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Review

Considerations for the Development of Mobile Phone Apps to Support Diabetes Self-Management: Systematic Review

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Abstract

Background: There is increased research interest in the use of mobile phone apps to support diabetes management. However, there are divergent views on what constitute the minimum standards for inclusion in the development of mobile phone apps. Mobile phone apps require an evidence-based approach to development which will consequently impact on their effectiveness. Therefore, comprehensive information on developmental considerations could help designers and researchers to develop innovative and effective patient-centered self-management mobile phone apps for diabetes patients.

Objective: This systematic review examined the developmental considerations adopted in trials that engaged mobile phone applications for diabetes self-management.

Methods: A comprehensive search strategy was implemented across 5 electronic databases; Medline, Scopus, Social Science Citation Index, the Cochrane Central Register of Controlled Trials and Cumulative Index of Nursing and Allied Health Literature (CINALHL) and supplemented by reference list from identified studies. Study quality was evaluated using the Joanna Briggs Critical appraisal checklist for trials. Information on developmental factors (health behavioral theory, functionality, pilot testing, user and clinical expert involvements, data privacy and app security) were assessed across experimental studies using a template developed for the review.

Results: A total of 11 studies (10 randomized controlled trials and 1 quasi-experimental trial) that fitted the inclusion criteria were identified. All the included studies had the functionality of self-monitoring of blood glucose. However, only some of them included functions for data analytics (7/11, 63.6%), education (6/11, 54.5%) and reminder (6/11, 54.5%). There were 5/11(45.5%) studies with significantly improved glycosylated hemoglobin in the intervention groups where educational functionality was present in the apps used in the 5 trials. Only 1 (1/11, 9.1%) study considered health behavioral theory and user involvement, while 2 (2/11, 18.1%) other studies reported the involvement of clinical experts in the development of their apps. There were 4 (4/11, 36.4%) studies which referred to data security and privacy considerations during their app development while 7 (7/12, 63.6%) studies provided information on pilot testing of apps before use in the full trial. Overall, none of the studies provided information on all developmental factors assessed in the review.

Conclusions: There is a lack of elaborate and detailed information in the literature regarding the factors considered in the development of apps used as interventions for diabetes self-management. Documentation and inclusion of such vital information will foster a transparent and shared decision-making process that will ultimately lead to the development of practical and user-friendly self-management apps that can enhance the quality of life for diabetes patients.

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KEYWORDS

mobile phone apps; diabetes melitus; self-management; developmental consideration; systematic review

Introduction

Background

Mobile apps refer to software installed on smart mobile devices that support medical and public health practices [1]. These apps can deliver health care anywhere, subduing geographical and organizational barriers as well as time constraints [2,3]. Their intended use is for diagnosis, self-management, mitigation, treatment or prevention of diseases such as diabetes [4]. Self-management of blood glucose minimizes the risk and health complications associated with the insidious and chronic nature of diabetes [5,6]. Diabetes self-management includes monitoring of glucose level, lifestyle modifications, medication management, prevention of complications and psychosocial care [7]. As a standard, diabetes self-management education is usually provided during outpatient visits; but it has been advocated that most patients require ongoing support to encourage and sustain behavior at the level that can maintain good health [8,9]. Hence, the necessity for a regularly accessible form of diabetes self-management education and support; which can be achieved with the use of mobile apps.

Although, mobile apps are a field that has continually attracted the interest of researchers and has excellent prospects, both for the improvement of health care and economic interest [10,11], comprehensive information on its developmental considerations seem somewhat limited. Studies have reported gaps in the understanding of formal standards and evidence-based approaches employed in the development and evaluation of the effectiveness of mobile apps [12,13].

Considerations in Mobile Phone App Development

Presently, knowledge about the standard recommended practice for mobile app development for chronic disease management seems divergent and inconclusive. Some studies have reported the benefits of developing mobile apps based on health behavior and communication change theories [14,15]. The main reason for using these theories is to adopt techniques and strategies and help patients embrace healthier lifestyles. Existing models and theories include transtheoretical model [16], social cognitive theory [17], self-determination theory [18], social ecological theory [17] and motivational interviewing [19]. These theories have served as guards in designing mobile app interventions to individuals' baseline characteristics.

Some authors are of the opinion that the development of health care tools for patient groups such as those with diabetes requires an understanding of current challenges and barriers to self-care [20]. This approach serves as an avenue for exploring users' needs at a specific time and envisaging what may evolve with time. This can help in visualizing the use of the app as users' demands change [21,22].

Chomutare et al [23] emphasized in their systematic review that good practice in designing mobile apps requires that inclusion of functionalities be anchored on evidence-based recommendations for the target groups. Furthermore, pilot testing with a target audience and incorporating feedbacks will aid identification of barriers to the usage of mobile apps and enhance the evaluation of its reliability, accuracy, usability, acceptability, and patient adherence [3]. Ensuring the incorporation of evidence-based recommendations and pilot testing into app development for diabetes care will allow for accurate interfaces, interpretations, and evaluation of the effectiveness of the mobile app.

Data privacy and security whereby the users' information is securely managed is another major developmental consideration [3,24]. Emphasising the use of 'privacy by design' approach such as encryption and protocols for anonymous communication and authentication helps to deter unauthorized users from gaining access to patients' medical data [25,26]. Furthermore, it has been recommended that involvement of clinical experts and multidisciplinary health teams should be an integral part of the developmental and testing process of diabetes mobile apps to ensure that medical guidelines and clinical best practices are followed in the management of diabetes [27].

The various views described above can be labeled as shared decision-making approach to the development of mobile app. Diabetes care and support using this approach in which patients, health care providers, and app developers make health care decision together; taking into account specific evidence as well as specific needs and preferences of patients, has been recommended by various studies because it is seen to produce effective health outcomes [28-30]. Such an approach focuses on patient empowerment, ensuring a transition from a state where patients are only seen as the recipients of care to a position where they also have their opinion considered, and they are allowed to make choices, thereby actively contributing to the decision-making process. Given that the organizational structure within the health care sector now recognizes the patients' greater role in their health care, this trend should also result in a shift in the process involved in the development of mobile apps. Patient engagement strategies in app development may not necessarily refer to their involvement in the algorithm design but rather in the incorporation of procedures that meet patients' expectations through the consideration of their experiences, needs, reasons for engagement and satisfaction with the usage of the app.

Mobile apps have been proven to be a useful lifestyle modification tool for providing ongoing individual self-care support for diabetes management and facilitating regular monitoring for improved health outcomes [31-36]. However, previous reviews have focused mainly on assessing the effectiveness of mobile apps to support diabetes self-management [11,33,34,36,37]. A mixture of shared decision-making approaches that include developmental considerations such as health behavioral theories, user and clinical expert involvement, pilot testing and data security are essential to help solve the problems of poor engagement experience and ineffective use of mobile apps [38].

The inclusion of robust, reliable and repeatable system design that involves end users early in the developmental consideration process will enhance ongoing support which is crucial to sustaining progress made by diabetes patients in their self-management [39]. To the best of our knowledge, no other study has collated evidence on the factors taken into consideration in the development of such apps. This evidence will further aid the advancement of evidence-based development and evaluation of mobile apps for effective diabetes management.

This systematic review aims to evaluate the factors taken into consideration in the development of mobile phone-based apps used as self-management interventions in experimental trials of adults with diabetes. Also, the review compares these mobile app developmental factors with their impact on the key clinical outcome variable glycosylated hemoglobin (HbA_{1c}). For this study, the developmental factors considered are categorized into the following: (1) Health behavioural change theory, (2) Function/Functionality (comprising documentation, analytics, reminder, and education), (3) Users involvement, (4) Clinical expert involvement, (5) Data security and privacy consideration, and (6) Pilot testing. These factors were considered based on extensive literature search and ingeminate brainstorming sessions among co-authors, with a focus to provide a guide on factors to consider in the development process of mobile app for diabetes self-management precluding the use of such apps in a full trial.

Methods

This systematic review was conducted following the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement [40]. Assessed developmental considerations are based solely on author reported descriptions directly available in the selected studies or referenced in another published article. For this review, we defined mobile phone apps as apps that are downloadable to mobile phones and take data inputs from users with a focus on improving one or more aspects of diabetes self-management domains.

Data Sources and Search Strategy

Published literature sources were identified by searching Medline, Cumulative Index to Nursing and Allied Health Literature (CINAHL, EBSCOhost), Scopus, Social Science Citation Index and Cochrane Register of Controlled Trials (CENTRAL) databases. In order for search results to have the maximum possible coverage, the combination of the following terms and medical subject headings were used during the search: (‘‘Type 1 diabetes mellitus’’ OR ‘‘Type 2 diabetes mellitus’’ OR diabet* OR IDDM OR NIDDM) AND (‘‘Mobile applications’’ OR , Smartphone* OR ‘‘app’’ OR ‘‘cellular phone’’ OR ‘‘mobile app’’ OR ‘‘portable electronic applications’’ OR ‘‘portable software application’’ OR ‘‘text messages’’). Searches were done between 5th-29thSeptember 2017. Searches were supplemented by manual searching of reference lists of identified studies.

Selection Criteria

Selected studies were any randomized controlled trial (RCT), quasi-experimental study, or pre-post study evaluating the use of mobile apps for self-management in patients (≥ 18 years) with type 1 or 2 diabetes. Studies included were those that used mobile phone-based app intervention which allows real-time interaction between patients and the software. Such interactions include input from the user (which may or may not allow for reinforcement of personalized or general advice), goal setting, data analytics, decision support or reminders to improve diabetes self-management. Strict inclusion criteria were applied to streamline and capture only diabetes interventional studies. Therefore, to ensure review of fully functional apps used as an intervention for diabetes management, only trials that evaluated at least one glycemia index of glycosylated hemoglobin (HbA_{1c}) or blood glucose levels as primary outcome were included. Selected studies were those published in the English language but not restricted to patients of any particular race.

Exclusion criteria included: (1) technological interventions not including mobile phone based app, for example systems which require patients to input data into a Web-based server for review by clinician or researcher, (2) systematic reviews, meta-analyses, conference papers or letters, (3) pre-diabetes, gestational and secondary diabetes, (4) obesity, (5) software solutions mainly for insulin pumps only, (6) studies on mixed populations of adults and children, and (7) studies still ongoing that presented interim results only.

Data Extraction

The titles and abstracts of all identified references were reviewed by the first author (MD). References that did not meet all of the inclusion criteria were excluded. The full-text article of all relevant references was retrieved and assessed. Data were extracted from each selected studies using an electronic form purposely developed for this review. All authors checked the extracted data for consistency. Discrepancies were resolved through discussion.

Quality Assessment

Assessment of study quality was performed by one author (MD) in consultation with a second author (BMA). The quality was evaluated using Joanna Briggs Institute’s pre-designed standardized critical appraisal tools [41]. For the RCTs the following criteria were considered: (1) true randomization of assignments, (2) allocation concealment, (3) blinding of outcome assessors, (4) intention-to-treat analysis, and (5) appropriateness of trial design. Criteria considered for the quasi-experimental trial included (1) clear description of cause and effect, (2) presence of a control group, and (3) pre and post intervention outcome measurements were assessed. For all studies, criteria included (1) details of similarity in baseline characteristics, (2) identical treatment for groups with the exception of intervention of interest, (3) degree and description of follow up, (4) similarities in group outcome measurements, (5) reliability of outcome (primary outcome of HbA_{1c} or blood glucose levels), and (6) suitability of statistical analysis were evaluated. Blinding of participants and personnel were part of the quality criteria in the tools but were omitted and termed non-applicable since the

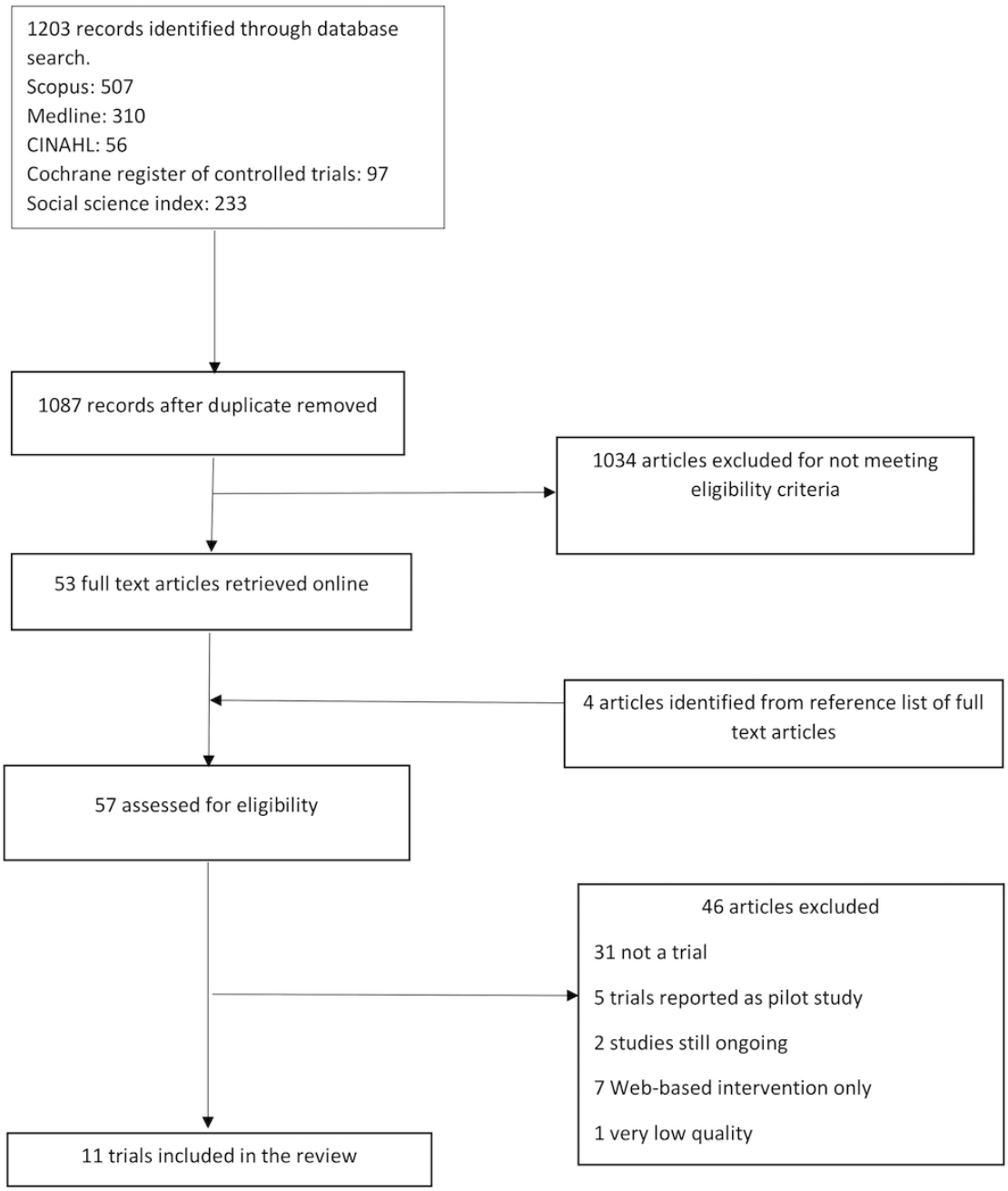
nature of the intervention under study makes it difficult to achieve blinding. All criteria on the tools were scored on a 2 point scale: Yes (1 point) or no or unclear (0 points). When adding all quality criteria, the maximum obtainable scores was 11 for the RCTs and 9 for the quasi-controlled trials. Depending on the number of criteria met by each study, the quality of each study was graded as High (≥7 points), moderate (4-6 points) or low (≤3 points). Disagreement were resolved through discussion among authors.

Results

Selection of Studies

The initial search from the 5 databases identified 1203 articles which included 116 duplicates that were removed. Based on the review of the titles and abstracts, 53 articles were potentially relevant. The full text of these articles was retrieved for further examination, and their references were manually screened to identify articles that were not included in the original search. This process yielded 4 additional articles. After reading the full articles, 12 studies met the set inclusion criteria. The studies by Quinn et al [42,43] reported on the same study population, with different group classifications. The studies by Rossi et al [44,45] engaged the same app but in different study populations. Therefore, 11 RCTs and 1 quasi-experimental study were eventually included. An adapted PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow-chart of study selection is shown in Figure 1.

Figure 1. Flow diagram of the study selection process.



Methodological Quality Assessment

There were 7/12 (58.3%) true randomization trials [44-50], and 2/12 (16.7%)trials had unclear evidence for their randomization method as there was insufficient detail to make a judgment [42,43]. Allocation concealment was documented in only 1/12 (8.3%) study [48].

A total of 7/12 (58.3%) studies reported an intention-to-treat analysis of their data [43-47,50,51]. There was 1/12 (8.3%) study that reported the use of a linear mixed methodology which allowed the inclusion of all randomized participants [48]. A total of 9/12 (75.0%) studies had details of attrition with reasons for drop out balanced across groups [42-46,48-50,52].

All studies had similar and reliable HbA_{1c} measure. All studies, except 1/12 (8.3%) by Istepanian et al [47], were judged to be appropriate in their statistical analyses and trial designs. Overall, 10/12 (83.3%) studies were graded as high quality because they met 7-9 criteria of the grading tool, 1/12 (8.3%) study met 6 of the criteria and was graded as moderate [47], and the last study (1/12, 8.3%) met only 2 quality criteria [53], was graded as poor and removed from the review.

Characteristics of Included Studies

The 11 studies selected evaluated 9 mobile apps and were published between 2009 and 2016. A total of 10/11 (91.1%) studies were RCTs, while 1/11 (9.1%) was a quasi-experimental study [52]. Participant numbers ranged from 54 [50] to 213 [43]. There were 4/11 (36.4%) studies which focused on type 1 diabetes [44-46,48], 6/11 (54.5%) studies were specific to type 2 diabetes while 1/11 (9.1%) study [47] involved both type 1 and 2 diabetes patients. Intervention duration for 8/11 (72.7%) studies ranged from 2 to 10 months, while the remaining 3/11 (27.3%) studies [42,43,51] had their follow up period extended to 1 year. Study locations were from four geographic regions including Europe (6/11, 54.5%), Oceania (1/11, 9.1%), Asia (2/11, 18.2%) and America (2/11, 18.2%).

All studies had major interventions using a mobile app. A total of 2/11 (18.2%) studies had 2 intervention groups [46,51] and another 2 studies had 3 intervention groups [42,43].

HbA_{1c} was the primary outcome measure in all trials. A total of 5/11 (45.4%) studies reported a positive and statistically significant improvement in HbA_{1c} in the intervention group [43,46,48-50]. A total of 5/11 (45.4%) studies had HbA_{1c} reduction in both the intervention and control groups [42,44,45,51,52]. While in 1/11 (9.1%) study, HbA_{1c} remained unchanged between the intervention and control groups [47]. A summary of these characteristics is shown in Multimedia Appendix 1.

Multimedia Appendix 2 and Multimedia Appendix 3 detail the developmental factors considered in each of the reviewed studies and the resulting key clinical outcome (HbA_{1c}).

Health Behavioral Theories

Only 1/11 (9.1%) study [49] reported on health behavioral theories. Specifically, motivation behavioural skills model was used for the formulation of an automated personalised feedback message content of the mobile app.

Functions of Mobile Apps

It was apparent from the review that functions of the mobile apps were diverse. However, documentation for self-monitoring of blood glucose (BG) either manually or through wireless transmission from BG meter was present in all studies. A total of 8/11 (72.2%) studies had mobile apps with capacity for diet management [42-46,48,50,51]. Three studies incorporated blood pressure function in their mobile apps [49,50,52]. There were 7/11 (63.6%) studies which had a physical activity function [44-46,48-51] and 2/11 (18.2%) studies incorporated weight tracking function [49,50]. There were specific functions to log or calculate insulin dosages in mobile apps employed in the 4/11 (36.3%) studies with type 1 diabetes participants [44-46,48]. A total of 2/11 (18.2%) studies reported a general medication log function in their mobile apps [42,43].

With the exception of 4/11 (36.4%) studies, all others (7/11, 63.6%) had capacity for mobile apps to allow patients to analyse logged data. These 4 studies had their logged data transferred to a web/cloud storage and analysed by either the researcher or the health provider [42,43,47,52].

There were 6/11 (54.5%) studies that utilised mobile apps with an educational function. Half 3/6 (50.0%) of the studies provided education as a personalised real-time automated educational feedback specific to logged data [42,43,49], while the other 3 provided a general information page [44,45,51].

A total of 6/11 (54.5%) studies utilized a mobile app with a reminder function [44,45,47,48,50,51].

