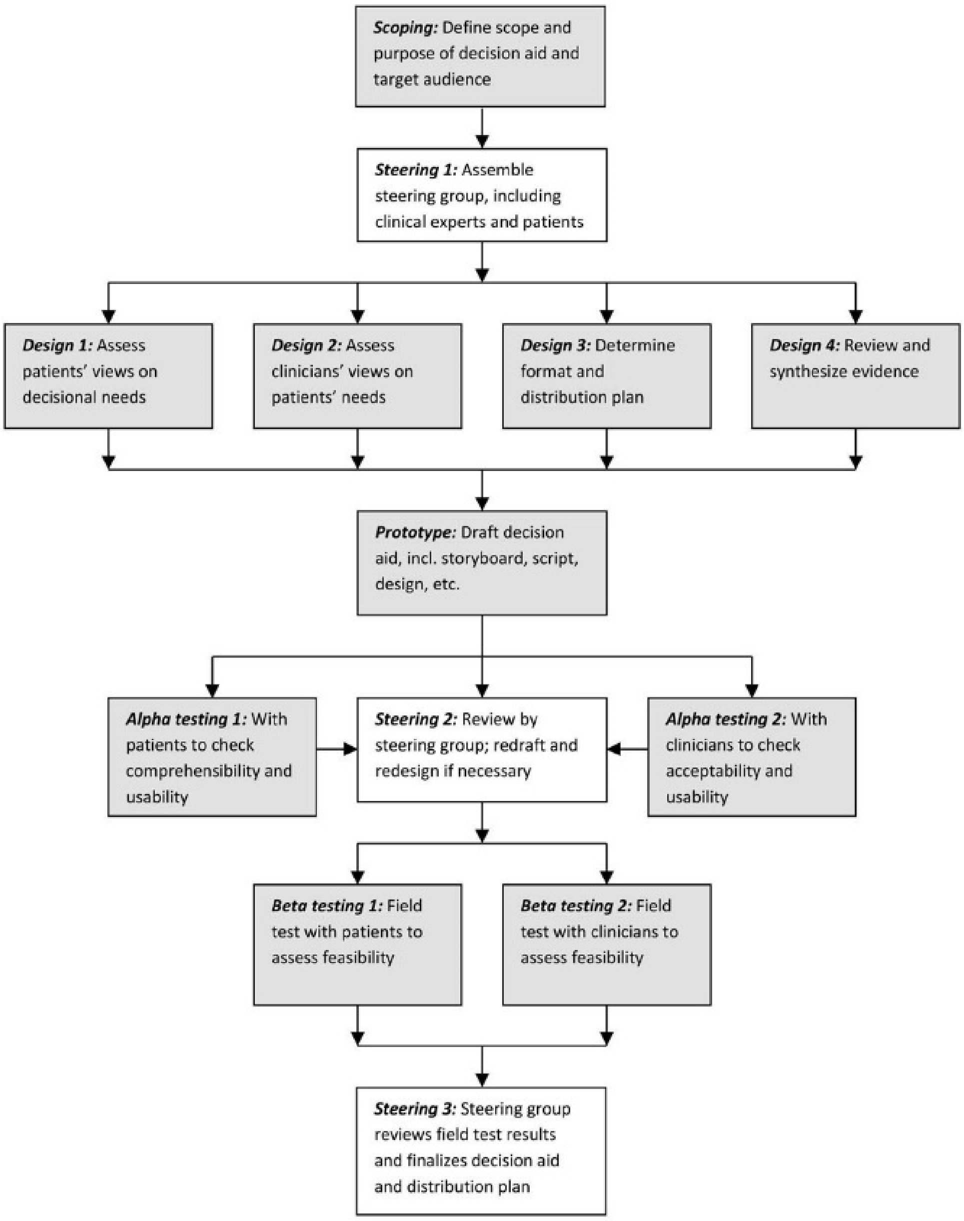


*Inadequate support and resources to make/implement the decision include: information inadequacy/overload; inadequate perceptions of others' views/practices; social pressure; difficult decisional roles; inadequate experience, self-efficacy, motivation, skills; inadequate emotional support, advice, instrumental help; and inadequate financial assistance, health/social services.

Study Design

To address the specific aims, this study used semistructured cognitive interviews and an ad hoc semistructured focus group. Figure 2 presents the IPDAS model [33] for rigorous and systematic patient decision aid development of patient decision aids. This study specifically addressed design steps 1 and 2. Previously, we engaged a stakeholder advisory panel of female cancer survivors, patient advocates, and oncology providers who guide the larger program of research. The advisory panel actively partners in each study, including contributing to the study design, protocol, materials, instruments, interpretation of results, presentations, and manuscripts. For this study, the advisory panel and research team defined the scope of this needs assessment to focus on assessing women with cancer's needs for information and decision support regarding whether to seek or accept a referral for fertility counseling as well as exploring whether an interactive website would be feasible. These decisions were based on 3 key factors: (1) previous studies had assessed decision making about choosing among preservation options but not the initial choice to seek or accept the referral to see a fertility specialist; (2) given the short time frame, survivors report needing access to information between consultations at all hours; and (3) a website could provide interactive features to allow self-tailoring by cancer type (eg, breast and ovarian), age, information level, deliberative style, or other factors. Subsequent planned studies will assess technological aspects, such as accessibility, usability, design, and acceptability, to create an optimized prototype for pilot testing. The MD Anderson Cancer Center Institutional Review Board provided ethical review and approval for this study (#2014-0130).

Figure 2. The International Patient Decision Aid Standards Collaboration model for systematic development of a patient decision aid.



Participants: Oncology Providers and Female Cancer Survivors

The principal investigator (TLW) purposefully invited oncology providers at the institution representing a variety of professional roles (surgeons, advance practice providers, etc), clinical expertise, experience, and sociodemographic characteristics. To recruit survivors, the research team distributed flyers in the waiting areas and lobbies throughout the MD Anderson Cancer Center and community clinics and invited survivors in person after their appointments at the Oncofertility Clinic. Over the past 10 years, the racial and ethnic distribution of survivors seen at the Oncofertility Clinic included 65% White, 11.6% Black, 10.5% Asian, 5.7% other, and 22.5% Hispanic individuals (7.2% declined to respond). Eligible survivors included English-speaking 18- to 45-year-old females diagnosed with cancer within the previous 5 years who received a potentially fertility-damaging treatment (eg, chemotherapy, radiation, or surgery on a reproductive organ). In the context of this sensitive survivorship topic, it is important to note that *women* is the inclusive term preferred by our survivors, as fertility counseling includes offering fertility preservation treatments and/or alternative family-building options to patients and survivors who may or may not currently have a uterus or ovaries. All participants provided informed consent.

Interviews

Following the Decisional Needs Assessment Workbook [37], the interview guide (Multimedia Appendix 1) asked providers and survivors to reflect on (1) their current experiences, (2) unmet needs, and (3) recommendations for the content and design of a patient decision aid. The Decisional Needs Assessment in Populations Workbook [37] provides templates of questions that may be readily adapted as appropriate for the clinical context and user(s). The advisory panel also edited questions for patient-centered language. For example, we tailored the questions to focus on referrals for fertility counseling and for survivors or providers (eg, What factors do you consider and/or discuss with patients to decide whether to refer for fertility? and What types of things were you thinking about when deciding whether to go see the fertility specialist?). The principal investigator and a trained research coordinator conducted the cognitive interviews, which were audio recorded using integrated overhead microphones and transcribed verbatim. Women also completed a questionnaire assessing their characteristics and ratings of the helpfulness of potential medium and delivery formats (to confirm, or add to, plans for web-based delivery). At the end of the interview, women received a US $50 gift card and paid parking. Both interviewers took field notes, which were compared and discussed to inform the interpretation of results. Recruitment continued until data saturation was reached, in terms of no new codes emerging in 2 cycles of transcript coding (ie, 2 batches of 2 to 3 transcripts).

Focus Group

While analyzing the cognitive interview transcripts, the research team observed that participants had introduced ideas that merited further exploration, including a variety of factors that drove their decisions (ie, their *decision-making values* [44]), and a variety of resources that they used during their decisions. Decision-making values are a key component of decision support, and many patient decision aids present a set of top-ranked values to engage patients in considering which factors are most important to them in this decision (ie, decision-making values clarification). After discussion with the advisory panel, the principal investigator and research assistant conducted an ad hoc survivor focus group to confirm coding and interpretation (including which decision-making factors were top priority) and to assess responses to relevant resources. The research assistant recontacted 2 individuals from the interviews who had made statements that merited additional discussion and recruited 5 additional survivors. Following the focus group discussion guide (Multimedia Appendix 2), the principal investigator invited women to complete an initial questionnaire that presented women with a set of selected values statement from the interview transcripts. Women ranked the importance of each statement individually, discussed their ranking as a group, and added additional ideas they felt were not yet well addressed. Next, the research assistant presented the group with the cancer center's patient information sheets, the existing patient decision aids [27-29], and examples of the web-based resources that interview participants had recommended. The research assistant used open-ended discussion prompts to assess women's perspectives on the wording, graphic design, utility, acceptability, and usefulness. Participants were provided with US $50 gift cards and paid parking.

Data Analysis

Interviews were coded and analyzed using the coding process by Strauss and Corbin [45] and NVivo 10 (2016 QSR International). Two research assistants coded the first 5 transcripts to create the codebook and then iteratively until saturation was reached (ie, no additional codes were identified in the next 2 transcripts). Each coder separately coded the remaining interviews in batches of 2 to 3. Additional codes were added, and the earlier interviews were reanalyzed and updated. A third coder rereviewed all transcripts to ensure fidelity to the codebook and to ensure that interrater reliability remained above 90%. The principal investigator resolved minor coding discrepancies through discussion and independent review of the transcripts.

Interview findings were summarized using an initial word frequency analysis, followed by keywords in context analysis to identify primary themes and subthemes. There were not sufficient distributions for subgroup analyses; however, exemplary quotes were purposively selected across age and parity subgroups. The research team also compared and contrasted interview transcripts to identify potential missing items or misconceptions that could be addressed in a patient decision aid. As the focus group was conducted to clarify specific points and obtain initial reactions to existing materials, the transcript was analyzed descriptively and the results were summarized in terms of notable points and recommendations that could inform the future design and user testing studies. All findings and interpretations were shared with the stakeholder advisory panel to confirm meaningful interpretations.

Results

Participant Characteristics

All 51 individuals who were recruited in person agreed to participate, including 18 oncology providers and 33 female cancer survivors. None of the women responded solely to public flyers. Interview recruitment continued until data saturation (n=46, including 18 providers and 28 survivors). The follow-up focus group reengaged 2 survivors from the interviews and 5 additional survivors (n=7).

Tables 1 and 2 present participants' characteristics. The average age of survivors was 32 years, and the majority were White, 2 years postdiagnosis, had a college degree, and were in heterosexual relationships without children. The majority of providers were White, female attending physicians with an average of 9 years of clinical experience. Survivors included women seen by participating providers and women seen by other providers.

Table 1. Providers' characteristics (n=18).

Characteristic	Value
Specialties, n (%)	
Medical oncology	1 (6)
Surgical oncology	1 (6)
Radiation oncology	4 (22)
Pediatric oncology	2 (11)
Gynecological oncology	3 (17)
Lymphoma or myeloma	3 (17)
Leukemia	2 (11)
Stem cell transplant	2 (11)
Years in practice, median (range)	9 (3-18)
Female, n (%)	13 (72)
Race, n (%)	
White	8 (45)
Black	2 (11)
Asian	6 (33)
Other	2 (11)
Ethnicity (Hispanic), n (%)	2 (11)
Provider type, n (%)	
Attending physician	13 (72)
Advanced practice provider	5 (28)

Table 2. Survivors' characteristics (n=33).

Characteristic	Value
Cancer site, n (%)	
Breast	11 (33)
Ovarian, cervical, or vaginal	5 (15)
Lymphoma or leukemia	14 (42)
Other	3 (9)
Age (years), median (range)	32 (20-45)
Years since diagnosis, mean (range)	2.1 (0-5)
Female, n (%)	33 (100)
Race, n (%)	
White	25 (76)
Black	4 (12)
Asian	3 (9)
Other	1 (3)
Ethnicity (Hispanic), n (%)	5 (15)
Highest education, n (%)	
Some college	7 (21)
Associate degree	4 (12)
Bachelor's degree	15 (46)
Master's degree	6 (18)
Professional degree	1 (3)
Relationship status at diagnosis, n (%)	
Single	10 (30)
In a relationship	14 (42)
Married	7 (21)
Divorced	1 (3)
Other	1 (3)
Nulliparous at diagnosis, n (%)	30 (90)
Completed fertility preservation therapy, n (%)	18 (55)

Interviews

Interviews and the focus group lasted 1 hour each and were conducted in private rooms at the cancer center. Across all participants, 3 primary themes emerged: (1) fertility preservation decisions are important for survivorship, (2) significant but potentially modifiable barriers to decision making exist, and (3) support exists for a carefully designed fertility preservation patient decision aid. Within the primary themes, 10 subthemes emerged from the 74 unique codes. The following sections describe providers' and survivors' comments by subtheme and provide exemplary quotes.

Primary Theme 1: Fertility Preservation Decisions Are Important for Survivorship

All participants emphasized the importance of fertility decisions, both for cancer treatment and for long-term survivorship. A total of 3 subthemes were identified (Textbox 1): fertility is important for quality of life during survivorship, knowing the options matters, and fertility desires change over time. The majority of survivors emphasized the importance of knowing that there were options and the benefit of both the discussion process and fertility preservation, if desired, for their overall treatment and recovery. Women who made fertility preservation decisions specifically commented about feeling empowered, hopeful, and/or able to look forward to the future while enduring their cancer treatments. In addition, several survivors described the value of explicitly acknowledging that family-building desires may change over time. Providers also reported the importance of fertility for survivorship. They added concerns about the number of women waiting until after cancer treatment to consider fertility. Several providers discussed the potential of shared decision making to minimize future regret.

Textbox 1. Subthemes and exemplary quotes for primary theme 1 (fertility preservation decisions are important for survivorship).

Subtheme 1: Addressing Fertility Is Important

- “It is really about [having] that conversation. I’ve learned from survivors, that they are: ‘I didn’t know, nobody told me. I have this question mark. I feel like this is cancer all over again.’ It is incertitude that is really...the most burdensome.” (Provider 17, leukemia nurse practitioner)
- “...if this is going to be a long-term cure, we need to look at the whole picture and stop just treating the one aspect of their life. Empowering patients themselves to ask about their risk of infertility I think is really important.” (Provider 4, gynecological oncologist)
- “It was just so amazing to know that I still had a shred of hope. The past few weeks with chemo have been hard, but knowing that I have something in the future to look forward to gets me through it. I’m not sure it would have been this easy if I didn’t have that embryo, because I feel like, ‘What’s the point, it is not like I can have kids.’ That embryo is just the icing on the cake. It made everything so much easier.” (Survivor 1, 22 years old, White, in a relationship)
- “We thought that there was no chance for us anymore. Then they gave us this information today about possible IVF...even if we are not overly concerned about getting pregnant, it is nice to know we still have that option.” (Survivor 28, 33 years old, Hispanic, single)

Subtheme 2: Understanding That There Are Options Is Important

- “They need...a decision aid that says, ‘[Protecting your fertility] is an option. These are all the different options that you have. You can choose to say No. You can choose all these different routes.’” (Provider 16, breast medical oncologist)
- “I did see [the fertility specialist], and she told me there were all these other options...Just hearing the options made me feel better. I never heard options from anyone until I came here.” (Survivor 25, 22 years old, White, in a relationship)
- “For me, [a key recommendation] is ‘make sure you know all your options.’ To me the worst decision we can make is not fully understanding what all of our options are at the time.” (Survivor 6, 35 years old, White, single)

Subtheme 3: Understanding That Family-Building Desires Change Over Time Is Important

- “Even that person who is, OK, well, no. I’ll just take my chances, and I’m not talking to anybody - I guess my fear is that they don’t really understand what I’m saying or what they have been told, that this will probably affect their ability to have children in the future.” (Provider 3, gynecological oncologist)
- “[I recommend fertility preservation counseling] even if you are not totally certain where your life is going at the moment. I would say, while you have those resources and options available...because you may feel very differently in 5 years. I know, for me, I didn’t want kids 5 years ago and now I am kind of open to the possibility.” (Survivor 2, 32 years old, White, single)
- “I was in a relationship, but I kept postponing things, thinking, ‘35 and then I’ll start thinking about kids.’ But it is one of those things that you are not 100% sure if you can plan it.” (Survivor, 37 years old, White, single)

Primary Theme 2: Significant but Potentially Modifiable Barriers Exist

All participants also reported that decision-making barriers still exist, and 4 subthemes emerged (Textbox 2). The majority of survivors raised issues of awareness and time for decisions and uncertainty about risks and costs. Many confirmed that they recalled hearing about fertility in the informed consent for chemotherapy; however, less than half reported understanding fertility preservation decisions. More than half reported feeling they did not have time to consider fertility decisions or collect needed information (eg, insurance paperwork and fertility status), although several acknowledged that they were anxious to start treatment quickly. Most women reported difficulty making decisions because of costs—either because they could not afford preservation without insurance or because they did not understand these decisions early enough to have time to plan for the short- and long-term out-of-pocket costs.

Textbox 2. Subthemes and exemplary quotes for primary theme 2 (significant but potentially modifiable barriers exist).

Subtheme 1: Need for Provider and Patient Education

- “Those are questions that are really best for...the reproductive [endocrinologist].” (Provider 7, radiation oncologist)
- “[I am] reasonably satisfied [with my fertility preservation knowledge]. I’m not an expert in that area...I provide some general counseling [and tell patients], ‘I certainly can’t deliver [personalized risks and rates of fertility preservation outcomes], but I’m pretty sure that [the reproductive endocrinologist] can.’” (Provider 16, breast medical oncologist)
- “The thing is, they didn’t tell me anything about it [chemotherapy affecting infertility], so I couldn’t say yes or no. Now I’m learning about all of this, that chemotherapy can affect it.” (Survivor 32, 23 years old, Black, in a relationship)
- “I had no idea. They didn’t tell me when I was diagnosed that this might cause problems having kids. Nobody told me that. It is still new to me. They didn’t tell me until a couple of months ago. That is why I am doing everything I can. I have been wanting kids since I was 9...always, always, always.” (Survivor 19, 21 years old, White, single)

Subtheme 2: Limited Time for Making Decisions and Facilitating Referrals

- “[Patients] come in on Monday, have tests on Tuesday and Wednesday, and by Friday we are starting treatment. There are times when you have to start that same day.” (Provider 10, gynecological oncologist)
- “...to go from chemo directly to fertility within that one hour is too much. So if there was...online resources [for fertility preservation education], that would help.” (Provider 16, breast medical oncologist)
- “I would say generally, less than 5 minutes. That would be my usual conversation.” (Provider 1, medical oncologist)
- “It was incredibly frustrating, because...there is not a direct path to get them a referral...your ovarian reserve declines, but we don’t really have a mechanism to actually test that routinely in patients and counsel patients with their true fertility potential.” (Provider 1, medical oncologist)
- “...you have cancer, and that’s hard enough. But then to be told that you have to make a decision right now, because we can’t delay it...[The doctor] says I can’t even think about it one night.” (Survivor 30, 33 years old, White, married)

Subtheme 3: Cost of Fertility Preservation Services

- “The barriers would probably be insurance. That is maybe number one; that is 100%.” (Provider 8, radiation oncologist)
- “Payment is a barrier for women but I think the ones that really want to pursue it, we find options for them.” (Provider 5, nurse practitioner)
- “...what I have been researching really has been around funding,...the cost factor, because I know that this is something that I want to do. However, [the cost] is my roadblock.” (Survivor 3, 39 years old, Black, single)
- “I was going to go through with the egg preservation...but then, like I said, once I saw the prices and everything, I was, as much as I want to do this, I think I have to accept if for what it is right now. And later on get over that when it comes...” (Survivor 25, 23 years old, Black, in a relationship)

Subtheme 4: Cultural and Financial Differences Are Important, but They Do Not Stereotype Services

- “I have over time learned...not to stereotype and pitch the whole thing based on ethnicity and religion...just say that these are personal decisions based on your own morals and religion, your previous experience, and your family’s experience.” (Provider 15, gynecological oncologist)
- “I guess more than anything, being mindful that there is not one cookie cutter approach, that every situation is so different.” (Provider 1, medical oncologist)

Most providers also discussed awareness, time, and cost barriers to decision making and added the need for additional education about the ASCO guidelines, updated risks of newer procedures, and the time or processes needed for fertility preservation. Many providers also discussed the need for information tailored to cancer type but viewed their role as introducing the topic and facilitating referrals to a reproductive endocrinologist for personalized decision counseling. A majority of providers expressed a need for practical support to identify appropriate women and facilitate the process (eg, navigating timely referrals and planning for the future). Notably, all oncologists reported feeling comfortable introducing treatment-related infertility; however, a few providers who expressed higher levels of knowledge and comfort also reported discussing decisions with patients more often and in greater detail.

Over half of the providers discussed the relevance of patients’ demographic characteristics (particularly age, culture, spiritual beliefs, and potential resources) for introducing the topic appropriately; however, they cautioned against making assumptions, noting that many women or families make unique decisions and find additional resources (eg, family contributions and fundraising). Seven providers brought up scenarios in which they initially felt it might be okay not to offer a fertility preservation decision aid (eg, noncurative treatment plan, single women, older age, multiple children already, low socioeconomic status, and religion). However, they quickly provided examples of exceptions (eg, a family who wants to freeze their dying daughters’ eggs or embryos and remarried mothers who strongly want more children) and emphasized offering information equally yet compassionately to all women.

Primary Theme 3: Support for a Carefully Designed Fertility Preservation Patient Decision Aid

All participants supported the use of a fertility preservation patient decision aid, provided it was carefully designed to overcome the barriers. Three subthemes arose in their recommendations: provide tailorable content, use appropriate and inclusive language, and design multiple delivery formats and routes (Textbox 3).

Textbox 3. Subthemes and exemplary quotes for primary theme 3 (strong support exists for a carefully designed patient decision aid).

Subtheme 1: Providing Tailorable Content

- "The 18- to 22-year-olds may be different than the 30 year-old because the parents are going to be watching more. Split it up between minors and non-minors." (Provider 16, breast medical oncologist)
- "[Tailor by] solid versus liquid tumor, because that would be different." (Provider 1, medical oncologist)
- "It would be really cool if you [could] put in a patient's age, history, results,...then it brings up their algorithm, including the known statistics about a given cancer and what their outcomes potentially are. That would help the patient and the provider." (Provider 3, gynecological oncologist)
- "I like details. I am going to click on that and get every detail possible. I'm like that. I think to grab someone's attention, something general, but then when you click on it, a bunch of details on that one topic." (Survivor 2, 21 years old, White, single)
- "I think they [patient stories] are helpful, because it shows that other people have gone through the same thing and how they came to their decisions." (Survivor 33, 24 years old, White, in a relationship)

Subtheme 2: Using Appropriate and Inclusive Language

- "Some countries like Qatar, have reproductive medicine and it is not a big deal (shipping international can be a barrier), but for Kuwait, Saudi Arabia, UAE, etc, it may be a big issue. Sometimes women cannot get married if they are infertile." (Provider 6, pediatric nurse practitioner)
- "...particularly Orthodox Jewish populations and having families is very important to them. While they don't talk about sex overtly, they are very interested in finding way to preserve fertility because that is so important to their religion. If they have concerns, it typically goes through the Rabbi." (Provider 10, gynecologic oncologist)
- "...with Arabic women, many of them are virgins, so doing a transvaginal ultrasound or a transvaginal procedure becomes an issue. I had one patient that declined because she wouldn't do that." (Provider 15, gynecological oncologist)
- "We only found one company [that]...was open to same sex adoptions." (Survivor 10, 31 years old, White, in a relationship)

Subtheme 3: Designing Multiple Delivery Formats and Routes

- "[New patients] need to hear it two or three different ways because they are not processing a lot in those first three visits (other than chemo and surgery)." (Provider 1, medical oncologist)
- "It could be part of the nursing intake (Are they 45 or under? Make sure you give them the fertility information to watch). I would involve nurses and midlevels." (Provider 16, breast medical oncologist)
- "We have different education backgrounds, so sometimes people can interpret a flowchart better than others, and people might relate better to the story of this person that went through it." (Provider 17, nurse practitioner)
- "The nurses have that way of going, 'What else is going on?' I think that is the perfect time to say, 'OK, you may not be thinking about it, but these are some of the things that you may want to consider and ask.'" (Provider 1, medical oncologist)
- "The simplest thing would be if there was one piece of paper that I could just hand them and say, 'You can go to this website and explore this decision aid, and we can discuss it next time.' And offer periodic [group] discussions." (Provider 9, radiation oncologist)
- "I use the [institution] website for a lot, so it is handy that it has the mobile application, and the desktop. Although they look a little bit different, they are pretty much the same. For simplicity, it is nice to have it optimized for the mobile device." (Survivor 30, 33 years old, White, married)
- "To be honest, probably because of my age, no. I don't like those stupid movies...I think it has to do with the fact that I have grown up and been taught to be a strong independent woman. I don't feel like I need to lean on those types of things." (Survivor 11, 22 years old, White, in a relationship)

Survivors' recommendations focused on the content and ability to select the level of information and support needed. Their recommendations varied from brief introductory overviews (leaving the majority of the information for the fertility consultation) to detailed comparison charts and suggestions for addressing uncertainty, managing emotions, and navigating the financial process. The majority of survivors recommended having a way to select only their relevant options to minimize information overload. They also requested implicit decision guidance (eg, examples and testimonials about decision making) and inclusion of multiple lifestyles, cultures, and beliefs.

Providers recommended a tool that presented options tailored to clinical factors, such as age and cancer type. They also recommended providing explicit decision-making activities (eg, value clarification exercises and preference elicitation) to assist in identifying who may benefit from a referral for fertility counseling. Several providers mentioned the need for low health literacy and culturally appropriate language, and many providers cited examples of the importance of virginity and fertility in many cultures.

The majority of recommendations in both groups focused on delivery. Both survivors and providers recommended offering a patient-facing decision aid at multiple time points using multiple media, with an emphasis on viewing outside the consultation. Suggestions included providing an initial handout, booklet, or email at the first and/or second visit after diagnosis that contained a URL link to an institutionally supported website, viewable on a computer, tablet, or phone. Survivors also suggested having a nurse or a peer volunteer personally recommend the decision aid to emphasize the importance of fertility and distinguish it among the many handouts received at diagnosis. Both groups supported offering a website to allow women to view it when optimal. Notably, providers recommended web delivery to address diagnostic consultation time limitations and to enable patients to self-refer to a fertility specialist. Survivors recommended web delivery to address information overload and coping barriers. A few survivors also mentioned wanting to revisit the information after cancer treatment.

Additional Informative Responses

In addition to the primary themes, a few individuals raised the following four points, which the stakeholder panel recommended reporting to inform decision counseling. One provider noted the importance of clearly discussing alternative family-building options, including acknowledging the potential challenges for cancer survivors considering surrogacy or adoption. Two survivors recommended including testimonials from women at various stages of cancer treatment and survivorship. Two others mentioned addressing their partners' preferences and support. A pediatric oncologist noted the communication barriers for young adults and their parents and suggested a pediatric version of a patient decision aid that offers tangible support:

> *[Tell patients:] We will help [you] talk to your mom. There are resources...our social worker may be able to help. We will talk to the oncologist.* [Provider 6, pediatric nurse practitioner]

Follow-up Focus Group

Participants in the ad hoc focus group confirmed and clarified the findings of the individual interviews and deepened explanations. There was unanimous agreement that fertility should be explained as early as possible. Survivors particularly commented on needing time to make the transition from initial awareness and comprehension to delving into the potential costs, insurance processes, ethical considerations, and future decisions. A few women reiterated needing to acknowledge that the "new normal" may include uncertainty when making decisions.

Women related several examples of feeling rushed, unaware, or pressured, which led to unanswered questions and unspoken preferences, with continued feelings of regret and sadness. Several mentioned feelings of reliving the trauma as survivors and "not being able to own that decision." Several comments were made regarding the need to include fertility preservation in their financial planning and acknowledging resources other than insurance, such as foundations, family contributions, and social fundraising.

During the review of the cancer center's patient information handouts, existing decision aid materials from other countries [5,28,46,47], and additional resources identified by interview participants, survivors appreciated the explanations of the process or timeline, examples or testimonials, and directly addressing fears about time. They also noted the importance of a "gentle" and "compassionate" tone. Survivors felt that some of the tools seemed outdated or would not be applicable across the diverse population in this health system. They also requested information for other types of cancer and optional sections discussing referrals, insurance coverage, and estimated costs. Finally, they also supported web delivery to provide links to financial resources and fertility specialists.

Focus group participants also brought up additional topics that they thought should be included in decision support materials, such as how to be your own personal champion, resolve family conflict or pressure, engage your partner in this decision, and have someone come with you to take notes and raise questions:

> *I kind of grieved it when I was first diagnosed with cancer, and for 7 years, kind of held my breath. [My husband] came into my life, and there was a real sad time after about a year of marriage where I was having to face it again.* [Survivor 30, 33 years old, White, married]
>
> *I was told [that I had cancer] on a Wednesday, by Thursday I was getting my port, and Friday and Saturday I started my treatment. All I was thinking at that time was, "Okay, do what you need to do." So my sister was there and she said, "Wait, wait, hold on, we have to discuss this. There are other options."* [Survivor 3, 39 years old, Black, single]
>
> *My mom and my boyfriend at the time were just, "We want you to be okay." But I wanted to have my own baby...one doctor kind of yelled at me, "You need to just survive it!" I said, "If I survive, I want to be able to have babies!"* [Survivor 6, 24 years old, Asian, single]

Discussion

Principal Findings

Overall, providers and survivors emphasized the importance of fertility preservation decision making for high-quality comprehensive cancer care. Both groups acknowledged existing barriers, such as awareness, time, and costs, and proposed potential solutions. All participants strongly supported offering women a website so that they could review the material at home. They recommended providing a lay language overview, interactive features to self-tailor (eg, by cancer type), guidance in decision making about seeking or accepting a fertility referral, and links to facilitate referrals and access financing programs. They noted the value of a patient decision aid for engaging women in the initial decision and the potential for this engagement and empowerment to improve hope during the treatment process and decrease downstream regret.

Comparison With Prior Work

These results confirm the results of previous studies regarding the multilevel challenges to providing high-quality fertility preservation counseling [8,14-16,29,48,49]. Providers and survivors noted patient-level barriers such as information overload, misinformation, coping needs, lack of awareness or knowledge, and difficulty understanding and personalizing complex medical information. They also described provider-level barriers (eg, familiarity and perceived role in the decision) and system-level barriers (eg, limited time, opportunities, and access). As in other studies, providers and survivors noted the desirability of patient stories to convey experiential knowledge; however, the potential for social matching bias (ie, attending more or less to information from someone who is more or less similar to you) remains a concern [16,50,51]. Furthermore, these findings complement the extant literature describing the tension between concerns about information overload while ensuring an informed decision-making process [52,53]. Providing accessible information that meets health literacy needs (eg, plain language, culturally aware, and relevant) may help women feel more supported and engaged in the decision-making process [52,53].

This study adds to the literature user-generated design recommendations, such as providing understandable medical information; explicitly addressing uncertainty; and helping personalize the information by providing estimates of costs, descriptions of the treatment or recovery processes, values clarification exercises, and example stories modeling decision making [29]. Providers and survivors also recommended multilevel information, literacy or numeracy support, responsive design (for use on tablets, cellular phones, etc), web delivery, and the ability to self-tailor by cancer type and cultural characteristics. Both groups described a tool that helped women prepare for a fertility consultation, emphasizing that the tool is not a replacement for a reproductive endocrinologist who can provide fertility testing and personalized counseling.

Notably, providers and survivors expressed a need for clear cost information. Providers stated that they rarely discussed costs, whereas survivors stated that costs played a significant role in their decision—either they assumed their insurance would not cover the treatments or the fertility counseling or they could not locate cost information in time to make an informed decision. The pressure to make these decisions with incomplete cost information may be forcing women to forego fertility counseling and fertility preservation treatments they need and desire. This suboptimal decision process may, in turn, compound long-term decisional regret because of a sense of unnecessary loss [54,55]. Future studies may wish to test whether a patient decision aid that includes cost estimates decreases decisional conflict and long-term regret.

Consistent with the distributions of survivors seen at the Oncofertility Clinic, this study recruited 24% non-White and 15% Hispanic women. However, a larger question remains as to whether these distributions represent optimal equitable care. Previous studies document variations in utilization of fertility preservation by race and gender and note a variety of barriers, including awareness, access, and insurance coverage [8,10,12,15,17,56-58]. We are conducting a parallel study focusing on culturally relevant features of fertility patient decision aids in Spanish and Arabic and exploring the degree to which variations are unwarranted or warranted based on cultural differences in informed patient preferences.

These results emphasize that fertility preservation decisions are as unique as the women who face them and support the ethical imperative of the guidelines to offer fertility counseling to all women who are interested or unsure [6,16,59,60]. Fertility preservation patient decision aids may be purposefully designed to raise awareness, address misconceptions, elicit informed preferences, and help women prepare for discussion. The primary goal would therefore be high-quality decision-making process and *appropriate referral*, defined as a referral that aligned with women's values and preferences once they were informed of the infertility risk and availability of fertility preservation and alternative family-building options.

Limitations

Providers and survivors were recruited from a comprehensive cancer with a reproductive endocrinologist; decision support needs may differ for community clinics that refer to private fertility centers. The focus group may have increased reflexivity; however, it allowed us to confirm data interpretations and explore emergent questions. For ethical reasons, we chose to interview survivors instead of newly diagnosed patients, but their wisdom provided an additional benefit—they generated a list of common *Myths and FAQs* (frequently asked questions), which will be incorporated into the planned patient decision aid. Data on childbearing preferences at diagnosis were not collected in this study; however, the results indicate that affective forecasting may be a topic to address within a patient decision aid. In addition, the findings indicate tensions and potential inconsistencies that we cannot explain within these data. Studies are needed that focus specifically on the rates and quality of shared decision-making discussions.

Conclusions

Providers and patients continue to report unmet needs regarding timely access to fertility preservation education and decision support. Survivors emphasize the importance of explicitly addressing fertility preservation early to allow them time to make decisions and plan financially. Providers emphasize designing tools to facilitate timely information and appropriate referrals and to improve adherence to guidelines. Both women and providers supported the development of a patient decision aid website to address these challenges and recommended interactive, self-tailoring features. Providing an accessible, tailored, and meaningful patient decision aid may increase awareness, decision making, and referrals; reduce regret; and improve long-term survivorship outcomes.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Survivor and provider interview guides.
[DOCX File , 35 KB - formative_v5i6e25083_app1.docx]

Multimedia Appendix 2
Focus group discussion guide.
[DOCX File , 27 KB - formative_v5i6e25083_app2.docx]

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Abbreviations

ASCO: American Society of Clinical Oncology
FAQ: frequently asked question
IPDAS: International Patient Decision Aid Standards

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Original Paper

Exploring the Potential of Personalized Dietary Advice for Health Improvement in Motivated Individuals With Premetabolic Syndrome: Pretest-Posttest Study

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Abstract

Background: Dietary quality plays an essential role in the prevention and management of metabolic syndrome (MetS).