Users' Involvement

There was only 1/11 (9.1%) study [51] that clearly described users' involvement in the design of its mobile app. It reported an iterative design process involving 12-15 diabetes patients using the approach of focus group meetings, semi-structured interviews, usability testing, questionnaires and paper prototyping. This approach generated the design requirements and answers to research questions [20].

Clinical Expert Involvement

There were 2/11 (18.2%) studies [42,43] which used the same mobile app and engaged the opinions of clinical experts in the field of diabetes during its development and design. The studies reported that the mobile app development involved an Endocrinologist and a Credentialed Diabetes Educator [54].

Data Security and Privacy Consideration

Report on data security and privacy varied among the studies with limited elucidation of information in most cases. In 2/11 (18.2%) studies [42,43] the authors reported a real time capturing of self-monitored blood glucose data into a Health Insurance Portability and Accountability Act-compliant secured Web-based system [54]. In 1/11 (9.1%) study, measured data from participants were transmitted to a server. With each new measurement the patient profile was updated allowing controlled access to patients' data and record history [50]. Transfer of mobile app data into a secured central server was the only information provided by Charpentier et al [46].

Pilot Testing of Mobile Apps

A total of 7/11 (63.6%) studies provided information with regards to pilot testing. Of these, 2/11 (18.2%) [42,43] reported three months test running of the mobile app on 30 patients with type 2 diabetes with the aim of evaluating the impact on HbA_{1c} and satisfaction of patients with the technology [54]. Likewise, 1/11 (9.1%) study [46] reported a 4-month open label observational pilot study on 35 type 1 diabetic patients with the aim of confirming if the use of the mobile app resulted in good control of post prandial blood glucose readings [55]. Only 1/11 (9.1%) study [50] reported a one-month piloting on 11 type 2 diabetes patients to assess usability and impact of the mobile app on HbA_{1c} outcomes and home blood pressure monitoring [56]. In 2/11 (18.1%) studies [44,45], 2 pilot programs were reported through a citation in another article. The first was with the use of a questionnaire to assess the feasibility and acceptability of the mobile app. The second was a 9-months follow up of 41 patients using the mobile app under routine clinical practice condition with the aim of investigating its effectiveness on metabolic control [57]. Lastly, 1/11 (9.1%) study [51] reported a 12 months pilot testing on 12 persons with type 2 diabetes [20].

Discussion

Theoretical Basis

Our review shows that most of the studies did not discuss consideration for health behavior theories in their mobile app development. The lack of report on theoretical basis may be as a result of reliance on evidence-based guidelines that relates to the essential self-care activities in people with diabetes to predict good outcomes [58]. While it is necessary for mobile apps to be guided by health behavioral theories, the current theories appear incapable of answering most of the questions likely to arise when mobile apps are employed as health interventions [14]. Dunton and Atienza [59] reported that current health behavior theories have not been able to incorporate within-person differences which allow for intra-individual tailoring of interventions. Boorsboom et al [60] noted that between people theories do not imply, test or support causal factors valid at the individual level. Therefore, there is a need for more research into intra-individual non-static regulatory models which can be incorporated in the development of mobile technology-based health behavioral interventions.

Functionalities of Mobile Apps

All the 11 trials reviewed in this study included mobile apps with documentation/monitoring component, where self-documentation of blood glucose readings was the most common. Only 3 studies used mobile apps that offer automated direct data transfer of blood glucose values from the glucometer or data from other measuring devices [47,50,51]. This corroborates the report by Demidowich et al [61], where only four of the 42 mobile apps studied offered direct data input from glucometer. Data entry is often perceived as a persistent burden in chronic disease management [39]. Therefore, it is imperative that data entry in mobile apps be as spontaneous as possible, requiring little time and effort to use [62]. Mobile app developers should prospectively consider including an interface between the app and biomarker measuring devices which allow users to automatically log measurements. Such interface may include Bluetooth which enables portable electronic devices to connect and communicate wirelessly [63]. The success of using this interface was demonstrated in the studies by Waki et al [50] and Holmen et al [51].

Data analytics as an app feature was included in only 7/11 (63.3%) studies. A consumer-directed software such as mobile app is better incorporated with functions that enable users to enter, analyze their health parameters and view graph trends and statistics. This can improve the patient's ability to observe the impact of their lifestyle and behavior on health indicators, access trends and even predict health outcome measures [64]. Additionally, decision-making and problem-solving skills of patients can be improved when mobile apps include visualization techniques such as color-coded charts or graphs which indicate when biomarkers, food carbohydrate component and physical activity are out of recommended range [65]. It is essential that analytic functions be dynamic, easily accessible and able to project trends to predict individual improvement in self-care activities which may invariably lead to better health outcomes [66,67].

Despite the emphasis by published guidelines for the need for ongoing patient education [7], very few studies used mobile apps that have education as a functionality. This finding is corroborated by another review where the authors confirmed personalized education as an underrepresented feature in diabetes mobile apps [23]. Patients may have difficulty consulting with their diabetes educators or other health care professionals, due to lack of time, financial constraints, and other limitations. Hence, an app with an educational component can supplement health care provider diabetes education and reinforce information about the importance of self-management and complication prevention. This can serve as an avenue for continual patient empowerment to successfully deal with the disease. However, it is essential that the personalized educational feedback and advice provided in mobile apps are accurate. This is especially true for those that are automatically generated because monitoring mobile apps pose serious harm to the patients if they fail to function as intended [68].

A total of 6/11 (54.5%) studies reported using mobile apps with reminder function either in the form of prompting to measure missed blood glucose readings or alerts for appointments scheduled for the assessment of complication [44,45,47,48,50,51]. They are sometimes referred to as 'push technology'; which enables messages to be delivered without any effort on the part of the recipient [69]. Such reminders can be in the form of text message, alarm, email, automated voice call or image message. Other review has illustrated the benefits of an alarm reminding patients to carry out their health activities [70]. Another study revealed improvement in treatment adherence as patients get fascinated using reminders to handle their health care activities [71].

Users' Involvement

Similar to an earlier review by El-Gayar et al [72] on the adoption of user-centered designed principles in mobile apps,

only one study [51] documented inquiry into users' expectations and perceived needs in the app developmental phase. Users' involvement in design process increases the success rate of computerized system usability [73], as it is essential to understand the reasons for use and user requirements [74,75]. In contrast, a design process lacking the involvement of users in the design loop will fail to recognize the particular odds and problems in the use of the intervention [76]. Design processes can use research tools such as questionnaires, focus group discussions, and personal interviews. These help to seek users' requirements, preferences, understand current challenges and barriers to self-care and subsequently incorporate the findings into the design process. Incorporation of feedback during app design process can help in producing a more user-friendly application and encourage long-term user engagement.

Clinical Expert Involvement

Many of the apps reported in the studies reviewed were designed without the involvement of health care professionals, and this observation is supported by an earlier review [77]. Involvement of health professionals in diabetes mobile app development can assure the quality of health information and support provided by such apps [78]. This is especially important in mobile apps involving advice on insulin dosing. It has to be mentioned that the 3/11 (27.2%) studies in this review which used mobile apps to assist participants in calculating insulin dosage failed to report whether clinical experts were involved in the development of these apps, even though HbA_{1c} levels in the intervention groups were not significantly lower compared to the control groups [44-46]. This finding highlights possible issues with the effectiveness, efficiency, and relevance of these mobile apps to users' health security. Insulin overdose in diabetics can result to severe hypoglycemia and coma while under-dose can cause diabetes ketoacidosis; both can have fatal consequences [79,80]. Participation of health professionals in the development of diabetes mobile apps may decrease the likelihood of such fatal occurrences and protect consumers from incorrect and misleading information. Furthermore, clinical expert involvement in diabetes mobile app development will foster avoidance of legal implications surrounding noncompliance to regulatory and medical standards that relate to digital health services especially those which empower people to track, manage and make decisions about their health [81,82].

Data Security and Privacy

Information on data security and privacy considerations in mobile app development were lacking in many of the trials in this review. Late consideration of privacy and security are app developers' errors that cannot be underestimated. Medical data breaches resulting from failed security attract huge financial implications (such as costs associated with a pecuniary penalty, potential liability claim, lost brand value, responding to lawsuits, negative press statements and essentially loss of patients' and health care providers' trust) for non-compliant organizations [82,83]. Studies have revealed that some users are concerned about the privacy of their personal health information stored on an electronic device [84,85]. Procedures to maintain health data privacy and security to avoid data breaches must, therefore, be considered during mobile app design. Encrypted storage which ensures logged data are protected against malicious attack is a security approach to protecting health data on mobile apps [86]. Furthermore, the privacy of users' information can be ensured through user authentication or enforcement of password requirements [86], and this can protect users' health data in case of mobile phone loss.

Pilot Testing

There were 5/11 (45.5%) studies that failed to report on pilot testing of their apps before use in the trial. A previous study also reported that most health apps do not offer patients ample opportunity for feedback on the level of satisfaction and usability of the product [87]. The importance of pilot testing mobile apps cannot be overemphasized. Apart from serving as an avenue for testing the impact of the app on glycemic control pilot testing can assess its user-friendly capacity and adherence for use as a self-management tool.

Developmental Factors Considered in Mobile Apps and the Key Clinical Outcome (Glycosylated Hemoglobin)

Multimedia Appendix 2 and Multimedia Appendix 3 show an overall evaluation of the developmental factors considered in the design of the mobile apps used in the reviewed studies and the resulting critical clinical outcome (ie, glycosylated hemoglobin, HbA_{1c}). Multimedia Appendix 3 highlighted 5/11 (45.5%) studies that had intervention groups with significantly improved HbA_{1c}. A comparison of these 5 studies showed that educational functionality was present in all. For example, 3/5 (60.0%) studies provided the educational information directly through the mobile app [43,49,50] while 2/5 (40%) provided additional text messaging or teleconsultation [46,48]. It is likely that the similar outcomes observed in these studies were partly due to similitude in the provision of self-management education to participants, as digital tools with decision support features such as education have been proven to have the capacity to enhance self-management outcomes [88]. This finding demonstrates the importance of consistent and ongoing provision of self-management education to people with diabetes. Diabetes education and diabetes management are inseparable because every patient would benefit from education in self-management. Therefore, in addition to other essential functionalities in mobile apps that support diabetes care, the inclusion of education functionality will provide the recommended ongoing support to promote the importance of self-management, build patient skills, increase motivation for self-care and ultimately improve glycemic control [89,90].

Furthermore, 3/5 (60%) studies with significant improvement in HbA_{1c} reported on pilot testing of their mobile apps before use in the full trial [43,46,56]. It is possible that excellent efficacy observed in these studies was due to pilot testing. Among other reasons, an essential aim of pilot testing a technology is to establish its usability. Usability testing of a mobile app examines end users' satisfaction and has been identified as one of the factors that determine its efficacy and success of users' engagement with it. [91].

Implication for Practice and Future Research

Much work is needed to address challenges limiting the documentation and the implementation of developmental factors in the design of mobile apps for diabetes management. The use of mobile phone interventions in which the developmental design are not explicitly documented is likely to result in a non-replicable app with significant levels of wasted resources. Therefore, future work is required to promote the development of evidence-based apps research and clinical use. These mobile apps should focus on integrating functions to core diabetes self-management practices and primarily with the provision of self-management education. Additionally, integrating theories of health behavioral change, users, and clinical experts' involvement while ensuring data privacy and security are essential factors to be considered in the development of future mobile apps.

Limitations of This Review

There are limitations to be considered when interpreting and extrapolating the findings of this systematic review. The results of this review were dependent on the terms used in the search strategy and the efficiency of the search engines used. An attempt to overcome this limitation was ensured by choosing common terms and combination of terms usually used in the literature review on mobile health apps. This review considered only trials that were reported in the English language with strict inclusion criteria and so the number of articles that met the study criteria was small, and this limits the ability to generalize the findings. Also, the process of extracting the data presented some risk of error and uncertainty because some studies were not explicit about their developmental considerations, and it is easy to miss or misunderstand some development description either reported directly within the article or referenced. However, to avoid this occurrence, the authors ensured that the assessment process involved independent verification and all pitfalls that might invalidate the findings were avoided. Despite these limitations, this review provides valuable information to future researchers and developers of mobile apps for diabetes management on the necessary factors to consider during app development.

Conclusion

This systematic review has presented the crucial steps that need to be taken in mobile app development to support effective self-management for people with diabetes. Most of the studies in this review offer a limited and non-expository degree of information on the factors considered in the development of the apps employed.

The main stakeholder in diabetes management is the patient. Shared decision-making between diabetes patients, health care professionals, and app developers can result in improved management. Therefore, this should be the basis for the development of mobile apps for diabetes support. Shared decision-making can be achieved through the process of patient and clinical expert involvement, ensuring data security and privacy, pilot testing and integration of core functions that support all aspects of diabetes self-care activities as indicated by evidence-based guidelines. Continual integration of these processes during app development (before actual use in clinical trials) will ensure that specific needs of diabetic patients are met in the finally developed app, and this will ultimately improve diabetes support, self-management and clinical outcomes for the patients.

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Authors' Contributions

MD and BMA conceived the concept. MD drafted the manuscript. All authors substantially contributed towards revising the paper and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Study Characteristics.

[PDF File (Adobe PDF File), 61KB - mhealth_v6i6e10115_app1.pdf]

Multimedia Appendix 2

Some of the developmental considerations in the reviewed studies.

[PDF File (Adobe PDF File), 35KB - mhealth_v6i6e10115_app2.pdf]

Multimedia Appendix 3

Other developmental considerations in the reviewed studies and key clinical outcome-glycosylated hemoglobin.

[PDF File (Adobe PDF File), 33KB - mhealth_v6i6e10115_app3.pdf]

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Abbreviations

BG: blood glucose
CINAHL: Cumulative Index to Nursing and Allied Health Literature
HbA_{1c}: glycosylated hemoglobin
HIPAA: Health Insurance Portability and Accountability Act
IDDM: Insulin Dependent Diabetes Mellitus
Medline: Medical Literature Analysis and Retrieval System Online
NIDDM: Non-Insulin Dependent Diabetes Mellitus
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis
RCT: Randomized Controlled Trial

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Original Paper

Sleep Tracking and Exercise in Patients With Type 2 Diabetes Mellitus (Step-D): Pilot Study to Determine Correlations Between Fitbit Data and Patient-Reported Outcomes

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Abstract

Background: Few studies assessing the correlation between patient-reported outcomes and patient-generated health data from wearable devices exist.

Objective: The aim of this study was to determine the direction and magnitude of associations between patient-generated health data (from the Fitbit Charge HR) and patient-reported outcomes for sleep patterns and physical activity in patients with type 2 diabetes mellitus (T2DM).

Methods: This was a pilot study conducted with adults diagnosed with T2DM (n=86). All participants wore a Fitbit Charge HR for 14 consecutive days and completed internet-based surveys at 3 time points: day 1, day 7, and day 14. Patient-generated health data included minutes asleep and number of steps taken. Questionnaires assessed the number of days of exercise and nights of sleep problems per week. Means and SDs were calculated for all data, and Pearson correlations were used to examine associations between patient-reported outcomes and patient-generated health data. All respondents provided informed consent before participating.

Results: The participants were predominantly middle-aged (mean 54.3, SD 13.3 years), white (80/86, 93%), and female (50/86, 58%). Use of oral T2DM medication correlated with the number of mean steps taken (r=.35, P=.001), whereas being unaware of the glycated hemoglobin level correlated with the number of minutes asleep (r=−.24, P=.04). On the basis of the Fitbit data, participants walked an average of 4955 steps and slept 6.7 hours per day. They self-reported an average of 2.0 days of exercise and 2.3 nights of sleep problems per week. The association between the number of days exercised and steps walked was strong (r=.60, P<.001), whereas the association between the number of troubled sleep nights and minutes asleep was weaker (r=.28, P=.02).

Conclusions: Fitbit and patient-reported data were positively associated for physical activity as well as sleep, with the former more strongly correlated than the latter. As extensive patient monitoring can guide clinical decisions regarding T2DM therapy, passive, objective data collection through wearables could potentially enhance patient care, resulting in better patient-reported outcomes.

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KEYWORDS

Fitbit charge HR; type 2 diabetes mellitus; sleep; health outcomes; health behaviors

Introduction

The Role of Wearable Technology

Diabetes mellitus is a chronic condition characterized by hyperglycemia, which arises due to anomalies in insulin-dependent metabolism [1]. In 2015, a Centers for Disease Control and Prevention report estimated that about 30.3 million people in the United States were affected by diabetes, with type 2 diabetes mellitus (T2DM) comprising 90% to 95% of all adult cases [2]. The onset and course of T2DM is strongly influenced by lifestyle-related health behaviors, such as the amount of physical activity and sleep [3-7]. Studies have shown that increased physical activity and weight loss lead to improved glycemic control and lower the risk of cardiovascular disease among diabetics [3,7]. The opposite is also true, as decreased physical activity and sleep leads to worsening glycemic control among patients with diabetes [4-6]. Optimum glucose control requires a combination of diet, exercise, and medication [8]. However, medications are considered only if lifestyle interventions fail. Due to the plethora of antidiabetic drugs with varying mechanism of actions and therapeutic effects available, prescribing optimal medication often becomes tedious. The availability of health-related big data can guide such clinical decisions and enhance patient care [9]. Thus, patients with T2DM comprise a population for which the accurate measurement of health behavior is critical for measuring outcomes and personalizing medication.

Data pertaining to health behaviors are typically collected from patients with T2DM through patient-reported outcome measures [10,11]. However, patient responses are subject to validity issues arising from recall problems and are also affected by other cognitive and emotional variables [12-14]. Moreover, paper-and-pencil administration of patient-reported outcomes may result in missing data, as participants have the option of skipping questions [15]. Mobile physiological monitoring devices (wearables), which collect patient-generated health data [16], are an alternative source of information that is increasingly recommended for use in studies of chronic illness populations [17-19] and in clinical care settings [20,21]. However, as wearable device technology is relatively new, the associations between wearable device data and information collected from other traditional collection methods are not fully understood.

Historically, health-related quality of life (HRQoL) research has been conducted on a small scale. However, organizations such as the Patient Centered Outcomes Research Institute (PCORI) are being established. PCORI is a United States federal funding agency for studies on outcomes research pertaining to patient quality of life. The budget for PCORI is part of the legislation of the Affordable Care Act, and the goal of the organization is to empower patients by providing them with evidence that helps them make informed health-related choices. Such organizations are developing extensive databases to systematically collect HRQoL data on a large scale. PCORI, in particular, aims to eventually include information collected from wearable devices as part of its data network, PCORnet [22]. This strategy of amalgamating health-related, patient-specific parameters could provide objective, detailed HRQoL data that cannot be captured by self-reported assessments and are not included in electronic medical record databases.

Fitbit—Strengths and Weaknesses

Consumer wearable devices, such as those produced by Fitbit, are relatively low-cost, consumer-level wearables that collect data across variety of domains, including physical activity and sleep quality. A recent systematic review indicated that Fitbit devices' step count estimates showed strong positive associations with laboratory-based devices that used step counting or accelerometer-based techniques [23]. However, the average error of underestimation was 4% to 6% [24]. Another study found that 2 Fitbit products correlated highly with laboratory research devices for step count, moderate-to-vigorous physical activity, energy expenditure (EE), and sleep [25]. Fitbit devices' step counts were also shown to strongly correlate with visual and ActiGraph accelerometer step counts during a 2-min walk test among community-dwelling older adults [26]. Finally, Fitbit EE estimates were on par with EE estimates from the SenseWear armband, a device that uses a combination of accelerometry, galvanic skin response, and heat-flux measurements to estimate EE [27]. A study of patients with chronic obstructive pulmonary disease reported a high correlation between EE estimates retrieved from Fitbit and those from the SenseWear armband [28]. However, recent systematic review data also indicated that wearables, including Fitbit, overestimated total sleep time and sleep efficiency and underestimated waking after sleep onset, compared with polysomnography, which is the current gold standard for the measurement of sleep quality [23].

Gaps in Previous Research

Few studies have described relationships between Fitbit metrics (or those of other newer wearable devices) and patient-reported outcomes measuring similar variables. However, there is an ongoing clinical trial to evaluate associations between wearable biosensor data, performance status, and patient-reported outcomes in patients with cancer [29].

This pilot study was conducted to determine the association between Fitbit-generated data and patient-reported outcomes pertaining to physical activity and sleep patterns in patients with T2DM.

Methods

Study Design

This noninterventional, pilot study was designed to assess the magnitude and direction of correlation between patient-reported outcomes (collected through internet-based surveys) and patient-generated health data (collected from Fitbit devices) in patients with T2DM. The study protocol was approved by the Sterling institutional review board (IRB; Atlanta, Georgia; registration number 5386-001IRB).