Objective: The aim of this pilot study is to organize personalized dietary advice in a real-life setting and to explore the effects on dietary intake, metabolic health, and perceived health.

Methods: We followed a one-group pretest-posttest design and included 37 individuals at risk of MetS, who indicated motivation to change dietary behavior. For a period of 16 weeks, participants received personalized advice (t=0 and t=8) and feedback (t=0, t=4, t=8, t=12 and t=16) on dietary quality and metabolic health (ie, waist circumference, BMI, blood pressure, lipid profile, fasting glucose levels, and C-peptide). Personalized advice was generated in a two-stage process. In stage 1, an automated algorithm generated advice per food group, integrating data on individual dietary quality (Dutch Healthy Diet Index; total score 8-80) and metabolic health parameters. Stage 2 included a telephone consultation with a trained dietitian to define a personal dietary behavior change strategy and to discuss individual preferences. Dietary quality and metabolic health markers were assessed at t=0, t=8, and t=16. Self-perceived health was evaluated on 7-point Likert scales at t=0 and t=16.

Results: At the end of the study period, dietary quality was significantly improved compared with the baseline (Dutch Healthy Diet Index +4.3; *P*<.001). In addition, lipid profile (triglycerides, *P*=.02; total cholesterol, *P*=.01; high-density lipoprotein, *P*<.001; and low-density lipoprotein, *P*<.001), BMI (*P*<.001), waist circumference (*P*=.01), and C-peptide (*P*=.01) were all significantly improved, whereas plasma glucose increased by 0.23 nmol/L (*P*=.04). In line with these results, self-perceived health scores were higher at t=16 weeks than at baseline (+0.67; *P*=.005).

Conclusions: This exploratory study showed that personalized dietary advice resulted in positive effects on dietary behavior, metabolic health, and self-perceived health in motivated pre-MetS adults. The study was performed in a do-it-yourself setting, highlighting the potential of at-home health improvement through dietary changes.

Trial Registration: ClinicalTrials.gov NCT04595669; https://clinicaltrials.gov/ct2/show/NCT04595669

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KEYWORDS

personalized nutrition; metabolic syndrome; dietary behavior; diet; metabolic; metabolic health; dietary advice; dietary feedback; digital health

Introduction

Background

Metabolic syndrome (MetS) is associated with a two-fold increased risk of cardiovascular diseases and a five-fold increased risk of type 2 diabetes [1,2]. Approximately 25% of adults globally are affected by MetS, and its prevalence increases with age [3,4]. MetS is defined by the coexistence of three or more of the following risk factors: abdominal obesity, high fasting blood glucose, reduced high-density lipoprotein (HDL) cholesterol, elevated fasting plasma triglycerides, and elevated blood pressure (BP) [5].

Unhealthy dietary habits are a major risk factor for developing MetS and are probably even more relevant than sedentary lifestyles [6]. Research has demonstrated dietary strategies that can be used to prevent or resolve MetS and associated metabolic abnormalities [6-9]. Adherence to a healthy diet rich in fruits, vegetables, whole grains, and oily fish, while limiting total fat, saturated fat, dietary cholesterol, added sugars, sodium, and excessive alcohol intake, has been shown to be effective in improving metabolic abnormalities associated with MetS [7,8,10]. Associations between dietary changes and individual risk factors for MetS have also been shown [11-21].

Personalized nutrition, that is, evidence-based dietary advice tailored toward an individual based on individual-specific information, is most likely an effective strategy to support dietary behavior change, resulting in measurable health benefits [22]. Previous studies have shown that personalized advice is more effective than giving a *one-size-fits-all* advice for improving dietary patterns, increasing physical activity and smoking cessation [23-30].

We distinguished two potential reasons for this effectiveness. First, each person receives advice that addresses the individual nutritional needs based on the person’s biology, thereby maximizing the individual health effect. In a study on healthy volunteers receiving placebo or anti-inflammatory dietary mix supplements, the inflammatory, oxidative, and metabolic responses were highly variable among individuals, suggesting different nutritional needs based on the person’s biology [31]. Indeed, the concept of personalized nutrition from a biological perspective began to emerge as extensively reviewed by van Ommen et al in 2017 [32].

A second reason for personalized nutrition being effective is increased adherence to the advice when it is made personal. Each person receives only the information based on their characteristics, rather than generic information based on the characteristics of the population. Therefore, people are more likely to pay attention and feel more involved, especially when the information is tailored to the personal level of motivation [23].

Celis-Moralis et al reviewed the evidence on personalized interventions and concluded that there is a strong need for further development, testing, and implementation of digitally delivered, evidence-based, personalized interventions that incorporate effective behavior change techniques (eg, personal goal setting and feedback on performance) and are delivered digitally [33,34]. In a web-based multicenter study, Forster et al [35] compared an automated feedback system with manual feedback and found good agreement between the manual and automated feedback systems, showing promise for the use of automated systems for personalizing dietary advice. With regard to scalability and expected contribution to sustained behavior change, new evidence on the effectiveness and acceptance of these digitally delivered interventions is highly relevant.

Objectives

The primary aim of this pilot study is to organize personalized dietary advice in a real-life setting. We build upon the research described by Doets et al [36] by exploring the combined effects of dietary intake, metabolic health, and perceived health. As we aim to conduct real-life implementation, we are targeting individuals at risk of MetS, who are intrinsically motivated to change their dietary behavior to improve their health, as they are likely to be easy adopters of personalized advice.

Methods

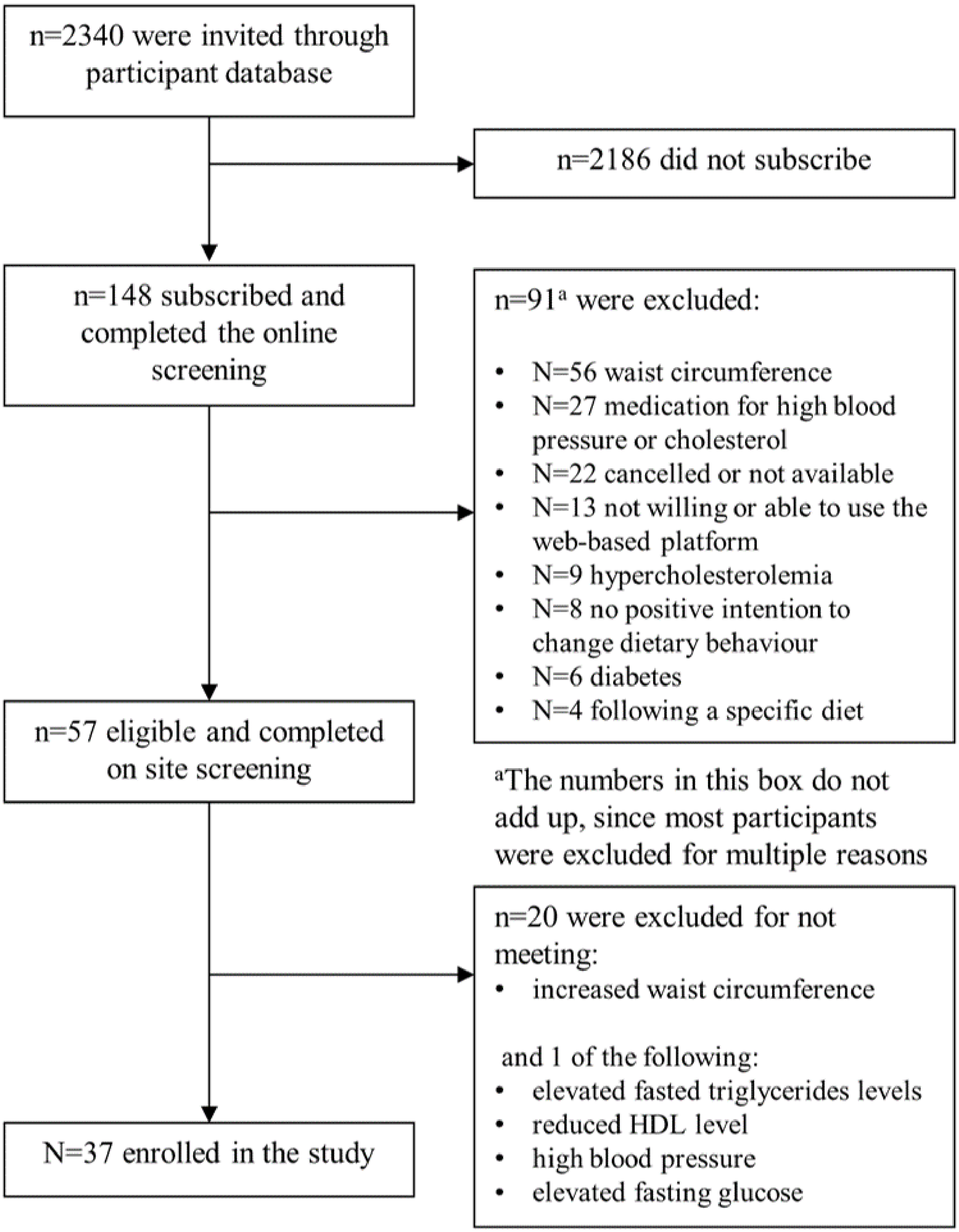
Ethics Statement

All participants provided informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Tilburg University (file number NL61382.028.17).

Recruitment and Screening

An overview of the recruitment procedure is shown in Figure 1. First, all members of the consumer database of Wageningen University & Research received an invitation letter for the study. Those interested in study participation completed a web-based screening questionnaire to verify the first set of inclusion and exclusion criteria: age ≥40 years, excessive waist circumference (self-reported ≥88 cm for women and ≥102 cm for men), positive intention toward changing dietary behavior, and willingness to use digital web-based applications during the study. To assess intention toward behavior change, we used an adapted version of 3 questions (7-point Likert scale) reported by Poinhos et al [37]. Participants with a mean score of ≥5 were considered to be motivated to change their dietary behavior. Exclusion criteria were as follows: taking medication known for its effects on blood glucose, cholesterol, or insulin; being diagnosed with diabetes or familial hypercholesterolemia; following a specific diet or having an alcohol consumption of >28 units (drinks) per week for men and >21 units per week for women.

Figure 1. Flowchart of recruitment and screening procedure. HDL: high-density lipoprotein.



To improve health and behavioral changes through personalized advice, we included individuals at risk of MetS (second set of inclusion criteria). Therefore, individuals eligible for study participation were invited for additional screening to verify whether they were at risk of MetS, defined as an excessive waist circumference (≥88 cm for women and ≥102 cm for men) combined with elevated fasted triglycerides levels (≥1.7 mmol/L), reduced HDL level (<1.03 mmol/L for men and <1.29 mmol/L for women), high BP (systolic: ≥130 mm Hg or diastolic: ≥85 mm Hg), or elevated fasting glucose (>5.6 mmol/L).

On the basis of the study by Doets et al [36], we performed a power calculation to estimate an adequate sample size to identify potential health effects. The effect size was based on the mean change in waist circumference (δ=1.85 cm, SD 2.67; significance level of 5%). The calculations revealed that a sample size of 16 would be sufficient to identify potential health effects based only on waist circumference. However, based on the sample sizes of previous pilot studies [36,38] and taking into account various combinations of MetS risk factors and potential dropout, we increased the number of participants to 40.

Study Design

The study followed a one-group pretest-posttest design with a duration of 16 weeks (Table 1). Reviews of behavioral intervention studies have shown that a period of 16 weeks is minimal to allow the first stages of behavior change [39,40]. Our study targeted individuals who were motivated to change their dietary behavior; therefore, a period of 16 weeks was considered sufficient. As the aim of the study was to explore the potential effects of personalized nutrition in real life, no control group was included. The intervention consisted of personalized dietary advice in combination with feedback on dietary behavior and health status (ie, waist circumference, BP, cholesterol, glucose, BMI, C-peptide, and triglycerides) at set time points throughout the study.

Table 1. Overview of study design: measurements, interventions, and planning.

Measurements and characteristics of the intervention	Timepoints (weeks), t
Diet	
Diet quality (Dutch Healthy Diet Index) per food category and total score	0, 8, 16
Carotenoids in blood (biomarker fruit and vegetable intake)	0, 8, 16
Food purchase data at retailer (via customer card)	4, 12
Subjective health	
Self-perceived health questionnaire	0, 16
Consumer experiences	
Evaluation questionnaire	16
Metabolic health	
Waist circumference	0, 8, 16
BMI	0, 8, 16
Blood pressure	0, 8, 16
Lipid profile (total cholesterol, HDL[a], LDL[b], and triglycerides)	0, 8, 16
Fasting glucose	0, 8, 16
C-peptide	0, 8, 16
Personalized advice	
Stage 1: automated advice based on individual diet quality and metabolic health status	0, 8
Stage 2: telephone consultation with dietitian to define behavioral change strategy and discuss personal preferences	0, 8
Feedback	
Diet quality discussed in telephone consultations with dietitian	0, 8
Alternatives for product purchases in email messages from dietitian	4, 12
Metabolic health via web-based platform	0, 8, 16
Integrated personal health score via web-based platform	0, 16

[a] HDL: high-density lipoprotein.

[b] LDL: low-density lipoprotein.

Study Procedures

During the 3 test days (t=0, t=8, and t=16 weeks), participants arrived in the morning in a fasted state to Wageningen University and Research, the Netherlands. Metabolic health parameters were assessed by trained research nurses using do-it-yourself devices, following standard operating procedures. Total cholesterol, HDL, low-density lipoprotein (LDL), and triglycerides were measured in finger-prick blood using the Mission Cholesterol 3-in-1 device (Acon Labs Inc). Glucose levels were assessed using a MediTouch 2 blood glucose meter (Medisana). BP was measured using a Medisana upper arm BP monitor. Both glucose and BP were measured twice for each participant, and the average result was used as input for feedback and personalized advice.

Dietary Quality

Dietary quality was assessed by using a web-based version of the Dutch Healthy Diet Index (DHDI; *Eetscore*, Division of Human Nutrition, Wageningen University) [41]. The DHDI evaluates adherence to the Dutch dietary guidelines per food category (score 1-10) and total score (score 8-80). In this study, we focused on food categories that have been shown to be effective for improving metabolic abnormalities due to reducing calorie intake or through direct effects on metabolic parameters. These food categories are fruit and vegetables [16,17,19], wholegrain products [13,14,16], dairy products [17,18,20], fish [10,16,21], saturated fat (butter, meat, and snacks) [12], and sugar-containing beverages [17]. The DHDI results were used as input for the dietary advice tool.

Metabolic Health Parameters

Waist circumference was determined directly over the skin at the midpoint between the lower part of the last rib and the top of the hip. Body weight was recorded on a calibrated weighing scale to the nearest 0.1 kg. Finger-prick blood was blotted on dried blood spot (DBS) cards (Protein Saver TM 903R Cards, Whatman). To suppress the degradation of carotenoids in the DBS samples, the first two circles in the DBS cards were impregnated with a proprietary stabilizing solution supplied by Vitas AS. After air drying for several hours, the cards were stored in airtight resealable aluminum bags (Whatman) with a desiccant pouch (Reàl Marine A/S Stavanger) to remove any moisture from the DBS cards. C-peptide and carotenoids were assessed via high-performance liquid chromatography with UV detection and liquid chromatography-mass spectrometry (Vitas AS) [42]. In brief, from each DBS, 3·2-mm disks were punched out and mixed with distilled water. Next, proteins were precipitated and carotenoids were extracted with isopropanol containing an internal standard (β-Apo-8 carotenal, Sigma-Aldrich). An aliquot of the isopropanol phase was analyzed using a 1100-series HPLC-UV system with a 1260 diode array detector (453 nm; Agilent Technologies). Separation was performed on a 3-mm YMC C30 column (150 mm×4·6 mm internal diameter, YMC).

Personalized Dietary Advice

At t=0 and t=8 weeks, the participants received personalized dietary advice. Personalized advice was generated in a two-stage process. During stage 1, the content of the advice was defined based on individual dietary habits (ie, DHDI and carotenoid levels as a biomarker of fruit and vegetable intake) and parameters of metabolic health. The results of these measurements were added to an automated personalized dietary advice system. First, the algorithm evaluated per food category (dairy, fats and oils, fish, fruit, nuts, sugar-containing beverages, vegetables, and wholegrain products) whether intake and nutrient status were sufficient based on predefined cut-off levels. If intake or nutrient status was insufficient, the food category was included in the advice. Second, the system evaluated the presence of metabolic abnormalities. If metabolic abnormalities were present, relevant food categories were included in the advice to emphasize the importance of adequate intake for a specific food category.

Stage 2 included a telephone consultation of 45-60 minutes, during which a trained dietitian discussed the system-generated advice with the participant following a standard protocol. During the consultation, a personal dietary behavior change strategy was defined by adapting the advice from stage 1 to individual preferences (eg, number of food groups to work on, selection of alternative products, and adjustment of portion sizes). In Table S1 of Multimedia Appendix 1, the steps followed by the dietitian are displayed. A summary of the dietary behavior change strategy was available to the participants through a web-based personal study portal. The provided dietary advice was in line with the national dietary recommendations provided by the Health Council of the Netherlands and the Netherlands Nutrition Centre [43,44].

Feedback

Feedback on behavioral parameters was provided to participants by a dietitian as part of the individual telephone consultations at t=0 and t=8 weeks and via email at t=4 and t=12 weeks. The feedback by telephone addressed adherence to Dutch dietary guidelines based on the DHDI. The feedback by email addressed healthy alternatives for recent product choices and was based on purchase data registered on a supermarket customer card that participants were asked to share with the research team. Feedback on metabolic health parameters (ie, waist circumference, BMI, BP, glucose, cholesterol, C-peptide, and triglycerides) was directly communicated to the subjects via a web-based personal study portal at t=0, t=8, and t=16 weeks.

Furthermore, at t=0 and t=16 weeks, each participant received an integrated personal health score based on their metabolic health parameters.

Personal Health Score

The personal health score was produced using a so-called *health space* model that was created on basis of the principle of van den Broek et al [45]. This type of model can produce an individual unitless score based on personal data that correspond to the individuals' health status after being trained on the data of two reference groups. The model in this study was trained on two reference groups from an independent data set (National Health and Nutrition Examination Survey 2003-2004 [2003]; [46]), a group of healthy subjects with no diagnostic characteristic for MetS versus subjects diagnosed with MetS (Table 2). The MetS group was selected based on the MetS definition of the International Diabetes Federation [47]. In turn, 135 subjects in the healthy group were selected from all available subjects by constraining BMI between 18 and 25 kg/m^2. Of these 135 subjects, the top 10 were selected based on their aggregated rank.

Table 2. Demographics and metabolic health parameters of study participants and the health space reference groups (N=85).

Variable	Study participants (n=34)	Healthy reference[a] (n=10)	MetS[b] reference[a] (n=41)
Sex, n (%)			
Male	9 (26)	5 (50)	19 (46)
Female	25 (74)	5 (50)	22 (54)
Age (years), mean (SD)	61 (8.2)	57.6 (16.2)	54 (21.0)
BMI (kg/m^2), mean (SD)	29.9 (4.18)	21.3 (1.88)	31.1 (5.68)
Waist circumference (cm), mean (SD)	102 (11.4)	83.2 (4.68)	105 (10.8)
Total cholesterol (mmol/L), mean (SD)	6.23 (0.78)	5.32 (1.10)	4.77 (1.02)
HDL[c] cholesterol (mmol/L), mean (SD)	1.14 (0.27)	1.49 (0.37)	1.01 (0.13)
LDL[d] cholesterol (mmol/L), mean (SD)	4.34 (0.74)	3.12 (1.02)	2.73 (0.99)
Triglycerides (mmol/L), mean (SD)	1.67 (0.85)	1.57 (0.52)	2.25 (0.95)
Glucose (mmol/L), mean (SD)	5.61 (0.65)	5.33 (0.70)	7.07 (3.08)
C-peptide (nmol/L), mean (SD)	0.52 (0.33)	0.75 (0.40)	1.46 (0.90)
Systolic blood pressure (mm Hg), mean (SD)	135 (18.0)	138 (18.5)	128 (21.5)
Diastolic blood pressure (mm Hg), mean (SD)	78.6 (9.54)	77.7 (14.0)	67.4 (18.6)

[a] Data for the reference groups were obtained from the National Health and Nutrition Examination Survey 2003-2004 (CDC 2003) [46].

[b] MetS: metabolic syndrome.

[c] HDL: high-density lipoprotein.

[d] LDL: low-density lipoprotein.

This aggregated rank is based on the features included in the trained model, where the highest rank corresponds to the healthiest values of these features. The aggregated rank of this collection of features was calculated using the *robust rank aggregation* algorithm proposed by Kolde et al [48]. The data used in the training of this model were taken from the National Health and Nutrition Examination Survey 2003-2004 data set (CDC 2003) [46].

A multivariate mixed-effects regression model was subsequently fitted to the data from the two selected reference groups with good classification performance with an accuracy of 99% and a Cohen κ coefficient of 0.94. The model includes triglycerides, LDL cholesterol, HDL cholesterol, glucose, and C-peptide as fixed effects and sex as a random effect. The random effect was included to allow for sex differences in the final model coefficients. Table S2 in Multimedia Appendix 1 shows the standardized contributions of each feature in the final model. Finally, individual health scores were calculated by feeding participants' metabolic health data into the regression model.

Self-Perceived Health and Consumer Experiences

At baseline and at the end of the study, participants reported self-perceived health, self-perceived healthiness of the diet, and satisfaction with the diet using a 7-point Likert scale ranging from 1=very unhealthy to 7=very healthy and 1=very unsatisfied to 7=very satisfied.

At the end of the study, participants filled out an evaluation questionnaire on personal experiences regarding advice, feedback, and the digital platform (statements on 7-point Likert scales, ranging from 1=completely disagree to 7=completely agree).

Statistical Analyses

Data on DHDI scores and metabolic health were analyzed using linear mixed models with *time* (t=0 vs t=8 vs t=16 weeks) as a fixed effect and *subject* as a random effect. Self-perceived health data were evaluated using ordinal mixed regression models with the same model structure. Post hoc analyses were performed on these models to identify significant differences between the individual time points. In the linear mixed model, observations with an absolute residual >3 times the root mean square error of the model were treated as statistical outliers.

In addition, Pearson correlation coefficients were calculated between the Δ of the single dietary behavior variables and the single metabolic health variables and between the Δ of dietary behavior and metabolic health variables. Only significant correlations that could be visually confirmed in the scatterplots were regarded as reliable (Figure S1 in Multimedia Appendix 1).

For the analyses of the individual food categories, only participants that actually incorporated the specific food category in their dietary behavior change strategy were included. *P* values reported from the mixed model post hoc tests were adjusted for multiple comparisons following the Benjamini-Hochberg procedure [49].

Statistical significance was set at *P*<.05 for all analyses. Statistical analyses were performed using R version 3.4.3 (R Core Team).

Results

Baseline Characteristics

A total of 37 individuals were enrolled in this study. During the study period, 3 subjects dropped out: 1 participant no longer met the inclusion criteria, and the other 2 experienced too many difficulties in using the web-based platform. The baseline characteristics of the 34 participants who completed the intervention as well as the reference populations used for modeling the health score are summarized in Table 2. Next to excessive waist circumference, most participants presented multiple risk factors for MetS. High BP, high glucose, high triglycerides, and low HDL were present in 21, 16, 14, and 22 subjects, respectively.

Effect of Personalized Advice on Dietary Quality

Most subjects (33/34, 97%) were provided with advice on multiple food categories in their individual dietary behavior change strategies. One participant chose to focus on only one food category. Advice was provided most frequently on vegetables (31/34, 91%), followed by oils and fat (21/34, 62%), nuts (20/34, 59%), wholegrain products (19/34, 56%), dairy (14/34, 41%), fish (12/34, 35%), fruit (9/34, 27%), and sugar-containing beverages (3/34, 9%). The mean DHDI scores over time per food category are shown in Table 3. An improvement over time was observed for wholegrain products (+1.6; *P*=.009; 19/34, 56%), nuts (+2.2; *P*=.009; 20/34, 59%), and total DHDI (+4.3; *P*<.001; 34/34, 100%). The change in total DHDI was significantly correlated in decreasing order with the change in oils and fats score (ρ=0.62; *P*<.001), nuts score (ρ=0.62; *P*<.001), dairy score (ρ=0.55; *P*<.001), fish score (ρ=0.39; *P*=.03), and fruit score (ρ=0.39; *P*=.02).

Table 3. Dutch Healthy Diet Index per food category (score 1-10) and total score (score 8-80) and total carotenoids (μmol/L) at baseline, 8 weeks, and 16 weeks.

Food category[a]	DHDI[b] score, mean (SD)			*P* value
	t=0 weeks	t=8 weeks	t=16 weeks	
Vegetable intake (n=31)	6.6 (2.9)	7.5 (3.0)	7.1 (3.3)	.53
Fruit intake (n=9)	5.8 (3.3)	8.2 (2.0)	8.4 (2.0)	.70
Intake of oils and fats (n=21)	3.7 (3.9)	3.6 (4.1)	3.5 (3.8)	.85
Fish intake (n=12)	6.6 (3.2)	7.5 (2.6)	8.6 (1.9)	.18
Intake of wholegrain products (n=19)	6.3 (2.5)[c]	7.7 (2.8)[c]	7.9 (2.8)[c]	.009
Dairy intake (n=14)	3.1 (2.6)	3.8 (3.1)	4.1 (2.7)	.84
Nut intake (n=20)	6.2 (3.3)[c]	7.0 (2.6)[c]	8.4 (2.5)[c]	.009
Intake of sugar-containing beverages (n=3)	1.9 (1.8)	5.5 (5.0)	6.6 (2.8)	—[d]
Total DHDI (sum of all food categories; n=34)	52.9 (13.1)[c]	56.5 (11.3)[c]	57.2 (11.5)[c]	<.001
Carotenoid levels in blood (μmol/L; t=0, n=36; t=8, n=34; t=16, n=33)	1.21 (0.43)	1.39 (0.46)	1.42 (0.56)	.66

[a] Only participants who included the specific food category in their individual dietary behavior change strategy are included in the analysis.

[b] DHDI: Dutch Healthy Diet Index.

[c] No significant difference following the post hoc analysis.

[d] Not available (as the sample size was not sufficient to obtain reliable statistical output).

Effect of Personalized Advice on Metabolic Health Parameters and Health Score

After 16 weeks of intervention, triglycerides, HDL cholesterol, LDL cholesterol, BMI, waist circumference, C-peptide, and HOMA-IR were all significantly improved (Table 4). Plasma glucose increased significantly by 0.23 nmol/L (*P*=.04; Table 4). The overall health score significantly improved by 0.27 points on a scale from 1 (MetS reference) to 2 (healthy reference; *P*<.001; Table 4). Improvement in HDL cholesterol had the strongest overall impact on the increase in the health score, indicated by the high correlation between their changes from week 0 to week 16 (ρ=0.97; *P*<.001), whereas glucose, C-peptide, triglycerides, and LDL cholesterol changes were not significantly correlated with the increase in health score.

No significant correlation was found between the changes in the total DHDI and health scores (ρ=0.12; *P*=.52; Figure 2). In particular, 9 subjects who did not improve total DHDI still showed an increased health score after 16 weeks (Figure 2). Significant correlations were found between changes in the total dietary scores and triglycerides (ρ=0.58; *P*<.001).

Table 4. Metabolic health parameters assessed at t=0, 8, and 16 weeks.

Parameter	t=0 weeks, mean (SD)	t=8 weeks, mean (SD)	t=16 weeks, mean (SD)	*P* value
Glucose (mmol/L)	5.61 (0.67)[a]	5.63 (0.64)[a]	5.84 (0.63)[a]	.04
C-peptide (nmol/L)	0.52 (0.32)[a]	0.52 (0.23)[a]	0.43 (0.16)[a]	.01
HOMA-IR[b]	7.45 (5.27)[a]	7.42 (3.95)[a]	6.31 (2.57)[a]	.049
Triglycerides (mmol/L)	1.67 (0.86)[a]	1.43 (0.60)[a]	1.39 (0.55)[a]	.02
Total cholesterol (mmol/L)	6.23 (0.78)	5.91 (0.84)[a]	5.90 (0.86)[a]	0.01
HDL[c] cholesterol (mmol/L)	1.14 (0.28)[a]	1.09 (0.28)[a]	1.44 (0.36)[a]	<.001
LDL[d] cholesterol (mmol/L)	4.34 (0.74)[a]	4.18 (0.79)[a]	3.87 (0.78)[a]	<.001
Systolic blood pressure (mm Hg)	135 (18.2)	133 (13.7)	132 (17.1)	.70
Diastolic blood pressure (mm Hg)	78.6 (9.60)	80.3 (8.93)	79.6 (9.77)	.30
BMI (kg/m^2)	29.9 (3.94)[a]	29.4 (3.60)[a]	29.2 (3.66)[a]	<.001
Waist circumference (cm)	102 (11.5)[a]	100 (9.43)[a]	99.4 (8.86)[a]	.01
Health score (arbitrary units)	1.30 (0.31)	1.23 (0.30)	1.57 (0.32)	<.001

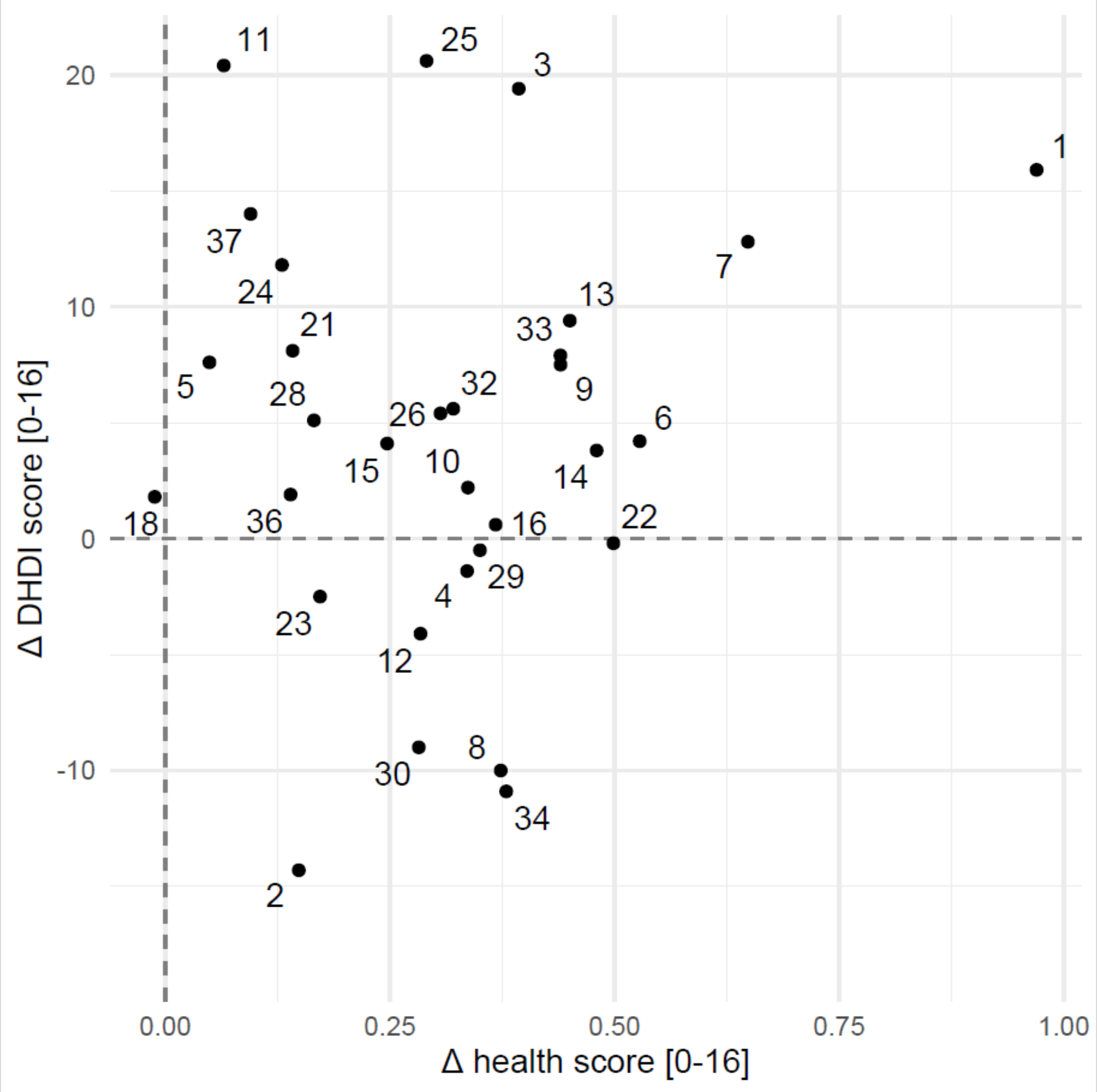
[a] No significant difference following the post hoc analysis.

[b] HOMA-IR: homeostatic model assessment–insulin resistance; calculated based on glucose and C-peptide [50].

[c] HDL: high-density lipoprotein.

[d] LDL: low-density lipoprotein.

Figure 2. Association between the Δ dietary scores and Δ health scores calculated between week 0 and week 16 of the study.



Self-Perceived Health and Consumer Experiences

The mean scores for self-perceived health, self-perceived healthiness of the diet, and satisfaction with the diet, as reported by the participants at baseline and end, are shown in Table 5. All three scores were significantly improved at the end of the study compared with baseline (self-perceived health: +0.67, *P*=.005; self-perceived healthiness of the diet: +1.06, *P*<.001; satisfaction with the diet: +0.94, *P*=.001). In addition, participants reported positive mean scores on how helpful the personalized advice and feedback were to improve their diet. In addition, they were positive about continuing the advice after completion of the study and on advising other people to obtain personalized advice, as in this study. Participants would not be willing to pay for (parts of) this program.

Table 5. Self-perceived health, self-perceived healthiness of the diet, and satisfaction with the diet as reported at t=0 and 16 weeks.