Participant Recruitment

Participants (N=1504) were recruited from adults who self-reported a diagnosis of T2DM while responding to either the 2014 or 2015 National Health and Wellness Survey

(NHWS). In 2014, 96,747 participants and in 2015, 97,700 participants completed the survey. Responses from these surveys are reported as part of the NHWS database, which is one of the largest international databases for patient-reported disease outcomes. Those who reported that they were not pregnant and were diagnosed with T2DM by a doctor and currently taking prescription medicine for the condition were considered to be eligible.

Procedure

Eligible participants were sent an email invitation to join the study in February 2016 (N=1504). People interested in participating clicked on an embedded hyperlink that took them to a secure webpage, which included study documentation, an electronic informed consent form, and a screening questionnaire. Those who met the screener criteria and agreed to participate (n=170) were mailed Fitbit Charge HR devices with user manuals (along with special instructions on how to charge and sync the Fitbit device). After device registration, participants were directed to an opt-in page that described study procedures in detail and included the informed consent form. Both consent forms notified the participants that involvement in the study was voluntary and that all responses would remain confidential. The forms also included information about the research goals, approximate survey length, duration of participation, compensation, and resources to address any concerns arising during the conduct of the study. Specifically, they were provided with the telephone number of the Sterling IRB and an email address to contact the researchers. Throughout the study, there were no paper surveys to store or destroy, and no manual data entry was required. Participants who completed the study kept their Fitbit Charge HR, and those who completed all 3 surveys (n=86) over the 2-week period were given an additional US $25. Selection bias was prevented by providing all the invitees an equal opportunity to participate. The final respondents were chosen only if the selection criteria as per protocol were satisfied.

Data Collection

The study was conducted over a period of 14 days. Questionnaires were administered on day 1 (beginning of week 1), day 7 (end of week 1), and day 14 (end of week 2). After successful device registration, participants were sent an email that included a link to the first of the 3 questionnaires. Responses to all surveys were instantaneously uploaded to a secure database. Fitbit data were collected passively over the entire 2-week study period. Participant responses to questionnaires were monitored, and activity data collected from the Fitbit were tracked through the course of the study. All participants could view their own Fitbit-related data. Those who did not activate the device or missed a survey were contacted via telephone and reminded of their participation in the study. Telephone calls were also used to help troubleshoot any problems that participants had with the device. Data collected through Fitbit devices were accessed through Fitabase (a third-party database), which aggregated all of the collected information into a single database. After the study, the devices were manually deactivated from the database by the researchers, so that no further data could be collected.

Measures

Physical activity and sleep patterns and quality were studied through internet-based patient-reported outcomes surveys and Fitbit-generated data. The number of steps was used as a measure of physical activity, and sleep quality was assessed in terms of hours of sleep via the Fitbit Charge HR. Further explanation is provided below.

Sociodemographic Characteristics, Type 2 Diabetes Mellitus Parameters, and Disease Management

The social and demographic characteristics of the population, such as age, gender, level of education, race, and income, were recorded as part of the first questionnaire administered to participants. Body mass index (BMI; weight in kg/height in m^2) was also captured, due to its impact on disease manifestation and progression. BMI were categorized as follows: normal (BMI ≥18.5 to <25), overweight (BMI=25 to <30), class 1 obese (BMI=30 to <35), class 2 obese (BMI=35 to <40), and class 3 obese (BMI ≥40).

Parameters pertaining to the way patients managed their disease were captured as part of the first questionnaire. These included variables, such as mode of treatment, oral therapy, use of insulin, and current glycated hemoglobin (Hb1Ac) levels, as well as the number, timing, and symptoms of hypoglycemic events.

Fitbit

The Fitbit Charge HR was used to measure physical activity and sleep quality. It is a compact device that is worn on the wrist. It synchronizes either with a Fitbit mobile app or a Fitbit computer-based dashboard using a Bluetooth or USB connection. The device quantified several parameters related to health behavior daily including, but not limited to, steps taken, current heart rate (HR), distance covered, calories burned, and floors climbed. All of this information is displayed on the device's screen, whereas information such as detailed HR history, number of active minutes, number of hours slept, and sleep quality are accessible to users through the synchronized app or dashboard. All the above parameters were recorded by Fitbit only for the duration that the device was worn.

Physical Activity Measured by the Fitbit Charge HR

Steps taken were measured by the Fitbit activity tracking algorithm, which uses triaxial accelerometry, based on piezoelectric or capacitance sensing of accelerative forces. The number of steps automatically resets to 0 at midnight, daily. However, step count history could be accessed through the Web dashboard or mobile app.

Sleep Quality Measured by the Fitbit Charge HR

Participants had to be wearing the device to track their sleep. Fitbit calculated the number of hours asleep by subtracting the time a participant was awake or restless from the total tracked time. The device assumed the participant was asleep if movement was not recorded for about an hour. Additional data that confirms sleep, such as rolling over, was also considered for sleep calculation. However, if sleep was incorrectly recorded when the participants were motionless for a long time, but not asleep, the participants were free to delete the sleep log data.

Patient Surveys

Patients reported their physical activity and sleep quality as part of each weekly questionnaire. Specifically, they were asked to report the average number of days in a typical week that they rigorously exercised for either improving or maintaining their health, losing weight, or for enjoyment on an 8-point Likert scale (0-7 days). In addition, they were asked to input the numerical value for the average number of days exercised per week. They were also asked to report (in hours and minutes) the time per day that they performed rigorous exercise and the duration that they held a gym membership, if at all.

Sleep duration was self-reported by the patients as the average number of hours they slept per night.

Statistical Analyses

Descriptive statistics (means and SD for continuous variables; percentages and frequencies for categorical variables) were calculated for sociodemographics, T2DM-related parameters, Fitbit data, and patient-reported outcomes. For categorical variables, chi-square tests were used to determine significant differences across groups, whereas *t* tests were used for continuous variables. Pearson correlations were used to measure the direction and association between patient-reported outcomes and Fitbit patient-generated health data. Analyses were conducted using the IBM SPSS Statistics for Windows, version 23 (IBM Corp, NY, USA).

Results

Sociodemographic Characteristics, Type 2 Diabetes Mellitus Parameters, and Disease Management

A total of 170 respondents completed the screener and received Fitbit devices. Of these, 98 completed the baseline questionnaire, 92 completed the first follow-up, and 86 completed all of the surveys. Out of the 170 respondents who received Fitbit, 72 did not activate the device. Among the 86 respondents that completed all the surveys, the average number of days not active with their Fitbit was 1.6 days (SD 4.2).

Respondents (n=86) were mostly white (93%, 80/86) and female (58%, 50/86), with a mean age of 54.3 years (SD 13.3, range 24-84) and a household income of <US $50,000 (54%, 46/86; Table 1). The mean BMI of the participants was 35.8 kg/m^2 (SD 8.9, range 22-59). Using standard WHO definitions for BMI classification [30], the respondents were classified into—normal (n=5), overweight (n=20), class 1 obese (n=21), class 2 obese (n=14), and class 3 obese (n=24). No one reported being underweight and 2 respondents did not provide their weight information.

Respondents were diagnosed with T2DM for a mean of 9.7 years (SD 7.0) and had a mean HbA_{1c} value of 7.1% (SD 1.4; Table 2). A total of 28% respondents (24/86) used insulin, and 88% (76/86) had a home glucose monitor. Among those with a home glucose monitor, 62% (47/76) checked their glucose *daily* or *multiple times per day*. Of the patients who checked their glucose levels at least daily with a monitor, 81% (38/47) knew their HbA_{1c} level, whereas 79% (23/29) of patients who had a monitor, but did not check their glucose levels at least daily, knew their HbA_{1c} levels.

Use of insulin or an oral T2DM medication did not differ between respondents aged <55 years and ≥55 years (31% vs 24%, P=.52 and 90% vs 97%, P=.18, respectively). However, respondents aged ≥55 years tended to use less noninsulin injectables than respondents aged <55 years (3% vs 20%, P=.02).

Physical Activity and Sleep Quality

Gym memberships were held by 17% (15/86) of the participants. On the basis of data retrieved from the Fitbit, on average, participants took 4955 steps per day. They also self-reported an average of 2 (SD 2.3) days of exercise per week on the questionnaires, with an average session lasting for 50.8 min (SD 31.4, range 10-124). Fitbit data showed participants slept for an average duration of 6.7 hours/ per day (SD 1.7) and self-reported that they had trouble falling asleep for an average of 2.3 (SD 2.7) nights in a typical week. Although steps taken and minutes asleep increased from week 1 to week 2 (4903 vs 5011 steps/day) and (396 vs 404 min), these differences were not statistically significant (P=.63 and P=.11, respectively). Similar nonsignificant results were observed when respondents aged <55 years (mean steps=4846.4, minutes of sleep=393.4) and respondents aged ≥55 years (mean steps=5103.1, minutes of sleep=411.6) were compared on mean steps walked and minutes slept (P=.70 and P=.45, respectively).

Negative correlations between BMI and the Fitbit-generated mean number of steps (r=−.24, P=.03) and household income and the Fitbit-generated number of minutes asleep (r=−.28, P=.02) were observed. In contrast, a positive correlation between employment status and the Fitbit-generated mean number of steps (r=.32, P=.005) was observed. Age, gender, race, marital status, and education did not correlate significantly with either of the Fitbit-generated parameters.

Among the T2DM characteristics and disease management parameters, use of oral T2DM medication positively correlated with the Fitbit-generated number of steps (r=.35, P=.001), whereas being unaware of the HbA_{1c} level negatively correlated with the Fitbit-generated number of minutes asleep (r=−.24, P=.04). HbA_{1c} level was not significantly correlated with the Fitbit-generated mean number of steps (r=.16, P=.17) or minutes asleep (r=−.21, P=.07). The association between length of diagnosis and Fitbit-generated mean number of steps (r=.20, P=.86) and Fitbit-generated mean minutes of sleep (r=−.04, P=.77) were not significant. Similarly, the association between use of insulin and Fitbit-generated mean number of steps (r=.15, P=.21) and Fitbit-generated mean minutes of sleep (r=−.13, P=.28) were not significant. Hypoglycemic events in the past 12 months did not correlate significantly with either of the Fitbit-generated mean number of steps (r=.03, P=.82) and Fitbit-generated mean minutes of sleep (r=.21, P=.07).

Table 1. Sociodemographic characteristics of participants.

Variable	Participants (n=86)
Age in years, mean (SD)	54.3 (13.3)
Body mass index, mean (SD)	35.8 (8.9)
Female, n (%)	50 (58)
White race, n (%)	80 (93)
Employed, n (%)	34 (40)
Married, n (%)	51 (59)
Completed university, n (%)	24 (28)
Income range, n (%)	
<US $15,000	13 (15)
US $15,000 to <US $25,000	6 (7)
US $25,000 to < US $35,000	10 (12)
US $35,000 to < US $50,000	17 (20)
US $50,000 to < US $75,000	20 (23)
US $75,000 to < US $100,000	9 (11)
US $100,000 to < US $125,000	5 (6)
US $125,000 to < US $150,000	3 (4)
US $150,000 to < US $200,000	1 (1)
US $200,000 to < US $250,000	–
US $250,000+	–
Declined disclosure	2 (2)
Comorbidities, n (%)	
Diagnosed with a cardiovascular or heart disease	9 (11)
Diagnosed with a chronic pulmonary disease	4 (5)
Diagnosed with sleep apnea	23 (27)
Diagnosed with insomnia	12 (14)

Table 2. Type 2 diabetes mellitus characteristics and mode of disease management.

Variable	Participants (n=86)
Diagnosis length in years, mean (SD)	9.7 (7.0)
HbA_{1c}[a] value, mean (SD)	7.1 (1.4)
Uses oral T2DM[b] medication, n (%)	80 (93)
Uses insulin, n (%)	24 (28)
Unaware of HbA_{1c} value, n (%)	17 (20)
Reported a hypoglycemic event in the past 12 months, n (%)	35 (41)
Reported a nocturnal hypoglycemic event in the past 4 weeks, n (%)	5 (6)
Timing of hypoglycemic event, n (%)	
Day	8 (62)
Night	5 (39)

[a]HbA_{1c}: glycated hemoglobin.

[b]T2DM: type 2 diabetes mellitus.

Similarly, nocturnal hypoglycemic events in the past 4 weeks did not correlate significantly with Fitbit-generated mean number of steps (r=−.03, P=.79) and Fitbit-generated mean minutes of sleep (r=−.11, P=.35). The association between the number of patient-reported days exercised in a typical week and the number of mean steps generated by the Fitbit device was strong (r=.60, P<.001). However, patient-reported sleep issues were only weakly correlated with the sleep variables measured by Fitbit. In general, the number of nights that patients had trouble falling asleep in a typical week was associated with more time spent in bed, based on Fitbit-generated data (r=.28, P=.02). Thus, patient-reported outcomes and Fitbit data were more strongly associated when parameters pertaining to physical activity were measured than when sleep variables were assessed.

Discussion

Relevance of This Work

Wearable devices have reshaped the way patient data are collected and analyzed. These devices provide a simple and relatively cheap alternative for data collection, as opposed to complex, expensive instruments present in hospitals. They also offer instant reporting to physicians, which is beneficial to monitor the chronically ill and the elderly, to avoid untoward health incidences [31]. Currently, most clinical and research data are collected via patient-reported questionnaires. Such self-reporting is often prone to bias, resulting in under- or over-reporting, which affects the study's reliability [32]. Therefore, utilization of data-driven, mechanical devices, such as wearables, can decrease self-reporting bias, enhance data integrity, and reduce reproducibility issues between studies. Furthermore, the difference in HR measures between Fitbit Charge HR and an electrocardiogram was found to be negligible (59.3 vs 60.3 bpm) [33]. In addition, the device showed high accuracy (91%) and sensitivity (97%) in detecting sleep, although the sleep duration was negligibly overestimated by 8 min [33]. These advantages are a reason to push for greater implementation of wearable technology in the clinical setting.

Several studies have established that physical activity and sleep regulation are critical components of lifestyle and behavior, which impact long-term outcomes in patients with T2DM [3-7]. Therefore, efficient means of tracking these variables can facilitate monitoring by both physicians and patients. However, the use of wearables is becoming increasingly common; consequently, it is important to study the associations between patient-reported and device-reported data so that they can be synthesized and reported as part of quality of life databases.

Principal Findings

This study was conducted to determine the association between Fitbit-generated data and patient-reported outcomes pertaining to diabetes, physical activity, and sleep patterns in patients with T2DM. Participants reported a mean HbA_{1c} value of 7.1%, exercising 2 days per week, and sleeping 6.7 hours per day, whereas Fitbit data showed the participants walked 4955 steps per day and had trouble sleeping 2.3 times a week. The association between self-reported and Fitbit-generated data was stronger for physical activity than for sleep quality.

Comparison With Previous Research

The results of this study corroborate previous work that has found positive correlations between data collected via Fitbit and objective tools for physical activity and sleep quality [23,25,26,28]. In general, physical activity parameters can be standardized by adjusting the Fitbit's settings. As parameters such as weight, height, and stride length are prone to fluctuation, measuring these parameters consistently at the same time each day or for an adequate duration as instructed in the device's manual will result in accurate readings for the user. However, sleep quality measurements are prone to error, as they are influenced by a variety of patient parameters, not all of which can be accounted for by changing the settings on the device. In our study, the weak correlation between patient-reported outcomes and Fitbit sleep data is most likely the result of under-reporting of sleep disturbances by patients with T2DM; a phenomenon that has been reported in the literature [12]. However, this does not necessarily mean that the Fitbit data are correct; specifically, previous work comparing polysomnography (the gold standard) and Fitbit have found that the latter is less accurate than the former.

Patients could see their daily step count on the Fitbit's screen, whereas viewing sleep data required access to the Web dashboard or mobile app. This may have resulted in patients tracking their step count on Fitbit more closely than sleep quality, leading to increased awareness and thus, a higher correlation for physical activity, but not sleep quality, parameters.

Nevertheless, this study adds to a growing body of literature [34-36] that supports the use of wearable devices as an important data collection tool when the use of gold standards, such as the doubly-labeled water technique for EE [37] or polysomnography for sleep, is not practical. Moreover, if this study's results are replicated in studies on larger populations, wearable devices could potentially be used to collect detailed and objective HRQoL data on a large scale by organizations such as PCORI [22].

Type 2 Diabetes Mellitus and Wearables

Due to the short duration of the study, we did not observe any change in HbA_{1c} levels after initiation of the program. However, as observed previously [38,39], a longer program might result in weight, BMI, and HbA_{1c} reduction. Although we observed a 100-odd increase in steps from week 1 to week 2, a beneficial effect in T2DM patients would be visible only if rigorous physical activity is performed for a long duration. Constant communication and encouragement through personalized messages has been shown to result in higher physical activity and reduced HbA_{1c} levels, as compared with patients who did not receive such messages [39,40]. Mobile apps such as DiaFit or MyCarolinas Tracker, which integrate physical activity, glucose level, nutrition, and medication data for easy review by health care providers, can also be used to communicate with patients [41,42]. In future, such personalized and secure communication between patients and health care providers could decrease the current diabetes epidemic.

Challenges for Wearables

Despite their numerous advantages, the use of wearables for large-scale data collection presents certain drawbacks as well. Currently, the monetary costs associated with Fitbit may preclude its use in many situations. For example, wearable devices could replace patients' physical activity–related outcomes for randomized clinical trials, where data precision is paramount. However, due to the costs associated with their use, wearables may not be optimal for use in large epidemiological studies. Patient adherence also plays an important role, as not wearing or charging the device leads to the problem of missing data, and these devices may yield inaccurate data if they are worn incorrectly. Furthermore, a wide range of wearable devices is available to consumers, and each of these differ in terms of the mechanisms and algorithms they use to estimate health behavior data [23,25]. Thus, data collected from these different devices can only be analyzed and interpreted correctly once a certain level of standardization between sources has been achieved.

Limitations

As this was a pilot study, the size of the population assessed was small. It is possible that a larger sample size may stabilize the correlations observed. Moreover, those who responded to the surveys tended to be younger and were more likely to be female than the target population, which may limit the external validity of the findings. Although people who did not respond were not pursued for an explanation, we can certainly speculate the reasons/s for nonparticipation. It is possible that the NHWS participants to whom we sent the email invitation did not have sufficient time to devote to the survey, or were not interested, or already had a wearable fitness tracker. Moreover, from the respondents who agreed to participate, it is possible that many did not activate their Fitbit devices because they did not find the additional compensation (US $25) reasonable.

In addition, the clinical characteristics pertaining to T2DM reported by patients were not verified by physician charts. Moreover, as with most patient-reported outcomes, the measures used in this study were also subject to several biases that, due to their variability, could not be accounted for in the study design. This study did not collect the number of steps taken per day from the patient's perspective. Furthermore, it was not possible to verify whether every respondent wore the device correctly or adequately charged the device for the duration of the study. Therefore, the accuracy of the Fitbit device could not be assessed. For data analysis only, descriptive bivariate analyses were conducted; regression models were not used due to the pilot nature of the study and the small sample size. Moreover, confounders were not analyzed while measuring physical activity or sleep duration. It should be noted that a variety of confounders are likely to have an impact on HRQoL (eg, comorbidities), physical activity (eg, BMI), and sleep quality (eg, experiencing sleep problems).

Conclusions

This study found that patient-generated health data from the Fitbit and patient-reported outcomes are positively correlated for physical activity and sleep parameters in patients with T2DM. Therefore, data collection through wearables can dramatically increase the level of patient-monitoring and help physicians deliver better care, resulting in enhanced patient-reported outcomes. Should additional studies support these results, it is possible that data collected from wearable devices could be incorporated into research databases, such as PCORnet, in the future.

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Conflicts of Interest

JW and YP are employees of Novo Nordisk Inc. TMM is an employee of Kantar Health; IK and EAW were employees of Kantar Health at the time this study was conducted.

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Abbreviations

BMI: body mass index
EE: energy expenditure
HbA_{1c}: glycated haemoglobin
HR: heart rate
HRQoL: health-related quality of life
IRB: institutional review board
NHWS: National Health and Wellness Survey
PCORI: Patient Centered Outcomes Research Institute
PCORnet: Patient Centered Outcomes Research Institute database
T2DM: type 2 diabetes mellitus

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Original Paper

A New Influenza-Tracking Smartphone App (Flu-Report) Based on a Self-Administered Questionnaire: Cross-Sectional Study

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Abstract

Background: Influenza infections can spread rapidly, and influenza outbreaks are a major public health concern worldwide. Early detection of signs of an influenza pandemic is important to prevent global outbreaks. Development of information and communications technologies for influenza surveillance, including participatory surveillance systems involving lay users, has recently increased. Many of these systems can estimate influenza activity faster than the conventional influenza surveillance systems. Unfortunately, few of these influenza-tracking systems are available in Japan.