Self-perceived health items	t=0 weeks, mean (SD)	t=16 weeks, mean (SD)	*P* value
Self-perceived health[a]	4.68 (1.07)	5.35 (1.10)	.005
Self-perceived healthiness of diet[a]	4.50 (1.05)	5.56 (0.96)	<.001
Satisfaction with diet[b]	4.35 (1.39)	5.29 (1.14)	.001
Consumer experiences[c]			
The personalized advice helped me to improve my diet	—[d]	5.7 (1.5)	—
The feedback helped me to improve my diet	—	5.4 (1.4)	—
If possible I would continue taking part in this program	—	4.7 (2.0)	—
I would recommend people in my surroundings to obtain personalized advice like in this study	—	5.0 (1.8)	—
I would be willing to pay for this program	—	2.5 (1.7)	—

[a] 7-point Likert scale, ranging from “very unhealthy” to “very healthy.”

[b] 7-point Likert scale, ranging from “very unsatisfied” to “very satisfied.”

[c] 7-point Likert scale, ranging from “completely disagree” to “completely agree.”

[d] Consumer experiences were only assessed at the end of the study (t=16).

Discussion

Principal Findings

With the aim of exploring the combined behavioral and metabolic health effects in relation to personalized nutrition, we have shown that personalized dietary advice delivered through an automated advice system and discussed by a dietitian with the participant has a significant positive effect on dietary behavior, with a concurring beneficial impact on metabolic health in consumers at risk of MetS. Moreover, the perception of health and healthiness of and satisfaction with the diet improved.

Most earlier studies have shown the impact of personalized dietary advice either on dietary intake or on metabolic health parameters. In this study, we build upon the research described by Doets et al [36] by focusing on the combined analysis of dietary intake, metabolic health, and perceived health. In this previous study, we evaluated the potential of digitally delivered personalized lifestyle advice for improving well-being compared with general dietary advice in a population of active seniors. Well-being was operationalized by self-perceived health and well-being as well as biological measures, including markers of metabolic health and physical function tests. Despite some clear limitations with respect to the target population (eg, already having a healthy diet), the short intervention duration (9 weeks), the provided feedback (all participants, including the control group, received individual feedback on their health and well-being), and the intake tools used for monitoring dietary behavior, the results showed that personalized lifestyle advice might have the potential to improve health outcomes as compared with general lifestyle advice.

Compared with Doets et al [36], the study design was improved by prolonging the study duration, including an individual behavior change strategy, selecting an at-risk population, and increasing the frequency of feedback on individual metabolic health.

Interestingly, our results revealed no correlation between the effect on dietary behavior and metabolic health, although both variables showed a significant improvement.

In our study, there was a large variation in the personalized advice between participants, as the advice was tailored to individual metabolic health status as well as dietary quality. Most participants in our study sample incorporated improved intake of vegetables, oils and fats, nuts, and wholegrain products in their behavior change strategy (n≥19). Among these, participants seemed to comply with the advice for wholegrain products and nuts, especially as these two food groups significantly improved over time. In contrast, no changes were observed in vegetables, oils, and fats. These results suggest that it is easier for motivated participants to replace refined products with wholegrain products or to include nuts in their dietary patterns as compared with increasing vegetable intake or changing the type of fat for the preparation of meals or for bread spread. Previous systematic reviews have shown significant pooled effects of dietary advice interventions on increased intake of fruits, vegetables, total fiber, and total fat [51-53]. However, most of these reviewed studies focused on changing a single dietary behavior aspect in line with general recommendations rather than optimizing dietary intake in view of improved individual health. A recent study by Rijnaarts et al [54] showed that providing fiber-rich alternatives via an automated, personalized advice system increased adherence to recommendations as compared with generic advice, confirming the effectiveness of a personalized advice system and replacing refined products with wholegrain products.

Although our results indicated an improvement over time for fruit, fish, dairy, and intake of sugar-containing beverages, these effects turned out to be nonsignificant as only a small number of individuals included these food groups in their behavior change strategy (n≤14).

Several studies have reviewed available behavior change techniques that are effective for dietary behavior change [55-57]. They demonstrated that tailoring, instructions, goal setting, and feedback are effective intervention elements for evoking dietary behavior change. The personalized intervention we used in the study combined several behavior change techniques to facilitate behavior change: feedback on health (what is the actual health situation), feedback on behavior (which dietary changes are relevant for the individual based on parameters of health and diet), advice on how to change behavior (how these changes can be made in terms of product choice), and individual goal setting (what does the individual want to change, ie, behavior change strategy) [57]. Problem solving and social comparison seem to be other relevant behavior strategies to further improve our intervention. These strategies may be especially relevant for improving compliance with advice on fruit and vegetable intake [52,55].

Effectiveness of Intervention on Metabolic Health

We hypothesized that by optimizing the quality of the diet in terms of adherence to Dutch dietary guidelines on specific food groups, we were able to improve the metabolic health of our participants. Our analysis indeed showed significant improvements in metabolic health; however, whether these effects were due to improvements in diet quality could not be substantiated. Previous reviews have shown that the restriction of total energy intake, carbohydrate, or fat is a successful strategy to improve metabolic health status. Furthermore, enriching the diet with monounsaturated fatty acids (nuts and olive oil) or omega-3 fatty acids (fish) has been proven effective, especially in improving lipid profiles [7,58,59].

Although the absolute health score is also determined by subtle changes in triglycerides, glucose, C-peptide, and LDL cholesterol, it seems that the relatively strong Δ HDL cholesterol is the main driver for the change in the health score. It is known from the literature that HDL levels are affected by the increased consumption of fish and unsaturated fatty acids and decreased consumption of saturated fatty acids [60,61]. Interestingly, in our data, the increase in HDL cholesterol could not be significantly related to any specific dietary improvement. Apart from the fact that the statistical power may not have allowed it, this observation may be related to a confounding effect of activity. Results from a meta-analysis showed a highly significant relationship between physical activity and HDL cholesterol levels [62].

Effectiveness of Intervention on Self-Perceived Health

Self-perceived health summarizes the objective and subjective aspects of health within the perceptual framework of an individual. Some studies suggest that although the criteria for judging health status may vary between individuals, it is a valid indicator of overall health status and use of health services [63,64]. However, the cross-sectional association between actual metabolic health and perceived health remains unclear [65]. Previous intervention studies have shown a clear link between improved health behaviors and better self-perceived health scores, supporting our findings [64,66,67]. From the perspective of maintaining behavior change, improvement in self-perceived health in the short term is highly relevant as it helps individuals to stay motivated, allowing the behavior change to persist over a longer period.

Lessons Learned

Participants may have become more aware of their dietary behavior throughout the study, which may have influenced their answers to the DHDI questionnaire, causing a learning bias [68]. Together with the fact that no control period was included, this may have influenced the dietary scores over time. In future studies, it is recommended to include a learning period before the start of the study to minimize the effect of learning.

No control group was included, which is a general challenge in studies investigating the efficacy of personalized nutrition. Therefore, it is not possible to separate the effect of diet from the potential effect of general health improvement as a behavioral consequence of taking part in the study. A semiplacebo control may be reached by comparing personalized advice with generic advice [54,69] or by allowing participants to be their own control by starting with a free-living run-in period without intervention. Furthermore, N-of-1 (or single-subject) study designs focusing on one individual could be a good fit to study research questions related to personalized dietary advice in the future. In N-of-1 designs, the optimal intervention for a specific individual is studied rather than an average individual from a target population.

Although we could confirm the assumption that personalized dietary advice is effective in improving both overall dietary behavior (total DHDI score) and overall metabolic health (health score), interestingly, there was no significant correlation. It should be noted that the pilot study only included 34 individuals, all of whom received personalized dietary advice. In addition, there are some limitations to the DHDI score, in which each food category is weighted equally in the total score. An adjusted total score in which the food categories relevant for MetS would outweigh the other food groups could possibly reveal a significant effect.

In addition to the positive effects of improved dietary quality, previous research has also demonstrated the beneficial effects of moderate- to high-intensity physical activity training on lipid profile, BP, and C-reactive protein [70,71]. In our study, we did not provide any advice on increasing physical activity; however, the study participants were invited to use a health watch, providing general feedback on daily activity levels. Owing to unforeseen practical reasons, these health watches were only available during the second half of the study period. Therefore, we were not able to evaluate possible changes in activity levels during the study. For future studies, it is highly recommended to include physical activity monitoring using either a device or a validated questionnaire.

Contrary to our expectations, these data illustrate that positive effects at the population level are not necessarily indicative of associations between diet and health. We can thus conclude that personalized dietary advice works for dietary behavior and health, but the data did not allow us to conclude that metabolic health was improved as a consequence of dietary improvement. A larger sample size with a more equal distribution of men and women and the addition of a control group to the study design are warranted to further investigate and understand the association between diet and health at the individual level. Furthermore, a follow-up after a longer period (eg, 6 months or 1 year) would allow to determine whether initiated behavior changes are maintained over time.

Conclusions

In this exploratory pilot study in individuals at risk for MetS and motivated to change behavior, personalized dietary advice was indicative of positive effects on self-perceived health, dietary behavior, and metabolic health. The lack of association between diet and health improvement is reflective of the individual nature of diet-health relations and underlines the need for an integrated analysis focusing on individual improvements. The study was performed in a do-it-yourself setting, highlighting the potential of evidence-based at-home improvement of health through dietary changes. Follow-up studies are needed to confirm these effects and evaluate the maintenance of dietary behavioral changes.

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Authors' Contributions

ELD, FPMH, MT, and AB designed the study; MT, AB, and TVDB designed the automated advice system; SVDH coordinated the study execution; TVDB, WJVDB, and SVDH analyzed the data; SVDH, FPMH, ELD, and WJVDB prepared the manuscript; MT, AB, and TVDB reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

An overview of the telephone consultation in stage 2 of the personalized advice with the trained dietitian (example of one food group for one participant) and standardized coefficients of the features in the health space model.

[DOCX File , 16 KB - formative_v5i6e25043_app1.docx]

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Abbreviations

BP: blood pressure
DBS: dried blood spot

DHDI: Dutch Healthy Diet Index
HDL: high-density lipoprotein
LDL: low-density lipoprotein
MetS: metabolic syndrome

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Original Paper

Tracking Stress, Mental Health, and Resilience Factors in Medical Students Before, During, and After a Stress-Inducing Exam Period: Protocol and Proof-of-Principle Analyses for the RESIST Cohort Study

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Abstract

Background: Knowledge of mental distress and resilience factors over the time span from before to after a stressor is important to be able to leverage the most promising resilience factors and promote mental health at the right time. To shed light on this topic, we designed the RESIST (Resilience Study) study, in which we assessed medical students before, during, and after their yearly exam period. Exam time is generally a period of notable stress among medical students, and it has been suggested that exam time triggers mental distress.

Objective: In this paper, we aim to describe the study protocol and to examine whether the exam period indeed induces higher perceived stress and mental distress. We also aim to explore whether perceived stress and mental distress coevolve in response to exams.

Methods: RESIST is a cohort study in which exam stress functions as a within-subject natural stress manipulation. In this paper, we outline the sample (N=451), procedure, assessed measures (including demographics, perceived stress, mental distress, 13 resilience factors, and adversity), and ethical considerations. Moreover, we conducted a series of latent growth models and bivariate latent change score models to analyze perceived stress and mental distress changes over the 3 time points.

Results: We found that perceived stress and mental distress increased from the time before the exams to the exam period and decreased after the exams to a lower level than before the exams. Our findings further suggest that higher mental distress before exams increased the risk of developing more perceived stress during exams. Higher perceived stress during exams, in turn, increased the risk of experiencing a less successful (or quick) recovery of mental distress after exams.

Conclusions: As expected, the exam period caused a temporary increase in perceived stress and mental distress. Therefore, the RESIST study lends itself well to exploring resilience factors in response to naturally occurring exam stress. Such knowledge will eventually help researchers to find out which resilience factors lend themselves best as prevention targets and which lend themselves best as treatment targets for the mitigation of mental health problems that are triggered or accelerated by natural exam stress. The findings from the RESIST study may therefore inform student support services, mental health services, and resilience theory.

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KEYWORDS

exam stress; perceived stress; mental distress; student mental health; mental health resilience; protective factors; resilience factors

Introduction

Background

Approximately 1 in 5 young people experience mental distress in the form of anxiety and depression [1,2]. According to the World Health Organization (ie, the Regional Office for Europe), the "early identification of such problems—and, when necessary, early intervention or timely management—is critically important...In the absence of appropriate support and intervention, such problems may continue, worsen or lead to mental illness" [2]. Resilience factors (RFs), such as self-esteem and friendship support, mitigate mental distress in the face of stressful experiences [3]. The literature contains a considerable amount of knowledge on RFs that mitigate concurrent and subsequent mental distress [4-8]. Yet, studies investigating RFs over the time span from before to after a stressor (ie, stress that causes or triggers mental distress) are scarce [9]. However, knowledge of mental distress and RFs *before* and *during* the stressor is crucial, as this (1) is necessary to determine whether mental distress and RFs are affected by the stressor [9,10], and (2) enables the identification of those RFs that are potentially promising prevention targets. Knowledge on mental distress and RFs *during* and *after* the stressor is equally essential, as this (1) enables us to identify whether mental distress and RFs recover after the stressor [11], and (2) indicates which RFs may be promising treatment targets at times of stress. To this end, we designed the RESIST (Resilience Study) study, in which we assessed perceived stress, mental distress, and RFs in Cambridge University medical students before, during, and after their yearly exam period.

A recent meta-analysis based on 122,356 medical students from 43 countries showed that the prevalence rate for depressive symptoms was 27.2% (range of individual studies: 1.4%-73.5%) [12]. This prevalence rate was higher than that for population-representative peers of a similar age [12], suggesting that medical students are a high-risk population. In addition to depression, anxiety and general distress levels were also found to be elevated in students pursuing medical degrees, when compared with population-representative samples [13]. Exam stress has been identified as a potential trigger for mental ill-health in medical students [13-15]. Hence, research suggests that medical students are prone to the development of mental health problems, particularly during times of high and unavoidable exam stress.

The RESIST study is designed to capture (1) a period of moderate stress during the university term several months before exams, (2) a period of high stress during exam time, and (3) a period of what we expected to be low or moderate stress after exams (ie, during the summer vacation for many students). In addition to perceived stress and mental distress, we assessed 8 putative *individual-level* RFs (eg, self-esteem), 5 putative *family-level* RFs (eg, parental involvement), and 1 putative *community-level* RF (eg, friendship support; a complete list of assessed RFs is provided in the *Methods* section). Importantly, all of these RFs are derived from our preregistered systematic review and are thus empirically supported [3]. In our review, RFs were defined as those factors that moderate and/or mediate, and thereby mitigate, the detrimental relationship between adversity and subsequent mental distress [3]. Moreover, all assessed RFs are expected to be amenable to intervention, as only those can be successfully targeted by mental health services [3].

Objectives

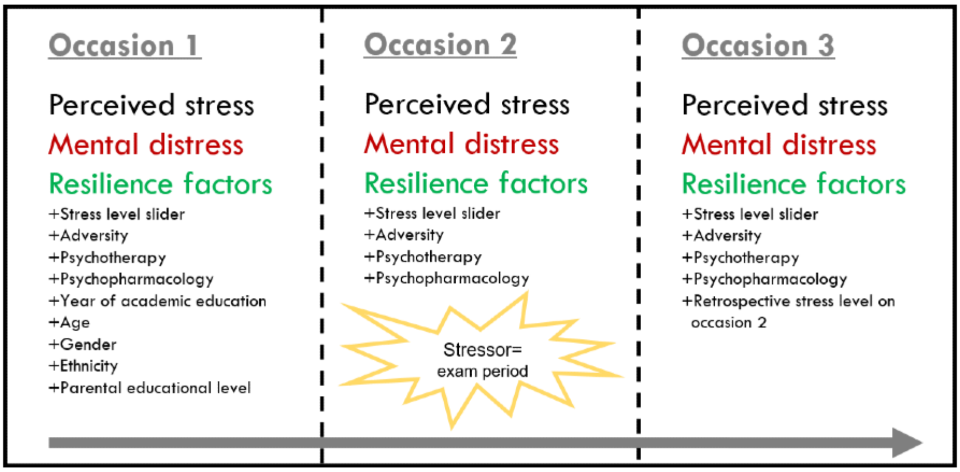
With the RESIST study, we intend to shed light on which RFs lend themselves best as prevention targets (before the stressor) and which lend themselves best as treatment targets (at times of stress) for the mitigation of mental health problems that are triggered or accelerated by a natural stressor. Therefore, the RESIST study may lay the foundations necessary to inform student support services, mental health services, as well as resilience and transdiagnostic mental health theory. Given that our design relies strongly on the assumption that stress and mental distress levels increase during the exam period, we here conduct proof-of-principle analyses to investigate whether this is indeed the case.

Methods

Design

RESIST is a cohort study with 3 occasions and a within-subject (natural) stress manipulation (ie, the exam period). Occasion 1 took place in a nonexam period during the university term (February and March 2018). Occasion 2 took place during the end-of-year exam period (approximately April to June 2018, depending on the timing of the exam period). Occasion 3 took place after the exam period, at the end of the term for year 6 students (for whom exams are earlier; approximately end of May to mid-July 2018), and in the summer vacation or autumn for year 1-5 students (approximately mid-August to mid-October 2018; Figure 1). At all 3 occasions, students were asked to complete a survey containing a series of web-based questionnaires. At occasion 2, students were provided with the questionnaires 3 weeks before their first final exam. The questionnaires had to be completed before attempting the last final exam. In this way, all participants were exposed to the same type of naturally occurring external stressor. We assessed perceived stress, mental distress, RFs, therapeutic treatment, and psychopharmacology usage on all 3 occasions. Past adversity, year of academic education, age, gender, ethnicity, and parental educational level were assessed at occasion 1, and adversity occurring in between the occasions was assessed at occasions 2 and 3 (Figure 1).

Figure 1. Study design. The Figure depicts the measures that have been assessed on the 3 occasions.



Sample

We recruited first- to sixth-year Cambridge medical students (from a cohort of approximately 1464 students). The inclusion criterion was that students had to be aged at least 18 years. Participants received monetary reimbursement for partaking (web-based vouchers: £5 [US $6.75] for occasion 1, £7 [US $9.50] for occasion 2, and £5 [US $6.75] for occasion 3). Participants who completed all 3 occasions were additionally enrolled in a prize draw (prize: five £50 [US $67.50] web-based vouchers). The maximum possible sample size we could have included was 800 participants, as we had a limited amount of money that we could spend on participant reimbursement. As a minimum sample size, we aimed for 225 participants. This is because we calculated that for a Gaussian regression-based model (minimum sample size = $[((p \times (p - 1))/2) \times 5]$ [16-18]) with 9 RFs and mental distress (resulting in $p=10$ variables) we would need at least 225 participants ($[((10 \times (10 - 1))/2) \times 5] = 225$), given no longitudinal missingness (which was highly unlikely). Eventually, 451 participants took part on occasion 1 but some dropped out on the other 2 occasions (occasion 2: n=275; occasion 3: n=283; Table 1).

Table 1. Sample size overview (N=451).

Sample	Occasion		
	Occasion 1, n (%)	Occasion 2[a], n (%)	Occasion 3[a], n (%)
Taken part on, at least, 1 occasion	451 (100)	275 (61.0)	283 (62.8)
Taken part on, at least, 2 occasions	324 (71.8)	275 (61.0)	283 (62.8)
Taken part on occasion 2 but not 3	41 (9.1)	41 (9.1)	N/A[b]
Taken part on occasion 3 but not 2	49 (10.9)	N/A	49 (10.9)
Taken part on all occasions	234 (51.9)	234 (51.9)	234 (51.9)

[a] On occasions 2 and 3, only participants who had already taken part on occasion 1 were invited.

[b] N/A: not applicable.

Procedure

The students received a web-based link to the questionnaire (survey software: REDCap [Research Electronic Data Capture]) via email. To prevent double partaking, we sent personalized emails with unique links to the students. We also advertised the study during lectures. Students who had not already participated received reminder emails until the end of the study occasion. For the first occasion, the link expired after 8 weeks. We sent the link for the second occasion approximately 3 weeks before the students' first final exam and asked the students to confirm that they will submit the survey before their last final exam of the academic year. For year 6 students, the study link for the third occasion was sent out approximately a month before the end of the summer term. For year 1-5 students, the study link for the third occasion was sent 6 weeks before the start of the new academic year (the link for the third occasion expired after 8 weeks for all students).

Measures

Before we finalized the web-based survey, we performed a user review with volunteering medical students. On the basis of this pilot study, we evaluated whether the survey was easily understandable and acceptable. We adapted small features, mainly regarding the survey layout (importantly, these data were not part of the study). On occasion 1, a total of 139 items were assessed.

Demographic and Clinical Characteristics

We assessed 8 demographic and clinical variables: academic course, year of academic education, gender, age, ethnicity, parental educational level, psychotherapeutic treatment, and psychopharmacology intake (ie, prescribed drugs).

Perceived Stress

We assessed the stress level during the last month using a 4-item short form of the validated Perceived Stress Scale (PSS) [19]. The self-report items assess topics such as confidence in handling problems and overcoming difficulties [19]. The short form of the PSS has been reported to have a Cronbach α of .72 [19]. In our sample, the PSS had an acceptable reliability (Cronbach α=.75; coefficient Ω=0.75). Moreover, we assessed the global stress severity during the last month on a zero-to-hundred slider.

Mental Distress

We assessed general mental health using the 12-item version of the General Health Questionnaire (GHQ-12) [20]. The GHQ-12 provides a broad indication of mental health and well-being across the spectrum from good-to-poor mental health but does not act as a measure of diagnosis for mental illness. The self-report items assess topics such as concentration, sleep, or happiness (measured on a 4-point scale). In a previous study, the GHQ was found to have a Cronbach α of between .78 and .95 [21]. The GHQ-12 previously had a mean area under the Receiver Operating Characteristic curves of 0.88 [22]. In our sample, the GHQ-12, in the remainder referred to as mental distress, had a good reliability (Cronbach α=.88; coefficient Ω=0.89).

RFs: Individual Level

We assessed 7 *individual-level* RFs that were empirically supported in our systematic review [3]: high distress tolerance, low ruminative reflection, low ruminative brooding, high self-esteem, high cognitive reappraisal, low expressive suppression, and low aggression potential. The content and psychometric details are shown in Table 2. In Table 2, we report Cronbach α values for previous studies, given that this was the reported internal consistency metric. However, for RESIST we report both Cronbach α and coefficient Ω [23], for completeness.

Table 2. Details of the resilience factor measures.

RFs[a]	Content and psychometric information
Individual-level RFs	
High distress tolerance	• 6-item subscale of the DTS[b] (15 items in total) [24] • Self-report items assessing distress tolerance levels such acceptability of being upset • Previous research found a good reliability (DTS Cronbach α=.82 to .85; 6-item tolerance subscale Cronbach α=.82 to .84) [24] • In RESIST[c], the distress tolerance subscale had a good reliability (Cronbach α: o1[d]=.82, o2[e]=.84, o3[f]=.83; coefficient Ω: o1=0.82, o2=0.85, o3=0.83)
Low ruminative reflection	• 5-item reflective rumination subscale of the RRS[g] (22 items in total) [25] • Self-report items assessing ruminative reflection levels such as trying to understand why you have a negative mood or why you feel in a given way • Previous research found an acceptable reliability (RRS Cronbach α=.90; 5-item reflective rumination subscale Cronbach α=.72) [25] • In RESIST, the reflective rumination subscale had an acceptable reliability (Cronbach α: o1=.75, o2=.76, o3=.79; coefficient Ω: o1=0.76, o2=0.76, o3=0.80)
Low ruminative brooding	• 5 item brooding subscale of the RRS (22 items in total) [25] • Self-report items assessing brooding levels such as why things do not work out better or why other people do not have comparable problems • Previous research found an acceptable reliability (RRS Cronbach α=.90; 5-item brooding subscale Cronbach α=.77) [25] • In RESIST, the brooding subscale had an acceptable reliability (Cronbach α: o1=.75, o2=.79, o3=.77; coefficient Ω: o1=0.76, o2=0.80, o3=0.78)
High self-esteem	• 10 items of the RSES[h] [26] • Self-report items assessing positive self-esteem levels such as being capable of doing things well and negative self-esteem levels such as feeling useless • Previous research found a good reliability (RSES Cronbach α=.88) [26,27] • In RESIST, the RSES had an excellent reliability (Cronbach α: o1=.93, o2=.94, o3=.92; coefficient Ω: o1=0.93, o2=0.94, o3=0.92)
High cognitive reappraisal	• 6-item cognitive reappraisal subscale of the ERQ[i] (10 items in total) [28,29] • Self-report items assessing cognitive reappraisal levels such as changing the content of thoughts to achieve a less negative or more positive mood • Previous research found an acceptable reliability (6-item cognitive reappraisal subscale Cronbach α=.79) [28,29] • In RESIST, the cognitive reappraisal subscale had a good reliability (Cronbach α: o1=.83, o2=.87, o3=.88; coefficient Ω: o1=0.83, o2=0.87, o3=0.88)
Low expressive suppression	• 4-item expressive suppression subscale of the ERQ (10 items in total) [28,29] • Self-report items assessing expressive suppression levels, that is, the extent to which individuals suppress positive and negative emotions • Previous research found an acceptable reliability (4-item expressive suppression subscale Cronbach α=.73) [28,29] • In RESIST, the expressive suppression subscale had an acceptable reliability (Cronbach α: o1=.75, o2=.73, o3=.76; coefficient Ω: o1=0.78, o2=0.76, o3=0.78)
Low aggression potential	• 12-item BAQ[j] [30] • Self-report about aggression levels including physical aggression, verbal aggression, anger, and hostility • Previous research found an acceptable-to-good reliability (BAQ Cronbach α=.76-.83) [30] • In RESIST, the BAQ had an acceptable reliability (Cronbach α: o1=.78, o2=.80, o3=.79; coefficient Ω: o1=0.79, o2=0.81, o3=0.78)
Family-level RFs	
High immediate family support	• 6-item abbreviated version of the PSS-Fa[k] (20 items in total) [31,32] • Self-report about family support, such as getting emotional support and having someone who can help out solving problems • Previous research found a low reliability (PSS-Fa Cronbach α=.90; 6-item abbreviated PSS-Fa Cronbach α=.69) [31,32] • In RESIST, the abbreviated PSS-Fa had a good reliability (Cronbach α: o1=.88, o2=.83, o3=.85; coefficient Ω: o1=0.88, o2=0.83, o3=0.85)

RFs[a]	Content and psychometric information
High extended family support	• 13-item KSS[l] [33,34] • Self-report about extended family and kinship support, such as asking relatives for advice when making decisions or confiding in relatives when having a problem • Previous research found an acceptable-to-good reliability (KSS Cronbach α=.72-.89) [33,34] • In RESIST, the KSS had an excellent reliability (Cronbach α: o1=.92, o2=.91, o3=.93; coefficient Ω: o1=0.92, o2=0.91, o3=0.93)
High family cohesion	• 5-item family cohesion subscale of the SFI-II[m] (36 items in total) [35,36] • Self-report about family cohesion, such as preferably spending time with the family rather than with others • Previous research found a low reliability (SFI-II Cronbach α=.91; 5-item family cohesion subscale Cronbach α=.60) [36] • In RESIST, the family cohesion subscale had a good reliability (Cronbach α: o1=.86, o2=.84, o3=.87; coefficient Ω: o1=0.87, o2=0.85, o3=0.88)
High positive parenting	• 6-item positive parenting subscale of the APQ[n] (42 items in total) [37,38] • Child (ie, in our study, young adult) report about positive parenting, such as positive encouragement, compliments, and praise from parents for doing a good job (ie, for the time when the participants lived with their parents) [39] • Previous research found an acceptable reliability (6-item positive parenting subscale Cronbach α=.72-.75) [37,38] • In RESIST, the positive parenting subscale had a good reliability (Cronbach α: o1=.87, o2=.88, o3=.88; coefficient Ω: o1=0.87, o2=0.88, o3=0.88)
High parental involvement	• 10-item parental involvement subscale of the APQ (42 items in total) [37,38] • Child (ie, in our study, young adult) report about parental involvement levels, such as doing activities together and asking about the child's friends and school performances (ie, for the time when the participants lived with their parents) [39] • We collapsed separate statements for "moms" and "dads" into a single "parent" statement (eg, original: "Your mom talks to you about your friends. How about your dad?," adaptation: "Your parents talk to you about your friends." as done in previous studies, such as in van Harmelen et al [39]) • Previous research found an acceptable-to-good reliability (10-item parental involvement subscale Cronbach α=.71-.83) [37,38] • In RESIST, the parental involvement subscale had a good reliability (Cronbach α: o1=.87, o2=.89, o3=.87; coefficient Ω: o1=0.87, o2=0.90, o3=0.87)
Community-level RF	
High friendship support	• 6-item abbreviated version of the PSS-Fr[o] (20 items in total) [31,32] • Self-report about friendship support, such as getting moral support and having companionship • Previous research found an acceptable reliability (PSS-Fr Cronbach α=.88; 6-item abbreviated PSS-Fr Cronbach α=.75) [31,32] • In RESIST, the abbreviated PSS-Fr had a good reliability (Cronbach α: o1=.80, o2=.81, o3=.79; coefficient Ω: o1=0.80, o2=0.81, o3=0.79)

[a] RF: resilience factor.

[b] DTS: Distress Tolerance Scale.

[c] RESIST: Resilience Study.

[d] o1: occasion 1.

[e] o2: occasion 2.

[f] o3: occasion 3.

[g] RRS: Ruminative Response Scale.

[h] RSES: Rosenberg Self-Esteem Scale.

[i] ERQ: Emotion Regulation Questionnaire.

[j] BAQ: Brief Aggression Questionnaire.

[k] PSS-Fa: Perceived Social Support from Family Scale.

[l] KSS: Kinship Social Support Measure.

[m] SFI-II: Self-Report Family Inventory Version II.

[n] APQ: Alabama Parenting Questionnaire.

[o] PSS-Fr: Perceived Social Support from Friends Scale.

RFs: Family Level

We assessed 5 *family-level* RFs that were empirically supported in our systematic review [3]: high immediate family support, high extended family support, high family cohesion, high positive parenting, and high parental involvement. The content and psychometric details are shown in Table 2. As items of the family-related scales may be hard to answer for participants if they have spent a large amount of their childhood in care homes or frequently changed foster families, we added some specific instructions to those survey parts (Supplement I in Multimedia Appendix 1).

RFs: Community Level

We assessed 1 *community*-level resilience factor, which was empirically supported in our systematic review [3]: high social support, here specifically friendship support. The content and psychometric details are shown in Table 2.

Adversity

Environmental childhood and youth adversity was assessed using an updated version of the 12-item Youth Trauma Scale (YTS) [40]. The 12 self-report items assess topics such as sexual abuse or severe mental or physical illnesses within the family. A complete list of items and assessment details can be found in Supplement II in Multimedia Appendix 1. The original scale was found to have a low internal consistency (Cronbach α=.63-.67). We adapted the questionnaire [40] so that the words *parent and sibling* were supplemented with *significant other*, as our participants were at an age at which some might have invested in significant interpersonal relationships outside the family, such as long-term romantic partners. Besides the presence versus absence of adversity, the questionnaire also assessed the severity of questions for which the presence of the respective adversity was positively confirmed. Moreover, for positively confirmed questions, we further assessed the frequency or duration of the adversity as well as during which age bins the adversity had taken place. We did not assess the frequency or duration for two of the adversity items: (1) “Were you separated from one of your parents for more than 1 year?” and (2) “Was either of your parents unemployed for more than 1 year when they wanted to be working?” as those have an inherent time requirement of at least one year. To also assess the potential criminality of parents, siblings, or significant others, we added such an item to the original scale (“Did parents, siblings, or significant others engage in criminal activities severe enough to cause significant stress or worry?”). In summary, we assessed the presence versus absence of the 13 adversities, and if present, the severity, frequency, and the age bin in which the respective adversity experience occurred. Owing to the adaptations we made, we will thoroughly evaluate the psychometrics of the amended scale in a separate manuscript [40].

Furthermore, we assessed the psychological maltreatment and neglect subscales of the Comprehensive Child Maltreatment Scale (CCMS) [41]. The psychological maltreatment subscale consists of 3 items that assess topics such as how frequently the individual was yelled at, ridiculed, or provoked [41]. The neglect subscale consists of 3 items that assess topics such as whether the individual was provided with sufficient warmth from family members, sufficient nutrition, and protection [41]. In a previous study, the CCMS psychological maltreatment subscale was found to have a Cronbach α of .78, and the CCMS neglect subscale had a Cronbach α of .84 [41]. The only adaptation we made to this scale was that we did not assess the questions up to the age of 13 years [41] but up to the age of 18 years. In our sample, the CCMS psychological maltreatment (Cronbach α=.81; coefficient Ω=0.81) and the CCMS neglect subscale both had a good reliability (Cronbach α=.84; coefficient Ω=0.81).

Measures for Occasion 2

We assessed psychotherapeutic treatment and the use of psychopharmacological drugs for the period between occasions 1 and 2.

We assessed perceived stress (Cronbach α=.74; coefficient Ω=0.75) and global stress severity in the same way as described for occasion 1, while this time specifically focusing on the exam period. Moreover, we quantified the number of exams (completed and not yet completed). The mental distress (Cronbach α=.89; coefficient Ω=0.89) and RF levels (for reliability coefficients, see Table 2) were assessed in the same way as on occasion 1.

Adversity was again assessed with the updated version of the YTS [40]; however, this time we only asked for experiences during the period between occasions 1 and 2 (“This section will ask you about your experiences of potentially traumatic events. Please indicate whether you have experienced those since the last time you filled in this questionnaire.”). Importantly, all the YTS adaptations explained above were applied again. We did not reassess the CCMS subscales [41], as we used the psychological maltreatment and neglect subscales to measure maltreatment during childhood and the teenage years, while living at home. Therefore, the subscales were not suitable for the time between occasions 1 and 2.

A total of 127 items were assessed.

Measures for Occasion 3

We assessed psychotherapeutic treatment and the use of psychopharmacological drugs for the period between occasions 2 and 3.

We assessed perceived stress (Cronbach α=.74; coefficient Ω=0.75) and global stress severity in the same way as described for occasion 1. Moreover, we asked the students whether they had stressful or significant work during the last 4 weeks. Mental distress (Cronbach α=.90; coefficient Ω=0.91) and RF levels (for reliability coefficients, see Table 2) were assessed in the same way as on occasions 1 and 2.

Adversity was again assessed with the updated version of the YTS [40], which this time asked for experiences during the period between occasions 2 and 3. All YTS adaptations explained for occasions 1 and 2 were applied again. We did not reassess the CCMS subscales [41] for the same reason as on occasion 2.

As occasion 2 took place during an exam period, we assumed that it could potentially be the case that missingness may not be completely random but dependent on the students' stress level during occasion 2. Therefore, we asked all participants how stressful the exam period had been.

A total of 129 items were assessed.