Objective: This study aimed to evaluate the flu-tracking ability of Flu-Report, a new influenza-tracking mobile phone app that uses a self-administered questionnaire for the early detection of influenza activity.

Methods: Flu-Report was used to collect influenza-related information (ie, dates on which influenza infections were diagnosed) from November 2016 to March 2017. Participants were adult volunteers from throughout Japan, who also provided information about their cohabiting family members. The utility of Flu-Report was evaluated by comparison with the conventional influenza surveillance information and basic information from an existing large-scale influenza-tracking system (an automatic surveillance system based on electronic records of prescription drug purchases).

Results: Information was obtained through Flu-Report for approximately 10,094 volunteers. In total, 2134 participants were aged <20 years, 6958 were aged 20-59 years, and 1002 were aged ≥60 years. Between November 2016 and March 2017, 347 participants reported they had influenza or an influenza-like illness in the 2016 season. Flu-Report-derived influenza infection time series data displayed a good correlation with basic information obtained from the existing influenza surveillance system (rho, ρ=.65, *P*=.001). However, the influenza morbidity ratio for our participants was approximately 25% of the mean influenza morbidity ratio for the Japanese population. The Flu-Report influenza morbidity ratio was 5.06% (108/2134) among those aged <20 years, 3.16% (220/6958) among those aged 20-59 years, and 0.59% (6/1002) among those aged ≥60 years. In contrast, influenza morbidity ratios for Japanese individuals aged <20 years, 20-59 years, and ≥60 years were recently estimated at 31.97% to 37.90%, 8.16% to 9.07%, and 2.71% to 4.39%, respectively.

Conclusions: Flu-Report supports easy access to near real-time information about influenza activity via the accumulation of self-administered questionnaires. However, Flu-Report users may be influenced by selection bias, which is a common issue associated with surveillance using information and communications technologies. Despite this, Flu-Report has the potential to provide basic data that could help detect influenza outbreaks.

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KEYWORDS

influenza; epidemiology; pandemics; internet; participatory surveillance; participatory epidemiology

Introduction

Seasonal influenza outbreaks cause 250,000-500,000 deaths worldwide annually and are a major public health concern [1]. Because influenza infections can spread rapidly, early detection of signs of an influenza pandemic is important to prevent global outbreaks. In Japan, the official sentinel surveillance system for influenza takes 1-2 weeks to report data on the intensity of influenza activity [2]. Globally, development of information and communications technologies for influenza surveillance has recently increased [3-5]. These systems can estimate influenza activity faster than the conventional influenza surveillance systems. Unfortunately, few influenza-tracking systems using information and communications technologies are available in Japan. However, a large number of Japanese households are connected to the internet, and 71.8% of households have a mobile phone [6]. Therefore, a mobile phone app focused on collecting influenza-related information may be able to monitor influenza activity more easily and faster than the conventional surveillance systems. "Flu-Report," a new flu-tracking iPhone app, was developed by the Department of General Medicine, School of Medicine, Juntendo University, and launched in November 2016. Flu-Report collects influenza-related information directly from users based on a self-administered questionnaire. This study aimed to evaluate the flu-tracking ability of Flu-Report.

Methods

Ethics Statement

All volunteers who wanted to join the study downloaded Flu-Report (for free) from the iPhone App Store, read the written informed consent document included in the app, and checked the "Agree" button on the consent form. Participants were able to withdraw from the study at any time. The study protocol was approved by the Ethical Review Board of Juntendo University (#2017007).

Flu-Report

Flu-Report, a new flu-tracking iPhone app, was developed with "ResearchKit," an open source framework (Apple, One Apple Park Way, Cupertino, CA, USA). Japanese users can download Flu-Report free of charge from the iPhone App Store. Flu-Report collects information about influenza virus infections based on a self-administered questionnaire. The main survey items were sex, age, home postal code, and influenza infection status. Screenshots of the survey report are shown in Multimedia Appendices 1 and 2. Information was also collected on any relatives who lived with participants, including the age and influenza infection status of each relative. In addition, when a participant or their relative developed physician-diagnosed influenza, information about the type of influenza and the names of prescribed antivirals were collected. In Flu-Report, influenza infections are defined as influenza diagnosed by a physician or antiviral medication prescribed by a physician. Self-reported influenza virus infections that did not meet these criteria were defined as influenza-like illnesses (ILI).

Study Population

This prospective observational study evaluated the use of Flu-Report to investigate influenza virus infections in Japan from November 2016 to March 2017. All iPhone users in Japan aged ≥20 years who agreed to join the study were able to participate in our survey. To recruit volunteers, we advertised Flu-Report on TV programs, posted articles about Flu-Report on the internet, and displayed posters about Flu-Report at cooperating medical facilities.

Data Collection

Participants who agreed to participate in the survey were encouraged to complete the influenza questionnaire on their iPhone. All participants were instructed to enter demographic information (age, sex, and home postal code). Subsequently, if a participant or their registered family members developed an influenza infection, participants entered additional information into the questionnaire, namely: onset date, name of prescribed antiviral medicines, and symptoms. Participants were expected to report as soon as possible when they or their relatives developed an influenza infection. However, participants could report that they had developed an influenza infection at a later date. Flu-Report also issued a message on the iPhone screen each month to remind participants to report any influenza infection. Participants could select the brand name of any prescribed antivirals from a list provided: oseltamivir phosphate (Tamiflu), zanamivir hydrate (Relenza), laninamivir octanoate hydrate (Inavir Dry Powder Inhaler), peramivir hydrate (RAPIACTA), others, and unknown. Participants were also asked to select symptoms of influenza infection from a displayed list: fever, cough, muscle pain, malaise, headache, sore throat, sneezing, runny nose, chills (enough to wear a coat), chills (requiring a thick blanket), chills (cannot stop trembling), and all symptoms. Screenshots of the influenza questionnaire are shown in Multimedia Appendix 2.

This study analyzed participants' background information and influenza virus infection status data. Inclusion and exclusion criteria are shown in Figures 1 and 2. Figure 1 shows the number of people who agreed to participate, the number of participants excluded, and the number of participants included in the final analysis. Initially, information for 5595 participants and 10,969 cohabitating relatives was entered in Flu-Report.

Reasons for exclusion were insufficient information, duplicated information, and withdrawal of consent. Finally, 4763 participants (2681 men; 2057 women; unknown 25) and 5331 cohabiting relatives were included, giving a total of 10,094 participants for the analysis.

Figure 2 shows the number of participants with influenza or ILI who registered, the number of participants who were excluded, and the number of participants finally analyzed in this study. Of these, 334 participants were considered to have been infected with influenza virus, and 13 were classified as ILI.

Figure 1. Inclusion and exclusion criteria for subjects who input basic information into Flu-Report.

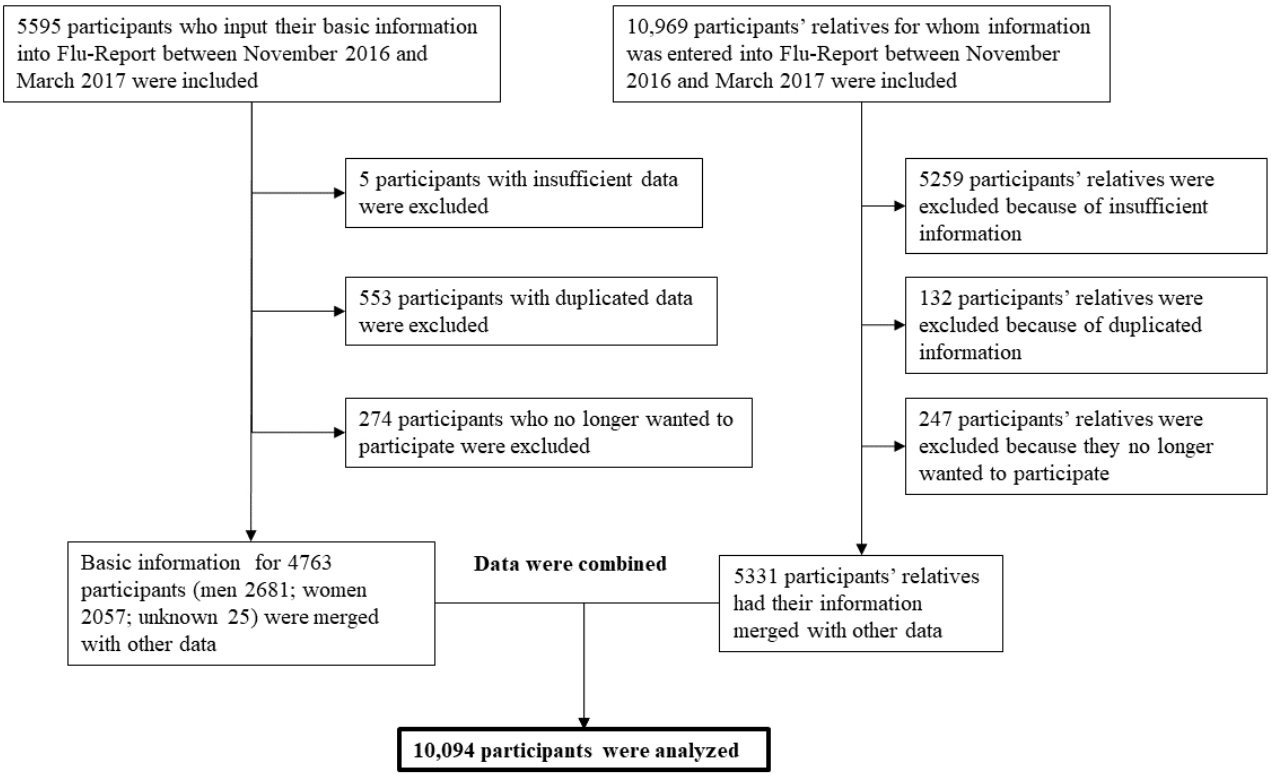
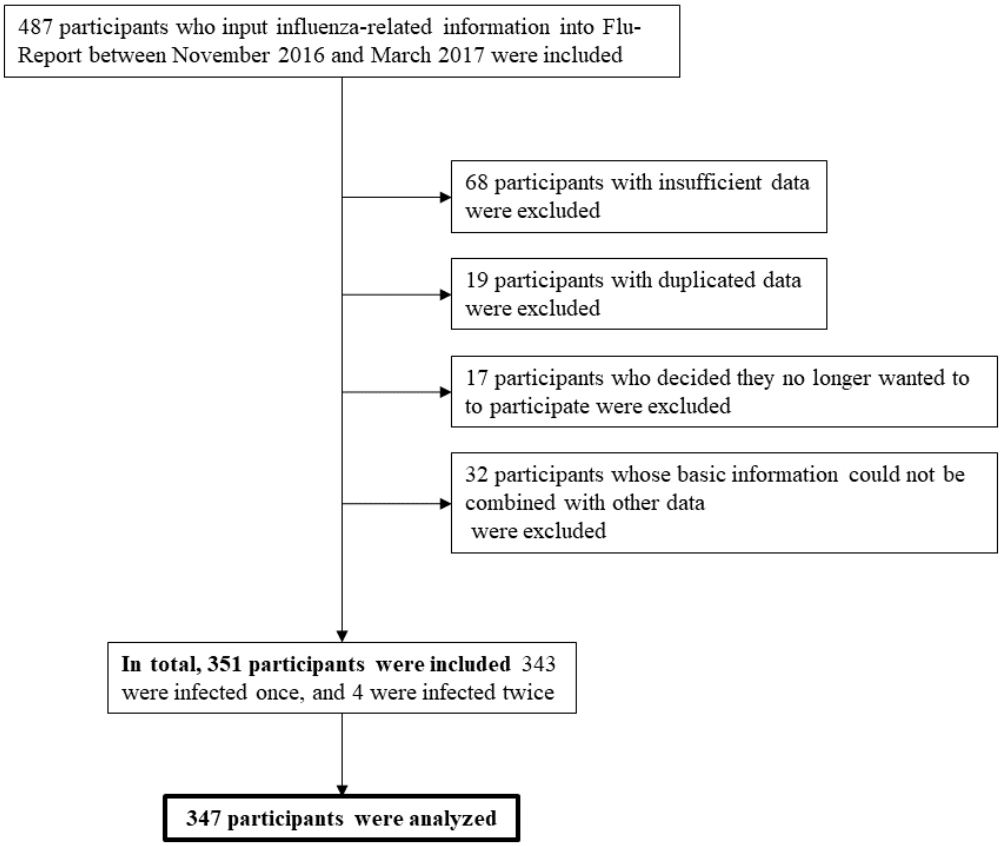


Figure 2. Inclusion and exclusion criteria for subjects who input influenza-related information into Flu-Report.



Data Handling

First, information about seasonal influenza activity obtained via Flu-Report was compared with basic information from a real-time prescription surveillance system [7,8]. Japan recently launched a real-time prescription surveillance system (ie, an automatic surveillance system based on electronic records

regarding prescription drug purchases). This system automatically collects information about prescriptions of antiviral medication from the electronic prescription record system (including information from over 10,000 pharmacies) and estimates the number of influenza cases based on this information. This system has been shown to be able to detect influenza activity earlier than the conventional influenza survey systems, and the results displayed a good correlation with data for influenza epidemics obtained using the conventional influenza survey systems [7]. In Japan, influenza activity is shown as the number of individuals with influenza during a specific period of time. To evaluate trends in influenza activity, the correlation between Flu-Report-derived influenza infection time series data and basic information obtained from the real-time prescription surveillance system was estimated. In addition, trends for morbidity and influenza activity were evaluated using data for participants, data for cohabiting relatives, and combined data for participants and cohabiting relatives. We analyzed data using the "date diagnosed with influenza" that participants entered into Flu-Report. Second, the research period was divided into 3 periods (first to third periods) every 4 weeks, and 2 periods every 5 weeks (fourth and fifth periods) according to the calendar. We have shown the distribution of subjects with influenza or ILI in Flu-Report and the real-time prescription surveillance system for each period. The distribution was calculated by dividing the number of participants with influenza or ILI in each period by the total number of participants with influenza or ILI for all periods. Third, the accuracy of the self-reported information about influenza and ILI provided via Flu-Report was evaluated through comparison with recent estimates of the number of influenza patients in Japan. The estimated number of patients with influenza in Japan was calculated based on reports from the Japanese Ministry of Internal Affairs and Communications and the Ministry of Health, Labour and Welfare [9,10]. In our study, we defined influenza cases per observed persons as the "morbidity ratio."

Statistical Analysis

The correlation between the 2 collection systems was estimated using Spearman rank correlation coefficient. All calculations were performed using the statistical software JMP Pro version 11 (SAS Institute Inc, Cary, NC, USA). $P<.05$ was considered statistically significant.

Results

Trends in Influenza Activity

Figure 3 shows the correlation between Flu-Report data and basic information from the real-time prescription surveillance system regarding trends in influenza activity. Flu-Report-derived influenza and ILI infection time series data (the combined data for participants and cohabiting relatives) were significantly associated with basic data for the real-time prescription surveillance system (rho, ρ=.65, P=.001). In addition, a similar tendency was found when using data for participants and data for cohabiting relatives (ρ=.54, P=.009; ρ=.72, $P<.001$, respectively; see Multimedia Appendix 3 for raw data).

In total, 64.6% (224/347) of influenza-infected participants registered their information on the day of their diagnosis or the next day, and 79.3% (275/347) registered their information within 3 days. Approximately 92.8% (322/347) of participants registered their information within 7 days (data not shown).

Figure 3. The correlation between Flu-Report data and basic information for the real-time prescription surveillance system.

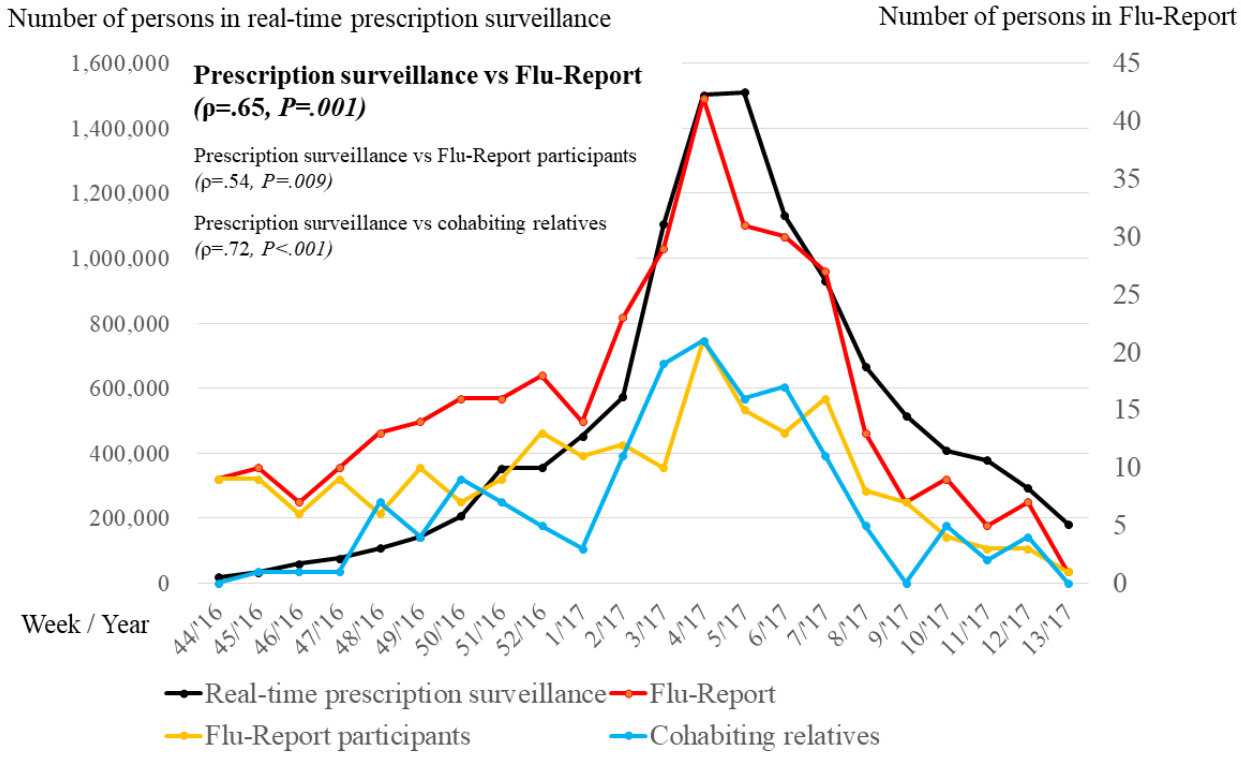


Table 1. Influenza morbidity ratios for study participants based on Flu-Report. All data were drawn from Flu-Report as entered by participants in this study.

Age, years	Participants, N	Participants affected by influenza, n (%)	Participants affected by ILI[a], n (%)
<20	2134	108 (5.06)	4 (0.19)
<1	107	1 (0.9)	0 (0.0)
1-5	522	27 (5.2)	1 (0.2)
6-12	808	46 (5.7)	1 (0.1)
13-19	697	34 (4.9)	2 (0.3)
20-59	6958	220 (3.16)	9 (0.13)
20-29	1705	78 (4.57)	5 (0.29)
30-39	1694	61 (3.60)	1 (0.06)
40-49	2103	60 (2.85)	3 (0.14)
50-59	1456	21 (1.44)	0 (0.00)
≥60	1002	6 (0.60)	0 (0.00)
60-69	621	2 (0.3)	0 (0.0)
70-79	233	3 (1.3)	0 (0.0)
≥80	148	1 (0.7)	0 (0.0)
Total	10,094	334 (3.31)	13 (0.13)

[a]ILI: influenza-like illness.

Table 2. Estimated influenza morbidity ratios for the general Japanese population according to age, based on Japanese Government reports. All data were drawn from reports of the Japanese Ministry of Internal Affairs and Communications and the Ministry of Health, Labour and Welfare.

Age, years	Population of Japan in 2016[a], N	Estimated number of patients with influenza during 2013-2014[a], n (%)	Estimated number of patients with influenza during 2014-2015[a], n (%)	Estimated number of patients with influenza during 2015-2016[a], n (%)
<20	21.74	8.24 (37.90)	6.95 (31.97)	7.95 (36.57)
20-59	62.16	5.07 (8.16)	5.64 (9.07)	5.40 (8.69)
≥60	42.85	1.16 (2.71)	1.88 (4.39)	1.65 (3.85)
Total	126.76	14.46 (11.41)	14.47 (11.42)	15.02 (11.85)

[a]Per million people.

Multimedia Appendix 4 shows the distributions of participants with influenza or ILI during each period. The distribution of participants in Flu-Report appeared to be greater than those in the real-time prescription surveillance system in the first and second periods and less in the fourth and fifth periods (see Multimedia Appendix 3 for raw data).

Influenza Morbidity Ratios

Table 1 shows the influenza morbidity ratios for our participants. Table 2 shows morbidity ratios for the Japanese population.

The age distribution of our participants was as follows: 2134 (21%) aged <20 years, 6958 (69%) aged 20-59 years, and 1002 (10%) aged ≥60 years. The estimated number of patients with influenza in Japan was calculated based on reports by the Japanese Ministry of Internal Affairs and Communications and the Ministry of Health, Labour and Welfare [9,10]. The influenza morbidity ratio from Flu-Report was 5.1% among those aged <20 years, 3.2% among those aged 20-59 years, and 0.6% among those aged ≥60 years. In contrast, the influenza morbidity ratios for Japanese individuals aged <20 years, 20-59 years, and ≥60 years were 32.0%-37.4%, 8.2%-9.1%, and 2.7%-4.4%, respectively.

Discussion

Principal Findings

This study investigated the utility of Flu-Report, a new flu-tracking iPhone app, to monitor influenza activity. Flu-Report gathered information for over 10,000 participants. We found that Flu-Report-derived influenza infection time series data showed a good fit with equivalent information obtained by an existing large-scale real-time prescription surveillance system. Therefore, Flu-Report may be an effective tool for real-time detection of influenza cases. To our knowledge, this is the first report about a new influenza-tracking system based on an iPhone app developed using “ResearchKit” in Japan.

Surveillance of influenza activity is generally labor-intensive. For influenza surveillance, the annual influenza activity survey in Japan is conducted with the cooperation of about 5000 medical institutions. The advantage of Flu-Report is that a large

amount of information can be obtained through a small amount of capital and labor. A previous study revealed that a mobile phone–based data collection system delivered data faster, produced fewer errors, and had lower running costs than a paper-based data collection system [11]. Therefore, surveillance of influenza activity via a mobile phone app is a feasible option for research under financial constraints. Incidentally, in our study, influenza morbidity ratios for individuals aged <20 years, 20-59 years, and ≥65 years obtained using Flu-Report were lower than influenza morbidity rates among equivalent sections of the Japanese population (approximately one-seventh, one-third, and one-seventh, for the 3 age groups, respectively). Regarding flu morbidity, the older age group had a lower morbidity ratio in both Flu-Report and surveillance information, suggesting that Flu-Report collected influenza development by age category to some extent. However, our results also suggest that Flu-Report has some limitations associated with influenza surveillance using information and communications technologies. A previous report showed that nowcasting and forecasting ILI using Web queries have different correlations in different age categories [12]. That report will help in interpreting our results in that use of information and communications technologies on personal devices vary by age categories (ie, adults frequently use a mobile phone, whereas older adults do not). This means that the user population of Flu-Report is affected by selection bias, that is, bias that occurs when selecting individuals or groups to participate in the study. Moreover, we speculate that study participants were more concerned about the flu and more frequently used information and communications technologies compared with the general Japanese population. Therefore, participants' age and health-conscious behaviors must be considered when evaluating disease surveillance using information and communications technology devices.

As mentioned, there are various strengths and limitations to influenza surveillance systems using information and communications technologies. Previous reports have shown that a combination of multiple datasets improves the ability of models designed to predict influenza outbreaks [13-15]. Combining information obtained using Flu-Report with data collected using other influenza surveillance systems may facilitate effective influenza outbreak surveillance.

Limitations

Several other limitations of this study need to be acknowledged. First, this study only obtained influenza-related information for one season. It is known that the epidemic strains of influenza change each year. Therefore, the extent of the spread of influenza infections differs each season. Further evaluations must include additional influenza seasons. Second, our study contained an insufficient number of participants to allow us to investigate influenza activity that occurs throughout Japan. More participants are needed to enhance the effectiveness of Flu-Report. Another limitation was that there were fewer influenza infection reports via Flu-Report than expected. In Flu-Report, many influenza infections were reported earlier in the influenza season, and influenza infection reports decreased later in the season. There were some cases in which our reminder system for influenza infection each month did not work well. This error may have caused a reduction of infection reports during the latter part of the influenza season. Finally, all data were obtained using a self-administered questionnaire, and participants might have provided inaccurate information. Unfortunately, it appears to be difficult to confirm data accuracy or response rates of self-administered survey questionnaires using mobile apps [16]. This is an issue to be resolved in future surveillance using information and communications technologies.

Comparison With Prior Work

Various influenza monitoring systems based on the internet, search engine query data, or Twitter data have recently been launched [4,5]. These systems can estimate influenza activity faster than the conventional influenza surveillance systems. However, it has been reported that there are discrepancies between information obtained via the internet, search engine query data, or Twitter data, and data collected via the conventional systems [17]. Extensive media reports about influenza may promote influenza-related searches by people without influenza, which could have affected the results obtained using internet-based systems. Flu-Report, which focuses on only collecting influenza-related information, may be less influenced by such issues.

Similar influenza participatory surveillance systems are already in operation around the world [18-20]. These systems allow users to report the presence or absence of ILI symptoms each week, and ask follow-up questions about health care seeking behavior and diagnosed influenza. However, our system allows participants to first report information on influenza diagnosis by a physician and/or antiviral prescriptions. In addition, our system encourages participants to report on the presence or absence of influenza infection each month. As an influenza epidemic survey method, the former systems emphasize sensitivity, whereas the latter system increases specificity. In the case of a survey system targeting seasonal influenza (which is strongly infectious and prevalent on a large scale in a short period of time), the former system types are thought to be more suitable. Flu-Report may be better suited for monitoring diseases that are not so high in terms of infectivity but are serious when infected.

Conclusions

Although information obtained via Flu-Report is affected by selection bias, Flu-Report makes it easy to obtain near real-time information about influenza activity via the accumulation of self-administered questionnaires using mobile phone. Flu-Report has potential to provide basic data that could help to detect influenza outbreaks.

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Authors' Contributions

FK, TH, and TM conceived and designed the study. UH and NT provided advice and guidance about influenza. FK wrote the manuscript. TH, UK, YH, and NT revised the manuscript. All the authors approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots for format of survey.

[PPTX File, 380KB - mhealth_v6i6e136_app1.pptx]

Multimedia Appendix 2

Screenshots for the influenza questionnaire.

[PPTX File, 412KB - mhealth_v6i6e136_app2.pptx]

Multimedia Appendix 3

The raw data of the correlation between Flu-Report data and basic information for the real-time prescription surveillance system.

[XLSX File (Microsoft Excel File), 10KB - mhealth_v6i6e136_app3.xlsx]

Multimedia Appendix 4

The distribution of subjects with influenza or influenza-like illness during each period.

[PPTX File, 37KB - mhealth_v6i6e136_app4.pptx]

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Abbreviations

ILI: influenza-like illnesses

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Original Paper

Electronic 12-Hour Dietary Recall (e-12HR): Comparison of a Mobile Phone App for Dietary Intake Assessment With a Food Frequency Questionnaire and Four Dietary Records

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Abstract

Background: One of the greatest challenges in nutritional epidemiology is improving upon traditional self-reporting methods for the assessment of habitual dietary intake.

Objective: The aim of this study was to evaluate the *relative validity* of a new method known as the current-day dietary recall (or *current-day recall*), based on a smartphone app called 12-hour dietary recall, for determining the habitual intake of a series of key food and drink groups using a food frequency questionnaire (FFQ) and four dietary records as reference methods.

Methods: University students over the age of 18 years recorded their consumption of certain groups of food and drink using 12-hour dietary recall for 28 consecutive days. During this 28-day period, they also completed four dietary records on randomly selected days. Once the monitoring period was over, subjects then completed an FFQ. The two methods were compared using the Spearman correlation coefficient (SCC), a cross-classification analysis, and weighted kappa.

Results: A total of 87 participants completed the study (64% women, 56/87; 36% men, 31/87). For e-12HR versus FFQ, for all food and drink groups, the average SCC was 0.70. Cross-classification analysis revealed that the average percentage of individuals classified in the *exact agreement* category was 51.5%; *exact agreement + adjacent* was 91.8%, and no participant (0%) was classified in the *extreme disagreement* category. The average weighted kappa was 0.51. For e-12HR versus the four dietary records, for all food and drink groups, the average SCC was 0.63. Cross-classification analysis revealed that the average percentage of individuals classified in the *exact agreement* category was 47.1%; *exact agreement + adjacent* was 89.2%; and no participant (0%) was classified in the *extreme disagreement* category. The average weighted kappa was 0.47.

Conclusions: Current-day recall, based on the 12-hour dietary recall app, was found to be in good agreement with the two reference methods (FFQ & four dietary records), demonstrating its potential usefulness for categorizing individuals according to their habitual dietary intake of certain food and drink groups.

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KEYWORDS

dietary assessment; food frequency questionnaire; 24-hour dietary recalls; dietary record; mobile phone app

Introduction

Many epidemiological investigations and intervention studies do not require a complete picture of the habitual diet (or average long-term consumption) [1], as it can represent both an unnecessary workload for study participants and an avoidable waste of the scarce resources available for research [2]. The essential concept of these studies is to determine habitual consumption of specific key groups of food and drink (hereafter referred to as 'food') [3-9]. Classifying individuals according to categories of habitual consumption of specific food groups is sufficient for identifying potential nutritional deficiencies [10] and for evaluating the relationship between relative ranking and disease [5,8-14], and effectiveness of personalized methods that are implemented to promote changes in dietary patterns regarding selected food groups [1,5,8-10,12].

The three principal and traditional self-reporting methods for determining dietary intake can be classified as follows: (1) Short-term methods: dietary record (DR) and 24-hour recall. (2) Long-term methods: food frequency questionnaire (FFQ). These methods present significant and well-documented limitations [5,11,15-18]. (1) DRs that require weighing food require too much preparation time and create a large workload for the study participants, which can lead to deviations in normal food intake (especially an underestimation of quantities), as well as both low participation and completion rates [5,11,15-17,19,20]. 24-hour recalls require trained personnel and depend on the short-term memory of participants. Additionally, a proper picture of habitual diet using short-term methods requires methods to be repeated multiple times [16,19], which increases problems inherent in these procedures. (2) FFQs depend primarily on long-term memory of the interviewed subject, do not account for intrapersonal variation in recording the daily consumption of food during the study period, and do not allow a precise estimation of serving sizes of food consumed. Due to these limitations, results obtained by these inexact methods over both the short- and long-term could lead to inexact conclusions and incorrect decisions [18].

Newer alternatives for determining dietary intake include audio signal processing, inertial sensing, image processing, non-intrusive near-infrared scanning, and gesture recognition interfacing [21-24]. Some authors maintain that more research is needed to develop these and other tools that are more objective and precise and that resources should be invested to this end [18]. Until these alternatives are available, digital technologies for self-reporting methods can, and must, be developed and utilized [25], as an improvement in traditional self-reporting methods. This progress constitutes one of the most important challenges in the field of nutritional epidemiology [4,20].

For these reasons, the need is evident to develop better methods that can eventually replace current traditional self-reporting ones and provide better accuracy in measuring usual dietary intake of free-living individuals. This upgrade would represent a great boon not only to researchers [10] but also to society in general, considering the critical repercussions from both epidemiological investigations and interventional studies regarding the dietary intake of the population at large [25].

The objective of this study was to determine the *relative validity* of the new method known as current-day dietary recall (or *current-day recall*), based on a smartphone app called 12-hour dietary recall (e-12HR—previously known as e-Epidemiology [25]), utilizing reference methods, such as a semiquantitative FFQ and four estimated DRs, to verify the comparability of consumption data regarding a list of key food groups in the three methods.

Methods

Recruitment

Students of the Schools of Medicine and Pharmacy at the University of Seville (Andalusia, Spain, South of Europe) participated in this study. Two classes from each School were randomly selected and one member of the research team presented the project. Participant recruitment took place from January to December 2017. Participants were incorporated in the study progressively during the entire recruitment period so that every day of the week and every season of the year could be represented [26]. Participation in the study was incentivized with a raffle that included school materials valued at 250 euros.

Study Sample

The study was presented to 219 students and of those, 26 were not interested, and 98 did not meet the inclusion criteria. Of the 95 individuals who signed the informed consent, 87 completed the study. Inclusion criteria: (1) Older than 18 years of age; (2) a student of the Schools of Medicine or Pharmacy (University of Seville); and (3) possesses a smartphone with internet access (3G/4G/Wi-Fi) and Android operating system.

First Interview: Participant Data Collection

The 95 students who were interested and met the inclusion criteria were scheduled for a first personal interview. The procedure of the interview was as follows: (1) the same research team member that presented the project personally explained the research protocol in detail; (2) each participant signed the informed consent form; (3) each participant was assigned a personal alphanumeric code; (4) each participant filled out an initial questionnaire (on paper) with date of birth, date of the interview, gender, and school; (5) each participant downloaded the e-12HR app for his or her personal smartphone; (6) the same member of the research team personally explained to each participant how to use the app with a practical demonstration before written instructions were given to the participants [14,27] to be consulted later, if necessary; (7) the same research team member personally gave each student detailed instructions on how to complete the four estimated DRs and how to estimate serving sizes consumed using an explanatory pamphlet that was also given to participants [12,13].

The researcher also insisted that participants maintain their habitual diet throughout the study.

Completing the 12-Hour Dietary Recall App

The e-12HR app was developed to record daily consumption of a list of 10 food groups. The list could not be too long to minimize the workload on participants as well as the research costs [28]. These food groups were selected as they are

indicators of health/disease and are considered protective factors (fruit, vegetables, legumes or fish) or risk factors (soft drinks, commercial baked foods, and precooked meals) for chronic illnesses [4,12,29]. They also provide consumption patterns that range from almost every day for every inhabitant of the population to infrequently for the majority [4] (Textbox 1).

The first time the e-12HR app was used, the participants were required to introduce their personally assigned alphanumeric code and the e-mail of the researcher who would receive the data from the app. Participants were instructed to complete the app after consuming the last food of the day [14,27]. The e-12HR app includes a notification option, so that the app can remind the participant, at the hour previously selected by the participant (between 20:00 h and 04:00 h), that it is time to complete the questionnaire. The app was structured according to food groups to facilitate completion of the e-12HR task. For each food group, the participant would choose the most appropriate image (or images) from a series of color photographs with 2-4 possible options, shown simultaneously [14,27], which illustrated the different serving sizes to assist with selecting the number of standard servings consumed [10,12,14,20,27]. To further assist with estimating serving sizes, each photograph was accompanied by explanatory text and three objects of known/predictable size for the students [30,31] (fiducial markers): a commonly used pencil, pen, and a marker. For example, on the first screen of the app, the following would appear: *How many pieces of fruit have you eaten today?*, with the *Rations* button, and *Next* button and a box with the value set to *0* by default. Supposing that the participant had, throughout the day, consumed an apple and three mandarins, they would proceed as follows: (1) tap the *Rations* button; (2) a new window opens with different photographs of fruit, an *Accept* button, and a *Cancel* button; (3) tap once on the photo corresponding to the apple and tap three times on the photograph corresponding to the mandarin; (4) tap the *Accept* button; (5) the app returns to the previous window but the box now has, instead of the *0* value, the corresponding number of standard rations for the fruit selected with the photographs, in this example, a value of *2.5* (1 × 1 standard ration + 3 × 0.5 standard ration); (6) tap the *Next* button to access the next food group and proceed as before; (7) if an error occurs, the participant can tap the *Cancel* button instead of Accept in step 4, starting the process over again (Figure 1).

The use of active images (accompanied by explanatory text and three reference objects of known/predictable size for the students [fiducial markers]) is the only modification of e-12HR regarding the previous version (known as e-Epidemiology). However, this single, apparently simple, modification to the app is actually an important evolution over the previous version. In fact, the inclusion of active images was designed with a double purpose: on the one hand, to facilitate completion of e-12HR (by tapping the images instead of directly introducing the number of standard servings consumed); and on the other to assist with estimating the quantity consumed (this new version of the app directly shows 2-4 possible options for serving sizes).

After completing the daily questionnaire with e-12HR, the information is automatically saved and sent, via 3G/4G/Wi-Fi, to the e-mail address of the research administrator (entered when first accessing the app). Once the questionnaire is completed and sent, the participant cannot change their responses or access the app until the following day.

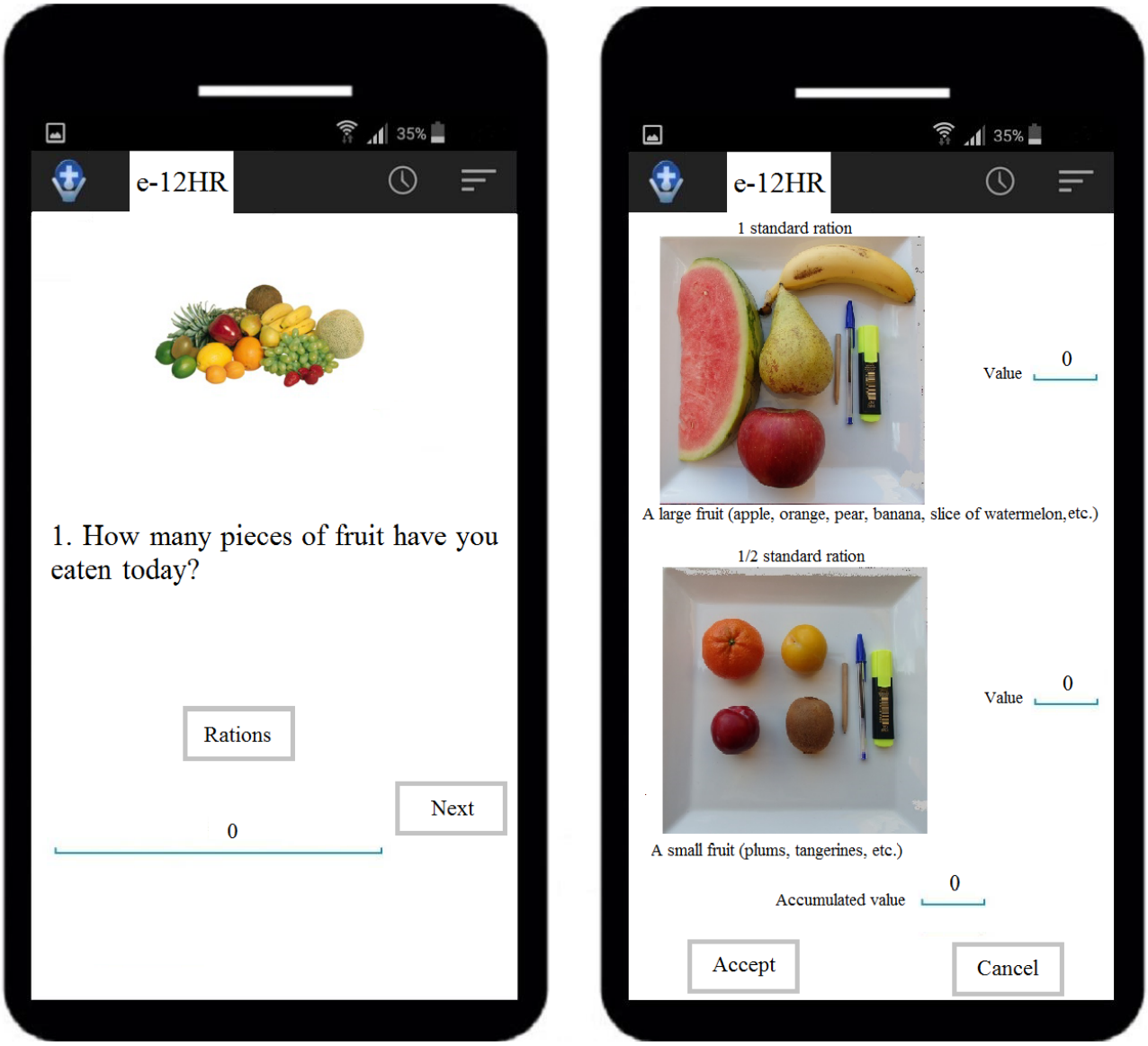
The consumption record of the selected food groups on the app was performed for 28 consecutive days. The time interval selected is similar to other comparison/validation studies [8,12,32-34].

The questionnaire and the size of the rations used in e-12HR are based on a semiquantitative FFQ previously validated for the population of Spain [35].

Textbox 1. Questionnaire used in 12-hour dietary recall (e-12HR).