Ethical Considerations

Informed Consent and Safety Considerations

Before starting the content part of the web-based survey, participants were asked to read the information sheet, which contained the major study aims, and to complete a consent form. Before completion of the survey, participants were enabled to download their consent form and the information sheet. Moreover, we provided details on how to get help and support, in case the study would bring up difficult feelings or in case a participant would want to report childhood maltreatment or a crime, in a mental health services information sheet, which could be downloaded from the web-based survey. Further details regarding participant safety considerations are provided in Supplement III in Multimedia Appendix 1.

Ethics Approval and Funding Information

RESIST was approved by the Cambridge Psychology Research Ethics Committee (PRE.2017.096). RESIST was funded by JF's Medical Research Council Doctoral Training Grant and by POW's personal research account.

Analytic Methods for the Proof-of-Principle Analyses

Handling Missing Data

To include both participants with incomplete and complete data, we used a full information maximum likelihood (FIML) estimator. The use of this estimator has been shown to function well in longitudinal structural equation models. For example, Kievit et al [42] report that "FIML usually performs as well or better than alternative methods." We decided to treat missing data, instead of performing a complete case analysis, to increase statistical power, reduce standard errors, decrease the probability of biased parameter estimates, and improve generalizability. We tested several potential variables as predictors for missing data patterns, including (1) perceived stress, global stress severity (ie, stress slider), mental distress, psychotherapeutic treatment, and psychopharmacological treatment on all 3 occasions; (2) gender, ethnicity, academic year, age, and childhood adversity on occasion 1; and (3) retrospective subjective stress levels for occasion 2 assessed on occasion 3. This was primarily done to enhance the understanding of missingness in the RESIST sample, and because variables that qualify as predictors for missing data patterns can, in conjunction with an FIML estimator, be used as auxiliary variables and thereby potentially enhance the estimation precision.

Latent Growth Models

We conducted a series of latent growth models (LGMs) to explore the mean change trajectory of perceived stress and mental distress over the 3 occasions. We fixed the slope loading of occasion 2 to 1, expecting this occasion to have the highest level of perceived stress (and mental distress), and the slope loading of occasion 3 to 0, expecting this occasion to have a lower level of perceived stress (and mental distress) than occasion 2. Hence, the slope loading of occasion 1 was freely estimated and provides an indication of where the (scaled) mean level lies in comparison to occasion 2 (fixed to 1) and occasion 3 (fixed to 0). We conducted the LGMs with invariant residual variances for the 3 occasions (M1). To test whether our latent growth model is significantly different from a *no-change* trajectory (ie, no change in overall mean levels), we estimated an additional LGM (M2) with the latent slope mean set to 0, modeling no overall change. In sum, we mainly used the models to identify the change trajectories of perceived stress and mental distress and to test whether these trajectories fit better than a *no-change* trajectory. For completeness, we refitted the LGMs with freely estimated residual variances (Supplement IV in Multimedia Appendix 1).

Bivariate Latent Change Score Models

We conducted a series of bivariate latent change score models (BLCSMs; as described by Kievit et al [42]) to investigate the change of perceived stress and mental distress in conjunction. More specifically, we conducted 3 BLCSMs, 1 for each pairwise combination of the 3 occasions, to allow for direct comparisons without estimating overly complex models. To enable the computation of the models, we used the standard BLCSM estimation (additional details are provided by Kievit et al [42]). We then investigated the relationship between perceived stress and mental distress on the earlier occasion as well as the relationship between the change scores of perceived stress and mental distress on the later occasion. Moreover, we investigated the autoregressive paths of perceived stress and mental distress with their respective change scores as well as the potentially mutualistic relationship between perceived stress and mental distress, that is, perceived stress predicting change in mental distress and mental distress predicting change in perceived stress.

Data and Analysis-Code Availability

All analyses were conducted in R version 3.5.1 (The R Foundation) [43], mainly using the packages lavaan [44] and semTools [45]. The analysis script can be found on the Open Science Framework [46] and the anonymized data used for the analyses in this manuscript have been uploaded to the Cambridge Data Repository [47].

Results

Demographic and Clinical Characteristics

Sample

Students were approximately uniformly distributed over all 6 academic years, with percentages ranging from 12.4% (56/451) to 20.6% (93/451) per year. A total of 57.4% (259/451) of the students were female (1.3% [6/451] preferred not to answer) and 58.3% (263/451) were White. Most students were between 18 and 23 years of age and had parents with higher education after secondary school. About 13.5% (61/451) of the students received psychotherapeutic treatment and 10.9% (49/451) received psychopharmaceutic treatment in the 6 months before occasion 1. Table 3 contains the descriptive statistics for all students who took part on occasion 1. Supplement V in Multimedia Appendix 1 contains the same table, with the inclusion of all students who provided data for at least two occasions (n=324).

Table 3. Demographic and clinical characteristics for the overall sample (N=451).

Characteristics	Sample size per answer category, n (%)
Academic year	
First year	93 (20.6)
Second year	83 (18.4)
Third year	66 (14.6)
Fourth year	88 (19.5)
Fifth year	56 (12.4)
Sixth year	65 (14.4)
Gender[a]	
Female	259 (57.4)
Male	185 (41.0)
Prefer not to say	6 (1.3)
Age[b] **(years)**	
18-20	170 (37.7)
21-23	196 (43.5)
24-26	65 (14.4)
≥27	17 (3.8)
Ethnicity[c]	
White	263 (58.3)
Non-White	184 (40.8)
Therapeutic treatment (in the 6 months before occasion 1)	
No	390 (86.5)
Yes	61 (13.5)
Psychopharmaceutic treatment (in the 6 months before occasion 1)	
No	402 (89.1)
Yes	49 (10.9)
Education (further or higher education after secondary school)	
Mother	
Yes	359 (79.6)
No	88 (19.5)
Unknown	4 (0.9)
Father[a]	
Yes	369 (81.8)
No	77 (17.1)
Unknown	4 (0.9)

[a] One student did not answer this question. Due to missingness, some percentages may not add up.

[b] Three students did not answer this question. Due to missingness, some percentages may not add up.

[c] Four students did not answer this question. Due to missingness, some percentages may not add up.

Perceived Stress and Mental Distress Variables

The mean levels suggest that perceived stress and mental distress increased from the time before the exams to the exam period and decreased after the exams to a lower level than before the exams. Table 4 depicts perceived stress and mental distress levels on the 3 occasions for participants who took part in the respective occasion. The corresponding table with only those participants who provided data for at least two occasions can be found in Supplement V in Multimedia Appendix 1.

Table 4. Perceived stress and mental distress levels for the 3 occasions.

Measure	Occasion 1		Occasion 2		Occasion 3	
	Score, mean (SD)	Participants, n	Score, mean (SD)	Participants, n	Score, mean (SD)	Participants, n
PSS[a]	10.42 (2.77)	451	11.61 (2.77)	274	9.89 (2.67)	282
GHQ-12[b]	25.40 (5.82)	445	27.39 (6.09)	273	23.31 (5.93)	282

[a]PSS: Perceived Stress Scale.

[b]GHQ-12: General Health Questionnaire, 12-item version.

Missingness Predictors

Gender and ethnicity as well as psychopharmacological medication and global stress severity (ie, stress slider) on occasion 1 were identified as predictors for missing data patterns (see test results in Supplement VI in Multimedia Appendix 1). Therefore, we decided to include these as auxiliary variables in our analyses. However, as adding the auxiliary variables to our models did not result in positive definite residual matrices, we here describe the models without auxiliary variables. We provide the results with auxiliary variables in Supplement VI in Multimedia Appendix 1. Importantly, all results remained largely the same when auxiliary variables were added to the models. Moreover, as additional robustness analysis, we reconducted all main analyses, while this time excluding one potentially influential case. Once again, all results remained largely the same (Supplement VII in Multimedia Appendix 1).

Latent Growth Models

Perceived Stress

The LGM showed that, on average, students experience most perceived stress during exams (occasion 2: slope loading fixed to 1) and least perceived stress after the exams (occasion 3: slope loading fixed to 0); before the exams, they experienced more perceived stress than after the exams, but less than during the exams (occasion 1: estimated slope loading=0.29; Table 5). The mean level trajectory is shown in Figure 2 (left panel). We further found that the model estimating the change trajectory of perceived stress fits significantly better than the *no-change* model (χ^2_1=72.4; *P*<.001; fit indices are presented in Table 6), indicating that perceived stress changed significantly over the 3 occasions. Additional post-hoc analyses confirmed that the mean levels differed significantly between all three occasions.

Figure 2. The left panel depicts the perceived stress (sum score mean level) trajectory and the right panel depicts the mental distress (sum score mean level) trajectory. The faded gray lines indicate person-level trajectories. The red line indicates the group-level sum score trajectory, which was averaged across the students. The dotted black line represents the group-level sum score for occasion 1. This was done solely to enhance the comparison with the other occasions. o1: occasion 1; o2: occasion 2; o3: occasion 3.

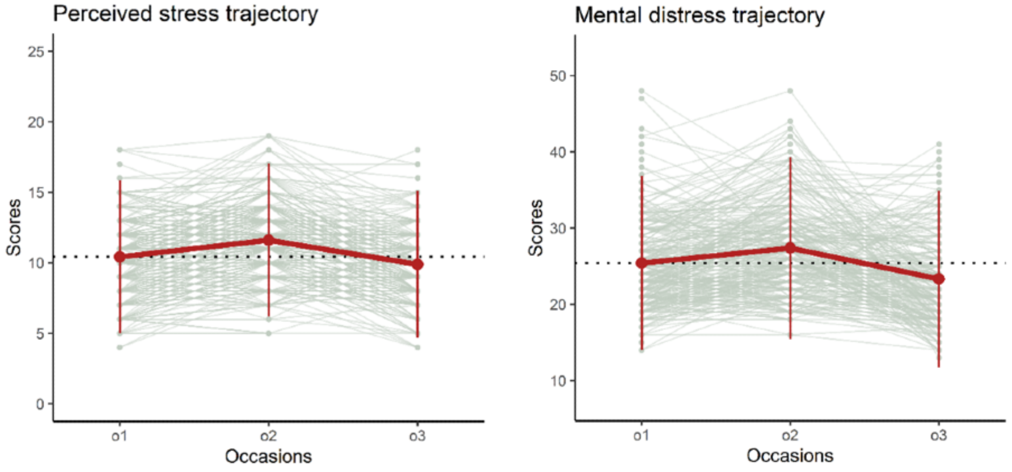


Table 5. Latent growth model summary.

Model	Slope loading, occasion 1	Slope loading, occasion 2	Slope loading, occasion 3	Intercept mean	Slope mean	Residual variance, occasion 1	Residual variance, occasion 2	Residual variance, occasion 3	Intercept slope covariance
Perceived stress									
M1[a]	0.29	1.00	0	9.92	1.79	3.78	3.78	3.78	0.45
M2[b]	0.52	1.00	0	10.54	0	3.68	3.68	3.68	−1.35
M1[c]	0.29	1.00	0	9.91	1.79	3.75	3.75	3.75	0.41
Mental distress									
M1	0.60	1.00	0	23.21	4.08	16.85	16.85	16.85	−8.71
M2	−4.41	1.00	0	25.44	0	37.50	37.50	37.50	−1.65
M2[c]	0.67	1.00	0	25.26	0	16.74	16.74	16.74	−18.07

[a] M1: freely estimated trajectory model.

[b] M2: no-change trajectory model.

[c] Variance for the latent slope constrained to >0 to render it nonnegative.

Table 6. Latent growth model fit.

Model	AIC[a]	BIC[b]	CFI[c]	TLI[d]	RMSEA[e]	SRMR[f]	Chi-square (*df*)	BICw[g] (%)	AICw[h] (%)
Perceived stress									
M1[i]	4718.05	4746.83	0.98	0.96	0.07	0.04	6.5 (2)	100	100
M2[j]	4811.92	4836.59	0.47	0.47	0.27	0.18	102.3 (3)	0	0
M1[k]	4718.06	4746.84	0.98	0.96	0.07	0.04	6.5 (2)	100	100
Mental distress									
M1	6295.92	6324.66	0.94	0.91	0.09	0.05	9.2 (2)	100	100
M2	6366.44	6391.08	0.32	0.32	0.24	0.19	81.7 (3)	0	0
M2[k]	6364.52	6389.17	0.34	0.34	0.24	0.18	79.8 (3)	0	0

[a] AIC: Akaike information criterion.

[b] BIC: Bayesian information criterion.

[c] CFI: confirmatory fit index.

[d] TLI: Tucker-Lewis fit index.

[e] RMSEA: root mean square error of approximation.

[f] SRMR: standardized root mean square residual.

[g] BICw%: weight percentage for the Bayesian information criterion (compared to the respective other model); the higher the weight, the more in favor is the model.

[h] AICw%: weight percentage for the Akaike information criterion (compared to the respective other model); the higher the weight, the more in favor is the model.

[i] M1: freely estimated trajectory model.

[j] M2: no-change trajectory model.

[k] Variance for the latent slope constrained to >0 to render it nonnegative.

Mental Distress

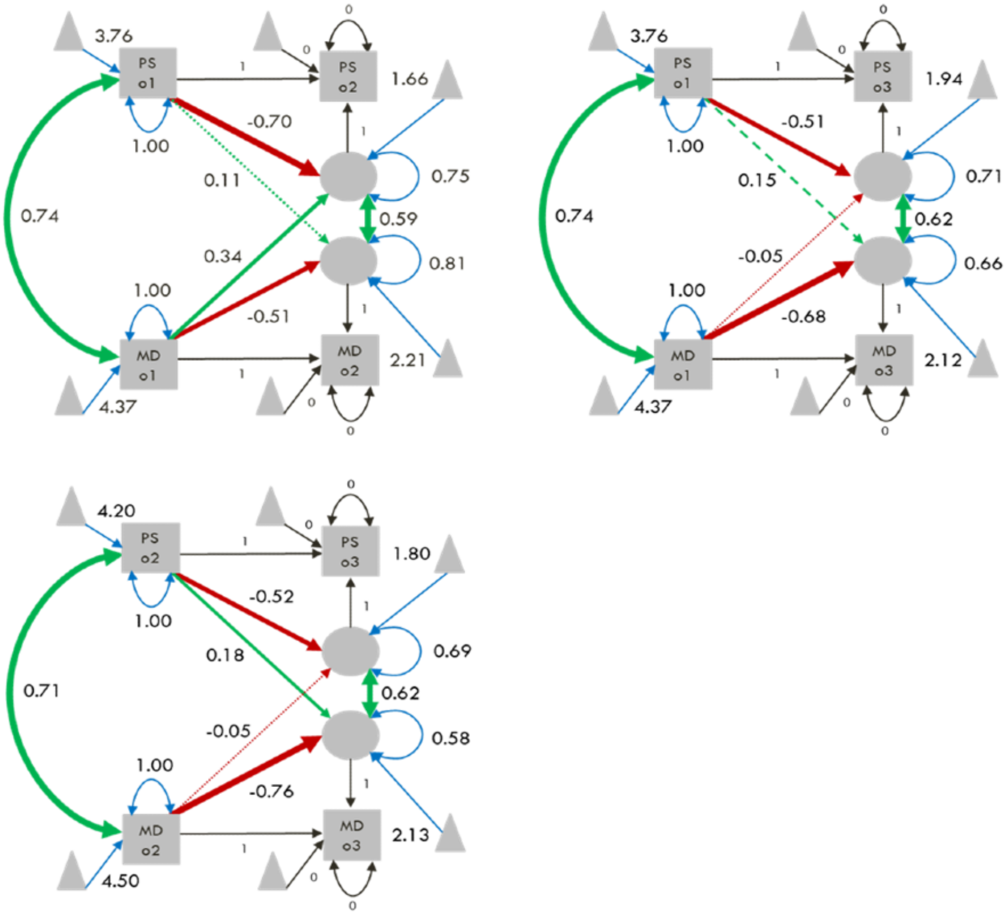
The LGM showed that, on average, students experience most mental distress during exams (occasion 2, slope loading fixed to 1) and least mental distress after exams (occasion 3, slope loading fixed to 0); before the exams, they experienced more mental distress than after the exams, but less than during the exams (occasion 1, estimated slope loading=0.60; Table 5). The mean level trajectory is shown in Figure 2 (right panel). We further found that the model estimating the change trajectory of mental distress fits significantly better than the *no-change* model (χ^2_1=58.8; *P*<.001; fit indices are presented in Table 6), indicating that mental distress changed significantly over the 3 occasions. Additional post-hoc analyses confirmed that the mean levels differed significantly between all three occasions.

Bivariate Latent Change Score Models

Occasions 1-2

The BLCSM showed that perceived stress and mental distress on occasion 1 are significantly positively associated, which indicates that students with higher perceived stress report on average higher mental distress (Figure 3, upper-left panel; for exact coefficients, see Supplement VIII in Multimedia Appendix 1). Similarly, changes in perceived stress and mental distress from occasion 1 to 2 are significantly positively associated, which indicates that students with more increase in perceived stress report on average also a greater increase in mental distress. The BLCSM revealed a significant and negative autoregressive effect for perceived stress and its change score, which indicates that higher perceived stress on occasion 1 results, on average, in less increase in perceived stress from occasion 1 to 2. Equally, mental distress had a significant and negative autoregressive effect with its change score, indicating that higher mental distress on occasion 1 results, on average, in less increase in mental distress from occasion 1 to 2. Perceived stress was not significantly associated with the change in mental distress from occasion 1 to 2. However, mental distress was significantly positively associated with the change in perceived stress from occasion 1 to 2, which indicates that higher mental distress on occasion 1 results on average a greater increase in perceived stress from occasion 1 to 2.

Figure 3. Bivariate Latent Change Score Models. The upper-left panel depicts occasions 1-2, the upper-right panel depicts occasions 1-3, and the lower-left panel depicts occasions 2-3. Green arrows represent positive associations, red arrows represent negative associations, black arrows represent fixed parameters, and blue arrows represent estimated intercepts and variances. Double-headed arrows represent covariances and variances, and single-headed arrows represent intercepts, regressions, and autoregressions. Solid lines indicate a significant association (*P*<.05), dashed lines indicate marginal association (.05≥*P*<.10), and dotted lines indicate nonsignificant association (*P*≥.10). Gray squares represent manifest variables, gray circles represent latent variables, and gray triangles represent intercepts. All depicted estimates are standardized. MD: mental distress; o1: occasion 1; o2: occasion 2; o3: occasion 3; PS: perceived stress.



Occasions 1-3

The BLCSM showed that changes in perceived stress and mental distress from occasion 1 to 3 are significantly positively associated, which indicates that individuals with a greater decrease in perceived stress report, on average, also a greater decrease in mental distress (Figure 3, upper-right panel; for exact coefficients, see Supplement VIII in Multimedia Appendix 1). Moreover, the BLCSM revealed a significant and negative autoregressive effect for perceived stress and its change score, which indicates that higher perceived stress on occasion 1 results, on average, in a greater decrease in perceived stress from occasion 1 to 3. Equally, mental distress had a significant and negative autoregressive effect with its change score, indicating that higher mental distress on occasion 1 results, on average, in a greater decrease in mental distress from occasion 1 to 3. Mental distress was not significantly associated with change in perceived stress from occasion 1 to 3. Perceived stress was not significantly associated with change in mental distress from occasion 1 to 3; however, the P value was marginal (β=.15;

P=.06). If one would opt to interpret the directionality of the effect, it would suggest that, on average, higher perceived stress is marginally associated with less decrease in mental distress from occasion 1 to 3. However, given that the effect was not significant, we suggest to err on the side of caution and shall not interpret it.

Occasions 2-3

The BLCSM showed that perceived stress and mental distress on occasion 2 are significantly positively associated, which indicates that individuals with higher perceived stress report on average higher mental distress (Figure 3, lower-left panel; for exact coefficients, see Supplement VIII in Multimedia Appendix 1). Similarly, changes in perceived stress and mental distress from occasion 2 to 3 are significantly positively associated, which indicates that individuals with a greater decrease in perceived stress report, on average, also a greater decrease in mental distress. Moreover, the BLCSM revealed a significant and negative autoregressive effect for perceived stress and its change score, which indicates that higher perceived stress on occasion 2 results on average in a greater decrease in perceived stress from occasion 2 to 3. Equally, mental distress had a significant and negative autoregressive effect with its change score, indicating that higher mental distress on occasion 2 results on average in a greater decrease in mental distress from occasion 2 to 3. Mental distress was not significantly associated with change in perceived stress from occasion 2 to 3. However, perceived stress was significantly positively associated with change in mental distress from occasion 2 to 3, which indicates that higher perceived stress results on average in less decrease in mental distress from occasion 2 to 3.

Discussion

Conclusions: Proof-of-Principle Analyses

Both perceived stress and mental distress were lower before the exams (ie, during the regular university term) than during the exam period, but higher before the exams than after the exams. Higher mental distress during term time was, on average, associated with a greater increase in perceived stress from the term time to the exam period, when controlling for perceived stress levels during the term time. Hence, students who already had mental health problems before the exam period were most prone to develop increased levels of stress during the exam period. Higher perceived stress during the exam period was, on average, associated with less recovery of mental distress after the exam time, when controlling for mental distress levels during exams. Thus, students who reported high stress during the exam period were less successful (or quick) in recovering from mental distress. Overall, we found that higher mental health problems before the exams increase the risk of developing more perceived stress during the exams, and higher perceived stress during the exams in turn increases the risk of a less successful (or quick) recovery of mental distress after exams.

Future Research and Outcomes

Plans for Research Questions and Analyses

Future analyses on the RESIST data are primarily set out to shed light on which RFs lend themselves best as prevention targets (before the stressor) and which as treatment targets (at times of stress) for the mitigation of mental health problems that are triggered or accelerated by natural exam stress. Therefore, the RESIST study may lay the foundations necessary to inform student support services, as well as mental health services, as well as resilience and transdiagnostic mental health theory.

Plans for Outcome Dissemination and Data Availability

We aim to publish all articles that are based on RESIST data in peer-reviewed journals, ideally under an open access agreement. Alongside the manuscripts, we aim to release the related and anonymized data on the Cambridge Data Repository.

Acknowledgments

This manuscript is based on the related ethics proposal coauthored by AVH and POW. The authors want to thank Pascal Schlechter (former MPhil student) for his help with the anonymization of the data and with the participant payments. They also want to thank all participants as well as the students who participated in the user review (ie, the pilot run). Moreover, the authors thank Dr Diana Wood and Dr Robbie Duschinsky, who additionally approved the ethics application as external scientists, and Dr Thelma Quince, who commented on an early sketch of the ethics application. The application was approved on December 20, 2017, by the Cambridge Psychology Research Ethics Committee (approval number: PRE.2017.096).

Data were collected and managed using REDCap [48] tools hosted at the University of Cambridge, supported by the BRC. REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

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Authors' Contributions

JS and RAK served as statistical advisers. AVH served as a topic-related adviser. POW obtained approval for the study from the Cambridge Medical School, helped recruit the participants, and served as principal investigator. AVH and POW approved the ethics protocol before submission. JF designed the study, wrote the ethics protocol, created the study materials (eg, the web-based survey), recruited the participants, conducted the analyses, and wrote the first draft of this manuscript. All authors commented on several previous versions and approved the final version of this manuscript. AVH and POW are the joint last authors of this manuscript.

Conflicts of Interest

JS disclosed consultation for Ieso Digital Health. None of the authors declared competing interests that affect the manuscript.

Multimedia Appendix 1

Contains 8 supplements (ie, Supplement I: Additional information for family-related questionnaires; Supplement II: Items of the adapted version of the Youth Trauma Scale; Supplement III: Participant safety considerations; Supplement IV: Latent Growth Models with varying residual variances; Supplement V: Demographic and clinical characteristics for the sample with data for at least 2 occasions; Supplement VI: Missingness predictors and analyses results when including the auxiliary variables; Supplement VII: Analyses results when excluding one potentially influential case; Supplement VIII: Model summaries and exact coefficients of the Bivariate Latent Change Score Models).

[PDF File (Adobe PDF File), 470 KB - formative_v5i6e20128_app1.pdf]

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Abbreviations

BLCSM: bivariate latent change score model
CCMS: Comprehensive Child Maltreatment Scale
FIML: full information maximum likelihood
GHQ: General Health Questionnaire
LGM: latent growth model
PSS: Perceived Stress Scale
REDCap: Research Electronic Data Capture
RESIST: Resilience Study
RF: resilience factor
YTS: Youth Trauma Scale

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Original Paper

The Development of a Digital Patient-Reported Outcome Measurement for Adults With Chronic Disease (The Parsley Symptom Index): Prospective Cohort Study

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Abstract

Background: The monitoring and management of chronic illness has always been a challenge. Patient-reported outcome measures (PROMs) can be powerful tools for monitoring symptoms and guiding treatment of chronic diseases, but the available PROM tools are either too broad or too disease specific for the needs of a primary care practice focused on longitudinal care.

Objective: In this study we describe the development and preliminary validation of the Parsley Symptom Index (PSI).

Methods: This prospective cohort study took place from January 5, 2018, to June 05, 2020, among a sample of 4621 adult patients at Parsley Health. After a review of literature, followed by binning and winnowing of potential items, a 45-item PROM that also served as a review of systems (ROS) was developed. The PSI was deployed and completed by patients via an online portal. Construct and face validity was performed by clinicians, tested on patients, and feasibility was measured by response rate, completion rate, and percentage of missing data.

Results: The response rate for 12,175 collected PSIs was 93.72% (4331/4621) with a 100% item completion rate. A confirmatory factor analysis confirmed the model structure was satisfactory by a Comparative Fit Index of 0.943, Tucker–Lewis index of 0.938, and root mean square error of approximation of 0.028.

Conclusions: A 45-item ROS-style PROM designed to capture chronic disease symptoms was developed, and preliminary validation suggests that the PSI can be deployed, completed, and helpful to both patients and clinicians.

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KEYWORDS

patient-reported outcomes; PROMs; chronic diseases; symptom management; Parsley Symptom Index; Review of Symptoms

Introduction

Chronic disease is now the primary cause of death and disability in the United States [1] and accounts for 90% of the nation's US $3.5 trillion in annual health care costs [2]. The incidence of chronic disease is on the rise, and people are developing chronic diseases long before they are bedbound, hospitalized, or even symptomatic. Epidemiological data indicate that chronic diseases such as diabetes, heart disease, and asthma are underdiagnosed up to 90% of the time in the developed world [3]. Current models also predict that prevalence of chronic disease will reach 80% by 2030 [2]. The existing health care system was designed for acute illness and is poorly suited for chronic disease, which now accounts for the majority of services provided [4]. The massive increase in chronic disease is rapidly unmasking the gaps in our health care delivery system, particularly in disease monitoring and management.

The monitoring and management of chronic disease is a challenge regardless of a medical practice size or physical location. For clinicians, a limited number of chronic disease monitoring and management tools exist that can be quickly deployed into the patient–clinician workflow, can integrate with an electronic medical record system, can be utilized across a variety of different conditions, can supplement a review of systems (ROS), are clinically validated, and can be brief enough to be collected on an ongoing basis. Patient-reported outcome measures (PROMs) can be incredibly helpful for monitoring and guiding treatment of chronic diseases [5-7]. Examples of PROMs that have been created to address some of the aforesaid challenges range from single-form assessments such as the Medical Symptom Questionnaire (MSQ) [8], which are akin to a ROS, to the Patient-Reported Outcomes Measurement Inventory System (PROMIS) that offers variations for general health and specific conditions [9].

The MSQ assesses physical symptoms in a brief form, and serves as a ROS within a medical note. However, the MSQ has yet to be validated and has inconsistent categorization of items. The items included within the MSQ range from clinical diagnoses such as asthma and arthritis, vital sign measurements such as weight, and symptoms that range from slurred speech to drainage from the ear. The MSQ also has complex instructions where the user must assess each item's frequency and severity at the same time, regardless of whether the item is for a symptom, condition, or vital sign. These and other concerns make the MSQ difficult to integrate into a clinician's workflow and patient visits.

By contrast, the PROMIS is one of the most rigorously developed sets of PROMs, and covers a wide range of chronic diseases in both short- and long-form versions [10] that capture physical and psychosocial domains. In comparison to the MSQ, the PROMIS short forms focus heavily on psychological well-being and overall quality of life questions, but not extensively enough to double as a ROS like the MSQ. PROMIS has also developed specific variations for individual chronic diseases [11]. The technical deployment of PROMIS variations (short versus long form, condition specific) can be managed by the information technology departments that exist within large medical practices (eg, academic medical centers), but can be burdensome for a small primary care practice without those resources.

Both the PROMIS and the MSQ are powerful tools in their own right, but neither offer a single, short-form assessment that could be easily integrated into the clinician workflow or electronic medical record, as well as capture symptoms across body systems like a ROS. Furthermore, neither allows for more opportunities to engage with patients like a digital health tracker (eg, smart watch, fitness tracker). Approximately 1 in 5 US adults say they regularly wear a digital tracker that can collect health information [12]. While the data collected from these devices can be motivational and promote behavioral change [13], long-term engagement is still a challenge for these trackers [14]. In summary, we envision a new type of PROM that could function like a ROS, feed into the collaborative patient–doctor conversation to promote personalized tailoring of care plans, while also offering opportunities for more continuous engagement like a digital health tracker. The aim of this study is to (1) describe the initial development of the Parsley Symptom Index (PSI) and (2) assess feasibility of the PSI among patients receiving care at Parsley Health.

Methods

Setting and Population

Parsley Health is a subscription-based model for delivering primary care and proactive chronic disease management through a functional medicine lens. Patients receive care from clinicians and health coaches in-person and virtually, and have additional access to their care team via email and a web portal. Parsley Health patients are predominantly female (85%), range from 18 to 83 years in age (mean age 37 [SD 6.7]), and are located primarily in metropolitan areas such as New York City and Los Angeles. Commonly reported diseases and health problems (ICD-10 chapters) for patients seeking treatment include mental, behavioral, and neurodevelopmental disorders (F41.9, Anxiety disorder; R53.83, Fatigue, G47, Insomnia), digestive system (K21.9, Gastro-esophageal Reflux Disease; K90.41, Non-celiac Gluten Sensitivity; K58.0, Irritable Bowel Syndrome), and diseases of the skin and subcutaneous tissue (L70.9, Acne; L20.9, Atopic Dermatitis).

Inclusion criteria were Parsley Health patients that had (1) an active "12-month complete care" membership between January 12, 2018, and June 05, 2020; (2) a minimum of 1 clinical visit within their membership period; and (3) located at 1 of the 3 locations: New York City, Los Angeles, or San Francisco. Exclusion criteria were (1) severe psychiatric disorders (particularly psychosis and depression requiring a change in treatment in the last 30 days); (2) under the age of 18; (3) unable to speak or read English; or (4) lacked access to a computer.

PSI Development

Overview

The PSI development and testing followed the frameworks outlined by the Federal Drug Agency (FDA) guide for PROM development [15], and the PROMIS investigators [9,16]. Our approach included initial item identification by literature review and secondary data analysis of 2 US national health surveys, item classification and selection (binning and winnowing), focus group exploration followed by item revision, and field testing followed by further revision. This study involved patient-reported survey data that were recorded in such a manner that participants could not be identified by the researchers. The institutional review board at Stony Brook University considered this study exempt from 45 Code of Federal Regulations requirements [17].

Review of Literature and Secondary Data Analysis

Item development started with a systematic literature review of PROM for adult patient populations. Our initial PubMed search was performed using the MeSH terms for PROMs: "patient outcome assessment" and "patient reported outcome measures." This search returned a list of 342 systematic literature review articles. The vast majority of results returned by the search focused on individual chronic diseases and quality of life (QoL).

Subsequent searches were focused on the identification of the most prevalent chronic diseases and their symptoms in the United States defined by the National Health Interview Survey (NHIS) [18] and the National Ambulatory Medical Care Survey (NAMCS) [19].

A secondary analysis of data pulled from the 2015 NHIS survey included a subsample of 17,201 unique patient responses between the ages of 18 and 50, and a sample of 3583 physician responses and 76,330 completed patient record forms from the 2012 NAMCS. Chronic diseases and their symptoms described in the NHIS and NAMCS were combined with the initial PROM MeSH terms to create additional PubMed searches. Approximately 320 individual items from 27 PROMs were inspected and entered into a document by our clinical team members to ensure the item list reflected common clinical symptoms.

Binning and Winnowing

Binning is a systematic process that groups items by meaning and construct, while winnowing is used to reduce an item pool to a representative and manageable set of items [16]. The clinician study team independently sorted 320 items into bins according to meaning and construct in order to identify redundant items, and ensure a representative sample of items. At the end of the binning process each team member compared bins and discussed discrepancies. For unresolved discrepancies, an additional team member was brought into the discussion until a resolution was reached. What remained was 78 items sorted into 15 domain bins (Figure 1).

Figure 1. Original PSI design: 78 items sorted into 15 domain bins. PSI: Parsley Symptom Index.

Next the team winnowed the remaining items and established exclusion criteria for each item in a bin. Exclusion criteria were constructed based on the clinical expertise of the team, and findings from the NHIS and NAMCS reports. A 3-reviewer consensus was required for item removal from a bin. The final result was a set of 45 items sorted into 9 bins (Multimedia Appendix 1). Based on a review of other similar assessments (Figure 2), each bin was relabeled with patient facing terminology to reflect bodily systems: Cardiac and Circulatory, Gastrointestinal, Metabolic, Hair and Skin, Neurological, Respiratory, Musculoskeletal, Mental, and Reproductive (Female and Male). The stem of each item was standardized to ask if the symptom was present or not present; then, double-barreled items (ie, items that assess more than 1 concept) were removed and the response time frame was set to a 14-day period. A 14-day window was selected to minimize recall bias [20] and allow for repeat testing. For questions answered present, an additional exploratory question was displayed to capture the symptom's intensity on a sliding Visual Analog Scale (VAS) of 1-10. Emoticons (smiley and sad faces) were displayed on each endpoint to clarify the meaning of the scale. A VAS was selected to quantify symptom severity because it is simple to use, requires no training, and is both accurate and sensitive [21]. To allow for straightforward calculation and interpretation by patients and clinicians, a total score was constructed by a sum of the VAS scores for all "yes" answers, with "no" being assigned a value of 0.

Figure 2. Logic for PSI bin relabeling with patient facing terminology to reflect bodily systems. ADL: activities of daily living; PSI: Parsley Symptom Index.