1. How many pieces of fruit have you eaten today?
2. How many portions of vegetables have you eaten today?
3. How many portions of legumes (lentils, garbanzos, beans, etc) have you eaten today?
4. How many portions of chicken/turkey have you eaten today?
5. How many portions of fish have you eaten today?
6. How many portions of red meat (beef, pork, lamb) have you eaten today?
7. How many servings of soft drinks have you had today?
8. How many portions of commercially produced sweets (not home-made) (cookies/pastries) have you eaten today?
9. How many portions of prepared/frozen foods have you eaten today (croquettes, pizza, etc)?
10. How many servings of beer have you consumed today?

Figure 1. Screen capture of the 12-hour dietary recall (e-12HR).



Completing the Four Estimated Dietary Records

During the 28-day period that e-12HR was in use for each participant, four estimated DRs (on paper) were scheduled on randomly assigned, non-consecutive days [9,32]: three days during the weekdays and one weekend day [9,12,13,32]. The choice of between three and seven DRs is normally considered sufficient to evaluate food group intake [9,36]. Four estimated DRs were chosen instead of weighed DRs for logistical reasons [9,12]. In the daily life of the participants that made up the sample (university students who spend a large part of their days outside the home at their center of study), weighing food is not feasible and represents a great workload when compared with estimating servings consumed.

Each participant, during the first interview, received an explanation of how to use the estimated DRs and how to estimate the serving size consumed [12,13], using a pamphlet with a series of 2-4 color photographs [10,13,14,27] (one series for each food group). To assist with estimating serving sizes, each photograph was accompanied by explanatory text and three reference objects of known/predictable size for the students [30,31] (fiducial markers): a commonly used pencil, pen, and a marker.

The DRs used were based on a DR previously validated for another European country [13], but structured according to the typical Spanish diet (breakfast, lunch, an afternoon snack, and dinner), and pre-codified with a column that included the same 10 food groups selected for the e-12HR. The serving sizes were based on a semiquantitative FFQ previously validated for the Spanish population [35].

Participants were told that they must record the consumption data on a separate page for each day [7], and immediately after consuming the food [7,13].

Second Interview: Completing the Semiquantitative Food Frequency Questionnaire

At the end of the e-12HR data collection period, each participant was scheduled for a second personal interview at their convenience. In this interview, the participant was required to fill out a structured, semiquantitative FFQ (on paper) that

included the same 10 food groups selected for the e-12HR. The same research team member who performed the first interview then explained to each participant, in this second interview, the process for completing the semiquantitative FFQ, and provided them with an explanatory pamphlet to estimate what was considered a standard serving for each food group. This pamphlet contained a photograph of a standard serving for each food group along with explanatory text and three reference objects of a known/predictable size for students [30,31] (fiducial markers): a commonly used pencil, pen, and marker. The time period considered by the FFQ corresponded to the 28 days of the app. All participants completed the semiquantitative FFQ within the first week of finishing the e-12HR app with the exception of two participants, who completed the FFQ 8 and 11 days later.

The semiquantitative FFQ, as well as standard serving sizes, was based on a semiquantitative FFQ previously validated for the Spanish population [35].

Finally, in the second personal interview, participants were asked how much time, on average, was needed to complete the daily questionnaire on the app. Participants could choose between various options. Of the total participants, 11% (10/87) selected the option *less than 1 minute per day*; 36% (31/87) selected the option *approximately 1 minute per day*; 28% (24/87) chose *approximately 2 minutes per day*; 17% (15/87) chose *approximately 3 minutes per day*; 7% (6/87) chose *approximately 4 minutes per day*; and 1% (1/87) chose the *5 minutes per day or more* option. Almost half of the participants, 47% (41/87) indicated that the task took 1 minute or less per day to complete and 75% (65/87) stated that it took 2 minutes or less. For this reason, the research team considers that the time necessary to complete the app is, normally, 2 minutes per day or less.

Legal Considerations

The study was carried out according to the rules established by the Declaration of Helsinki and the Law on Biomedical Research [37].

All of the personal information collected in this study was anonymized in accordance with current Spanish legislation [38]. To achieve this, each participant was assigned a personal alphanumeric code that they had to enter into the e-12HR app (only when first accessing the app) and include on the different paper questionnaires that were provided: the initial questionnaire (personal information), on the four estimated DRs, and on the semiquantitative FFQ. The personal alphanumeric code was used to match all of the data pertaining to the participant while at the same time respecting their anonymity.

Data Conversion

Using the e-12HR app, each participant recorded the number of standard serving sizes consumed daily for each food group throughout the 28-day study period. With the four estimated DRs, each participant collected the number of standard serving sizes consumed daily for each food group on four different days throughout the 28-day monitoring period. On the semiquantitative FFQ, each participant selected the number of standard serving sizes habitually consumed for each food group throughout the 28-day monitoring period.

For each participant, the data from the e-12HR app, the four DRs and the FFQ had to be expressed in the same categories of habitual consumption to make comparisons: *Less than once a week; Once or twice a week, 3-4 times a week, 5-6 times a week; Once or twice a day, and 3 or more times a day*. On the FFQ, these different options for habitual consumption were already available for the participants to choose from and, as such, the FFQ data was not modified. Regarding the e-12HR app, the data needed to be transformed. As an example, one participant registered an average daily consumption of 0.52 standard servings of legumes over 28 days using the app. This average consumption represents 3.64 standard servings per week (0.52 × 7 = 3.64), which would be classified as *3–4 times per week* [25]. As for the four DRs, the information they contained also needed to be converted [9]. As an example, one participant recorded consuming 0, 0.3, and 1 standard piece of fruit on the DRs during the weekdays and 1.5 standard pieces of fruit on the DR completed at the weekend. This consumption represents an average daily consumption during weekdays of: (0 + 0.3 + 1)/3 = 0.43 standard pieces. As for weekly consumption, the conversion was as follows: (0.43 × 5 weekdays) + (1.5 × 2 weekend days) = 2.17 + 3 = 5.17 standard pieces, which would then be classified as *5-6 times per week*.

To enable making comparisons, the three tools registered the consumption of the same food groups, used the same standard servings as a reference and the intake record corresponded to the same time period, to avoid possible variations in the specific diets during different periods [20,32,39,40].

Statistical Analysis

In this study, when comparing e-12HR with the FFQ and the four DRs for each of the selected food groups, the association between the categories of habitual consumption was evaluated using the Spearman correlation coefficient (SCC) whereas the degree of agreement between the categories of habitual consumption was evaluated using cross-classification analysis and the weighted kappa index [1,41]. For the cross-classification analysis, the percentage of participants classified in the same group was labeled *exact agreement*; in the same category or adjacent categories, *exact agreement + adjacent*; or in opposite categories, *extreme disagreement*, using different methods. For weighted kappa, partial values were assigned using the statistical program Stata: from 1.00 for an exact agreement to 0.00 for extreme disagreement.

The comparison criteria considered in this study were: average SCC≥0.5 [1,32]; average cross-classification percentage in the *exact agreement* category ≥50% [1], in the *exact agreement + adjacent* ≥75% [32], and in the *extreme disagreement* category <10%; with an average κ≥0.41 [1].

The statistical analysis was performed utilizing STATA MP 13.1 (Stata Corp LP, College Station, Texas, USA), and a *P* value < .05 was considered statistically significant [42].

Results

Overview

Of the 95 participants who signed the informed consent, 8 did not complete the study. Results of these individuals were not included in later statistical analyses. Participants who did not complete the study were those who performed the task fewer than 22 days, did not complete the FFQ and did not complete the four DRs.

Of the 87 participants who completed the study, 78% (68/87) completed the task every day (28 days of monitoring), 94% (82/87) of the participants completed the app at least 24 days, whereas the remaining 6% (5/87) completed the app for 22 days (Table 1).

The average age of participants was 19.2 years old; 64% (56/87) were women, and 36% were men (31/87), and 67% (58/87) were medical students and 33% (29/87) were pharmacy students (Table 1). No statistically significant differences in the variables studied were found among participants who completed the study and those who did not.

12-Hour Dietary Recall Versus Food Frequency Questionnaire

For all food groups: the average SCC was .70 (per food group, from .50 [legumes] to .86 [beer]; Table 2). Cross-classification analysis showed that the average percentage of individuals classified in the *exact agreement* category was 51.5% (per food group, from 37.9% [chicken/turkey] to 70.1% [beer]); *exact agreement + adjacent* was 91.8% (per food group, from 85.1% [sweets] to 96.6% [legumes & prepared foods]; Table 3); and no participants (0%) were classified in the *extreme disagreement* category. The average weighted kappa was .51 (per food group, from .34 [chicken/turkey] to .66 [fruit & beer]; Table 4).

12-Hour Dietary Recall Versus the Four Dietary Records

For all food groups: the average SCC was 0.63 (per food group from 0.46 [legumes] to 0.83 [fruit]; Table 2). Cross-classification analysis showed that the average percentage of individuals classified in the *exact agreement* category was 47.1% (per food group, from 31.0% [chicken/turkey] to 66.7% [beer]); *exact agreement + adjacent* was 89.2% (per food group, from 83.9% [soft drinks] to 95.4% [legumes]; Table 3); and no participants (0%) were classified in the category of *extreme disagreement*. The average weighted kappa was 0.47 (per food group, from 0.26 [fish] to 0.72 [fruit]; Table 4).

Table 1. Characteristics of study participants.

Characteristics	n (%)	Mean (SD)	95% CI
Participants who completed the study	87	–[a]	–
Number of days completed the app			
28	68 (78.2)	–	–
27	5 (5.7)	–	–
26	3 (3.4)	–	–
25	5 (5.7)	–	–
24	1 (1.1)	–	–
22	5 (5.7)	–	–
Age (years)	–	19.2 (3.3)	–
Gender			
Female	56 (64.4)	–	74.4-53.4
Male	31 (35.6)	–	25.6-46.6
Faculty			
Medicine	58 (66.7)	–	55.7-76.4
Pharmacy	29 (33.3)	–	44.3-23.6

[a]Not applicable.

Table 2. Spearman correlation coefficient (SCC) derived from 12-hour dietary recall (e-12HR) versus the food frequency questionnaire (FFQ) and from e-12HR versus the four dietary records (DRs).

Comparison	e-12HR vs FFQ		e-12HR vs DRs	
	SCC	*P* value	SCC	*P* value
Fruit	0.84	<.001	0.83	<.001
Vegetables	0.80	<.001	0.72	<.001
Legumes	0.50	<.001	0.46	<.001
Chicken/turkey	0.53	<.001	0.60	<.001
Fish	0.65	<.001	0.47	<.001
Red meat	0.69	<.001	0.50	<.001
Soft drinks	0.81	<.001	0.72	<.001
Sweets	0.71	<.001	0.74	<.001
Prepared foods	0.61	<.001	0.60	<.001
Beer	0.86	<.001	0.70	<.001
Average	0.70	N/A[a]	0.63	N/A

[a]N/A: not applicable.

Table 3. Cross-classification analysis derived from electronic 12-hour dietary recall (e-12HR) versus the food frequency questionnaire (FFQ) and from e-12HR versus the four dietary records (DRs).

Comparison	e-12HR vs FFQ		e-12HR vs DR	
	Exact agreement[a] (%)	Exact agreement + adjacent[b] (%)	Exact agreement (%)	Exact agreement + adjacent (%)
Fruit	54.0	87.4	65.5	93.1
Vegetables	49.4	92.0	39.1	90.8
Legumes	56.3	96.6	55.2	95.4
Chicken/turkey	37.9	86.2	31.0	87.4
Fish	48.3	90.8	32.2	88.5
Red meat	58.6	95.4	39.1	88.5
Soft drinks	52.9	95.4	57.5	83.9
Sweets	40.2	85.1	40.2	89.6
Prepared foods	47.1	96.6	44.8	88.5
Beer	70.1	92.0	66.7	86.2
Average	51.5	91.8	47.1	89.2

[a]Exact agreement: % of cases cross-classified into the same category.

[b]Exact agreement + adjacent: % of cases cross-classified into the same or adjacent category.

Table 4. Weighted kappa derived from electronic 12-hour dietary recall (e-12HR) versus the food frequency questionnaire (FFQ) and from e-12HR versus the four dietary records (DRs).

Comparison	e-12HR vs FFQ		e-12HR vs DRs	
	Kappa	*P* value	Kappa	*P* value
Fruit	0.66	<.001	0.72	<.001
Vegetables	0.61	<.001	0.51	<.001
Legumes	0.38	<.001	0.34	<.001
Chicken/turkey	0.34	<.001	0.36	<.001
Fish	0.41	<.001	0.26	<.001
Red meat	0.54	<.001	0.34	<.001
Soft drinks	0.59	<.001	0.60	<.001
Sweets	0.48	<.001	0.49	<.001
Prepared foods	0.41	<.001	0.44	<.001
Beer	0.66	<.001	0.63	<.001
Average	0.51	N/A[a]	0.47	N/A

[a]N/A: not applicable.

Discussion

Overview

Current-day recall is a modified 24-hour recall focused on a series of food groups and completed at the end of every day during the monitoring period. This method has been designed to classify individuals according to categories of habitual consumption of selected food groups and is not intended to be used to determine total food consumption for an individual [25]. This study is the first time that current-day recall, based on the e-12HR app, has been compared with two different reference models, one long-term (the FFQ) and the other short-term (four DRs) to determine the utility of this new method as a tool for estimating the usual dietary intake of a series of food groups.

Reference Methods

Evaluating the *true validity* of a method requires measuring, with a high degree of accuracy, the habitual diet of free-living individuals during a prolonged period of time, which is not feasible [1]. As a result, the researchers of this study have evaluated the *relative validity* of the method by comparing it with an alternative method of dietary assessment, with its own limitations [1]. Given that none of the comparison methods are perfect [5,8,39,43], as all are subjective, it is of crucial importance for their errors to be as independent as possible to avoid falsely attributing validity to the method in question [5,6,8,16,20,34,44]. For this reason, the research team considered the FFQ and DRs to be possible reference methods and not 24-hour recalls (current-day recall is a modified 24-hour recall). As neither the FFQ nor the DRs can be considered definitive reference methods, the research team selected both methods for this validation study. Aware that the quantity of work for participants could be excessive, a semiquantitative FFQ was selected (to be completed at the end of the e-12HR monitoring period) and four DRs (estimated).

Principal Results

12-Hour Dietary Recall Versus the Food Frequency Questionnaire

For all food groups: the average SCC was 0.70 (in 10/10 food groups SCC≥0.50 [1,32]). Cross-classification analysis showed that the average percentage of individuals classified in the category of *exact agreement* was 51.5% (in 5/10 food groups ≥50% [1]); *exact agreement + adjacent* was 91.8% (10/10 food groups ≥75% [32]); and no participants (0%) were classified in the category of *extreme disagreement* [1]. The average weighted kappa was .51 (in 8/10 food groups κ≥0.41 [1]). These values indicate good agreement between the two methods [1,32]). Values obtained were very similar to those from previous studies with the older version of the e-12HR app, which did not use photographs to facilitate estimation of servings consumed [45].

12-Hour Dietary Recall Versus the Four Dietary Records

For all food groups: the average SCC was 0.63 (in 8/10 food groups SCC≥0.50 [1,32]). Cross-classification analysis showed that the average percentage of individuals classified in the category of *exact agreement* was 47.1% (in 4/10 food groups ≥50% [1]); *exact agreement + adjacent* was 89.2% (10/10 food groups ≥75% [32]); and no participants (0%) were classified in the *extreme disagreement* category [1]. The average weighted kappa was 0.47 (in 6/10 food groups κ≥0.41 [1]). These values indicate good agreement between the two methods [1,32]). This is the first time that the e-12HR app has been compared with the DRs and as such there are no prior results for reference.

It is important to note that the cross-classification analysis and k depend on the number of categories used [1]. With the goal of reducing this dependence when evaluating the degree of agreement between different methods, the six original categories could have been reorganized into three [1,8,25], four [32,33] or five [46,47], as other authors have done. Notwithstanding, this research team preferred to maintain six categories for the statistical analysis [45] as a greater number of categories of

habitual consumption provides compact information on the ability of methods to assign individuals according to agreement with the distribution of dietary intake [46]. Comparison criteria applied to this study were also considered by Masson et al [1] and Forster et al [32]. However, considering that these authors only used three and four categories of habitual consumption, respectively, the demands of this study are much more restrictive. In this study, the classification of the *exact agreement* categories *suffered* especially, whereas the criteria used by Mason et al (*exact agreement* ≥50%) was defined by three categories versus the six considered here.

The results demonstrate good agreement between e-12HR and both reference methods (FFQ and DRs). Nevertheless, certain disagreement was observed with the app. Regarding the FFQ: the average cross-classification analysis showed that 8.2% of participants were classified at a distance of 2–4 categories. As for the DRs: the average cross-classification analysis showed that 10.8% of participants were classified at a distance of 2-4 categories. The three methods (e-12HR, FFQ, and DRs) are all based on self-administered and anonymized questionnaires and use the same color photographs for directly estimating servings. Because these questionnaires were both self-administered and anonymized (with the use of alphanumeric codes), they enabled researchers to avoid information biases, such as obsequiousness bias and researcher bias in all three methods. Using the same photographs also favors the same precision in the three methods when estimating servings. In this sense, each participant serves as their own *control*, thereby minimizing differences when considering servings consumed. In any case, consumption frequency seems to have a greater impact on dietary intake than on serving size [5,9].

However, differences between the three methods are factors that could potentially contribute to the discrepancies observed. The fundamental differences between the methods are centered on both the regularity in collecting data on dietary intake and the format used in the questionnaires.

Regularity in Collecting Data on Dietary Intake

With DRs, the collection of data was performed after consuming each food group throughout the four days selected; with the e-12HR app, data collection takes place at the end of each day during the 28-day monitoring period; in the FFQ, data was collected at the end of the monitoring period. These differences in regularity mean that the accuracy of the information depends on both the memory of the participant and the daily variation in dietary intake among free-living individuals.

With DRs, dependance on memory is not an issue [12]; the e-12HR app is short-term memory dependent; while FFQs depend on long-term memory.

The e-12HR does not interfere with daily variation as it is completed every day; however, an effect is seen on the FFQ, with only one point of data collected, and the DRs, where data is collected sporadically (only 4/28 days during the monitoring period).

Format Used in Questionnaires

The app is digital and both the FFQ and DRs are completed on paper. Paper formats are typically associated with errors such as unanswered questions, questions with multiple responses [10] (FFQ), and not registering the quantity consumed for some of the different food groups selected (DRs) [48]. In addition, the information on paper questionnaires must be converted subsequently to digital format for analysis, which increases both the workload and costs for the research team [17,40]. Online FFQs and DRs, or even smartphone apps, offer direct solutions to these limitations [10,13,20,30-32,40,49-53], by reducing paper waste and mailing costs, and removing the need for secure storage space and organization inherent with paper documents [50]. Additionally, online administrative methods can be used to gain access to specific population groups that would otherwise be difficult to study due to geography, for example, as they can be used remotely [32]. Despite the potential advantages of utilizing FFQs and DRs in digital format, in the end it was decided to use paper formats in this study. The research team took into account that evidence shows that data collected from smartphone apps and both Web-based FFQs and DRs are comparable with data from paper formats [7,14,16,27,29,31-34,40,46,54]. The team also considered the characteristics of this study and the potential disadvantages of developing FFQs and DRs in a digital format that could outweigh the possible benefits. In fact, in this study, the paper-based FFQ and the DRs were very short and simple (they only contain 10 food groups), and the sample population is made up of students at the Schools of Medicine and Pharmacy at the University of Seville, which was easily accessible for the research team.

The simplicity of the paper-based FFQ and DRs minimized possible errors, the amount of paper used, problems with storage space, and costs associated with data conversion. These costs were minimal when compared with the potential costs of developing an online or smartphone-based FFQ and DRs.

Easy access to the sample made it possible to complete the paper FFQ in person, without the need for researchers or participants to travel or pay mailing costs [25].

Strengths and Limitations

The strengths of this study include that the e-12HR is a tool that depends only on short-term memory (the app is completed at the end of each day), it does not interfere with variability of dietary intake in daily life (the app is completed daily). In addition, it has a digital format (young people and adolescents have shown their preference for methods that use digital technology versus traditional methods [31,53]—improving motivation and completion rates [48]). These characteristics support greater accuracy in assigning the category of habitual consumption in those cases where the ranking assigned by current-day recall is different from that assigned by reference methods. Also, with the e-12HR app, data collection is performed digitally, eliminating the need for investigators to enter the data manually; it is a self-reporting tool, not requiring interviewers; it is both simple and intuitive to use, with photographs to assist with estimating servings consumed; and overall research costs are greatly reduced.

Limitations of this study include that the sample used was extremely educated, which is a convenient sample and not representative of the youth population on the national level. Another limitation derives from the need to have a smartphone with an Android operating system. Access to these technologies is not universal and could exclude those students with less purchasing power [25]. Also, even though two different reference methods were used for the e-12HR app, it is important to note that the high degree of association and agreement between the data collected when comparing different methods does not indicate that current-day recall is exact, as there is no true measurement of dietary intake [5,8,39,43]. Ideally, validation studies should include the use of nutritional biomarkers, but currently there are few biomarkers for specific foods [12,43,44,55] and they cannot measure habitual intake [43].

Future Research

Future research will focus on the selection of other study samples, additional food groups, different monitoring periods for comparison, and with varying regularity for completing the app from daily, as in this study, to two days, three days, etc.

Conclusions

The good agreement between e-12HR and both reference methods, as illustrated by the results of various statistical analyses demonstrate the *relative validity* of current-day recall for determining categories of habitual intake for specific food groups, and even for those foods that are consumed infrequently. For large-scale epidemiological studies with samples of individuals who have grown up using new technologies and that do not require determining the complete diet, e-12HR can be a useful tool to replace other methods which are oftentimes longer, more expensive, and require a larger workload for both participants and researchers. Additionally, e-12HR can be a useful tool in a clinical context. Healthcare professionals can use the app with patients/users who are accustomed to new technologies. Individual information obtained through the app could be used as a baseline for health education and promotion activities: specific activities for each patient/user focused on those specific food groups that require a change in consumption patterns.

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Conflicts of Interest

None declared.

Authors' Contributions

LMB performed the conception and design of the study, developed the app, analyzed and interpreted data, and wrote the paper. OAR and MDG were involved in data collection and interpretation of the data, and contributed in drafting the article.

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Abbreviations

DR: dietary record
e-12HR: electronic 12-hour dietary recall
FFQ: food frequency questionnaire

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Original Paper

Association Between Self-Reported and Objective Activity Levels by Demographic Factors: Ecological Momentary Assessment Study in Children

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Abstract

Background: To address the limitations of the retrospective self-reports of activity, such as its susceptibility to recall bias, researchers have shifted toward collecting real-time activity data on mobile devices via ecological momentary assessment (EMA). Although EMA is becoming increasingly common, it is not known how EMA self-reports of physical activity and sedentary behaviors relate to the objective measures of activity or whether there are factors that may influence the strength of association between these two measures. Understanding the relationship between EMA and accelerometry can optimize future instrument selection in studies assessing activity and health outcomes.

Objective: The aim of this study was to examine the associations between EMA-reported sports or exercise using the accelerometer-measured moderate-to-vigorous physical activity (MVPA) and EMA-reported TV, videos, or video games with the accelerometer-measured sedentary time (ST) in children during matched 2-h windows and test potential moderators.

Methods: Children (N=192; mean age 9.6 years; 94/192, 49.0% male; 104/192, 54.2% Hispanic; and 73/192, 38.0% overweight or obese) wore an accelerometer and completed up to 7 EMA prompts per day for 8 days during nonschool time, reporting on past 2-h sports or exercise and TV, videos, or video games. Multilevel models were used to assess the relationship between the accelerometer-measured ST and EMA-reported TV, videos, or video games. Given the zero-inflated distribution of MVPA, 2-part models were used assess the relationship between the accelerometer-measured MVPA and EMA-reported sports or exercise.

Results: EMA-reported TV, videos, or video games were associated with a greater accelerometer-measured ST (beta=7.3, 95% CI 5.5 to 9.0, P<.001). This relationship was stronger in boys (beta=9.9, 95% CI 7.2 to 12.6, P<.001) than that in girls (beta=4.9, 95% CI 2.6 to 7.2, P≤.001). EMA-reported sports or exercise was associated with a greater accelerometer-measured MVPA (zero portion P<.001; positive portion P<.001). This relationship was stronger on weekends, in older children, and in non-Hispanic children (zero portion all P values<.001; positive portion all P values<.001).

Conclusions: EMA reports highly relate to accelerometer measures. However, the differences in the strength of association depending on various demographic characteristics suggest that future research should use both EMA and accelerometers to measure activity to collect complementary activity data.

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KEYWORDS

sedentary behavior; physical activity; measurement; mobile devices; children

Introduction

Low physical activity (PA) is associated with cardiometabolic risk factors such as adiposity, insulin resistance, and elevated diastolic blood pressure in children [1]. Separate from PA, sedentary behaviors, typically accumulated in the form of screen time, are also associated with health consequences in children. For example, sedentary time (ST) is associated with higher body mass index (BMI) [2] and other cardiometabolic risk indicators such as increased triglyceride and blood glucose levels [3]. Furthermore, the combination of low levels of PA and high levels of ST may be particularly detrimental for children's health because of the potentially synergistic nature of their health consequences [4]. To reduce morbidity and mortality, existing research has focused on gaining a better understanding of these health behaviors in children. However, research in this area is only as effective as the tools utilized to measure these variables.

Prior to the development of objective measures of activity, retrospective self-report measures, which ask participants to recall the intensity, duration, and frequency of activities over one or more days, were often utilized; however, these measures can be subject to recall errors and biases, especially in children [5,6]. Recalling PA and time spent engaged in sedentary behaviors is a demanding cognitive task for children, whose activities tend to be intermittent and vary in nature [5]. The field of behavioral health research shifted toward the use of device-based measures of activity, such as accelerometers, due to investigators becoming increasingly cognizant of the limitations of retrospective self-reports for activity data.

Accelerometers can be used to objectively quantify the frequency and duration of PA and ST in children [7] by detecting accelerations in movement [8]. These small hip- or wrist-worn devices are capable of measuring movement on 3 axes, vertical, anteroposterior, and lateral planes [8]. Thus, accelerometers are able to determine the frequency, duration, and intensity of movement in various directions and also do not require the cognitive demands of recalling activity behaviors, making them useful for measuring activity in children in a free-living environment [8]. However, there are some limitations to using accelerometers to assess PA and ST. Depending on their placement, accelerometers do not accurately capture upper body movements [9]. Furthermore, distinguishing wear time from ST can be a challenge when utilizing accelerometers [9]. Accelerometers also cannot provide insight with regard to the type of sedentary behaviors that are being performed by the participant. Evidence suggests that different types of sedentary behaviors, such as screen time and reading, have different relationships with physical and mental health indicators, such as BMI [10] and symptoms of emotional disorders in youth [11,12]. Thus, understanding the types of PA or sedentary behaviors undertaken is essential to investigate health outcomes. Therefore, accelerometers alone are limited in their ability to provide fully comprehensive information with regard to activity data.

To address the limitations associated with retrospective self-reports and to provide complementary activity data to accelerometers that otherwise would not be captured (eg, differentiating reading from sedentary screen time), investigators can use real-time self-report methods such as ecological momentary assessment (EMA) to assess the levels and types of PA and sedentary behaviors [13]. Using mobile technology, EMA methods address the limitations of retrospective self-report (eg, recall error and biases) by prompting participants to answer survey questions about recent behaviors occurring across limited time windows ranging from a few minutes to a few hours [14].

Traditional retrospective self-report methods of PA and sedentary behavior are only weakly correlated with device-based approaches such as accelerometry owing to the challenges described above [15]. Whether EMA reports provide measures of PA and sedentary behavior that are associated with accelerometer measures in children has yet to be tested in depth. Furthermore, multiple studies have indicated that correspondence between self-reports and accelerometer measures can differ based on demographic characteristics [16,17]; thus, investigating the role of potential modifiers is essential to optimizing measurement selection. Therefore, the aim of this study was to provide a preliminary assessment of the construct validity of EMA measures of structured leisure time PA (ie, sports or exercise) by comparing these measures with an accelerometer-measured moderate-to-vigorous PA (MVPA) in children. Evidence across multiple studies suggests that leisure time PA often occurs in the form of MVPA in youth [18,19]. Additionally, this study aimed to assess the construct validity of EMA measures of sedentary screen behaviors (ie, TV, videos, or video games) by comparing these measures with the accelerometer-measured ST in children. A secondary aim was to investigate whether the associations between the levels of activity measured by EMA and an accelerometer differ by child age, sex, ethnicity, or weight status; and on weekends versus weekdays—given that children's levels of PA and time spent in sedentary behaviors can differ according to these variables [20,21].

Methods

Participants

Data were collected from children participating in the longitudinal observational Mothers' and Their Children's Health (MATCH) study. Baseline data were used for this analysis. The goal of the MATCH study was to examine the effects of maternal stress on obesity risk in children living in Southern California. Participant recruitment occurred via flyers and in-person research staff visits at public elementary schools and community events. The inclusion criteria for mother–child dyads were (1) the child is in the 3rd-6th grade (aged 8-12 years), (2) more than half of the child's custody belongs to the mother, and (3) both mother and child are able to read English or Spanish. Dyads were excluded from the study if the mother or the child (1) was taking medications for thyroid function or psychological

conditions, (2) had a health condition that limited PA, (3) was enrolled in a special education program, (4) was currently using oral or inhalant corticosteroids for asthma, (5) was pregnant, (6) the child was classified as underweight by a BMI percentile <5% adjusted for sex and age, or (7) the mother worked more than 2 weekday evenings (between 5-9 pm) per week or more than 8 h on any weekend day. The MATCH study protocol is described in further detail elsewhere [22].

Data Collection

Mothers provided in-person parental consent, and children provided written assent. Mothers completed paper and pencil questionnaires on their child's age, sex, and race or ethnicity during a 90-min data collection session. Additionally, anthropometric measures of the child participants were taken at this time. Specifically, height (centimeters) and weight (kilograms) were collected in duplicate and averaged. Age- and sex-adjusted BMI z-scores were then calculated using the Centers for Disease Control EpiInfo 2005, Version 3.2 resource [22].

The children downloaded a custom-made EMA app for Android mobile phones (Google Inc., Mountain View, CA) on their personal mobile phones. If they did not have their own mobile phone, they were provided with a Moto G mobile phone (Motorola Mobility, Chicago, IL) to use for the duration of the study. After doing so, each child received random EMA prompts after 5:00 pm on the day of the data collection session (day 1) across the next 6 complete days (days 2-7) and up until 5:00 pm on the last day when the phone was returned to the researchers (day 8). On weekends, EMA surveys were prompted up to 7 times per day (between 7:00 am and 8:00 pm). On weekdays, EMA surveys were prompted up to 3 times per day (between 3:00 and 8:00 pm). Participants were instructed to proceed with their normal daily routines during the assessment period. The participant's mobile phone would chime and vibrate to prompt the child to stop his or her current activity and answer EMA survey, which took approximately 2 min to complete. Assessments did not occur during school holidays or summer. At each prompt, children were asked: "In the past 2 HOURS, which of the following have you done? (choose all that apply)." Response options included "sports or exercise" and "TV, videos, and/or video games."

Children were also provided Actigraph accelerometers (Model GT3X, Actigraph Corp., Pensacola, FL) and instructed to wear the devices on their right hip for the same 8 consecutive days as EMA data collection. MVPA was defined based on age-specific Freedson cut points [23], whereas ST was defined as <100 activity counts per minute [24]. Nonwear was defined as 60 min of consecutive zero count epochs [25], and only valid accelerometer wear time was used for this analysis. All accelerometer measurements were time-stamped so that they could be linked to the same time windows as EMA prompts. The University of Southern California Institutional Review Board approved all the procedures.

Statistical Analysis

Frequencies and mean values were calculated for participant demographic characteristics and for EMA and accelerometer variables stratified across participant demographic characteristics and weekends versus weekdays. The mean and standard deviation of the accelerometer-measured activity stratified by yes or no EMA reports of PA (sports or exercise) and sedentary behavior (TV, videos, or video games) were also calculated. EMA prompt compliance was calculated as the proportion of prompts answered out of the total prompts. Additionally, multilevel logistic regression models were utilized to investigate whether age, sex, ethnicity, BMI-z, or weekends versus weekdays were associated with EMA prompt compliance (scored as yes or no). Linear mixed models were used to assess whether age, sex, ethnicity, BMI-z, or weekends versus weekdays were associated with nonvalid accelerometer time.

The relationship between the minutes of the accelerometer-measured ST within the last 2 h and EMA reports of sedentary screen behaviors within the same 2-h time window was investigated via linear mixed models using PROC MIXED in SAS v9.4 (SAS Institute, Cary, NC). Mixed models were used to adjust for the clustering of EMA responses that were nested within each child [26]. The dichotomous EMA reports of sedentary behaviors (ie, TV, videos, or video games) in the past 2 h were the independent variable, and the total minutes of the accelerometer-measured ST in the past 2 h were the dependent variable. All ST models were adjusted for age, sex, ethnicity, BMI-z, and weekends versus weekdays. These covariates were also tested as moderators by multiplying the main effect terms together to create 2-way interaction terms between EMA reports of ST with age, sex, ethnicity, BMI-z, and weekends versus weekdays. They were then entered into the models separately to test the significance of the interaction. Post hoc analyses were conducted where the models were stratified by any significant interaction variables identified. All models were also controlled for between-subject (BS) effects; this was done by creating BS and within-subject (WS) versions of the predictors to indicate an individual's mean variation from the grand mean (using grand-mean centering) and one's variation from his or her own mean (using person-mean centering) at any given prompt [27].

Traditional linear mixed models that assume a normal distribution are not appropriate for MVPA data because they are typically skewed with an inflated number of zero values [28]. Therefore, we used a 2-part model, which utilizes a mixture of logistic regression for zero MVPA values and gamma regression for positive MVPA values [28-30]. The logistic regression portion (zero portion) of the model predicts whether the participant was not active (odds of no activity), whereas the gamma regression portion (positive portion) predicts the expected amount of MVPA on occasions when the participant was active [28]. Thus, there are two interpretations of the results when utilizing this modeling method—the likelihood of no activity (zero portion) and the expected amount of activity when the participant was active (positive portion).

The 2-part models assessed the association between EMA reports of sports or exercise within the last 2 h and accelerometer-measured minutes of MVPA during that same 2-h time window using the "gsem" command in Stata 14.2. These models were adjusted for age, sex, ethnicity, BMI-z, and weekends versus weekdays. The aforementioned covariates

were also tested as moderators by multiplying the main effects terms together to create 2-way interaction terms between EMA reports of PA with age, sex, ethnicity, BMI-z, and weekends versus weekdays. They were then entered into the models one at a time to test the significance of the interaction. Post hoc analyses were conducted, in which the models were stratified by any significant interaction variables identified. All models were also controlled for BS effects by creating BS and WS versions of the predictors using the same method, as previously mentioned [27].

Results

Description of Data Availability and the Study Sample

Our sample consisted of 192 children with available EMA and accelerometer data of the 202 children, in total, enrolled in the MATCH study (Figure 1). As indicated by the flow diagram, exclusion may have occurred for a number of reasons, ranging from technical issues to unanswered EMA prompts. The mean (SD) age of the participants was 9.6 (0.9) years. Half (49.0%, 94/192) of the sample were boys, and 54.2% (104/192) were Hispanic. Of the participants, 38.0% (73/192) of the children were classified as overweight or obese based on their BMI-z. EMA prompt compliance was 75.7% (2158/2851), which is approximately the average level of compliance compared with EMA studies conducted on other samples of children [31]. A total of 157 participants (81.8%) completed 50% or more of possible EMA surveys, consistent with other studies on similar samples [32]. In total, 16 participants (8.3%) completed 100% of EMA surveys prompted during the assessment period of this study. Multilevel logistic regression analyses indicated that the likelihood of EMA prompt compliance was greater on weekends than on weekdays (odds ratio, OR 1.3, 95% CI 1.1 to 1.5). However, there were significantly more nonvalid accelerometer minutes on weekends than on weekdays (beta=16.9, P<.001). Additionally, as the child BMI-z score increased, there was a lower likelihood of EMA compliance (OR 0.8, 95% CI 0.7 to 0.9). No other demographic characteristics were significantly associated with EMA prompt compliance. No demographic characteristics were associated with nonvalid accelerometer time.

Descriptive Statistics

The mean (SD) of the accelerometer-measured MVPA in the 2 h before EMA prompt was 10.4 (14.6) min. The mean (SD) of the accelerometer-measured ST in the 2 h before EMA prompt was 65.8 (21.2) min. Children reported sports or exercise in 37.4% (807/2158) of EMA prompts, and TV, videos, video games were reported in 47.3% (1021/2158) of prompts. Table 1 presents additional descriptive statistics on the accelerometer and EMA variables across participant demographic characteristics and on weekends versus weekdays, whereas Table 2 presents the mean (SD) accelerometer-measured activity stratified by EMA-reported sports or exercise and TV, videos, or video games.

Table 1. Descriptive statistics of accelerometer-measured activity and ecological momentary assessment (EMA)-reported activity during matched 2-h time windows stratified by demographic factors and weekends versus weekdays (Level 1 N=2158, Level 2 N=192).

Characteristic	Accelerometer-measured MVPA[a] (minutes), mean (SD)	EMA-reported sports or exercise (yes), n (%)	Accelerometer-measured ST[b] (minutes), mean (SD)	EMA-reported TV, videos, or video games (yes), n (%)
Sex				
Boys	12.7 (18.7)	370 (36.2)	66.2 (22.2)	496 (48.5)
Girls	8.3 (9.1)	441 (38.8)	65.8 (20.4)	531 (46.7)
Age				
Above 9.6 years	8.28 (10.5)	451 (39.0)	68.3 (20.1)	543 (47.0)
Below 9.6 years	12.9 (18.1)	360 (35.9)	63.2 (22.3)	484 (48.3)
Ethnicity				
Hispanic	10.6 (16.7)	437 (38.8)	65.7 (21.8)	494 (43.9)
Non-Hispanic	10.2 (12.0)	374 (36.2)	66.2 (20.7)	533 (51.7)
BMI-z[c]				
Normal	11.6 (12.6)	538 (38.7)	65.5 (21.7)	691 (49.6)
Overweight or Obese	8.3 (10.3)	273 (36.6)	66.7 (20.44)	336 (43.9)
Weekend vs weekday				
Weekend	9.3 (14.6)	313 (31.7)	69.0 (21.9)	542 (54.9)
Weekday	11.3 (14.7)	498 (42.6)	63.5 (20.5)	485 (41.5)

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

[b]ST: sedentary time.

[c]BMI-z: body mass index z-score.

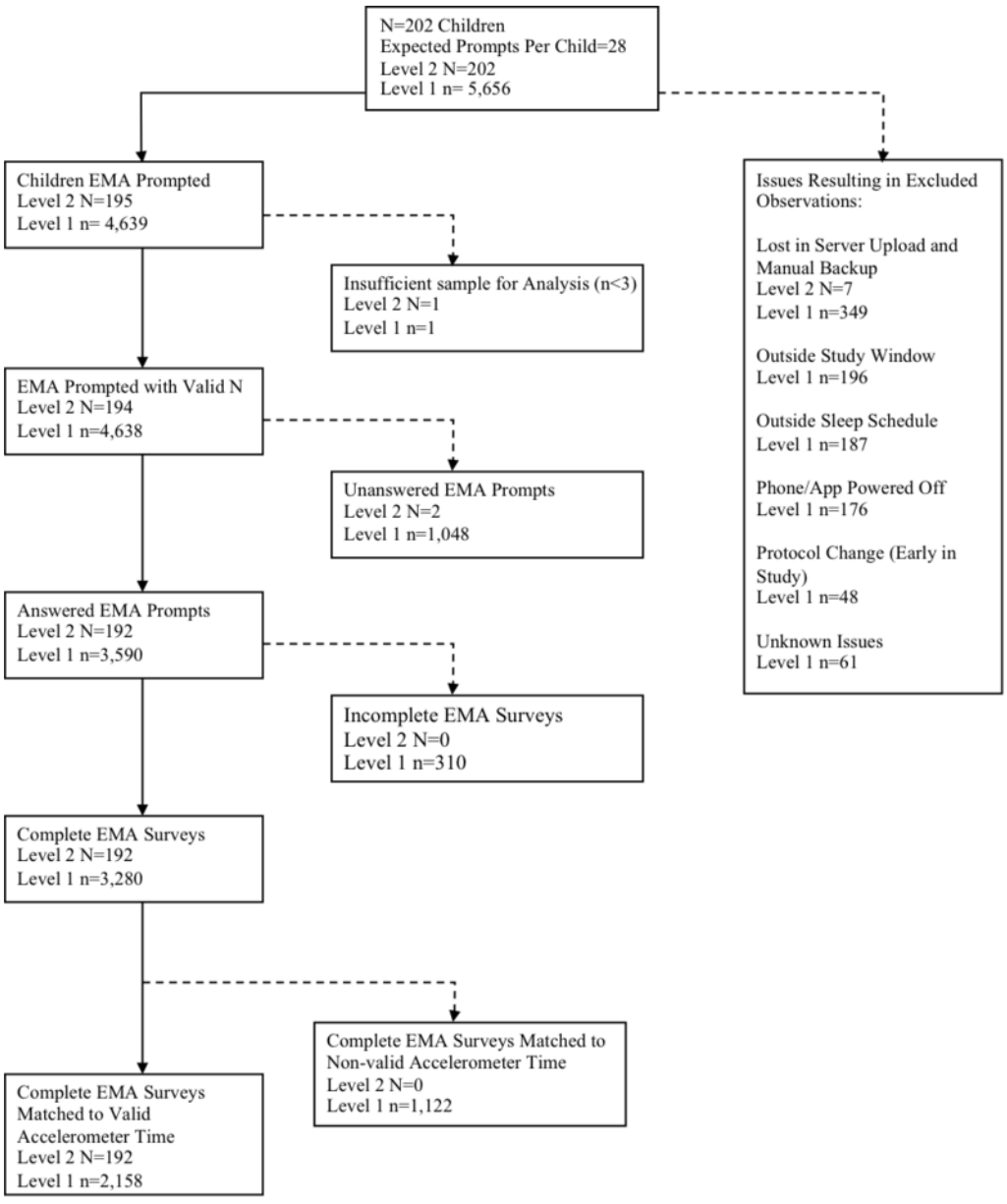
Table 2. Descriptive statistics of the accelerometer-measured activity stratified by yes or no ecological momentary assessment (EMA) reports of sports or exercise and TV, videos, or video games during matched 2-h time windows (Level 1 N=2158, Level 2 N=192).