ICD-9 Domains	ICD-10 Domains	Medical Symptom/ Toxicity Questionnaire	Cleveland Clinic Buckets	Functional Medicne Matrix	AHRQ Health Assessment in Adults	CA Healthy Healthy Assessment	Human Body Systems
Infectious and parasitic diseases	Infectious and parasitic diseases	Digestive	Autoimmune	Assimilation	ADLs	Nutrition	Cardiovascular /circulatory
Neoplasm	Neoplasms	Head	Cancer	Structural Integritiy	Alcohol Use	Physical Activity	Digestive/Excretory
Endocrine, nutritional, and metabolic diseases and immmunity disorders	Disease of the blood and blood-forming organs and certain disorders involving immune	Mouth/Throat	Energy / Mitochondria	Communication	Anxiety	Safety	Endocrine
Diseases of the blood and blood-forming organs	Endocrine, nutritional, metabolic, mental, and behavioral	Ears	Gut	Transport	Depression	Dental Health	Integumentary
Mental	Mental and behaviorial	Heart	Heart	Defense and Repair	General Health	Mental Health	Lymphatic/Immune
Nervous	Nervous system	Nose	Hormones (Sex M vs F)	Energy	Medication Adherence	Alcohol, Tabacco, Drug Use	Muscular/Skeletal
Sense	Eye and ocular adnexa	Emotions	Infections	BioTransformation and Elimination	Nutrition / Eating Patterns	Sexual	Nervous/Sensory
Circulatory	Ear and mastoid process	Joints/Muscles	Mood/ Mental Health	Mental	Pain	Other	Reproductive
Respiratory system	Circulatory	Skin	Neuro	Emotional	Patient Priorities		Respiratory
Digestive system	Respiratory	Energy/Activity	Nutrition/ Metabolic	Spiritual	Personal Safety		
Genitourinary system	Digestive	Lungs	Skin		Physical Activity		
Pregnancy, childbirth, and puerperium	Skin and subcutaneous	Weight	Structure/MSK		Sex		
Skin and subcutaneous	Musculoskeletal system and connective tissue	Mind	Trauma		Sleep		
Musculoskeletal system and connective tissue	Genitourinary	Eyes	Allergen/Toxin		Social / Emotional Support		
Congenital anomalies	Pregnancy, childbirth, and puerperium	Other			Stress		
Perinatal period	Perinatal period				Substance Use		
Symptoms, signs, and ill-defined conditions	Congenital malformations, deformations, chromosomal abnormalities				Tabacco Use		
Injury and poisoning	Symptoms, signs, and abnormal clinical/lab findings						
External causes of injury and supplemental classification	Injury, poisoning, and certain other external causes						
	External causes of morbidity and mortality						
	Influencing health status and contact with health services						
	Codes for special purposes						

To quickly identify gaps in item coverage, time to complete the PSI, and assess clarity of item language, a convenience sample of 76 patients (mean age 34 [SD 4.3]; 62/76, 82% female) provided preliminary feedback [22,23]. Patients were asked to provide open-ended qualitative feedback in a free-text box at the end of the assessment. For 82% (62/76) of patients the PSI took less than 5 minutes to complete, for 14% (11/76) between 5 and 10 minutes, and more than 10 minutes for 4% (3/76). Two team members (HW and RB) reviewed all patient responses to identify missing content or functionality. Patient feedback on individual PSI items were generally positive. Patient feedback on functionality focused on user interface and user experience; examples included the addition of a progress bar, preferences on multipage versus single-page layouts, and how to make the

PSI more engaging through the addition of animations and visual changes as the patient completes the PSI. Despite the overwhelming positive feedback, a dilemma did occur for patients that experienced symptoms over the 14-day window that had resolved, which was why a sub category was added to the yes response: “Yes—ongoing” and “Yes—resolved.”

Integration Into Clinical Workflow

Patients were provided instructions to login to their “My Parsley” web portal to complete the PSI 24-48 hours before each clinical visit. Because the initial visit requires multiple data collection forms (medical, family, and social histories) as well as the PSI, there was greater motivation to complete all the forms for the first visit than for follow-up visits. Initial visits were rescheduled if all the forms were not completed, whereas follow-up visits were never postponed for lack of a completed PSI. To encourage compliance, a clinical operations coordinator looked for a recorded online PSI response before each follow-up visit, and prompted the patient to fill one out if missing.

Patients and providers both interacted with the PSI at several points. Before the clinical visit patients completed the PSI and viewed their score online, which provided them with immediate feedback. Within the clinical visit the PSI score was used as a touch point for the patient–provider discussion, and assisted the clinician by removing the need to spend visit time collecting ROS information. In subsequent visits, clinicians were able to share PSI trend data with patients to support longitudinal care.

Statistical Approach

Analyses were conducted with Python (version 3.6.4) and R (version 4.0.4) [24]. Descriptive statistics to summarize age, gender, membership duration, and participant location were generated using the Python package TableOne (version 0.7.10) [25]. Feasibility of the PSI was examined by response rate, completion rate, and percentage of missing data. We considered a response rate of over 85% to be adequate [26,27]. The response rate was calculated by determining the percentage of patients who had at least one clinical visit between January 12, 2018, and June 05, 2020, that completed at least one PSI. Skewness, kurtosis, and response distributions were reviewed for each PSI item to help assess relevance and response frequency. To translate the PSI total score into clinically meaningful values, preliminary cut-off points based on quartile ranges were calculated. Lastly, we did not expect missing values due to the fact that only a fully completed PSI can be submitted, so if missing values were to occur, they would be likely related to a software defect.

A confirmatory factor analysis (CFA) was conducted to examine the proposed factor structure of the PSI as opposed to an exploratory factor analysis (EFA). In an EFA each item would be free to load on to any factor, potentially leading to a model that is inconsistent with the theory-derived determination of PSI items and factors, whereas a CFA allows data to be fitted to a theory-derived model, with each item only loading to the factors it was designed to measure, helping to address potential weaknesses of specific items. The minimum sample size for the CFA was calculated with an item-to-respondent ratio of 30:1 [28,29]. Kline [28] notes the N:q rule, which states that the sample size should be determined by the number of q parameters in your model with a recommended ratio that can range from 15:1 to 30:1. With a 45-item assessment, the minimum sample size would be 900 participants based on a 30:1 ratio.

To prepare the data for the CFA, each item was recoded into a numerical dummy variable (0 for symptom not present; 1 for symptom present or resolved). The CFA was conducted in R with the lavaan latent variable analysis package version 0.6.8 [30] using diagonally weighted least squares (DWLS). The DWLS estimator has growing consensus among researchers as the best approach for the analysis of binary variables [31]. Model appropriateness was assessed via the root mean square error of approximation (RMSEA; 0.05 < cut-off < 0.08) [32,33], the Tucker–Lewis index (TLI; cut-off ≥ 0.90) [34], and the Comparative Fit Index (CFI; cut-off ≥ 0.90) [35]. The model was improved based on the removal of items with small factor loadings and the through assessment of expected versus observed counts for each categorical indicator variable. Standardized factor loadings (β) less than 0.30 or CIs below 95% were deemed poorly performing items [36,37]. These cut points were used as a guide rather than strict rules [38]. We focused on the relative size of these indicators to inform choices around item retention and removal, in conjunction with the impact to the overall model fit following item removal, and the theoretical coverage of the remaining items.

Results

A total of 12,175 PSI-unique assessments were collected from 4621 patients. Females accounted for 80.22% (3707/4621), the mean age was 38.9 years (SD 11), and each patient had an average of 2.96 (SD 1.7) clinician visits per 12-month membership period (Multimedia Appendix 2). The PSI response rate was 93.72% (4331/4621). Over the duration of the study the PSI was completed 1 time by 24.41% (1128/4621), 2-3 times by 43.26% (1999/4621), and 4 or more times by 26.73% (1235/4621) of study patients.

The 3 bodily domains with the highest frequency of present or resolved symptoms were neurological (10,113/12,175, 83.06%), mental (9667/12,175, 79.40%), and gastrointestinal (9428/12,175, 77.44%), while the bodily domain with the lowest frequency was sexual health (3165/12,175, 25.99%). The top reported individual symptoms across all bodily domains were “fatigue or low energy” (7954/12,175, 65.33%), “nervousness or anxiety” (7449/12,175, 61.18%), and “bloating or abdominal pain” (7086/12,175, 58.20%). The normality, skewness, and kurtosis for the reported VAS of each item are displayed in Multimedia Appendix 1.

Quartiles calculated for the total score resulted in the following 4 cut-off ranges: 0-24, 25-43, 44-71, and greater than 71. The clinical study team assigned the following terminology for these ranges: “well” (0-24), “symptomatic” (25-43), “very symptomatic” (44-71), and “sick” (71+). These ranges provide a preliminary rubric that allowed clinicians to quickly interpret the total score and assess changes to symptoms over time.

Of note, the PSI cannot be submitted with incomplete responses. Nonresponders (290/4621, 6.27%) included those who filled out the PSI partially and those who did not fill it out at all. While completion rates for the PSI decreased over time with subsequent clinical visits, clinicians reported that when patients did complete follow-up PSIs, they were helpful for longitudinal tracking and improved their ability to trend symptoms over time. Furthermore, clinicians reported that modeling the PSI on a ROS increased perceived workflow efficiency, and motivated them to encourage their patients to complete the PSI prior to each visit. Additional feedback indicated that the PSI assisted in making the patient feel heard, and provided meaningful context for the visit.

For the CFA, 2 items were initially removed ("hives" from the skin factor and "genital itch" from the male factor) due to having only a single level (symptom not present). The initial fit statistics for the model were satisfactory (CFI=0.929, TLI=0.923, and RMSEA=0.031). Nearly all items had β values >.3 except for "snoring" (β=.246). With the removal of "snoring" the model marginally improved (CFI=0.931, TLI=0.925, and RMSEA=0.031). To explore ways of improving the model further, items with high modification indices were investigated for cross-loading. Two items with poor conceptual specificity that loaded onto several other dimensions were "wheezing/chest tightness" within the respiratory factor (high cross-loading onto "shortness of breath" [cardiac] and "chest pain" [cardiac]) and leg swelling from the cardiac factor (high cross-loading onto "joint swelling" [musculoskeletal] and "limited range of motion or function" [musculoskeletal]). The removal of these 2 items improved the model to a small degree (CFI=0.943, TLI=0.938, and RMSEA=0.028).

Discussion

Principal Findings

Our goal in designing the PSI was to create a new type of PROM that could function like a ROS, feed into the collaborative patient–doctor conversation to promote personalized tailoring of care plans, and offer opportunities for continuous engagement like a digital health tracker. The preliminary data described within this study set the groundwork for future research that can further assess the efficacy and ecological validity of the PSI, and explore the PSI's potential impact on the patient–clinician interaction within a visit.

During the data-collection phase of the study, we quickly realized that in asking patients to fill out the PSI, we were competing with digital health trackers for our patients' engagement. In general, patients have become increasingly interested in tracking their own habits and symptoms [39], and there is an ever-growing patient demand for more engaging monitoring technologies [40,41]. Many of our own patients already use digital health trackers to monitor activities related to physical movement, sleep behaviors, heart rate and blood pressure, weight, and nutritional intake. Most of these trackers involve the recording of one's own data and receiving immediate feedback, yet the majority still lack the ability to provide feedback to the patient that is personalized and actionable.

In competing for our patients' engagement, we drew inspiration and borrowed what has worked for digital health trackers and attempted to address their shortcomings. First, we focused on the importance of a user-centered design that emphasizes the importance of the user interface and user experience. In the design process we paid particular attention to the visual styles, design elements, and the overall user experience. Second, because providing immediate results in digital health trackers has been shown to influence behavioral change [42,43], we designed the PSI to provide an immediate result upon completion, a total score. At the current stage in PSI development there is no automated interpretation of the total score. The score is interpreted by the clinician within the patient visit where it is contextualized based on recent patient illnesses, stressors, and treatments. Third, we have addressed the inability of most trackers to provide individualized interpretation of health data by incorporating the results into the clinical encounter. Through this approach the PSI goes beyond generic recommendations, and assists the clinician with creating a personalized, actionable treatment plan that is patient centered. Going forward, we suggest that future enhancements to the PSI and other PROMs are performed through the lens of digital health trackers to expand engagement and utilization beyond a traditional questionnaire.

An important finding within this study was the PSI's high completion rate (4331/4621, 93.72%) for initial visits. While preliminary data showed PSI completion rates declined after initial visits, clinician feedback was extremely positive for patients that did continue to fill out the PSI for follow-up visits. This further highlights that the monitoring of chronic disease symptoms over a long period is a difficult challenge, regardless of patient condition or technology used.

In our attempt to enhance long-term engagement and completion of the PSI, we have initiated and continue to engage in quality improvement efforts. Two areas of improvement that have been identified by our patients and staff are reminder notifications and reporting of results. Related to notifications, we are exploring the impact of (1) delivery time (day, weekend, morning, evening), (2) phrasing of messaging in reminder notifications, and (3) delivery medium (email, text, telephone). As for PSI reporting, we are exploring (1) addition of longitudinal line graph of total scores, and (2) a stacked line graph visualizing each body system over time. Graphical presentations of data are used to make information "stickier" with existing digital health trackers, so we believe both clinicians and patients may derive further benefits from seeing a picture of their progress over time at the macro level (total score) and micro level (bodily system).

Limitations

The PSI generalizability may be limited due to our sample being largely female. In future validation studies, testing in populations with greater gender diversity will help improve ecological validity. Second, due to workflow issues around initial data entry, we do not have sufficient data to describe race and ethnicity. Future external validation of the PSI should include testing in diverse patient populations.

Conclusion

This study details the process and methodology for how the PSI was created. With a response rate of nearly 94% (4331/4621, 93.72%), the initial findings suggest that the PSI can be used in clinical practice. Drawing lessons from digital health trackers, the PSI offers immediate feedback that informs the patient–clinician dialogue, and may promote enhanced tracking and management of chronic disease symptoms over time.

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Authors' Contributions

HW and RB designed the study, and were involved in the data collection, analysis and interpretation, and reporting. SS was involved in the analysis and interpretation, and reporting.

Conflicts of Interest

RB and SS are full-time employees of Parsley Health, and HW is an employee of Stony Brook University. The views expressed by the authors in the publication do not necessarily reflect the views of the Parsley Health or Stony Brook University.

Multimedia Appendix 1
Descriptive statistics of individual PSI items.
[DOCX File , 23 KB - formative_v5i6e29122_app2.docx]

Multimedia Appendix 2
Descriptive statistics of sample.
[DOCX File , 16 KB - formative_v5i6e29122_app1.docx]

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Abbreviations

PROM: patient-reported outcome measure
PROMIS: Patient-Reported Outcomes Measurement Inventory System
PSI: Parsley Symptom Index
ROS: review of symptoms
TLI: Tucker–Lewis index

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Viewpoint

Using Emerging Telehealth Technology as a Future Model in Vietnam During the COVID-19 Pandemic: Practical Experience From Phutho General Hospital

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Abstract

Telehealth has emerged as a model of modern technology for health care services in Vietnam during the COVID-19 pandemic. To actively prevent the outbreak of COVID-19 by using a national digital transformation program, the Vietnamese Ministry of Health launched project 2628/Quyet dinh-Bo y te, which approved a scheme for remote medical examinations and treatments for 2020 to 2025. The project aims to connect 1000 hospitals to strengthen the quality of medical services by using the expertise of central hospitals to support rural areas via provincial hospitals. Phutho General Hospital (PGH) is one of leading provincial hospitals that participated in and applied the early telehealth systems in Vietnam. By using telehealth systems, PGH can offer valuable support to doctors' activities by streamlining and facilitating their work. Telehealth was demonstrated to be feasible, acceptable, and effective at PGH in Vietnam, and it resulted in considerable improvements in health care outcomes. The COVID-19 pandemic has facilitated the acceleration and enhancement of telehealth in Vietnam. The success of telehealth in Phutho may be a useful reference for other parts of the world. However, this telehealth system focuses on the connectivity among doctors rather than the connectivity between doctors and patients, which is an area that needs further assessment.

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KEYWORDS

telehealth; telemedicine; teleconsultation; COVID-19; Vietnam; digital health; pandemic

Introduction

Since the outbreak of COVID-19, which originated in Wuhan, China, in 2020, the disease has spread widely across the world [1,2]. The disease has affected 221 countries, and the latest data show that the outbreak has affected over 106 million people and has resulted in over 2.3 million deaths [3,4]. The primary symptoms of COVID-19 include fever, dry cough, and breathing difficulty [5,6]. Older adults and those with underlying medical problems such as hypertension, heart disease problems, and diabetes are more susceptible to developing the most severe form of the disease [7]. COVID-19 has impacted both health services and the global economy [8]. The COVID-19 outbreak has diminished prospects of an economic recovery, and many key sectors have been affected, particularly travel and tourism, retail, and other service sectors [8,9].

A method for controlling the transmission of SARS-CoV-2 is social distancing, which is made possible by the reduction of person-to-person contact [10,11]. In the context of the ongoing COVID-19 pandemic, telehealth has emerged as an ideal method for facilitating communication among people and has played a critical role in supporting the diagnosis and treatment of diseases in many hospitals [12]. Vietnam is a country that has controlled the pandemic very effectively—according to an assessment by the World Health Organization—thanks to political systems as well as the active application of new and advanced technology [13]. In the war against the COVID-19 pandemic, the Vietnamese Ministry of Health launched project 2628/Quyet dinh-Bo y te (QD-BYT) on June 22, 2020, which approved a scheme for remote medical examinations and treatments for 2020 to 2025 [14]. The National Steering Committee established the Vietnam Telemedicine Center for COVID-19 Outbreak Control in June 2020. The center frequently holds web-based consultations that involve the participation of leading professors across the country to provide advice on critical cases, discuss optimal treatments, and share experiences of inpatient treatment and care with participating experts and hospitals as if there were no distance between North and South Vietnam or high and low levels of health care. Such web-based consultations have greatly contributed to the treatment of patients with COVID-19; as of June 15, 2020, there have been no COVID-19 cases. The establishment of the Vietnam Telemedicine Center for COVID-19 Outbreak Control marked the development of medical examinations and treatment systems that are based on scientific and technological advances, especially those for dangerous infectious diseases such as COVID-19.

This paper aims to present the results of applying telehealth in Vietnam at Phutho General Hospital (PGH), which is the largest provincial hospital in the northwest region of Vietnam, as well as the advantages and challenges of early-stage telehealth in Vietnam.

PGH's Experience in Developing a Model for the Application of Telehealth in Vietnam

PGH, the largest public hospital in the northwest region of Vietnam, has over 1500 beds, 20 departments, and 9 centers. Currently, PGH is a satellite hospital that consists of 8 national hospitals. Hospital facilities and equipment are being enhanced, and many advanced medical technologies and techniques are being applied to medical examinations and treatments. Recognizing the importance of advancements in technology, PGH implemented telehealth technologies, which has allowed the hospital to connect with national hospitals via information technology systems. PGH has registered and signed agreements with 8 national hospitals (Table 1) as part of project 1628/QD-BYT to launch official telehealth models for medical examination and treatment services for 2020 to 2025, including teleconsultations, telesurgery consultations, telemedicine, and videoconferences.

Table 1. Application of telehealth at Phutho General Hospital and national hospitals.

Model	Hospital network	Achievements	Challenges	Launch year
Teleconsultation	Bach Mai Hospital, Viet Duc University Hospital, National Hospital of Tropical Diseases, and Vietnam National Cancer Hospital	• Many cases on resuscitation, emergency and intensive care, surgery, respiratory diseases, oncology, etc • Teleconsultations became a useful routine for the hospital network. • The information technology system is relatively complete. • Improving the knowledge, qualifications, and abilities of physicians • Learning by doing via real cases • A huge amount of recorded data for training	• Information technology supporting staff is not always available • Investing into the information technology systems among hospital networks • Time differences and daily work among hospital networks • Unavailable payment insurance • Patients' privacy • Internet speed	2015
Heart surgery telementoring	Hanoi Heart Hospital	• 10 heart operations	• Only performing simple heart surgery cases • Patients' privacy • Internet speed	2020
Telemedicine	Hanoi Medical University Hospital	• Daily support for patients who need the service, including patients with neurological disease, hypertension, diabetes, etc	• Only cooperating with Hanoi Medical University Hospital • Unavailable payment insurance • Patients' privacy	2020
Videoconference	Vietnamese Ministry of Health	• Monthly meetings for direction and management	• Internet speed	2020

Implementing Telehealth to Improve Knowledge and the Quality of Treatment and Education

On June 22, 2020, given the complex issues resulting from the COVID-19 pandemic, the Vietnamese government comprehensively reviewed its epidemic prevention plan and decided to approve a scheme for “remote medical examination and treatment for 2020 - 2025.” The scheme has rapidly received strong support from the medical community, doctors, and citizens. After nearly 3 months of preparation, on September 24, 2020, the Ministry of Health of Vietnam officially launched the remote medical examination and treatment program, thereby connecting 1000 hospitals, including 20 central hospitals. The project aims to reduce the burden on central hospitals, increase the quality of medical examination and treatment in primary health care facilities, save costs, and improve patients’ experiences and satisfaction while ensuring the safety of medical staff, doctors, and patients during the COVID-19 pandemic. The program receives financial support from the Vietnamese Government for both inpatients and outpatients, regardless of whether patients have insurance or not, and telehealth services are provided free of charge. The medical specialties include the cardiology, oncology, respiratory and musculoskeletal fields.

As one of the earliest hospitals to participate in the project, PGH launched a telehealth clinic on November 14, 2020. Teleconsultations were one of the applications that physicians in PGH used commonly to consult with specialists from Bach Mai hospital, Viet Duc Hospital, the National Hospital of Tropical Diseases, and the Vietnam National Cancer Hospital (Table 1). The teleclinic office is equipped with a 52-inch screen, a 48-inch screen, and 2 computers with a high-speed internet connection. Doctors in PGH have to prepare PowerPoint presentations about patients in advance to present cases to and discuss them with specialists (ie, cases that need help and expertise). Teleconsultations helped PGH improve their medical staff’s knowledge, improve the quality of treatment via treatment plans, ensure that appropriate referrals or evacuations were conducted, improve the accuracy of diagnoses, and provide opportunities for education. The telehealth network was high in quality and resulted in faster decision making, shorter diagnosis times, faster and better patient management, shorter lengths of hospitalization and intensive care unit stays, improved diagnostic accuracy in triage, reduced anxiety, better education, increased confidence, and fewer unnecessary procedures.

Another breakthrough of telemedicine in PGH was successfully applying telemedicine in surgery. For example, on August 6, 2020, PGH organized a telemedicine cardiovascular surgery program for PGH and Hanoi Heart Hospital for the case of a 55-month-old child with a ventricular septal defect hole under 2 aortas (Figure 1). Before the operation, surgeons and technicians had a teleconsultation with cardiologists from Hanoi Heart Hospital to plan the surgery strategy. During the operation, a camera livestreamed the operation. The surgeons received advice and guidance from the cardiologists during the operation. Furthermore, doctors at Hanoi Heart Hospital have successfully carried out the first web-based heart surgeries in Vietnam for patients at PGH via the telehealth system that was developed by Viettel Group (Figure 2). Currently, the hospital has conducted 10 heart operations, including treatments for mitral stenosis, mitral regurgitation, ventricular septal defects, aortic valve stenosis, mucous tumors, atrial fibrillation, and heart failure.

Figure 1. Real-time heart surgery telementoring for a case involving a 55-month-old child with a ventricular septal defect hole under 2 aortas. Telementoring was conducted during the COVID-19 outbreak between Phutho General Hospital and Hanoi Heart Hospital.

Figure 2. Telesurgery consultation via the web-based platform.

Telehealth Has Changed the Way That Doctors From PGH and National Hospitals Collaborate During the COVID-19 Pandemic

The COVID-19 outbreak has changed the way that people contact and communicate with PGH and national hospitals. Telehealth is a model that uses electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health–related education, public health care facilities, and health administration agencies. Telehealth technology helps doctors connect patients with physicians through video calls, emails, and web-based patient portals and enables real-time consultations between specialists. A quick web-based visit can improve diagnosis and treatment efficiency, help with improving patients' experiences, and reduce the number of complications and hospital admissions. Recently, many researchers have indicated that using telehealth for specialty visits connects primary care physicians, specialists, and patients, resulting in the enhanced coordination of care and speedy diagnoses [15]. This service is also comfortable and beneficial for patients who need follow-up care without a physical exam for monitoring medication side effects or patients who have nonurgent questions after surgery [12].

Telemedicine has changed the approach of health care services and how they are delivered. Telemedicine has also offered many advantages for doctors and patients in PGH, as shown in the following sections.

Strengthening the Quality of Health Care Services in Primary Health Care Centers and Remote Communities

Doctors and physicians in remote, rural areas of Phutho province can learn from experienced doctors. This is an opportunity for PGH to receive professional support remotely and gradually improve the quality of medical services. Often, using smartphones to transmit images and videos is much more convenient than using formal videoconferencing technology and is often preferred by doctors [16].

Patients can easily receive consultations and prescriptions from leading physicians in national hospitals without having to travel long distances, which saves time and money. From a psychological perspective, rural patients in Vietnam always want to be examined and cared for by central medical staff who are believed to have more experience, knowledge, and skills than lower-level medical teams. Therefore, telemedicine increases patients' access to care when it involves extended specialist and physician access. This results in telemedicine improving patient engagement and satisfaction.

Telemedicine Can Effectively Slow Down the Spread of Infection

Telehealth is an effective option for supporting the fight against the outbreak of COVID-19, as it reduces the risk of coming into contact with people with SARS-CoV-2 infection [17]. Hospital-acquired infection is a serious problem in Vietnam—a tropical country that has a high risk of nosocomial infection. Telemedicine has the advantage of digital health care solutions that can prevent the spread of the pandemic nationwide because they help reduce the amount of direct contact with patients and decrease the risk of infection for health staff. Thus, the benefits of telemedicine are obvious when it comes to social distancing and decreasing the spread of diseases.

Limitations

Telehealth and telemedicine have emerged as new models of health technology and have been applied in many hospitals in Vietnam during the COVID-19 outbreak. However, there are some limitations.

First, telemedicine may not suit every person or situation. Second, medical data maybe at risk of being violated by hackers and being accessed by other criminals, especially if a patient accesses telemedicine services on a public network or via an unencrypted channel. Third, care may be delayed when a person needs emergency care, as accessing telemedicine services first may delay treatment, particularly since a doctor cannot provide lifesaving care or conduct laboratory tests digitally. Fourth, technological concerns can be challenging; a weak internet connection can make it especially difficult to offer quality care. Fifth, not all hospitals are equipped for telemedicine, particularly those that lack computer terminals, which are necessary for implementing telemedicine services.

Data Availability

The data reported in this paper can be made available by the corresponding author upon request from qualified investigators.

Conclusion

Telehealth has emerged as a model of modern technology for health care services in Vietnam during the COVID-19 outbreak. This report is the first to provide the early results of counseling and support activities of remote examination and treatment activities in Vietnam. It is expected that these remote examination and treatment consultancy activities, which are based on an information technology platform, will increasingly promote and ensure the efficiency and sustainability of telehealth in Vietnam.

The results from PGH show the advantages of using telehealth in remote examinations that adhere to the treatment system standards of the Ministry of Health. By integrating modern data transmission technology and using high-speed internet, the system is capable processing data in real time and supporting the remote delivery of surgery. Doctors at higher-level hospitals can directly guide surgeons of lower-level hospitals, thereby shortening the process of treating patients in emergencies.

The COVID-19 pandemic has allowed unprecedented opportunities for telemedicine to develop. These opportunities require heightened engagement from the government to make sure that a regulatory foundation is implemented. A synchronized telemedicine system should be built in Vietnam in the future.

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Authors' Contributions

All authors were involved in the drafting of the manuscript and agreed to its publication. All authors read and approved their sections of the final manuscript. NHN and AQN read and approved all sections of the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

PGH: Phutho General Hospital
QD-BYT: Quyet dinh-Bo y te

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Original Paper

Health Perceptions and Adopted Lifestyle Behaviors During the COVID-19 Pandemic: Cross-National Survey

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Abstract

Background: Social isolation measures are requisites to control viral spread during the COVID-19 pandemic. However, if these measures are implemented for a long period of time, they can result in adverse modification of people's health perceptions and lifestyle behaviors.

Objective: The aim of this cross-national survey was to address the lack of adequate real-time data on the public response to changes in lifestyle behavior during the crisis of the COVID-19 pandemic.

Methods: A cross-national web-based survey was administered using Google Forms during the month of April 2020. The settings were China, Japan, Italy, and India. There were two primary outcomes: (1) response to the health scale, defined as perceived health status, a combined score of health-related survey items; and (2) adoption of healthy lifestyle choices, defined as the engagement of the respondent in any two of three healthy lifestyle choices (healthy eating habits, engagement in physical activity or exercise, and reduced substance use). Statistical associations were assessed with linear and logistic regression analyses.

Results: We received 3371 responses; 1342 were from India (39.8%), 983 from China (29.2%), 669 from Italy (19.8%), and 377 (11.2%) from Japan. A differential countrywise response was observed toward perceived health status; the highest scores were obtained for Indian respondents (9.43, SD 2.43), and the lowest were obtained for Japanese respondents (6.81, SD 3.44). Similarly, countrywise differences in the magnitude of the influence of perceptions on health status were observed; perception of interpersonal relationships was most pronounced in the comparatively old Italian and Japanese respondents (β=.68 and .60, respectively), and the fear response was most pronounced in Chinese respondents (β=.71). Overall, 78.4% of the respondents adopted at least two healthy lifestyle choices amid the COVID-19 pandemic. Unlike health status, the influence of perception of interpersonal relationships on the adoption of lifestyle choices was not unanimous, and it was absent in the Italian respondents (odds ratio 1.93, 95% CI 0.65-5.79). The influence of perceived health status was a significant predictor of lifestyle change across all the countries, most prominently by approximately 6-fold in China and Italy.

Conclusions: The overall consistent positive influence of increased interpersonal relationships on health perceptions and adopted lifestyle behaviors during the pandemic is the key real-time finding of the survey. Favorable behavioral changes should be bolstered through regular virtual interpersonal interactions, particularly in countries with an overall middle-aged or older population. Further, controlling the fear response of the public through counseling could also help improve health perceptions and lifestyle behavior. However, the observed human behavior needs to be viewed within the purview of cultural disparities, self-perceptions, demographic variances, and the influence of countrywise phase variations of the pandemic. The observations derived from a short lockdown period are preliminary, and real insight could only be obtained from a longer follow-up.

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KEYWORDS

health behavior; self-report; cross-national survey; COVID-19; behavior; perception; lifestyle; nutrition; real-time

Introduction

The World Health Organization (WHO) declared the outbreak of COVID-19 a pandemic on March 11, 2020 [1]. As of March 24, 2020, the most affected regions in the world were the Western Pacific region (China, the Republic of Korea, Japan, etc), with a total of 96,580 reported confirmed cases, and the European region (Italy, Spain, Germany, the United Kingdom, etc), which accounted for a total of 195,511 positive cases [2]. There was a global panic due to the shifting of the COVID-19 epicenters from China to Europe, mainly Italy, which reported the worst outcomes up to March 25, 2020 (69,176 reported cases and the maximum number of COVID-19 deaths of 6820) [2].

Global disease outbreaks impact varied aspects of physical and mental health, even suicidality [3-5]. As observed in the infectious disease epidemic of severe acute respiratory syndrome (SARS) in 2003, exposure to new pathogens can manifest as a qualitatively distinct mental impact [6]. Social isolation measures (large-scale quarantines, long-term home confinements, and nationwide lockdowns) [7-11], although essential for controlling viral spread, go against the inherent human instinct of social relationships [12,13]. If these measures are implemented for a long duration, they can be detrimental to mental health, as observed in recent reports from China and Vietnam [14-17], and they are expected to result in modification of people’s lifestyle behaviors, such as increased adoption of unhealthy dietary habits and sedentary behavior. These changes can exacerbate the burden of the “pandemics” of behavioral and cardiovascular diseases that already prevail in modern societies [18,19]. The latest trends of re-emergences of such infectious disease outbreaks merit timely preparedness involving community engagement and focus on healthy lifestyle behaviors [20,21]. Although the mental impact of the COVID-19 pandemic is being addressed in a timely fashion [22,23], the associated real-time influences on people’s health perceptions and lifestyle choices remain underresearched [24,25]. Careful consideration of the demographic and cultural impact of tailored public health intervention strategies on human behavior is also greatly needed when designing such strategies. Here, we report the findings of a cross-national survey that aimed to generate rapid perspectives on the status of health-related perceptions and their influence on the likelihood of adoption of healthy lifestyle choices during the COVID-19 pandemic. The settings were China and Japan, two nations in the Western Pacific region that were greatly impacted by COVID-19; Italy, from the European region; and India, a highly populous South Asian country that was a potential threat region at the time of the survey [2,7-9,11].

Methods

Sampling and Data Collection

Given the restricted mobility restrictions and confinement due to the COVID-19 lockdown, we conducted a cross-sectional survey using a web-based platform. We disseminated the survey through the circulation of a Google Form via institutional websites and private social media networks, such as Facebook and WhatsApp. We also used the group email lists of a few social organizations, universities, academic institutions, and their interconnections to share the questionnaire links, which further facilitated the snowball sampling. The respondents were residents of China, Japan, Italy, and India who were aged 18 years or older. We anonymized the data to preserve and protect confidentiality. The study was approved by the institutional review boards and institutional ethics committees of the respective nations: Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA), India; Sarva Yoga International, Italy; Shanghai Jiao Tong University, China; and Japan Yoga Therapy Society, Japan. Respondents were informed about the objectives of the survey and the anonymity of their responses. Informed consent was obtained through a declaration of the participants of their voluntary participation, the confidentiality of the data, and the use of the collected information for research purposes only. The survey period was April 3-28, 2020. Once submitted, the responses were directly used for the analysis, and revisions of the responses were not allowed.

Questionnaire Structure

We chose a short format for the questionnaire, with 19 questions to facilitate rapid administration. The first set of questions (Q1-Q5) were related to the respondents’ demographic details: age, gender, country of residence, working status, and the presence of any chronic illness or disability diagnosed by a physician. The next set (Q6-Q14) contained perception-related questions on self-rated physical and mental health, sleep quality, coping ability, energy status (a psychological state defined as an individual's potential to perform mental and physical activity [26,27]), coping flexibility, and perceptions related to interpersonal relationships as well as the fear of the pandemic. The questions were phrased as statements, with responses recorded on 3- or 5-point scales. For example, the respondents were requested to self-rate their mental and physical health status with the questions “How do you rate your physical health at present as” and “How do rate your mental health at present as” with answer modalities of (1) excellent, (2) very good, (3) good, (4) average, and (5) poor. These single-item self-health assessment questions are validated tools used in national surveys and epidemiological studies to assess health perceptions among individuals, strongly related to various morbidities, and mortality, and they have been validated across various ethnicities [28-33]. A further set of questions (Q15-Q19) focused on items related to the respondents’ recent lifestyle behavior choices: eating habits, engagement in physical activity or exercise, and substance use. Permitted responses for these behavior-related questions were either yes or no. For eating habits, the respondents provided self-rated scores for their time of eating; nourishment related to intake of vegetables and fibers; and daily intake of “junk food” (described as packaged and processed sweets or salty snacks); the combined scores were dichotomized into “good” (score ≥3) and “poor” (score ≤2).

Data Analysis

An exploratory factor analysis using the principal axis factoring and varimax rotation suggested that three factors were present in the data. Items related to health perceptions were used to form a scale for perceived health status (the health scale); the scores were represented as mean (SD). For the remaining two factors, we could not form scales, as they scored Cronbach α values <.6; instead, we used the most relevant single item to represent the factor. The two primary outcomes of the study were the health scale and the adoption of healthy lifestyle choices. The health scale was derived as mentioned above; further health scale scores were categorized based on tertile distribution into low (poor), middle (average), and high (good) scores. Adoption of healthy lifestyle choices was defined as the engagement of the respondent in any two of three healthy lifestyle choices (eating habits, substance use, and exercise). Multivariate linear and logistic regression analyses were used to test the influence of the perceptions and the personal variables on the primary outcomes. Most of the items in the survey were recorded as 3-point responses. Hence, to achieve homogeneity in the analyses of the survey items, the 5-point Likert responses of the self-rated health items, excellent, very good, good, average, and poor, were collapsed into three categories: (1) very good/excellent, (2) good, and (3) average/poor. Analysis of variance was used to assess comparisons between continuous variables, and *P*<.05 was considered significant. Chi-square analysis was used for cross-country comparisons for categorical variables.

Results

The aim of this survey was to understand the cross-national psychosocial and behavioral impact of the lockdowns and social isolations imposed due to the COVID-19 pandemic. We received 3370 responses: 1342 from India (39.8%), 983 from China (29.2%), 669 from Italy (19.8%), and 377 from Japan (11.2%). The demographic profiles of the respondents are presented in Table 1.

Table 1. Countrywise representation of the personal characteristics of the survey participants.

Variable	Overall (N=3371)	India (n=1342)	China (n=983)	Japan (n=377)	Italy (n=669)	*P* value[a]
Age (years), mean (SD)	36.04 (15.54)	29.42 (12.29)	29.77 (11.98)	53.49 (9.35)	48.43 (13.65)	<.001
Age group (years), n (%)						<.001
18-24	1200 (35.6)	685 (51.0)	490 (49.8)	1 (0.3)	31 (4.7)	
25-34	503 (14.9)	267 (19.9)	152 (15.5)	4 (1.1)	84 (12.5)	
35-54	1176 (34.9)	330 (24.6)	314 (32.0)	217 (57.5)	309 (46.2)	
55-64	330 (9.8)	40 (3.0)	21 (2.1)	98 (26.0)	169 (25.2)	
>65	162 (4.8)	20 (1.5)	6 (0.6)	57 (15.1)	76 (11.4)	
Female gender, n (%)	2535 (75.2)	880 (65.6)	802 (81.6)	348 (92.0)	506 (75.6)	<.001
Working, n (%)	1709 (50.7)	582 (43.4)	406 (41.3)	335 (89.0)	395 (59.0)	<.001
Has a chronic illness, n (%)	647 (19.2)	169 (12.6)	84 (8.5)	151 (40.0)	314 (46.9)	<.001

[a] Cross-country comparisons for categorical variables were conducted using chi-square analysis. Analysis of variance was conducted to assess comparisons among the continuous variable of age. A *P* value <.05 was considered significant.

The mean age of the respondents was 36.04 years (SD 15.54) (Table 1); the average age of the Indian and Chinese respondents (29.42 years, SD 12.29, and 29.77 years, SD 11.98, respectively) was lower than that of the Japanese and Italian respondents (53.49 years, SD 9.35, and 48.43 years, SD 3.65, respectively). Overall, there was a higher representation of the female gender (2535/3371, 75.2%). Japan had the highest representation of women (348/377, 92.0%) and working people (335/377, 89.0%) (Table 1). Italy and Japan had the highest representations of respondents with a known status of chronic illness (314/669, 46.9%, and 151/377, 40.0%, respectively).

Table 2 shows the countrywise status of the perceptions of health and psychosocial factors reported in response to the ongoing outbreak of COVID-19. The health status score was highest for Indian respondents (9.43, SD 2.43) and lowest for Japanese respondents (6.81, SD 3.44). Overall, 846/3371 (25.1%) of the respondents had good health status; Japanese and Chinese respondents had the highest representation of low health status (236/377, 62.6%, and 562/983, 57.2%, respectively). Sleep quality was perceived well by the majority of Indians (917/1342, 68.3%), and the majority of Japanese and Chinese respondents perceived their sleep quality as average/poor (264/377, 70%, and 554/983, 56.3%, respectively). Italian respondents had almost equal representations of good and average sleep qualities. Coping abilities during social isolation were perceived as good by 1264/3371 (37.5%) of the overall population, with the countrywise trend of India (672/1342, 50.1%) > Italy (283/669, 42.3%) > Japan (131/377, 34.8%) > China (178/983, 18.1%). Fear response was almost equally distributed in positive or intermediate categories for most of the country respondents, except for Italians, among whom the intermediate or partial fear response was the most evident (469/669, 70.1%). Coping flexibility responses were very similar across all the countries except Japan, wherein the majority of respondents (317/377, 84.1%) reported experiencing little challenging response to sudden changes in living norms**.** Responses to interpersonal relationships followed the trend of India (733/1342, 54.6%) > Japan (183/377, 48.5%) > Italy (287/669, 42.9%) > China (337/983, 34.3%). Adopted lifestyle behavior yielded the trend of India (1129/1342, 83.9%) > Italy (361/669, 54.0%) > China (436/983, 44.4%) > Japan (137/377, 36.2%).

Based on the regression analysis on the perceived health status, female respondents had a 0.14 lower score compared to male respondents (Table 3). Participants with a positive history of chronic illness and those who were not working also had lower health status scores, by 0.11 and 0.04, respectively, compared to their counterparts. Increased personal relationships and positive fear response were associated with increases in health status across all the countries, particularly Japan, which showed the highest value of β (.60). For Indian respondents, an increase in age was significantly associated with increase in health status by a score of 0.12.

Increased interpersonal relationships was a significant predictor of adoption of health lifestyle choices across the respondents in all the countries except for Italy (adjusted OR 1.93, 95% CI 0.65-5.79) (Table 4). Positive perception of fear was significantly associated with likelihood of adoption of healthy lifestyle choices only in Indian respondents (adjusted OR 2.41, 95% CI 1.18-4.96). Perceived health status categories were significantly associated with the likelihood of adoption of healthy lifestyle choices across all the countries; most prominently, high health status increased adoption of healthy lifestyle choices by approximately 6-fold in China and Italy.

Table 2. Countrywise representation of perceptions and behavioral changes among the survey respondents related to the COVID-19 outbreak.

Perception or behavior and response	Overall (N=3371)	India (n=1342)	China (n=983)	Japan (n=377)	Italy (n=669)	*P* value[a]
First factor[b]						
Health status, mean (SD)	8.26 (3.36)	9.43 (2.43)	7.09 (2.92)	6.81 (3.44)	8.43 (2.56)	.01
High, n (%)	846 (25.1)	556 (41.4)	71 (7.2)	69 (18.3)	150 (22.4)	
Medium, n (%)	1062 (31.5)	413 (30.8)	350 (35.6)	72 (19.1)	225 (33.6)	
Low, n (%)	1463 (43.4)	413 (30.8)	562 (57.2)	236 (62.6)	294 (43.9)	
Self-rated physical health, n (%)						<.001
Excellent/very good	1357 (40.2)	629 (46.9)	467 (47.5)	88 (23.3)	173 (25.9)	
Good	1283 (38.1)	573 (42.7)	200 (20.3)	135 (35.8)	375 (56.0)	
Poor/average	731 (21.7)	140 (10.4)	316 (32.1)	154 (40.8)	121 (18.1)	
Self-rated mental health, n (%)						<.001
Excellent/very good	944 (28.0)	645 (48.1)	0 (0)	93 (24.7)	206 (30.8)	
Good	1670 (49.5)	535 (39.9)	642 (65.3)	122 (32.4)	371 (55.4)	
Poor/average	757 (22.5)	162 (12.1)	341 (34.7)	162 (43.0)	92 (13.8)	
Self-rated sleep quality, n (%)						<.001
Good	1787 (53.0)	917 (68.3)	429 (43.6)	113 (29.9)	328 (49.0)	
Average	1305 (38.7)	354 (26.4)	477 (48.5)	234 (62.1)	240 (35.9)	
Poor	279 (8.3)	71 (5.3)	77 (7.8)	30 (8.0)	101 (15.1)	
Self-rated coping abilities, n (%)						<.001
Good	1264 (37.5)	672 (50.1)	178 (18.1)	131 (34.8)	283 (42.3)	
Average	1492 (44.3)	539 (40.1)	516 (52.5)	139 (36.8)	298 (44.5)	
Poor	615 (18.2)	131 (9.8)	289 (29.4)	107 (28.5)	88 (13.2)	
Second factor , n (%)						
Fear/anxiety related to COVID-19[c]						<.001
Not at all (positive)	1380 (40.9)	628 (46.8)	470 (47.8)	157 (41.6)	125 (18.7)	
Partially (intermediate)	1829 (54.3)	662 (49.3)	485 (49.3)	213 (56.5)	469 (70.1)	
Extremely (negative)	162 (4.8)	52 (3.9)	28 (2.8)	7 (1.9)	75 (11.2)	
Self-perception of low energy						<.001
Never	1449 (43.0)	667 (49.7)	282 (28.7)	239 (63.4)	261 (39.0)	
Sometimes	1835 (54.5)	641 (47.8)	672 (68.4)	132 (35.0)	390 (58.3)	
All the time	87 (2.6)	34 (2.5)	29 (3.0)	6 (1.6)	18 (2.7)	
Challenging response to sudden changes in living norms (coping flexibility)						<.001
Least/not at all/little	845 (25.1)	436 (32.5)	221 (22.5)	44 (11.7)	144 (21.5)	
Little	1454 (43.1)	417 (31.1)	411 (41.8)	317 (84.1)	309 (46.2)	
Extremely/somewhat	1072 (31.8)	489 (36.4)	351 (35.7)	16 (4.2)	216 (32.3)	
Third factor, n (%)						
Interpersonal relationships[c]						<.001
Increased	1540 (45.7)	733 (54.6)	337 (34.3)	183 (48.5)	287 (42.9)	
Not changed	1572 (46.6)	533 (39.7)	550 (56.0)	179 (47.5)	310 (46.3)	

Perception or behavior and response	Overall (N=3371)	India (n=1342)	China (n=983)	Japan (n=377)	Italy (n=669)	*P* value[a]
Reduced	259 (7.7)	76 (5.7)	96 (9.8)	15 (4.0)	72 (10.8)	
Motivating influence of COVID-19 on lifestyle						<.001
Completely	1175 (34.8)	605 (45.1)	217 (22.1)	132 (35.0)	221 (33.0)	
Partially	1919 (57.0)	641 (47.8)	695 (70.7)	223 (59.2)	360 (53.8)	
Not at all	277 (8.2)	96 (7.1)	71 (7.2)	22 (5.8)	88 (13.2)	
Adoption of ≥2 healthy lifestyle choices	2643 (78.4)	1126 (83.9)	750 (76.3)	283 (75.1)	485 (72.5)	<.001
Adoption of healthy eating behavior	1801 (53.4)	867 (64.6)	436 (44.4)	137 (36.3)	361 (54.0)	<.001
Decreased dependency on and use of tobacco, alcohol, or any other substances	3173 (94.1)	1277 (95.2)	918 (93.4)	355 (94.1)	623 (93.1)	<.001
Increased engagement in exercise or similar activities	2280 (67.6)	910 (67.8)	672 (68.4)	272 (72.1)	426 (63.7)	<.001

[a] Cross-country comparisons for categorical variables were conducted using chi-square analysis; all the *P* values were significant.

[b] An exploratory factor analysis using principal axis factoring and varimax rotation suggested that there were 3 factors present in the data. The first factor consisted of health-related perceptions; composite scores for perceived health were generated as summative scores of the included items.

[c] For the remaining 2 factors, scales could not be formed; rather, the single items that were thought to best summarize the respective factors were considered for further association analyses.

Table 3. Multivariate linear regression analysis (β coefficients, standard errors, and *t* and *P* values) of the association between health status, personal variables, and perceptions.

Predictors	Overall				India				China				Japan				Italy			
	β	SE	*t*	*P*	β	SE	*t*	*P*	β	SE	*t*	*P*	β	SE	*t*	*P*	β	SE	*t*	*P*
Demographic variables																				
Age	.14	0.01	5.12	<.001	.12	0.01	3.74	<.001	.07	0.01	1.79	.07	.08	0.02	1.55	0.12	–.07	0.02	–0.66	.51
Gender (reference: male)																				
Female	–.14	0.12	–7.51	<.001	–.09	0.14	–3.24	<.001	–.01	0.23	–0.35	.72	.01	0.64	–0.30	0.77	<.001	0.52	–0.03	.97
Working status (reference: working)																				
Not working	–.04	0.13	–2.04	.04	–.01	0.15	–0.32	.75	–.02	0.23	–0.54	.59	–.04	0.56	–0.71	0.48	–.03	0.55	–0.36	.72
Chronic illness (reference: no)																				
Yes	–.11	0.15	–5.63	<.001	–.16	0.20	–6.12	<.001	–.06	0.31	–2.04	.04	–.14	0.35	–2.81	0.01	–.09	0.47	–0.96	.34
Perceptions																				
Interpersonal relationships (reference: decreased)																				
Increased	.37	0.21	10.76	<.001	.38	0.28	6.48	<.001	.21	0.31	4.12	<.001	.60	0.85	4.86	<.001	.27	0.68	2.17	.03
No change	.14	0.21	4.15	<.001	.21	0.29	3.71	<.001	.05	0.29	1.08	.28	.33	0.84	2.66	0.01	019	0.66	1.56	.12
Fear response (reference: poor)																				
Positive	.54	0.30	10.84	<.001	.59	0.33	8.69	<.001	.71	0.52	8.02	<.001	.54	1.38	2.72	0.01	.50	1.02	3.03	<.001
Fair	.29	0.30	5.82	<.001	.35	0.33	5.22	<.001	.38	0.51	4.35	<.001	.26	1.37	1.30	0.20	.30	0.97	1.77	.08

Table 4. Role of perceptions in the adoption of healthy lifestyle choices.

Perception	Overall		India		China		Japan		Italy	
	OR[a] (95% CI)	Adjusted[b]OR (95% CI)	OR (95% CI)	Adjusted OR (95% CI)	OR (95% CI)	Adjusted OR (95% CI)	OR (95% CI)	Adjusted OR (95% CI)	OR (95% CI)	Adjusted OR (95% CI)
Health status (reference: low)										
High	3.67 (2.87-4.68)	3.42 (2.51-4.64)	2.98 (2.07-4.28)	2.62 (1.75-3.92)	6.02 (2.38-15.20)	5.83 (2.30-4.79)	3.64 (1.59-8.37)	2.83 (1.18-6.77)	3.33 (2.01-5.51)	6.22 (1.90- 20.40)
Medium	2.09 (1.72-2.54)	2.00 (1.59-2.50)	1.76 (1.24-2.50)	1.57 (1.07-2.31)	2.61 (1.85-3.69)	2.43 (1.72-3.45)	1.33 (0.72-2.45)	1.06 (0.54-2.08)	2.10 (1.42-3.12)	2.46 (1.03-5.83)
Interpersonal relationships[c] (reference: decreased)										
Increased	2.21 (1.64-2.98)	2.42 (1.70-3.45)	1.86 (1.03-3.37)	2.16 (1.15-4.08)	2.01 (1.18-3.41)	1.77 (1.03-3.05)	4.43 (1.49-13.15)	5.25 (1.46-8.92)	1.86 (1.07-3.22)	1.93 (0.65-5.79)
Not changed	1.25 (0.94-1.7)	1.18 (0.84-1.66)	1.09 (0.60-1.97)	1.18 (0.63-2.21)	1.03 (0.64-1.68)	0.99 (0.61-1.62)	1.87 (0.65-5.42)	1.88 (0.54-6.52)	1.59 (0.93-2.73)	1.40 (0.50-3.96)
Fear response[c] (reference: poor)										
Positive	2.43 (1.69-3.50)	2.50 (1.54-4.05)	2.72 (1.38-5.36)	2.41 (1.18-4.96)	2.38 (1.06-5.33)	2.18 (0.96-4.94)	1.84 (0.34-9.99)	4.85 (0.73-32.19)	1.62 (0.86-3.04)	2.20 (0.41-11.71)
Fair	1.36 (0.95-1.93)	1.33 (0.83-2.14)	1.37 (0.71-2.65)	1.32 (0.65-2.65)	1.46 (0.66-3.23)	1.32 (0.59-2.96)	0.93 (0.18-4.93)	1.97 (0.31-12.55)	1.34 (0.80-2.27)	1.25 (0.27-5.80)

[a] OR: odds ratio.

[b] Adjusted for sex, age, work status, and history of chronic illness.

[c] Factor represented by a single item that was thought to best represent the underlying notion.

Discussion

The aims of this short cross-national behavioral survey study were to generate rapid ideas regarding perspectives on health and lifestyle behavior and to provide initial insights into designing global but culturally tailored public health policies.

Health Perceptions: Countrywise Status

A differential countrywise response was observed toward perceived health status across the survey participants; Indians had a better representation of high health status (41.4%) compared to respondents from other countries (China, 7.2%, Japan, 18.2%, and Italy, 22.5%). Despite the inconsistencies in health perceptions, there was a consistent influence of social support measured by perceptions of interpersonal relationships and fear of perceived health status. However, there were countrywise differences in the magnitude of the impact of perceptions on health status; perception of interpersonal relationships was most pronounced in the comparatively older Italian and Japanese respondents (β=.68 and .60, respectively) and that of fear in the Chinese respondents (β=.71). These findings favor the implementation of regularized virtual interpersonal interactions toward combating the adverse health impact of the pandemic, particularly in countries with a higher proportion of older people [34]. Controlling the fear response through counseling would also aid the improvement of health outcomes in populations affected by pandemics. The findings of this survey related to the influence of gender on health perceptions (the health status score of female respondents was lower by 0.14 units compared to that of male respondents) are in line with the global trend of poorer health perception in women than in their male counterparts [35]. These real-time findings observed during the pandemic also relate with reports documented before the COVID-19 pandemic, with a generally higher prevalence of adverse mental health symptoms in women compared to men [36]. Overall, there seemed to be a differential influence of demographic variables on health perceptions across the global population during the pandemic.

The comparatively high scores of the perceived health status in Indian respondents could be underlined by an early phase of the pandemic with slower progression in India during the survey period [11]. The younger age of the Indian respondents (mean age 29.42 years, SD 12.29) seemed to further facilitate interpersonal relationships (54.6%) during the lockdown, which also explains their better health status (β=.38) [34,37]. Younger age identity has been associated with well-being and better perceptions of health [38]. However, in this survey, an unexpectedly positive linear relationship was observed between increasing age and better perception of health status (β=.12) in young Indian respondents. This finding can be attributed to the compounding effect of the COVID-19 pandemic on already existing emotional distress among young adults (related to their examinations, uncertainties, social relationships, etc) [39].

Unfortunately, in line with previous reports [14,15], we could also observe a continued/posttraumatic impact of the pandemic in Chinese respondents, reflected in their comparatively low perception of health status (poor health status was reported by 57.2% of these respondents). We believe the poor health perceptions in the Chinese respondents is due to the underlying influence of fear perceptions (β=.71). Further, since the country had successfully emerged from the first wave of the pandemic during the survey, and social norms had also almost returned to normal, with fewer imposed lockdowns, the moderate increase in interpersonal relationships (34.3%) may not be sufficient to facilitate health status.

The observed low status of perceived health in the Japanese respondents (low health status, 62.6%) is in accord with a health paradox in that country, which is a tendency to perceive health poorly despite the advanced economy [40,41]. Although this influence is not direct, an indirect influence of the comparatively old, middle-aged demographic profile of the Japanese respondents along with the mediatory impact of chronic diseases on health status (β=–.14) could also underlie the lower health perceptions of the Japanese respondents [42]. The perception of poor sleep quality in the Japanese respondents also needs attention, as this finding is in line with reports of the suicidal tendencies in this country [43].

On a positive note, amid the aggravated pandemic at the time of the survey, the majority of the Italian respondents who were middle-aged perceived only partial fear of the pandemic (70.1% response), and they reported better health perceptions (health status score 8.43, SD 2.56) than Japanese respondents (health status score 6.81, SD 3.44) and Chinese respondents (health status score 7.09, SD 2.92). Approximately 55% of the responses for self-rated physical and mental health were in the moderate/fair tier, which is in accord with the reported tendency of Italian people toward intermediate categories of health perception [44]. The lack of negative influence of middle age and chronic illness on health perception can be attributed to the highly efficient medical care and adequate access to social support provided in Italy during the lockdown (improved interpersonal relationships were reported by 42.9% of Italian respondents).

Role of Perceptions in the Adoption of Lifestyle Choices: Countrywise Comparisons

Despite the imposed social isolation and home confinement and the prevailing fear during the COVID-19 pandemic, we observed a positive behavioral response toward lifestyle. Overall, 78.4% of the respondents adopted at least 2 healthy lifestyle choices during the COVID-19 pandemic. The majority of the respondents (67.6%) reported increased engagement in physical activity or exercise as opposed to the expected sedentary behavior due to home confinement. This favorable although unexpected outcome can be attributed to the timely release of the advisory recommendations made by various global and government agencies, including the WHO, on home-based or other easy - to - perform exercises under physical restrictions [45,46]. One of the crucial affirmative responses observed in this survey was the overwhelming response toward substance use (94.1%), which is more justifiable by lack of availability [47] than motivational influence. Along similar lines, in a recent survey on the immediate response to COVID-19, a 3% reduction in smoking was reported in Italians, which was attributed to the fear of increased risk of respiratory distress or mortality [48]. To this end, we suggest the implementation of internet-based and cost-effective behavioral therapies, particularly cognitive behavioral therapy, which may aid the successful alleviation of maladaptive coping tendencies, thereby reducing the risk of future health catastrophes in the post–COVID-19 era [49,50].

Social connectedness is an important dimension that controls population health and healthy lifestyle behavior [51]. In this cross-national survey, perception of increased social support and capital, manifested through enhanced interactions among close friends and family members (measured as interpersonal relationships in the survey), seemed to fill the void of missing social connectedness and encouraged the adoption of healthy lifestyle choices (adjusted OR 2.42, 95% CI 1.70-3.45). The substantial representation of the adoption of healthy lifestyle choices in Chinese and Japanese respondents (~75%), irrespective of their overall poor health perceptions, could be related to reverse causality. In the Japanese respondents (who had an older, middle-aged demographic profile), their working status (OR 4.37, 95% CI 1.19-16.02) (Table S1, Multimedia Appendix 1) and interpersonal relationships (OR for the adoption of healthy lifestyle choices 5.25, 95% CI 1.46-18.92) also seemed to contribute significantly to the adoption of healthy lifestyle behavior.

The influence of interpersonal relationships on the adoption of healthy lifestyle choices was not consistent across different countries and was absent in the Italian respondents. However, this finding aligns with the previously reported relationship between a healthy lifestyle and self-perceived health in the European population [52]. Perception of good health was a prominent predictor of adoption of a healthy lifestyle (adjusted OR 6.22, 95% CI 1.90-20.40) in the middle-aged Italian respondents, with a 36.6% proportion of older individuals (>55 years). Even intermediate scores of health perceptions (health status) also significantly predicted the likelihood of the adoption of healthy lifestyle choices (OR 2.43, 95% CI 1.72-3.45) in the Chinese respondents compared to the respondents from other countries, explained by their demographic characteristic of younger age. These countrywise differential cultural influences of perceptions on health and health behaviors during pandemics indicate that endorsement of the same, such as family support and togetherness, should consider existing disparities, especially for western countries [13].

The findings of this report, particularly those regarding varied health perceptions and their differential influence on the likelihood of adopting healthy lifestyle choices, should be considered within the purview of the survey period with countrywise phase variations of the pandemic. Chinese respondents displayed the continued impact of the pandemic, as they had already witnessed one phase of the pandemic [2]. Younger Indian respondents scored better for their health- and behavior-related perceptions due to the stable and early phase of the pandemic (as of April 22, there was a comparatively steady expansion of COVID-19 cases in India compared to other countries, with 18,985 confirmed cases [11]). However, the responses of Japanese and Italian respondents related to their older age; these countries were also witnessing rising waves of COVID-19 at the time of the survey [7,53]. Japan was under an extended state of national emergency, as the number of "untraceable" cases was soaring [7]. Italy was also under an extended period of lockdown and was one of the hardest-hit nations, with an apparent mortality rate of approximately 13% [53,54].

The observed predominantly female participation in the survey indicates a lack of stringent sampling but also highlights the active involvement of women, who are considered to be at high risk of socioeconomic vulnerability toward disease outbreaks such as the COVID-19 pandemic. The positive response for self-care in women is also a sign of improving gender equity toward health awareness. The observed overwhelmingly female participation level (75.2%) could not be ascribed to the gender representation of countries such as India and China [55] but could be ascribed to the high readiness of the female population to interactively use the internet, in particular to research health-related information and programs, as observed in recent reports [56-58].

The study is limited by the lack of inclusion of perceptions of preventive behaviors and did not compare the respondents' views on precautionary measures, such as the use of face masks [59]. In a recent cross-country comparison between Polish and Chinese respondents, higher use of face masks in Chinese respondents (Polish respondents, 35.0%; Chinese respondents, 96.8%; $P<.001$) was found to be associated with better physical and mental impact of the COVID-19 pandemic [59]. Further, the observations of the adopted lifestyle choices presented here are derived from a short lockdown period during the COVID-19 pandemic and are preliminary, influenced mostly by self-perception; demographic and cultural differences and realistic insight could only be obtained from a longer follow-up. Due to the self-reported nature of the observations, positive behavioral responses toward lifestyle are likely to be inflated.

Good perceived health was associated with improved interpersonal relationships. Older respondents were least likely to report a positive relationship change, as observed in the responses of Italian and Japanese survey participants. However, there was a strong influence of improved interpersonal relationships on perceived health as well as adoption of healthy lifestyle choices in Japanese respondents. These findings indicate the potential of regularized virtual interpersonal interactions to attenuate the adverse psychosocial impact of such pandemics.

In conclusion, the key finding of the survey is that the consistent positive influence of increased interpersonal relationships and good perceptions of health were found to have a significant influence on adopted lifestyle behaviors during the adverse time course of the COVID-19 pandemic. These favorable behavioral perceptions should be bolstered through enhanced health awareness, and regularized virtual interpersonal interactions, particularly in countries with an overall middle-aged or older population. Simultaneously, controlling the fear response through counseling would also help improve health outcomes in nations affected by pandemics. However, the observed human behavior has cultural influences, and it may not be globally generalizable.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author.

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Authors' Contributions

MNK conceptualized the survey, performed the literature search, collected data from public sources, and contributed to the manuscript writing. VM wrote the manuscript and performed the literature search and statistical analyses. NR conceptualized the study and revised the manuscript. HR reviewed the manuscript. MNK and VM finalized the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary table.
[DOCX File , 20 KB - formative_v5i6e23630_app1.docx]

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Abbreviations

SARS: severe acute respiratory syndrome
SVYASA: Swami Vivekananda Yoga Anusandhana Samsthana
WHO: World Health Organization

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Short Paper

Acceptability of Research and Health Care Visits During the COVID-19 Pandemic: Cross-sectional Survey Study

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Abstract

Background: The COVID-19 pandemic has had a widespread impact on attendance in biomedical research and health care visits.

Objective: This study aimed to identify when and how American adults might feel comfortable about resuming in-person research and health care visits.

Methods: Cross-sectional questionnaire data were collected from 135 adults (age: median 48 years; women: n=113, 83.7%; White participants: n=92, 68.2%) who were engaged in health-related research.

Results: More than half of the respondents (65/122, 53.3%) felt that the COVID-19 pandemic positively affected their desire to participate in research. Although 73.6% (95/129) of respondents also indicated a willingness to attend in-person health care visits while Centers for Disease Control and Prevention (CDC) guidelines are implemented, 85.8% (109/127) indicated a willingness to attend in-person, outdoor visits, and 92.2% (118/128) reported a willingness to attend drive-through visits (with CDC guidelines implemented during both visit types). Videoconferencing was the most preferred format for intervention visits; however, adults over the age of 65 years preferred this format less than younger adults (*P*=.001).

Conclusions: Researchers and clinicians should continue to provide opportunities for continuing the conduction of remote-based interventions while enforcing CDC guidelines during in-person visits.

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KEYWORDS

COVID-19; health care access; telehealth; research recruitment; telemedicine; belief; access; willingness; cross-sectional; survey

Introduction

Lockdown and stay-at-home orders that were enacted to contain the spread of COVID-19 [1] have disrupted biomedical research and health care [2,3]. There has been a rapid increase in the adoption of telehealth methods that provide remote care delivery [4,5], which has offset some of the impacts of the COVID-19 pandemic [6]; however, it remains important to understand how to resume the provision of research and clinical care in a manner that individuals feel is safe. Identifying these factors could provide insights into feasible and acceptable approaches to conducting research and health care visits both during the ongoing pandemic surge and, importantly, during future postpandemic recovery [7]. Thus, this study investigated the acceptability of in-person and remote research and health care visits during the COVID-19 pandemic in order to characterize when and how American adults would feel comfortable about resuming research and health care–related clinic visits.

Methods

This study was a cross-sectional analysis of US adults who were enrolled in biomedical research studies. An email describing this study and a link for participating in the web-based survey was sent to 250 adults who had previously completed a survey that assessed COVID-19 impacts on research participation and mental health outcomes [8], and additional participants were recruited through professional networks. Networks included colleagues of study investigators who were conducting behavioral intervention trials across the United States. They were informed via email and social media (Facebook and Twitter) to share the study information and survey link with participants who were enrolled in their studies. Potential respondents who clicked the survey link were provided with a description of this study and were asked to provide informed consent before completing the survey. Consent was obtained and data were collected via REDCap (Research Electronic Data Capture; Vanderbilt University) [9] between September 17 and October 17, 2020.

The 87-item questionnaire, which was developed by the study team, was used to collect sociodemographic information (ie, age, gender, race and ethnicity, educational attainment, and household income), query respondents about the number of underlying health conditions that were suspected to increase COVID-19 severity [10], and ask other questions about physical and mental health and research participation. This study used data collected from 10 items that focused on engagement with research and the willingness to attend research and health care visits (Multimedia Appendix 1). The University of Florida Institutional Review Board provided ethical approval for this study.

Descriptive statistics were computed to describe research participation and health care engagement. In total, 3 items for querying respondents about their beliefs regarding participating in research and whether the COVID-19 pandemic has positively or negatively affected their desire to participate in research were scored on 5-point, Likert-style scales (Multimedia Appendix 1). For analysis purposes, responses to each item were converted into binary indicators; “Not at all” was categorized as “No,” and the responses “A little bit,” “Moderately,” “Quite a bit,” and “Extremely” were categorized as “Yes.” Furthermore, 4 items for querying respondents about their willingness to attend various types of health care visits were scored on a 3-point scale. Similarly, binary variables were used to indicate whether a respondent would feel comfortable with each health care visit type (ie, in-person visits, outdoor visits, and drive-through clinic visits). Chi-square and Fisher exact tests were used for bivariate analyses involving participants’ age, gender, and race. Analyses were conducted by using SAS (Statistical Analysis System) version 9.4 (SAS Institute), and statistical significance was assessed based on a 2-sided *P* value of <.05. Study findings were reported by using the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Results

Responses were collected from 135 adults participating in biomedical research. Table 1 provides the full sample’s characteristics (see Multimedia Appendix 2 for a correlation table between these variables). The median age of respondents was 48 years, and the sample was predominately female (113/135, 83.7%) and Non-Hispanic White (92/135, 68.2%). Moreover, the sample was highly educated (at least a college degree: 103/135, 76.3%), had generally high incomes (respondents reporting a household income of ≥US $75,000 per year: 77/135, 57.1%), and was well-insured (respondents reporting having private or public health insurance: 127/135, 94.1%).

Table 1. Sample characteristics.

Characteristic	Value
Age (years), median (IQR)	48 (38-57)
Age group (years), n (%)	
18-39	40 (29.6)
40-54	50 (37)
55-64	28 (20.7)
≥65	17 (12.6)
Gender, n (%)	
Women	113 (83.7)
Men	22 (16.3)
Race and ethnicity, n (%)	
Non-Hispanic White	92 (68.2)
Non-Hispanic Black	11 (8.1)
Hispanic	7 (5.2)
Asian	2 (1.5)
Other or multiple races	23 (17)
Education, n (%)	
High school or less	6 (4.4)
Some college	26 (19.3)
College graduate	31 (23)
Some graduate or professional	13 (9.6)
Graduate or professional degree	59 (43.7)
Household income (US $), n (%)	
<25,000	19 (14.1)
25,000-49,999	23 (17)
50,000-74,999	16 (11.9)
75,000-99,999	21 (15.6)
≥100,000	56 (41.5)
Health insurance, n (%)	
Private	92 (68.2)
Public	35 (25.9)
Uninsured	8 (5.9)
Number of underlying conditions, n (%)	
0	98 (72.6)
1	29 (21.5)
≥2	8 (5.9)

Table 2 presents participants' beliefs and willingness to attend research and health care–related clinic visits. Respondents were more likely to indicate that the COVID-19 pandemic positively (vs negatively) impacted their desire to participate in research (65/122, 53.3% vs 49/122, 40.2%; *P*=.04). Moreover, a majority of respondents (77/120, 64.2%) indicated that they did not believe that such participation put them at greater risk of contracting COVID-19. The most preferred methods of engaging in behavioral interventions included videoconferencing (60.7%) and in-person sessions (53.3%). Regarding future research participation, respondents were most interested in engaging in clinical (108/135, 80%) and public health research (85/135, 63%) and were least interested in vaccine development research (59/135, 43.7%).

Table 2. Research participants’ preferences for engaging in research and clinical care during the COVID-19 pandemic.

Questions and responses	Value, n (%)[a]
Research participation	
Do you believe that participating in research puts you more at risk for COVID-19?	
No (not at all)	77 (64.2)
Yes (a little bit to extremely)	43 (35.8)
Has COVID-19 positively affected your desire to participate in research?	
No (not at all)	57 (46.7)
Yes (a little bit to extremely)	65 (53.3)
Has COVID-19 negatively affected your desire to participate in research?	
No (not at all)	73 (59.8)
Yes (a little bit to extremely)	49 (40.2)
What type of research would you be interested in participating in at a future time? (multiple responses allowed)	
Public health (eg, hand washing to prevent flu)	85 (63)
Emergency preparedness (eg, preparing for a natural disaster)	68 (50.4)
Vaccine development (eg, COVID-19 vaccine development)	59 (43.7)
Clinical research (eg, studies that help you improve your own health)	108 (80)
Clinic visit	
Attending in-person clinic visits during the COVID-19 pandemic while adhering to social distancing, sanitation, and mask-wearing protocols	
Not comfortable	34 (26.4)
Somewhat or very comfortable	95 (73.6)
Attending in-person, outdoor clinic visits during the COVID-19 pandemic while adhering to social distancing, sanitation, and mask-wearing protocols	
Not comfortable	18 (14.2)
Somewhat or very comfortable	109 (85.8)
Attending drive-through clinic visits during the COVID-19 pandemic with masks	
Not comfortable	10 (7.8)
Somewhat or very comfortable	118 (92.2)
Attending drive-through clinic visits during the COVID-19 pandemic without masks	
Not comfortable	76 (59.8)
Somewhat or very comfortable	51 (40.2)
At what point would you be willing to go back to in-person clinic visits? (multiple responses allowed)	
When there is a COVID-19 vaccine	41 (30.4)
When there is a medication for effectively treating COVID-19	30 (22.2)
When cases have decreased in my area for 2 weeks or more	23 (17)
When hospitals have the capacity to treat cases	10 (7.4)
I already feel comfortable attending an in-person clinic visit	71 (52.6)
I don’t think I will feel comfortable going to an in-person visit until there are no cases of COVID-19 in the United States	8 (5.9)
What is your preferred way of engaging in treatment if enrolled in behavioral intervention? (multiple responses allowed)	
In person	72 (53.3)
Phone	49 (36.3)
Videoconferencing platforms (eg, Zoom and Google Hangouts)	82 (60.7)
Other platforms (eg, Slack, WeChat, and GroupMe)	33 (24.4)

[a]Sample size is not equal across questions due to missing responses.

Almost three-quarters of respondents (95/129, 73.6%) felt comfortable with attending in-person, indoor clinic visits, and over 85% felt comfortable with attending outdoor (109/127, 85.8%) and drive-through (118/128, 92.2%) clinic visits while adhering to Centers for Disease Control and Prevention (CDC) guidelines (social distancing, sanitation, and mask wearing; Table 2). Although respondents indicated the highest level of comfort with attending drive-through visits while wearing a mask (118/128, 92.2%), fewer respondents were comfortable with attending drive-through visits without masks (51/127, 40.2%). Over half of the respondents (71/135, 52.6%) reported a willingness to attend in-person clinic visits at the time the survey was conducted; one-third (41/135, 30.4%) reported a willingness to attend in-person clinic visits when there is a COVID-19 vaccine, and over 20% (30/135) reported a willingness to attend in-person clinic visits when there is a medication for effectively treating COVID-19. Fewer participants reported considering local or national case counts (23/135, 17% and 8/135, 5.9%, respectively) or hospital capacity for treating COVID-19 cases (10/135, 7.4%) when determining their willingness to attend in-person clinic visits.

There were no significant differences between men and women or between White participants and people of color in terms of responses for any survey items (all P values were >.05); however, younger adults (aged 18-64 years) were significantly more likely to report feeling comfortable with videoconferencing platforms than adults over the age of 65 (78/118, 66.1% vs 4/17, 23.5%; P=.001).

Discussion

Research participants felt that engaging in biomedical research studies did not increase their personal risk of contracting COVID-19 and were interested in future research activities. Interestingly, over half of respondents indicated that the COVID-19 pandemic positively impacted their desire to participate in research (65/122, 53.3%), and fewer indicated that the COVID-19 pandemic had a negative impact (49/122, 40.2%). Although we do not have additional data to explain this finding, it is possible that the greater news coverage of biomedical research during the pandemic has increased individuals' appreciation for this scientific process [11] and increased individuals' interest in participating in research. It also may be possible that some individuals (especially younger adults and those with high incomes [12,13]) have experienced increased scheduling flexibility due to the pandemic (eg, due to cancelled travel and events and restrictions on many leisure-time activities [14]) and thus may have more free time to participate in research.

With the ongoing pandemic, most respondents reported a willingness to attend in-person, health care–related clinic visits while adhering to CDC guidelines (95/129, 73.6%); however, even more were comfortable with outdoor (109/127, 85.8%) and drive-through (118/128, 92.2%) formats. Our results also suggested that the availability of vaccines and effective COVID-19 treatments may improve individuals' willingness to resume attending in-person clinic visits. Overall, videoconferencing was the most preferred format. Videoconferencing offers greater flexibility in scheduling compared to in-person visits, and this format can also retain the visual cues (eg, eye contact and body language) that are lost in phone-based delivery formats [15]. The increased use of smartphones and other mobile devices [16] coupled with advances in mobile internet speeds have made videoconferencing an accessible delivery format for a large proportion of the population, although access to unlimited data packages and poor coverage (eg, in rural areas) still remain substantial barriers for many people [17]. Considerations should also be made regarding the technology literacy of target populations (eg, our results demonstrated that adults over the age of 65 preferred this format less than younger adults).

Taken together with other findings that support the role of telehealth approaches in health care delivery [15], our results suggest that researchers and clinicians should provide opportunities for continuing the conduction of remote-based intervention after the pandemic. As research and health care centers move beyond stopgap telehealth approaches, such opportunities will require the development of sustainable, secure telehealth systems that can link to existing medical record networks, provide access to affiliate providers, and provide critical data security and patient privacy [7].

The limitations to this study included the use of a convenience sample of biomedical research participants that consisted predominately of highly educated White women with health insurance. Although this sample is generally reflective of research populations within the nutrition and obesity intervention fields [18,19], this limited our results' generalizability to other populations. The fact that respondents were already participating in biomedical research may have also resulted in bias, as personal experiences with web-based or in-person research may affect the perceived acceptability of these formats and promote a greater willingness to participate in future research studies. Further, due to the descriptive nature of the analysis, additional studies (including those with larger and more generalizable samples) are necessary to replicate our results and to explore other facilitators and barriers to attending health-related research and clinic visits. Finally, there were no approved vaccines for COVID-19 at the time when the questionnaire was distributed; however, several vaccines have since received approval in the United States [20,21], with distribution starting in early December 2020 [22]. Thus, future studies should assess whether the actual (vs hypothetical) availability of these vaccines affects individuals' willingness to attend research and clinic appointments (especially given the unexpectedly high prevalence of vaccine hesitancy during the initial vaccine rollouts [23]). Despite these limitations, the results from this study provide timely evidence for informing practitioners and researchers about how to reopen and resume research and clinic operations.

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Authors' Contributions

All authors contributed to the study design, development of the questionnaire, drafting of the manuscript, and review of the final manuscript. YRH conducted the data analyses.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey questions used in this study.
[DOCX File , 28 KB - formative_v5i6e27185_app1.docx]

Multimedia Appendix 2
Correlation matrix between the sample's characteristics.
[DOCX File , 19 KB - formative_v5i6e27185_app2.docx]

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Abbreviations

CDC: Centers for Disease Control and Prevention
NHLBI: National Heart, Lung, and Blood Institute
NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases
REDCap: Research Electronic Data Capture
SAS: Statistical Analysis System
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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Original Paper

Potential Impact of a Paper About COVID-19 and Smoking on Twitter Users' Attitudes Toward Smoking: Observational Study

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Abstract

Background: A cross-sectional study (Miyara et al, 2020) conducted by French researchers showed that the rate of current daily smoking was significantly lower in patients with COVID-19 than in the French general population, implying a potentially protective effect of smoking.

Objective: We aimed to examine the dissemination of the Miyara et al study among Twitter users and whether a shift in their attitudes toward smoking occurred after its publication as preprint on April 21, 2020.

Methods: Twitter posts were crawled between April 14 and May 4, 2020, by the Tweepy stream application programming interface, using a COVID-19–related keyword query. After filtering, the final 1929 tweets were classified into three groups: (1) tweets that were not related to the Miyara et al study before it was published, (2) tweets that were not related to Miyara et al study after it was published, and (3) tweets that were related to Miyara et al study after it was published. The attitudes toward smoking, as expressed in the tweets, were compared among the above three groups using multinomial logistic regression models in the statistical analysis software R (The R Foundation).

Results: Temporal analysis showed a peak in the number of tweets discussing the results from the Miyara et al study right after its publication. Multinomial logistic regression models on sentiment scores showed that the proportion of negative attitudes toward smoking in tweets related to the Miyara et al study after it was published (17.07%) was significantly lower than the proportion in tweets that were not related to the Miyara et al study, either before (44/126, 34.9%; *P*<.001) or after the Miyara et al study was published (68/198, 34.3%; *P*<.001).

Conclusions: The public's attitude toward smoking shifted in a positive direction after the Miyara et al study found a lower incidence of COVID-19 cases among daily smokers.

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KEYWORDS

COVID-19; smoking; Twitter; infodemiology; infodemic; infoveillance; impact; attitude; perception; observational; social media; cross-sectional; dissemination; research

Introduction

Background

COVID-19 is caused by SARS-CoV-2 [1], and given that it is mainly a disease of the respiratory tract, researchers have investigated whether cigarette smokers or vapers are at higher risk of SARS-CoV-2 infection, worse COVID-19 disease severity, worse clinical outcomes, or mortality. Although most literature shows that smoking worsens COVID-19, there is seemingly paradoxical evidence regarding this association. Smoking history appears to increase the risk of severe disease in hospitalized patients, particularly among younger patients without diabetes [2]. An increased risk of mortality has also been shown among current smokers [3]. On the other hand, SARS-CoV-2 binds the angiotensin-converting enzyme 2 (ACE2) receptor. While it is unclear whether smoking increases the level of ACE2 receptor expression in the respiratory tract, nicotine may also compete with SARS-CoV-2 for binding of the nicotinic acetylcholine receptor [4]. The interrelationship among smoking, nicotine, SARS-CoV-2, and COVID-19 is an active and evolving area of research, where new studies emerge regularly.

Researchers in France—Miyara et al—conducted a cross-sectional study on patients infected with COVID-19 in a large French university hospital, which was placed on a preprint server on April 21, 2020 [5]. The results showed that the rate of current daily smokers was significantly lower among outpatients and inpatients with COVID-19 (6.1% and 4.1%, respectively) as compared to that in the French general population after standardization by age and sex [5], which was estimated to be between 22.4% and 26.9% [6]. The authors concluded that their results suggest that active smokers may be protected against symptomatic COVID-19 [5]. However, they did note that health care workers were overrepresented in the outpatient group; patients in intensive care units were excluded; smoking status may have been under- or overreported; smoking status was assessed only in symptomatic patients with COVID-19, even though many infected individuals are asymptomatic; and the association found does not imply causality [5]. Furthermore, the authors of this paper emphasized that nicotine and the nicotinic receptor were of interest and acknowledged the negative consequences of smoking cigarettes [5]. A follow-up report suggested studying nicotine patches as a preventative option against COVID-19 [7]. Despite the limitations being noted in the paper, the title and nature of the main results could mislead the general public, who typically attend to headline findings and not caveats. This study on COVID-19 incidence among smokers was published in Qeios, an open science publishing platform, in May 2020. The article metrics on Qeios demonstrate that the paper was mentioned by one news outlet and mentioned directly by 126 tweets, 8% of which were in the United States, and has a top 5% attention score as measured by Altmetric.

Twitter, a *microblogging* platform [8], can contribute to scientific knowledge dissemination and translation [9]. Throughout the COVID-19 pandemic, Twitter has served as a platform for users to express their opinions, share information, and receive information from others—over 63 million English tweets worldwide used COVID-19–related keywords from January to July 2020 [10]. With the evidence arising from the Miyara et al study regarding the relationship between smoking and the novel coronavirus, conversations on Twitter about the study may provide an interesting case study in the transmission of potentially controversial or contrarian findings.

Objective

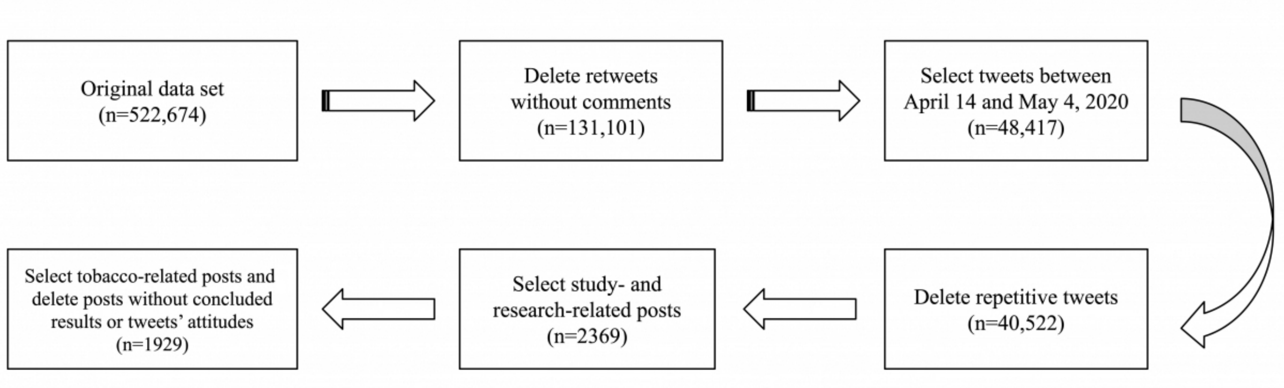
A previous Twitter study on COVID-19 and smoking—the only other Twitter analysis on this topic, to our knowledge—showed that preprints suggesting the benefits of smoking might increase reactions to tweets on tobacco products and the virus [11]. During this pandemic, people may be looking for something they can do to lower their risk. Methods for reducing the spread of the virus, such as using masks and quarantine, and discussion of fear and stress due to the lack of preventative options were found to be popular topics among Twitter users [12]. There is a possibility that those looking for a preventative action against COVID-19 could use the Miyara et al study as a rationale to take up smoking or vaping or to delay quitting. This paper presents a novel view of the change in sentiment toward smoking *before and after a specific paperwas published* suggesting that the incidence of COVID-19 was lower among smokers compared to the general population. In this report, we aim to examine the spread of the Miyara et al study among Twitter users, attitudes toward the study, attitudes toward smoking, and whether there was a shift in sentiment toward smoking and nicotine after April 21, 2020.

Methods

Data Collection and Preprocessing

The related tweets (ie, Twitter posts) posted from April 14 to May 4, 2020, were crawled by the Tweepy stream application programming interface using keyword queries with COVID-19–related keywords, including “CORONA,” “corona,” “COVID19,” “covid19,” “covid,” “coronavirus,” “Coronavirus,” “CoronaVirus,” and “NCOV.” The analysis period was chosen due to the nature of our study objective. Because we were interested in the change in sentiment before and after publication of the paper, we analyzed tweets that were posted immediately before and after the day it was published. Next, retweets without comments were deleted, since simple retweets typically do not explicitly reflect personal opinions; the behavior of retweeting can mean supportive, oppositional, or neutral attitudes toward the original tweet. Repetitive tweets were also removed from the collected data set, as the majority were copied news headlines without personal sentiments. Afterward, research- and tobacco-related tweets were filtered out in sequence using keyword matching: we first filtered research-related tweets using “study” and “research,” then tobacco-related tweets were filtered using “smok,” “cigarette,” “tobacco,” “nicotine,” and “ace2.” Tweets discussing studies without clear findings were removed as those having no impact in shifting people’s opinions. Finally, 1929 tobacco- and research-related tweets remained and discussed, in some way, the effects of smoking on COVID-19 infections and symptom development. Figure 1 shows the data preprocessing procedures for obtaining our final data set of 1929 tweets.

Figure 1. Data set preparation procedures.



Sentiment Analysis

Three categories were used to categorize each tweet: (1) whether it was about the Miyara et al study (yes or no), (2) the article's attitude toward smoking (positive, negative, or neutral), and (3) the user's attitude toward smoking as expressed in the tweet (positive, negative, or neutral). For the first category, whether or not each tweet was related to the published Miyara et al study was manually coded for all the selected tweets. For the second category, the article's attitude toward smoking as discussed in the tweet was manually coded as positive, neutral, or negative. For example, if the tweet discussed an article that found smokers were at more risk for COVID-19, it was considered negative. For the third category, each tweet was manually coded as positive, neutral, or negative based on the user's attitude toward smoking. For example, if the user said, "smoking is bad for you," the tweet was categorized as negative. The term *smoking* referred to in this category was not necessarily used in regard to cigarettes and could refer to the use of other tobacco products as well.

Two coders from the study team coded each tweet separately and disagreements were discussed among team members to achieve final agreements. High agreements were achieved between the two independent coders on coding the 1931 selected tweets into different categories. The Cohen κ value was 0.92 (95% CI 0.90-0.94) for categorizing whether the tweet discussed the French study. Regarding the article's attitude toward smoking, the Cohen κ was 0.93 (95% CI 0.92-0.95) for categorizing the attitude into positive, neutral, and negative groups, indicating very high agreement. The Cohen κ was also very high when categorizing the tweet's attitude toward smoking into positive, neutral, and negative groups, with almost perfect agreement (κ=0.86, 95% CI 0.85-0.88).

Statistical Analysis

According to whether the tweet was related to the Miyara et al study and whether the tweet was posted before or after the publication date of the Miyara et al study (ie, April 21, 2020), all selected tweets were classified into three groups: (1) tweets not related to the Miyara et al study before publication, (2) tweets not related to the Miyara et al study after publication, and (3) tweets related to the Miyara et al study after publication. The tweets' attitudes toward smoking and the articles' attitudes toward smoking were compared among the above three groups using multinomial logistic regression models through the *multinom* function in the *nnet* package in the statistical analysis software R, version 4.0.5 (The R Foundation). The significance level of all two-sided tests was set at 5%. The follower counts of posters within groups related and not related to the Miyara et al study were analyzed to reveal the impacts of when tweets were posted by these accounts.

Topic Analysis

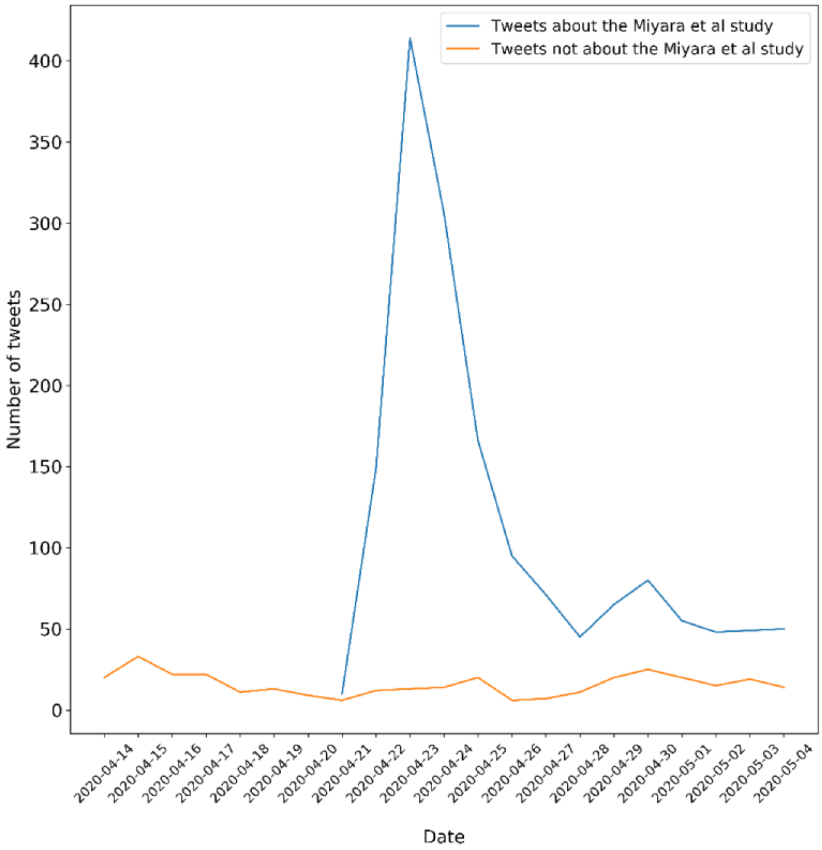
In order to capture certain themes that were prevalent within the tweets, the two members of the study team that hand-coded the tweets also created topics based on the content they read. The tweets were separated into two basic categories to allow for a more efficient comparison of themes: tweets that were not about the Miyara et al study and tweets that were about the Miyara et al study. Different focuses were adopted during the theme-capturing process, considering the fact that people react differently within these two groups. Specifically, themes from tweets about the Miyara et al study were mainly people's attitudes toward the research itself or speculations about unseen driving forces. Contrary to a comparably narrow but concentrated scope, tweets that were not related to the Miyara et al study discussed diverse aspects of the field. For example, users showed sentiments beyond attitudes toward smoking, such as generally distrusting research, stating reasons to support their stances, and requesting information for truth finding. Such diversity has also been observed through various research directions that analyzed smokers' risks of COVID-19 infections, which include but are not limited to the analysis of existing health conditions and harmful life habits. To obtain a comprehensive understanding of these themes, which are not necessarily correlated with each other, multiple groups are, thus, needed for illustrations. As shown in the Results section below (Tweets Related to the Miyara et al Study subsection), groups defined as *stances on smoking*, *other sentiments*, and *research focus on association between smoking and COVID-19* are used to reflect the uniqueness of sentiments. Based on the themes that were notably expressed most in the tweets, topics were created for each of the two categories: tweets that were not about the study and tweets that were about the study. The topics for both tweets that were about and that were not about the Miyara et al study were chosen by the manual coders, who noted recurring themes throughout the hand-coding process. Each tweet was then categorized under one of the topics or put under the category *miscellaneous* (ie, unsorted). For each topic, tweets were chosen as a representative example of other tweets within that topic.

Results

Temporal Analysis

The temporal analysis of the Miyara et al study was done by compiling the hand-coding results after the sentiment analysis. A clear comparison between numbers of tweets that were about the Miyara et al study versus those that were not about the Miyara et al study can be drawn from Figure 2. As shown, tweets that were not related to the Miyara et al study remained relatively steady through the study period. In contrast, tweets related to the Miyara et al study sharply increased beginning on April 22, 2020, the day after publication, with a spreading peak observed between April 23 and 24, 2020, when discussion appeared to be most intense. Throughout the whole period until May 4, 2020, the number of tweets related to the Miyara et al study surpassed all other tobacco- and COVID-19–related tweets, confirming its prevalence on Twitter.

Figure 2. Temporal analysis of the Miyara et al (2020) study’s influence.



Sentiment Analysis

Figure 3 shows the classification of the final 1929 tweets in different categories (Cohen κ ranged from 0.86 to 0.93). Among the 1929 selected tweets that cited articles with either positive or negative attitudes toward smoking, 324 tweets (16.80%) were not related to the Miyara et al study, while 1605 tweets (83.20%) were related to the Miyara et al study.

Figure 4 shows the proportions of negative, neutral, and positive tweets regarding their attitudes toward smoking in the three different tweet groups. In tweets not related to the Miyara et al study before April 21, 2020, 17 out of 126 tweets (13.5%) showed positive attitudes, 65 out of 126 tweets (51.6%) showed neutral attitudes, and 44 out of 126 tweets (34.9%) showed negative attitudes toward smoking. In tweets not related to the Miyara et al study after April 21, 2020, 26 out of 198 tweets (13.1%) showed positive attitudes, 104 out of 198 tweets (52.5%) showed neutral attitudes, and 68 out of 198 tweets (34.3%) showed negative attitudes toward smoking. In tweets related to the Miyara et al study, 311 out of 1605 tweets (19.38%) showed positive attitudes, 1020 out of 1605 tweets (63.55%) showed neutral attitudes, and 274 out of 1605 tweets (17.07%) showed negative attitudes toward smoking. Multinomial logistic regressions were conducted to compare the differences in proportions of positive and negative attitudes toward smoking across the three different groups. The proportion of tweets showing a negative attitude toward smoking that were not related to the Miyara et al study was significantly higher ($P<.001$) than the proportion of tweets showing a negative attitude toward smoking that were related to the Miyara et al study ($P<.001$). Meanwhile, the proportion of tweets showing a positive attitude toward smoking that were not related to the Miyara et al study was significantly lower ($P<.001$) than the proportion of tweets showing a negative attitude toward smoking that were related to the Miyara et al study ($P<.001$).

Figure 3. Final tweet classification into different categories.

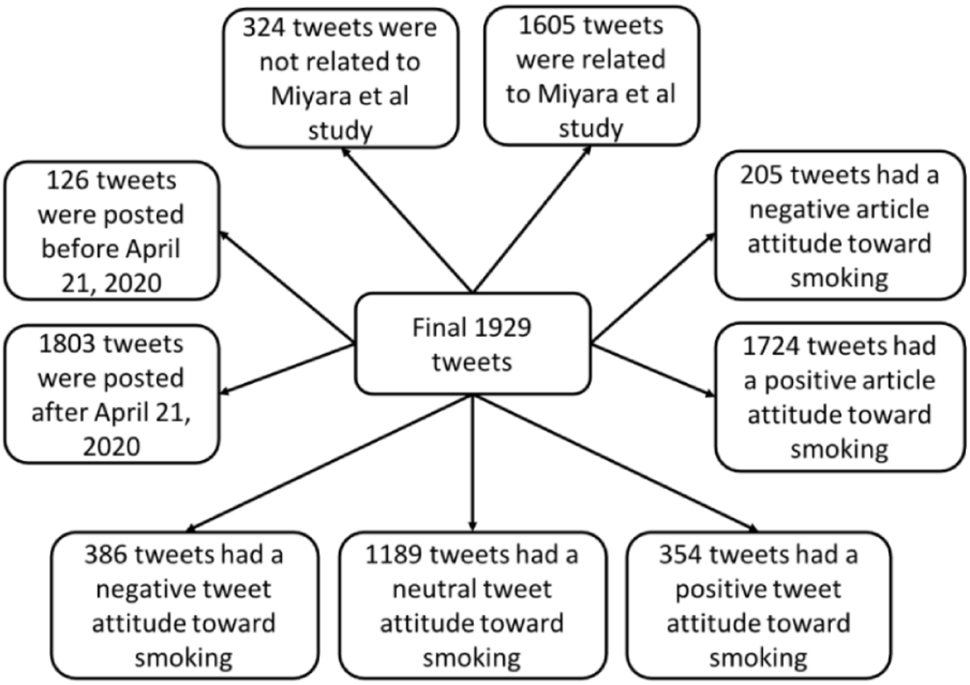
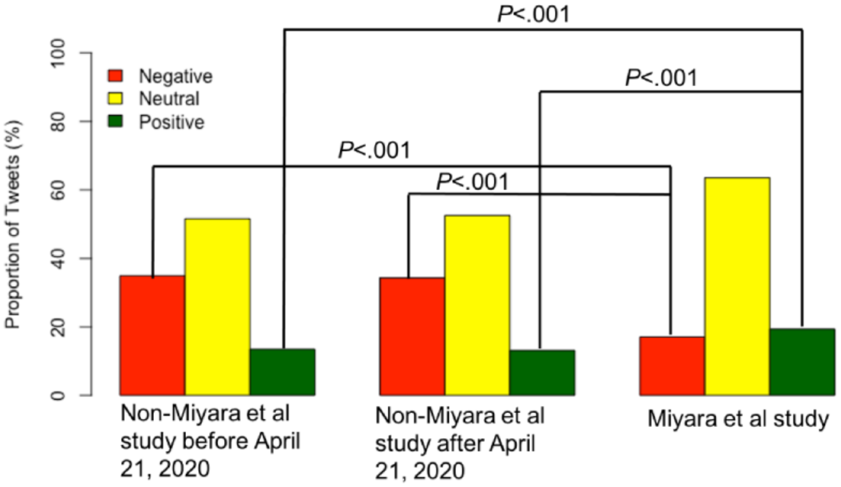


Figure 4. Proportion of negative, neutral, and positive tweets regarding their attitudes toward smoking in three different tweet groups: (1) tweets not related to the Miyara et al study (Non-Miyara et al) before April 21, 2020; (2) tweets not related to the Miyara et al study (Non-Miyara et al) after April 21, 2020; and (3) tweets related to the Miyara et al study. *P* values were obtained from the pairwise comparisons within the multinomial logistic regression model framework.



Topic Analysis

Tweets That Were Not Related to the Miyara et al Study

For the 324 tweets that were not related to the Miyara et al study, 126 (38.9%) tweets were posted before April 21, 2020, and 198 tweets (61.1%) were posted on April 21 or after April 21, 2020. The 324 tweets were categorized into three groups of perspectives to analyze users' opinions, various sentiments, and the research focus of the studies mentioned: *stance on smoking*, *other sentiments*, and *research focus on association between smoking and COVID-19*, respectively (Table 1). To better capture topic details, many posts were coded into more than one category. After comparison, similar weight distributions were seen between the two periods—before and after April 21, 2020—within the group *stance on smoking*, with the majority of tweets falling into the category *stating the finding*, followed by those within the categories *discourage tobacco* and *encourage tobacco*. Significant changes were found between the two periods in the weights within the categories *more info requested* (P=.006), *advocating quitting smoking* (P=.01), and *health conditions* (diabetes, asthma, etc) (P<.001) using the two-proportion Z test. With weight decreases of 6.99%, 6.80%, and 12.79%, their two-proportion Z test scores were 2.75, 2.47, and 4.56, respectively, which shows that there were statistical differences with a 5% confidence interval with respect to these three categories between the two periods. For other categories, no clear change was observed. Table 1 shows a breakdown of categories with two example tweets provided for each topic.

Table 1. Topic categories for tweets not related to the Miyara et al study.

Group and topics	Tweets before April 21, 2020 (n=126), n (%)	Tweets after April 21, 2020 (n=198), n (%)	Example tweets[a]
Stance on smoking			
Stating the finding	58 (46.0)	97 (49.0)	“shocking result smokers are far less likely to be hospitalized with coronavirus than non smokers” “smoking is associated with doubling of covid 19 progression risk center for tobacco control research and education”
Discourage tobacco	39 (31.0)	67 (33.8)	“this study is simple and others published since have made it pretty clear smokers die more from covid than nonsmokers” “this suggests that there has never been a better time to quit smoking to protect yourself from covid 19 study shows an incredibly high correlation between serious covid symptoms and habitual smoking”
Encourage tobacco	13 (10.3)	23 (11.6)	“bibber indepth if you split current and former smokers current smokers will end up with a lower risk for hospitalization than or 0 7 and former smokers with a higher or there is no misleading this is a well done study of 4 103 corona patients in a nyc health system” “nicotin from tobacco can cure covid19 clinical trials are on in australia tobacco nicotin used as last remedy cure in medical science tobacco is best medicine for neurological disorder do some research goi is right”
Other sentiments			
Advocate quitting smoking	13 (10.3)	7 (3.5）	“a new study shows that cigarettes can help the coronavirus enter lung cells meaning it’s time to stop smoking” “correct in fact most research on vaping and respiratory health shows that smokers who quit by switching to vaping experience better lung function reduced pneumonia risk and less severe asthma and emphysema”
More info requested	12 (9.5)	5 (2.5)	“are there any official recording of those who smoke are more likely to suffer from covid19” “love your show do you have any more info about the study that said smokers are less likely to die from coronavirus thank you”
Debate with others	4 (3.2)	5 (2.5)	“kwaza really please reference one scientific study that proves that smoking decreases your chance of surviving a covid19 infection specifically a study by the cdc found that just over 1 of those who died from a covid19 infection were smokers and just over 2 were previous smokers” “ok this isn t being reported enough you are at risk of covid if you are obese have asthma and smoke on a regular basis it is your responsibility to do your own research and act accordingly you can literally get rid of these conditions in weeks if you act now”
General distrust in research	3 (2.4)	5 (2.5)	“such a musical chair this research on covid19 has become smokers will be at higher risk then smokers have a better chance of surviving this is when you shut it all off fda says smokers may have higher risk of catching covid 19” “those researchers based their recommendation against smoking on general attributes of the virus eg covid attacks the respiratory system it doesn t appear they consulted the covid specific data at all before issuing their advisory”
Research focus on association between smoking and COVID-19			
Smoking itself	97 (77.0)	185 (90.9)	“smoking does not increase covid 19 susceptibility” “smoking protects against covid 19 symptoms says new research hiptoro interesting given the need for oxygen uptake of covid 19 victims”
Health conditions	18 (14.3)	3 (1.5)	“only half of urban and rural pakistanis are aware of the fact that diabetics smokers and asthmatics are at a higher risk of falling severely ill from covid 19 study by aga khan university aku coronavirus” “it looks like the best chance to survive coronavirus is to be an overweight smoker according to the latest research justsaying”

Group and topics	Tweets before April 21, 2020 (n=126), n (%)	Tweets after April 21, 2020 (n=198), n (%)	Example tweets[a]
ACE2[b] related	11 (8.7)	12 (5.6)	“icilondres one theory is that nicotin blocks ace2 receptors the backdoor to the lungs for covid19 however research needs to be done before we all reach out to our patches” “some researchers suspect that nicotine binds to ace2 as well and that this makes i via”

[a] During preprocessing and before hand-coding, punctuation and capitalization were removed from the tweets to facilitate content analysis.

[b] ACE2: angiotensin-converting enzyme 2.

Tweets Related to the Miyara et al Study

While manually coding the 1605 tweets about the Miyara et al study, certain common themes arose: encouraging tobacco use, expressing feelings of surprise about the findings of the Miyara et al study, stating the main finding of the Miyara et al study, discussing the follow-up nicotine patch study, highlighting the negative consequences of tobacco use, and questioning whether or not the Miyara et al study was funded by the tobacco industry. Table 2 shows a breakdown of these categorized tweets along with two example tweets per topic. There is a possibility of topic overlap of these tweets that has not been accounted for here. From the table, we can see that the most common theme was tweets that stated the main finding of the study (40.06%). Following the *stating the finding* topic, the next most prevalent topic was the *nicotine patch follow-up study* (30.97%).

Table 2. Topic categories for tweets related to the Miyara et al study.

Group and topics	Tweets (n=1605), n (%)	Example tweets[a]
Stance on smoking		
Encouraging tobacco use	51 (3.18)	“that's hilarious so nicotine is actually good for something lol smoke em if you got em lol study finds smoking reduces chance of getting coronavirus symptoms” “you may have quit smoking too soon a study shows that nicotine addiction may play a protective role against contracting covid 19”
Stating the finding	643 (40.06)	“a cross sectional study strongly suggests that those who smoke every day are much less likely to develop a symptomatic or severe infection with covid 19 compared with the general population” “french researchers reveal that smokers are less likely to get covid 19”
Other sentiments		
Shocked or surprised	28 (1.74)	“shocking study supports smoking as preventive measure against covid19” “in surprising results and a warning from smoking a Miyara et al. study finds that nicotine may help to fight corona”
Tobacco consequences highlighted	24 (1.50)	“french research suggests nicotine could protect against covid 19 but smoking remains biggest killer in france 75 000 people die every year from smoking related complications” “france finds smoking may help you resist covid 19 if you don t mind dying of something else in a reversal of prevailing covid 19 wisdom a Miyara et al. study appears to show smokers are less at risk from virus affirming results of an earlier chinese study”
Tobacco industry funded	34 (2.12)	“this is insane to even suggest using substance such nicotine less likely to catch coronavirus is it tobacco companies is paying for this study” “this is based on data analysis not a controlled study and i m deeply suspicious of possible big tobacco influence but as a 63 yr old still hooked on nicotine mints i m hoping hard”
Research focus in the future: nicotine patch study	497 (30.97)	“french researchers to test nicotine patches on coronavirus patients” “the study at a major paris hospital suggests a substance in tobacco possibly nicotine may be stopping patients who smoke from catching covid 19 clinical trials of nicotine patches are awaiting the approval of the country's health authorities”
Unsorted: miscellaneous	328 (20.44)	“treat this research with caution it was my solid understanding that this virus affects smokers far worse than a non smoker as the lungs are already compromised from damage by smoking” “not gonna read this as i m not a smoker but all i can say is of course it s a Miyara et al. study”

[a] During preprocessing and before hand-coding, punctuation and capitalization were removed from the tweets to facilitate content analysis.

Tweet Topics Related to Versus Not Related to the Miyara et al Study

By topic comparison, both similarities and differences were seen. Regarding consistency, topics found within tweets related to the Miyara et al study and those found in tweets not related to the study showed that the majority simply stated the finding of the study; 643 out of 1605 (40.06%) tweets related to the Miyara et al study belonged to this category, compared to 155 out of 324 (47.8%) tweets not related to the study. However, while both groups contained tweets that held negative attitudes toward smoking, tweets related to the Miyara et al study discouraged tobacco use in a more comprehensive way. For example, within the 1605 tweets related to the Miyara et al study, 24 (1.50%) highlighted the risks of tobacco use and 34 (2.12%) speculated whether the study was funded by the tobacco industry. Within the 198 tweets that were not related to the study, 67 (33.8%) discouraged tobacco use, while 23 (11.6%) encouraged tobacco use. Furthermore, there were tweets that demonstrated doubts regarding the potential benefits of smoking, but many did not absolutely reject such possibilities. This suggests that users may have been open to exploring whether there was a positive effect of smoking on COVID-19 but that they proceeded with caution. Before the publication of the Miyara et al study, such rejections were frequently observed, which indicates that most users shared a neutral or more negative opinion of smoking's influence on COVID-19 and suggests that users may have begun to think more critically about smoking's impact on the novel coronavirus after the Miyara et al study was published. The distributions of the number of followers of Twitter users who posted either tweets related to the Miyara et al study or tweets not related to the study were both highly skewed to the left. The median number of followers of Twitter users who posted tweets related to the Miyara et al study was 585 (IQR 3407). The median number of followers of Twitter users who posted tweets that were not related to the study was 630 (IQR 2681). The number of followers of Twitter users indicated the bandwidth of outreach of those posted tweets.

Discussion

Principal Findings

This report presents novel findings observing a shift in attitudes toward smoking among Twitter users after publication of a Miyara et al study that reported lower rates of daily smoking among COVID-19 cases. The relatively large number of median followers of Twitter users who posted tweets related to the Miyara et al study indicated that the results of the Miyara et al study were widely disseminated. Overall, the findings suggest that this study was successfully disseminated and appears to have led to more positive attitudes toward smoking among our population. Every post that stated the main finding of the Miyara et al study, which was considered a neutral sentiment, can be looked at as an instance of spread of information from one user to other users, leading to even greater spread of the study. When comparing tweet sentiments before and after April 21, 2020, there was a significantly more positive attitude toward smoking among all tweets.

The largest percentage of tweets, from before and after April 21, 2020, and that were about the Miyara et al study, had a neutral sentiment toward smoking, including mentions of wanting more information and a sense of uncertainty regarding the study's findings. The most prevalent tweets stated the main finding of the study and/or mentioned the nicotine patch follow-up study. The main findings of the articles tweeted about in this sample—those that were not about the Miyara et al study—reflected both the benefits and risks of smoking on COVID-19 [13,14]. People's opinions of smoking varied a lot throughout the periods, encouraging or discouraging nicotine use. Among different studies, the up- or down-regulation effects of ACE2 receptor proteins, to which viruses bind, were frequently discussed to explain smoking's impact on COVID-19 [14,15]. The similar distributions of the number of followers of Twitter users who posted tweets that were either related to or not related to the Miyara et al study indicated similar bandwidths of outreach of those posted tweets.

Nevertheless, differences in people's opinions and study focuses were observed in some ways. Even among posts not directly discussing the Miyara et al study, there was still a shift to a more positive attitude toward smoking after its publication. Not necessarily shifting all others' attitudes toward smoking from negative to positive, the release of Miyara et al study did at least waver the stances of those who opposed smoking, confirming its positive impact. This speculation was supported by a 6.82% weight decrease of tweets that were not related to Miyara et al study that advocated quitting smoking. To conclude, a different reaction pattern was seen between tweets within French and non-French groups. Beyond the study's influence of changing people's attitudes toward smoking, it also informs a critical thinking mindset behind how people observe the effects of smoking. For example, while people's stances varied regarding the effect of smoking on COVID-19, more tweets (10.3%) were observed that called on people to quit smoking before April 21, 2020, compared to after (3.5%). This decrease was perhaps due to the impact of the Miyara et al study, which highlighted a potential benefit of smoking.

Significant changes were also seen regarding how people analyzed the impacts of smoking on COVID-19. Before April 21, 2020, many tweets (14.3%) discussed the increased risks of infection if smokers had existing health conditions, such as diabetes and asthma [16]. Some tweets cited articles that stated former smokers would be at higher risks of infection compared to current smokers [17]. These mixed perspectives did not analyze the direct impact of smoking and reiterated the combined effects of existing health issues and smoking on COVID-19 infection. The findings of these articles reflect the uncertainty of research directions about smoking itself, which was expressed in the tweets that were not related to the Miyara et al study. However, the publication of the Miyara et al study could have led to less uncertainty about the impact of smoking on COVID-19 after April 21, 2020, with only 1.5% of tweets discussing the influence of smokers' health conditions on infection, compared to 14.3% before.

Strengths

Twitter is a valuable tool used in health research and can be used to analyze up-to-date data about a specific topic while it is at its peak discussion point [18]. Another study examining Twitter sentiments on smoking and COVID-19 found that the sentiment of tweets was generally negative but became less negative in April 2020, which is when the Miyara et al study was released [11]. We observed a shift toward positive sentiments revolving around smoking among posts discussing the Miyara et al study after April 21, 2020, compared to posts before the publication. Overall, this study presents a useful example of the impact of the dissemination of a particular contrarian study and how it can shift the field of discussion on a topic. That is, one particular finding can color a conversation.

Limitations

Although the results met our original expectations of the impact of the Miyara et al study on people's opinion changes, several limitations of our analysis can be found. Firstly, some posts might be missing, since keywords were used to filter out tweets before hand-coding. The potential problems of this are whether or not all posts about our topic contained the chosen keywords. For example, the keywords "study" and "research" were used to filter out research-related posts; however, users might use words like "result" and "report," among other words, to reflect a research finding. In our case, "result" and "report" would bring in a lot of off-topic tweets; thus, those were not included in the keyword list. Nevertheless, an alternative analysis could consider adding those tweets and starting the filtering process afterward. Similar problems might be relevant if some users comment on a research result without referring to the subject, in which case users' sentiments would still be related to our analysis but would be ignored. Secondly, we analyzed tweets written only in English and missed tweets in other languages, which might bias the study results. However, analyzing tweets written only in English could avoid misinterpreting translations. Thirdly, we did not collect and analyze the numbers of likes and retweets of the original posts, which could also help to analyze the impact of those tweets. Furthermore, although intercoder variances were small enough to make the results valid, hand-coding is a subjective method, implying potential cognitive differences in coding. Tweets were posted globally, which suggests that tones from distinct regions might imply different meanings (eg, sarcasm). Though hard to eliminate, such limitations could be alleviated by incorporating more coders with diverse backgrounds. Lastly, it is possible that smokers tended to tweet more about smoking-related studies. They may even have had positive attitudes toward smoking before seeing any studies demonstrating smoking's beneficial effects. To address that, studies quantifying such likelihood may be needed and should be taken into consideration during analysis to more precisely observe the impact of the Miyara et al study.

Implications and Future Directions

Note that this paper is not a criticism of the Miyara et al study's authors or their research—our focus here is on using that paper and its findings as a jumping-off point for exploring how a particular study is disseminated on Twitter, and how that information may influence the sentiment of tweets moving forward. Information-based communication strategies can be used to modify people's attitudes by providing evidence for or against an idea. Previous literature has described the impact of research and research dissemination as affecting knowledge, attitudes, and behavior with respect to health risks [19]. Our findings suggest that among Twitter users discussing tobacco research, a substantial number of posts were related to the Miyara et al study on COVID-19 and smoking for several days after its publication on April 21, 2020. There was a significant increase in the number of tweets with a positive sentiment toward smoking, both when comparing tweets posted before and after the Miyara et al study publication date and when comparing tweets related to and not related to the Miyara et al study, after April 21, 2020. Therefore, the results of the Miyara et al study could have contributed to a positive shift in attitude toward smoking among some Twitter users. We understand the number of tweets used in the analysis might be only 1% of the total number of tweets related to the Miyara et al study on COVID-19. However, given the assumption that the tweets obtained from free Twitter streaming could be treated as a random sample from all tweets related to the Miyara et al study on COVID-19, the statistical significance of a positive shift in attitude toward smoking is valid. Given the negative consequences of tobacco use, it is imperative to disseminate accurate messaging and concise evidence and recommendations regarding the relationship between COVID-19 and nicotine to prevent initiation of tobacco product use and encourage cessation. Given the dissemination of the Miyara et al study's results and the confusion expressed by users, there is a need for further research on the true effects of nicotine and the novel coronavirus. The World Health Organization has since published a scientific brief stating that "smoking is associated with increased severity of disease and death in hospitalized COVID-19 patients" and that "there is no evidence to quantify the risk to smokers of hospitalization with COVID-19 or of infection by SARS-CoV-2" [20]. Twitter can serve as a useful resource to monitor the spread of, and reactions to, tobacco research to identify potentially problematic public interpretations or misrepresentations of findings.

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Authors' Contributions

ZX, DL, and ROC conceived and designed the study. ZX, CT, and LC extracted and preprocessed the data. CT, DD, and DL analyzed the data. CT, DD, ZX, LC, DL, and ROC wrote the manuscript, assisted with interpretation of the analyses and results, and edited the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ACE2: angiotensin-converting enzyme 2
FDA: US Food and Drug Administration
NIH: National Institutes of Health

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Original Paper

Teleconsultation in the Management of Elective Orthopedic and Spinal Conditions During the COVID-19 Pandemic: Prospective Cohort Study of Patient Experiences

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Abstract

Background: The global adoption of teleconsultation has been expedited as a result of the COVID-19 pandemic. By allowing remote communication, teleconsultation may help limit the spread of the virus while maintaining the crucial patient-provider relationship.

Objective: The aim of this study is to evaluate the value of teleconsultation compared to in-person visits in the management of elective orthopedic and spinal procedures.

Methods: This was a prospective observational cohort study of 853 patients receiving orthopedic and spinal care at a private outpatient clinic in New Zealand. Patients were randomly divided into two groups: (1) patients receiving telephone consultation remotely, and (2) patients receiving in-person office consultations at the outpatient clinic. All patients received telephone consultations for 4 weeks during the mandated COVID-19 lockdown, followed by 4 weeks of telephone or in-person consultation. Patient preference, satisfaction, and duration of visit were recorded. Comparisons of patient preference between groups, visit type, sex, and location were performed using chi-square tests; similarly, satisfaction scores and visit durations were compared using a general linear model.

Results: We report that 91% (353/388) of patients in the telephone group preferred teleconsultation over in-person office visits during the COVID-19 lockdown (*P*<.001). A combined-group analysis showed that 55.3% (446/807) of all patients preferred teleconsultation compared to 31.2% (252/807) who preferred in-person office visits (*P*<.001). Patients in the telephone group reported significantly higher satisfaction scores (mean 9.95, SD 0.04, 95% CI 9.87-10.03) compared to patients in the in-person group (mean 9.53, SE 0.04, 95% CI 9.45-9.62; *P*<.001). Additionally, in-person consultations were significantly longer in duration compared to telephone consultations, with a mean visit time of 6.70 (SE 0.18) minutes, 95% CI 6.32-7.02, compared to 5.10 (SE 0.17) minutes, 95% CI 4.73-5.42 (*P*<.001).

Conclusions: Patients who use telephone consultations are more likely to prefer it over traditional, in-person visits in the future. This increased preference, coupled with higher patient satisfaction scores and shorter duration of visits, suggests that teleconsultation has a role in orthopedic surgery, which may even extend beyond the COVID-19 pandemic.

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KEYWORDS

telemedicine; patient satisfaction; orthopedic surgery; telehealth; COVID-19; pandemic

Introduction

With the unexpected arrival of COVID-19, there has been a rapid uptake in the use of digital technology in health care, including orthopedic surgery [1,2]. By providing a secure platform for remote communication, teleconsultation permits patients and physicians to stay connected despite strict lockdown restrictions. Such technologies limit virus exposure and preserve limited hospital supplies, while maintaining continuity of care [3]. Teleconsultation can be conducted using either asynchronous or synchronous delivery methods [4]. Most teleconsultation delivery systems use an asynchronous “store and forward” approach in which patient information is electronically delivered to physicians, and responses can be generated later. Synchronous methods that allow for real-time delivery of health care, such as through videoconferencing or telephone interviews, are more favorable as they maintain the patient-provider relationship that may otherwise be compromised in a “store and forward” delivery system [5].

A strong patient-provider relationship enhances patient satisfaction, compliance, and overall health outcomes [6]. In a recent systematic review and meta-analysis, we demonstrated that teleconsultation was equivocal to traditional face-to-face office visits in regard to patient and physician preference and satisfaction [7]. In fact, we found that patients who used teleconsultation were roughly 1.5 times more likely to prefer it for subsequent appointments over traditional office visits, indicating a potential role for such technologies beyond COVID-19.

The purpose of this study is to evaluate patient perceptions of telephone consultations compared to traditional, in-person consultations in the management of elective orthopedic and spinal procedures. We assess patient preference, satisfaction, and duration of consultation, hypothesizing that teleconsultation is comparable to in-person consultation in these regards. Consistent with the literature, we also hypothesize that first-hand exposure to teleconsultation will positively influence a patient’s preference for its use in the future [7].

Methods

Study Protocol

A four-level national lockdown alert system was introduced in New Zealand for the COVID-19 outbreak. From a medical perspective, level 1 permitted normal interactions and consultations. In contrast, level 4 meant no in-person contact for elective care. The level 4 New Zealand national lockdown for COVID-19 was between March 25 and April 27, 2020. Following this, New Zealand moved down alert levels and entered level 1 on June 8, 2020. New Zealand remained at alert level 1 until August 12, 2020.

This was a prospective observational cohort study of 853 patients (10-94 years old) evaluated at a private outpatient clinic in New Zealand for orthopedic and spinal procedures. The first cohort included 364 patients who had teleconsultations during the four weeks of level 4 lockdown (March 25 to April 27, 2020). The comparator group comprised 487 patients who had in-person consultations during the first four weeks of level 1 (June 8 to July 6, 2020). Consultations were conducted by two orthopedic surgeons (DK and MW). All patients were reviewed within five days of referral for new patients and a designated two-week or six-week appointment postoperatively for postoperative patients. Follow-up patients were reviewed either at six weeks or after an investigation was obtained. No change in this schedule occurred between the two groups.

Consultation durations were recorded as phone call duration or time from entry to exit in the consultation room. Patients were contacted, either by telephone or email, by the physician assistant within two weeks of their consultation to rate their satisfaction and preference for either teleconsultation or in-person visit. Evaluations were rated on a scale of 0-10, with 0 being the worst experience and 10 being the best experience possible. Preference was obtained via a 3-item questionnaire (phone, in-person, none) at final follow-up. All patients in the teleconsultation group received in-person follow-up within three months of their teleconsultation to ensure that the diagnosis and management was deemed appropriate by the treating clinician.

Informed patient consent was obtained from each patient. Ethical approval was sought but deemed unnecessary as this was part of a clinic audit.

Outcomes

The primary outcome measures in this study were patient preference, satisfaction, and duration of consultation.

Statistical Analysis

The percentages of participant preference for in-person, phone, or no preference were compared between in-person and phone consults using chi-square tests. Location was categorized into city dwellers (>30 minutes of travel time) and rural dwellers (<30 minutes of travel time). Similarly, comparisons of preferences between sex, consultation type, and location were compared using chi-square tests. The scores assigned to each consultation (0-10) and the durations of the consultations were compared between in-person and telephone consults, sex, consultation type, and location using a general linear model incorporating all factors in a single model for each outcome measure. Least square means derived from these analyses with 95% CIs are used to summarize these analyses. A two-tailed *P* value <.05 is taken to indicate statistical significance and all analyses were undertaken using SPSS (version 25.0; IBM Corp).

Results

Overview

In total, 14 of 364 total patients (3.8%) in the teleconsultation group did not attend their telephone appointment during the four-week level 4 lockdown; these same patients did not respond to the follow-up questionnaire assessing patient preference and satisfaction. Overall, 18 of 487 total patients in the in-person group (3.5%) did not attend their office visit during the first four weeks of the level 1 lockdown, and 32 patients (6.6%) did not respond to the follow-up questionnaire. Therefore, patient preference and satisfaction were reported by 807 patients, with the exception of preference by location; 32 patients reported mixed abode and were excluded from this measure.

There were two cases for which the surgeons felt the telephone consult was inappropriate: two initial consultations of coccydynia, due to the sensitive location of the pain and uncomfortable conversation that would best be delivered in-person. In addition, during the teleconsultations, two patients were incorrectly diagnosed as L5 radiculopathy, which when reviewed in person were clearly greater trochanteric pain syndrome, both cases of which resolved with a trochanteric bursal steroid injection. In addition, two patients in the teleconsultation group showed up in-person and were therefore counted as in-person visits.

Patient Preference

Table 1 shows the overall patient preference for consultation in both the in-person and telephone group during the COVID-19 lockdown. The vast majority of patients in the telephone group (353/388, 91%) preferred teleconsultation over in-person office visits compared to 51.8% (217/419) of patients in the in-person group who preferred in-person office visits. When looking at the combined groups, 55.3% (446/807) of patients preferred teleconsultation over in-person visits compared to 31.2% (252/807) who preferred in-person office visits (*P*<.001). Teleconsultation was preferred over in-person office visits by 87.5% (126/144) of those evaluated postoperatively, as well as 48.5% (200/412) and 47.8% (120/251) of patients receiving checkups and initial consults, respectively (Figure 1). In contrast, those who preferred in-person office visits were mostly evaluated for initial consults (96/251, 38.2%), followed by checkups (142/412, 34.5%) and postoperative visits (14/144, 9.7%). No preference for either teleconsultation or in-person visits was reported in 13.5% (109/807) of total patients.

When analyzed by sex, both males and females reported a stronger preference for teleconsultation over in-person office visits (Figure 2). Out of all the patients evaluated, 54.5% (234/429) of males and 56.1% (212/378) of females chose teleconsultation over in-person visits for future visits (Table S1 in Multimedia Appendix 1; *P*<.001). In fact, roughly 90% of both males and females in the telephone group indicated that they would prefer teleconsultation for subsequent visits.

Table 1. Patient preference for consultation according to visit type.

Visit type	Consult preference			*P* value
	In person	No preference	Phone	
Checkup (n=412), n (%)				<.001
In person	130 (49.1)	70 (26.4)	65 (24.5)	
Phone	12 (8.2)	0 (0)	135 (91.8)	
Total	142 (34.5)	70 (17)	200 (48.5)	
Initial consult (n=251), n (%)				<.001
In person	74 (56.9)	35 (26.9)	21 (16.2)	
Phone	22 (18.2)	0 (0)	99 (81.8)	
Total	96 (38.2)	35 (13.9)	120 (47.8)	
Postoperative (n=144), n (%)				<.001
In person	13 (54.2)	4 (16.7)	7 (29.2)	
Phone	1 (0.8)	0 (0)	119 (99.2)	
Total	14 (9.7)	4 (2.8)	126 (87.5)	
Total (n=807), n (%)				<.001
In person	217 (51.8)	109 (26)	93 (22.2)	
Phone	35 (9)	0 (0)	353 (91)	
Total	252 (31.2)	109 (13.5)	446 (55.3)	

Figure 1. Preference for consultation by visit type. CHK: checkup; IC: initial consult; PO: postoperative.

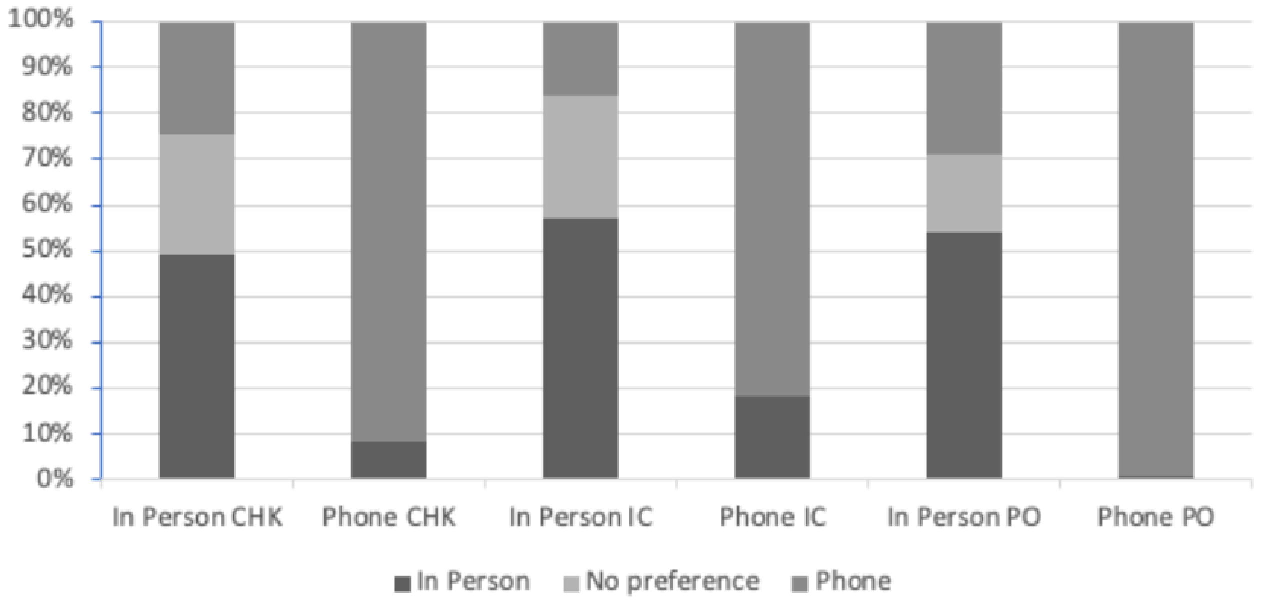
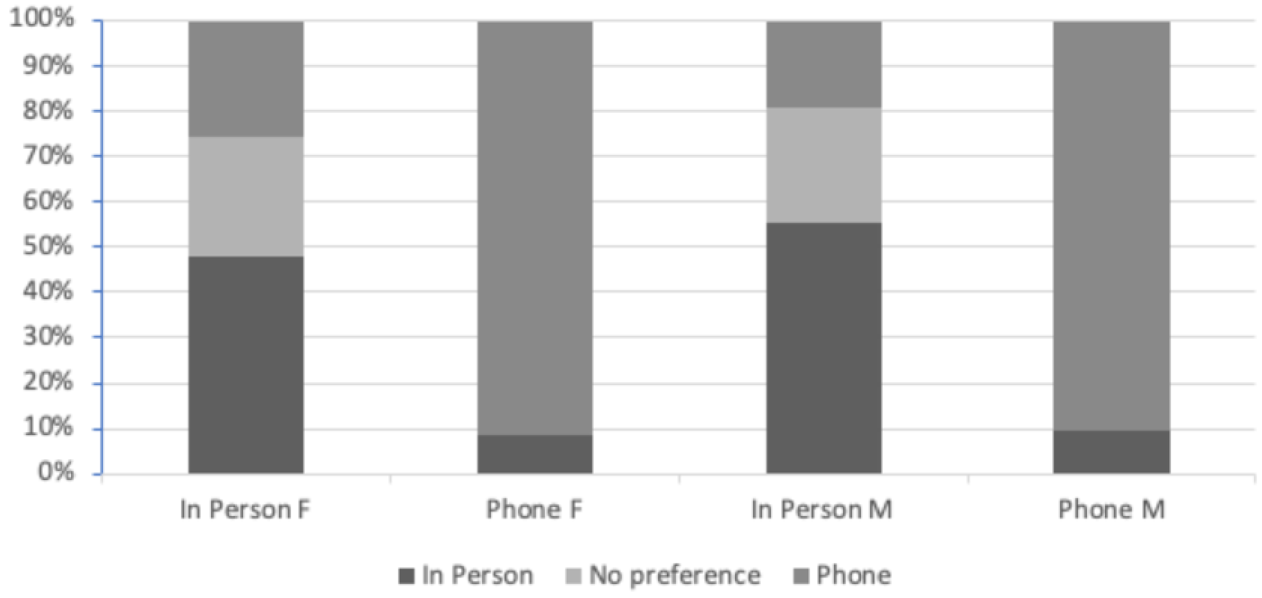
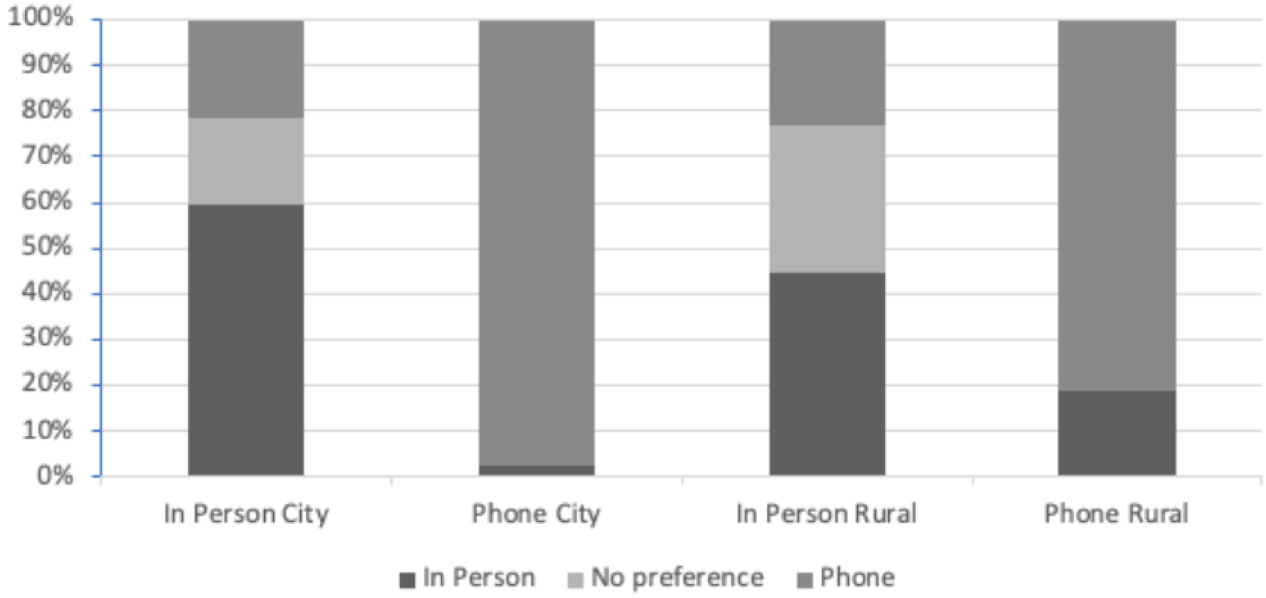


Figure 2. Preference for consultation by sex. M: male; F: female.



When analyzed by location, teleconsultation was preferred over in-person office visits by both city and rural community dwellers (Figure 3). Out of all the patients evaluated, 58.9% (234/397) of patients living in the city preferred teleconsultation compared to 47.6% (180/378) of patients living in a rural community (Table S2 in Multimedia Appendix 1; *P*<.001). A striking 97.4% (191/196) of city dwellers in the telephone group preferred teleconsultation over in-person office visits compared to 81.3% (130/160) of patients living in a rural community.

Figure 3. Preference for consultation by location. City: <30 minutes of travel; rural: >30 minutes of travel.



Patient Satisfaction

Overall, there was a significantly higher satisfaction rating among the telephone group (mean 9.95, SE 0.04, 95% CI 9.87-10.03; *P*<.001) compared to the in-person group (mean 9.53, SD 0.04, 95% CI 9.45-9.62; *P*<.001; Table 2). A significant difference between the different types of visits was observed, with checkup patients reporting the highest satisfaction (mean 9.82, SE 0.04, 95% CI 9.74-9.89), followed by postoperative (mean 9.78, SE 0.07, 95% CI 9.65-9.92) and initial consultations (mean 9.62, SE 0.05, 95% CI 9.53-9.72; *P*=.006). No significant difference was detected between groups in regard to sex or location.

Table 2. Patient satisfaction (on a scale from 0-10, with 10 being the most satisfied) according to sex, location, consultation, and visit type.

Variables	Mean (SE)	95% CI	
		Lower bound	Upper bound
Sex			
Female	9.73 (0.04)	9.64	9.81
Male	9.75 (0.04)	9.68	9.83
Location			
City (<30 minutes of travel time)	9.71 (0.04)	9.64	9.79
Rural (>30 minutes of travel time)	9.77 (0.04)	9.68	9.85
Consultation			
In person	9.53 (0.04)	9.45	9.62
Phone	9.95 (0.04)	9.87	10.03
Type			
Checkup	9.82 (0.04)	9.74	9.89
Initial consult	9.62 (0.05)	9.53	9.72
Postoperative	9.78 (0.07)	9.65	9.92

Duration of Consultation

In-person consultations were significantly longer in duration compared to telephone consultations, with a mean visit time of 6.70 (SE 0.18) minutes, 95% CI 6.32-7.02, and 5.10 (SE 0.17) minutes, 95% CI 4.73-5.42, respectively (*P*<.001). Initial consultations took the longest to conduct (8.50 minutes, SE 0.20 minutes, 95% CI 8.067-8.87), followed by checkup (5.0 minutes, SE 0.16 minutes, 95% CI 4.73-5.37) and postoperative visits (4.10 minutes, SE 0.29 minutes, 95% CI 3.54-4.67; *P*<.001). No significant difference in consultation duration was observed in regard to sex or location.

Discussion

We report an increased preference for teleconsultation, greater patient satisfaction, and shorter duration of visits in patients who had telephone consultations during the COVID-19 lockdown. Studies have shown that a strong patient-physician relationship is correlated with greater medical adherence and positive health outcomes [6]. However, the abrupt onset of the COVID-19 pandemic has threatened this fundamental relationship by limiting in-person consultations and impeding communication between patients and physicians. Teleconsultation offers a potential solution by providing a platform through which patients and physicians can establish and maintain communication to better manage elective orthopedic and spinal conditions [2,8]. Despite the advantages of teleconsultation, one of the biggest threats to its implementation is patient satisfaction and willingness to adopt such new technologies [9,10]. Previous studies suggest that patient preference and satisfaction are key indicators of how effective teleconsultation modalities will be in clinical practice [9].

In this study, we compare the patient perception of teleconsultation with that of traditional, in-person consultations in the management of elective orthopedic and spinal procedures during the COVID-19 lockdown. We found that patients receiving telephone consultation had a significantly higher preference for teleconsultation than those receiving in-person visits, regardless of the type of visit (ie, checkup, initial, postoperative). Similarly, patients receiving in-person consultation had a higher preference for in-person consultation, suggesting that familiarity and convenience may play a role in patient preference for consultation type [11]. A closer look at the data reveals the greatest preference for teleconsultation is among patients presenting postoperatively, followed by those undergoing checkup visits and initial consultations, respectively. This is consistent with the literature showing that patients are more likely to prefer teleconsultation for follow-up appointments, as opposed to primary encounters, given the nature of the visits [12]. Initial consultations tend to be more thorough, with the focus being on building rapport between patient and physician [13]. As a result, patients may be more resistant to disclose personal information via telephone if a strong patient-physician relationship has not already been established. This is in contrast to postoperative or checkup visits in which a strong relationship has most likely been achieved at prior visits, making teleconsultation a suitable method of care.

Interestingly, we found that patients living in the city (<30 minutes of travel time) were more likely to prefer teleconsultation compared to patients living in rural communities (>30 minutes of travel time). One might assume that patients living in rural communities would have a stronger preference for teleconsultation given the health disparities typically seen in rural communities [14]. We hypothesize that this is due to the busier lifestyles and greater time demands experienced by city dwellers, thus making remote consultations more desirable.

In terms of patient satisfaction, statistically higher levels were achieved in the telephone consultation group compared to the in-person group, across all visit types. Such findings may be indirectly linked to the significantly shorter duration of visits observed among the teleconsultation group. Not surprisingly, initial consultations took the longest to conduct, followed by checkups and postoperative visits, respectively. Although not assessed in this study, the higher patient satisfaction observed in the teleconsultation group may also be attributed to a reduction in travel time [15], cost reduction [16], and improved access to care [16].

While these results show strong evidence in favor of teleconsultation, this study has a few limitations. First, telephone consultations were performed during a mandated lockdown when people were required to stay at home, without the option for in-person reviews. Therefore, we must consider the impact of the COVID-19 pandemic on patients' preference for teleconsultation. It is possible that patients would have preferred in-person consultation if the pandemic was not a threat. For this reason, a re-review would be prudent outside of the COVID-19 pandemic to reinforce the results of this study. Second, this study was conducted at a single outpatient clinic in New Zealand. Additionally, patient preference and satisfaction ratings were assessed through self-reported measures, with 78 patients lost to follow-up.

Despite such limitations, our results suggest that teleconsultation may have real therapeutic value in the management of orthopedic and spinal conditions. From a patient perspective, teleconsultation does not appear to be inferior to traditional, in-person office visits in terms of preference and overall satisfaction. Although this study was conducted during the mandated COVID-19 lockdown, it should be noted that teleconsultation has been on the rise across health care fields internationally for the past decade. Therefore, our findings further support the use of teleconsultation, even beyond the COVID-19 pandemic.

Authors' Contributions

CM is the corresponding author, performed the data analysis, wrote the original draft, and revised the manuscript. CF performed the formal analysis. MW contributed to data curation, and reviewed and edited the manuscript. DK contributed to conceptualization and data curation.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplementary data.
[DOCX File , 15 KB - formative_v5i6e28140_app1.docx]

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