EMA-reported activity	Accelerometer-measured MVPA[a] (minutes), mean (SD)	Accelerometer-measured ST[b] (minutes), mean (SD)
EMA-reported sports or exercise		
Yes	13.4 (15.9)	60.7 (20.6)
No	7.6 (11.0)	69.3 (20.0)
EMA-reported TV, videos, or video games		
Yes	8.0 (11.9)	70.1 (19.7)
No	11.4 (14.4)	62.4 (20.7)

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

[b]ST: sedentary time.

Figure 1. Solid Lines indicate available data, while dashed lines indicate data lost due to reasons indicated within each box. EMA: ecological momentary assessment.



Associations Between EMA and Accelerometer Measures

Results from the linear mixed models investigating the relationship between EMA-reported sedentary behaviors and accelerometer-measured minutes of ST are shown in Table 3. Child EMA reports of engagement in the past 2-h TV, videos, or video games were associated with the greater minutes of the accelerometer-measured ST during the same time window (beta=7.3, 95% CI 5.5 to 9.0, *P*<.001). Additionally, the interaction between EMA-reported ST and sex was significant (beta=4.9, 95% CI 1.4 to 8.5, *P*=.01, Table 3); the strength of the association between EMA and accelerometer measures of ST was significantly different between boys and girls. Stratified post hoc analyses indicated that this association was twice as strong in boys (beta=9.9, 95% CI 7.2 to 12.6, *P*<.001) than that in girls (beta=4.9, 95% CI 2.6 to 7.2, *P*≤.001). No other significant moderators were found.

The results of the models investigating the relationship between EMA-reported sports or exercise and accelerometer-measured minutes of MVPA are shown in Table 4. The positive portion (the expected amount of activity measured by the accelerometer on occasions when the participant reported sports or exercise via EMA) and zero portion (likelihood of no activity measured by the accelerometer on occasions when the participant reported being active via EMA) of the 2-part model indicate a significant relationship between EMA and the accelerometer-measured activity in the total sample (zero portion estimate=−0.8, 95% CI −1.1 to −0.6, *P*<.001; positive portion estimate=0.6, 95% CI 0.5 to 0.7, *P*<.001). When the participant was active (according to the accelerometer) and reported sports or exercise via EMA in the last 2 h, this was associated with an 80.4% increase in the minutes of MVPA within that same time frame. Furthermore, when sports or exercise was reported via EMA, the odds of no MVPA measured by the accelerometer decreased by a factor of 56.8%.

The interaction term between EMA reports of sports or exercise and weekends versus weekdays was statistically significant, indicating a moderation of the association between EMA-reported sports or exercise and accelerometer-measured MVPA (zero portion estimate=−0.3, 95% CI −0.8 to 0.2, *P*=.24; positive portion estimate=0.2, 95% CI 0.05 to 0.4, *P*=.01). The relationship between the accelerometer-measured MVPA and EMA reports was stronger on weekends than on weekdays (Table 4). According to the positive portion of the model, if the participant had any accelerometer-measured MVPA, reporting sports or exercise via EMA was associated with a 103.4% increase in minutes of MVPA on weekends compared with only a 53.7% increase in minutes of MVPA on weekdays. Furthermore, when sports or exercise was reported via EMA, the odds of no accelerometer-measured MVPA decreased by 65.7% on weekends, whereas this was 30.2% on weekdays, according to the zero portion of the model.

In addition to weekends versus weekdays, age was found to be a significant moderator of the relationship between EMA-reported sports or exercise and accelerometer-measured MVPA (zero portion estimate=−0.1, 95% CI −0.4 to 0.2, *P*=.43; positive portion estimate=0.1, 95% CI 0.02 to 0.2, *P*=.02). This relationship was stronger in participants above the mean age of 9.6 years than in those below the mean age (Table 4). In children with an age above the mean age, if he or she had accelerometer-measured MVPA and reported sports or exercise, then there was a 101.4% expected increase in minutes of MVPA, whereas this expected increase was just 60% in children below the mean age, according to the positive portion of the model in each subsample. Furthermore, the odds of no accelerometer-measured MVPA decreased by a factor of 60.7% when exercise or sports were reported via EMA in children above the mean age compared with the reduced odds by a factor of 49.8% in children below the mean age, as indicated by the zero portions of each model.

Table 3. Coefficients with standard errors, 95% CI, and *P* values of mixed model with ecological momentary assessment (EMA) reports of sedentary screen behaviors as the predictor at level 1 on the accelerometer-measured sedentary time and mixed model with the significant interaction between EMA-reported sedentary screen behaviors and sex (Level 1 N=2158, Level 2 N=192).

EMA-reported activity	Model 1[a]			Model 2[a]		
	β (SE)	95% CI	*P*	β (SE)	95% CI	*P*
Accelerometer-measured ST[b] with Level 1 predictor						
EMA-reported TV, videos, or video games	8.1 (0.9)	6.3 to 9.8	<.001	8.1 (0.9)	6.3 to 9.8	<.001
Accelerometer-measured ST with Level 1 predictor adjusted for covariates at Level 2						
EMA-reported TV, videos, or video games	7.3 (0.9)	5.5 to 9.0	<.001	4.9 (1.2)	2.5 to 7.4	<.001
Accelerometer-measured ST with cross-level interaction						
EMA-reported TV, videos, or video games x sex	N/A[c]	N/A	N/A	4.9 (1.8)	1.4 to 8.5	<.01

[a]The models are adjusted for sex, age, ethnicity, body mass index z-score, and weekends versus weekdays at level 2.

[b]ST: sedentary time.

[c]N/A: not applicable.

Table 4. Estimates with SE, 95% CI, and *P* values of the 2-part model with ecological momentary assessment (EMA) reports of leisure time physical activity predicting the accelerometer-measured MVPA in the total sample and stratified by the significant moderators of weekends versus weekdays, age, and ethnicity (Level 1 N=2158, Level 2 N=192).

EMA report of sports or exercise	Zero portion			Positive portion		
	Estimate (SE)[a]	95% CI	*P*	Estimate (SE)[a]	95% CI	*P*
Total sample (L1 N=2158)[b]	−0.8 (0.1)	−1.1 to −0.6	<.001	0.6 (0.1)	0.5 to 0.7	<.001
On weekends (L1 n=988)[b]	−1.1 (0.2)	−1.4 to −0.8	<.001	0.7 (0.1)	0.6 to 0.9	<.001
On weekdays (L1 n=1170)[b]	−0.4 (0.2)	−0.8 to 0.1	.10	0.4 (0.1)	0.3 to 0.5	<.001
Above 9.6 years old (L1 n=1156)[b]	−0.9 (0.2)	−1.2 to −0.6	<.001	0.7 (0.1)	0.6 to 0.8	<.001
Below 9.6 years old (L1 n=1002)[b]	−0.7 (0.2)	−1.1 to −0.3	.001	0.5 (0.1)	0.4 to 0.6	<.001
Non-Hispanic (L1 n=1032)[b]	−0.8 (0.2)	−1.2 to −0.4	<.001	0.7 (0.1)	0.6 to 0.9	<.001
Hispanic (L1 n=1126)[b]	−0.9 (0.2)	−1.2 to −0.5	<.001	0.5 (0.1)	0.4 to 0.6	<.001

[a]The models are adjusted for sex, age, ethnicity, body mass index z-score, and weekends versus weekdays.

[b]The abovementioned estimates have been exponentiated in the body of the paper for ease of interpretation.

Finally, ethnicity was also determined to be a significant moderator of the relationship between the accelerometer-measured MVPA and EMA-reported sports or exercise (zero portion estimate=−0.1, 95% CI −0.6 to 0.5, *P*=.86; positive portion estimate −0.2, 95% CI −0.4 to −0.1, *P*=.01). This relationship was stronger in non-Hispanic versus Hispanic children (Table 4). According to the positive portion of the model, if the participant had accelerometer-measured MVPA and reported sports or exercise, there was a 107.5% expected increase in minutes of MVPA in non-Hispanic children, whereas this increase in daily minutes of MVPA was only expected to be 61.6% in Hispanic children. The estimates from the zero portion of the model indicated that when the participant reported activity via EMA, the odds of no accelerometer-measured MVPA reduced by a factor of 56.0% in the non-Hispanic children. Similarly, these odds were reduced by a factor of 57.3% in the Hispanic participants. No other significant moderators were found between the accelerometer-measured MVPA and EMA reports of sports or exercise.

Discussion

Principal Findings

This is the first study comparing ST and MVPA measured concurrently by accelerometry and EMA-reported sedentary behaviors (ie, TV, videos, or video games) and PA (ie, sports or exercise) in children while also testing the moderators of the aforementioned relationships. Results indicated that EMA-reported sedentary behaviors were strongly positively associated with the accelerometer-measured minutes of ST during the same 2-h time frame. These findings indicate that EMA may be a promising method for capturing the specific forms of sedentary behavior through self-report with a very short-term recall window. Furthermore, EMA can provide contextual information such as where and with whom the behavior was performed [13]. The social and physical environments are important in understanding complex health behaviors, including sedentary behaviors [33]. For example, the built environment [34], peer relationships [35], and the day of the week [36] have all been shown to influence the levels of sedentary behavior in children. Other retrospective self-report tools for assessing sedentary behavior, such as the outdoor playtime recall questionnaire, are unable to provide such details surrounding sedentary behaviors and have demonstrated weak correlations with the accelerometer-measured ST [37,38]. Therefore, EMA may be more effective at capturing factors relevant to ST than other self-report measures previously utilized by investigators.

Although this evidence suggests that EMA is a helpful tool for gaining a better understanding of sedentary behavior in children, the results suggest that it may perform better in boys. The relationship between the accelerometer-measured ST and EMA reports of TV, videos, or video games was stronger in boys than in girls. These differences may emerge from the differences in leisure time sedentary behavior preferences in boys versus girls [39]. Studies indicate that boys spend more time playing computer games [40], whereas girls may prefer sedentary activities such as painting or drawing and playing musical instruments [39]. Therefore, EMA item capturing screen-based behaviors such as video games may have been a better indicator of the boys' ST in our sample.

Results also showed a strong association between the accelerometer-measured MVPA and EMA reports of sports or exercise. When sports or exercise was reported in the past 2 h via EMA, significantly more minutes of MVPA were recorded by accelerometers during this time frame, and this was consistent with previous findings in adults [41]. A recent study comparing retrospective self-reports of PA and accelerometer-measured PA in youth found no relationship between the two [37]. Moreover, participants have been shown to overestimate the amounts of PA that they engaged in by an average of 596 minutes per week when utilizing retrospective questionnaires [17], highlighting the need for more effective self-report methods, particularly in children. The results of this study suggest that EMA self-reported PA highly relates to the accelerometer-measured PA, and children did not necessarily overestimate physical activity to the same degree when reporting

via EMA. Secondary analyses of our data further support this notion; when there were zero minutes of the accelerometer-measured MVPA in the previous 2 h, participants in our sample only self-reported sports or exercise via EMA on 18% of occasions. Therefore, EMA has the potential to address the aforementioned weaknesses of other self-report PA measures by reducing the prevalence of over reports of PA.

However, when utilizing EMA as a PA data capture tool in children, investigators should be cognizant of time-variant and time-invariant variables that may influence the construct validity of EMA prompts. Specifically, the accelerometer-measured MVPA was more strongly related to EMA reports of sports or exercise on weekends than on weekdays. Multiple studies have demonstrated that the amount and types of PA that children participate in can differ between weekdays and weekends [36,42]. Children may be more likely to engage in nonrecreational types of PA during weekdays, such as active school transport (ie, walking), which may not be effectively captured by EMA item assessing leisure time PA in this study. Furthermore, a recent study conducted in more than 6200 children aged 9-11 years indicated that engaging in active school transport during the week was related to a greater accelerometer-measured MVPA during those days [43]. Therefore, activities such as active school transport during the week may contribute to the greater discrepancy observed between the accelerometer-measured MVPA and leisure time PA reported via EMA during weekdays.

Additionally, we found that the strength of the association between EMA self-reports of sports or exercise and accelerometer-measured MVPA differed between age groups. In those above the mean age of 9.6 years, the observed association between the two measures was stronger. In a study of more than 1000 active children aged 5-15 years, the investigators found that younger participants engaged in a more intermittent type of active play, whereas older children accumulated PA through walking and organized sport [44]. These differences in PA patterns may account for the age variations in the measurement associations that were observed within the current sample. Therefore, EMA item measuring sports or exercise, specifically, may be more successful at capturing the types of PA accumulated by older children, whereas the objective measures may be considered as the preferred method for capturing younger children's physical activity behaviors, consistent with previous findings [45].

Finally, EMA reports of sports or exercise were more strongly related to the accelerometer-measured MVPA in non-Hispanic versus Hispanic children. In a nationally representative survey of children aged 9-13 years, it was determined that non-Hispanic children were significantly more likely to be involved in organized sports than their Hispanic counterparts [46]. To further support this notion, a large study of Hispanic children determined that first-generation Hispanic participants were less likely to report engaging in sports compared with their second- and third-generation peers [47]. Therefore, it may be that Hispanic children are accumulating PA through activities other than sports as a result of cultural preferences [47]. Thus, the current EMA items regarding leisure time sports or exercise may not be optimal for capturing PA behaviors in Hispanic participants.

This study highlights the strengths and weaknesses of EMA as a self-report tool for assessing leisure time PA and sedentary behavior data in children. Overall, EMA reports relate highly to the accelerometer-measured MVPA and ST. However, the moderators of this relationship reveal the limitations of EMA. EMA prompts asking about TV, videos, or video games might be a better indicator of ST in boys than in girls. Additionally, EMA prompts measuring sports or exercise appear to be a better indicator of PA on weekends than on weekdays. Finally, EMA self-reports of sports or exercise may be more effective for assessing PA in older (above 9.6 years old in our sample) and non-Hispanic children. To address the limitations of EMA, investigators may tailor EMA items to capture the types of PA and sedentary behaviors typically performed by individual participants in their samples. If tailoring EMA items is not feasible, the moderators of the relationship between EMA reports and objectively measured activity levels should be considered when analyzing and interpreting EMA data. As a general recommendation, it is also suggested that future investigators utilize both accelerometers and EMA simultaneously, depending on the scope of the investigation. It may be more useful to utilize EMA in studies assessing different types of behaviors (eg, reading vs computer use) that are being performed at any given moment, whereas accelerometers may be more useful in circumstances when investigators are interested in the overall frequency or duration of activity behaviors. Informed instrument selection will ultimately increase our understanding of PA and sedentary behaviors and how they relate to preventable health issues.

Limitations

Although our study has several strengths, there are limitations to note. Depending on their placement, accelerometers cannot detect all bodily movements such as upper body activities, and their detection of activity is sensitive to chosen cut points. Furthermore, EMA responses may be subject to recall bias, though to a lesser extent, compared with the traditional retrospective self-report strategies [13]. Therefore, a study comparing two tools that have inherent limitations may ultimately be considered as a weakness. Additionally, we were not able to assess whether the amount of time elapsed between EMA prompt and the provision of an answer moderated EMA-accelerometer associations in this study. Furthermore, children were not EMA-prompted before 3 pm on weekdays; therefore, the results from this study may not generalize the behaviors and activities performed during school hours. In addition to this, the first prompt after 3 pm on weekdays asked participants about their behaviors "since you woke up this morning," as opposed to asking about the previous 2-h behaviors. Therefore, the behaviors reported during this EMA prompt may not reflect the past 2-h activity levels measured via accelerometer. However, post hoc exploratory analyses removing the first prompts of weekdays (the prompts asking about behaviors since the participant woke up that morning) minimally altered our parameter estimates and results. This pattern suggests that these EMA items did not influence our findings.

Another limitation of this study is that contextual (eg, environmental or social) data were not assessed, and this may influence EMA-accelerometer associations; future studies should attempt to address this limitation. EMA prompt compliance was greater on weekends and in children with lower BMI-z. Thus, our findings may not be as generalizable to data captured on weekdays as well as data collected in heavier participants. Additionally, there was more nonvalid accelerometer time on weekends, which presents as an additional limitation for generalizability. Finally, our sample from Southern California metropolitan community, which contains more than 50% Hispanic participants, may differ from the general population of youth living in the United States and therefore may limit the generalizability of our results. Future studies should attempt to address these generalizability issues.

Conclusions

Findings indicate that EMA reports of TV, videos, or video games were strongly related to the accelerometer-measured ST during the same 2-h time frame. However, this relationship was stronger in boys than in girls. Although EMA reports of sports or exercise were associated with the accelerometer-measured MVPA, time-variant (weekends vs weekdays) and -invariant (age and ethnicity) variables were found to be the moderators of this relationship. EMA reports of sports or exercise and accelerometer-measured MVPA were more strongly associated on weekends, in older children, and in non-Hispanic participants. These moderators can be addressed by tailoring EMA items designed to capture PA and sedentary behaviors based on specific participant demographics and the day of the week. Taken together, this study supports EMA as a useful self-report tool for capturing PA and sedentary behavior in children because it demonstrates a high correlation with objectively measured activity levels.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
EMA: ecological momentary assessment
MVPA: moderate-to-vigorous physical activity
PA: physical activity
ST: sedentary time

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Original Paper

Learnability of a Configurator Empowering End Users to Create Mobile Data Collection Instruments: Usability Study

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Abstract

Background: Many research domains still heavily rely on paper-based data collection procedures, despite numerous associated drawbacks. The QuestionSys framework is intended to empower researchers as well as clinicians without programming skills to develop their own smart mobile apps in order to collect data for their specific scenarios.

Objective: In order to validate the feasibility of this model-driven, end-user programming approach, we conducted a study with 80 participants.

Methods: Across 2 sessions (7 days between Session 1 and Session 2), participants had to model 10 data collection instruments (5 at each session) with the developed configurator component of the framework. In this context, performance measures like the time and operations needed as well as the resulting errors were evaluated. Participants were separated into two groups (ie, novices vs experts) based on prior knowledge in process modeling, which is one fundamental pillar of the QuestionSys framework.

Results: Statistical analysis (*t* tests) revealed that novices showed significant learning effects for errors (P=.04), operations (P<.001), and time (P<.001) from the first to the last use of the configurator. Experts showed significant learning effects for operations (P=.001) and time (P<.001), but not for errors as the experts' errors were already very low at the first modeling of the data collection instrument. Moreover, regarding the time and operations needed, novices got significantly better at the third modeling task than experts were at the first one (*t* tests; P<.001 for time and P=.002 for operations). Regarding errors, novices did not get significantly better at working with any of the 10 data collection instruments than experts were at the first modeling task, but novices' error rates for all 5 data collection instruments at Session 2 were not significantly different anymore from those of experts at the first modeling task. After 7 days of not using the configurator (from Session 1 to Session 2), the experts' learning effect at the end of Session 1 remained stable at the beginning of Session 2, but the novices' learning effect at the end of Session 1 showed a significant decay at the beginning of Session 2 regarding time and operations (*t* tests; P<.001 for time and P=.03 for operations).

Conclusions: In conclusion, novices were able to use the configurator properly and showed fast (but unstable) learning effects, resulting in their performances becoming as good as those of experts (which were already good) after having little experience with the configurator. Following this, researchers and clinicians can use the QuestionSys configurator to develop data collection apps for smart mobile devices on their own.

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KEYWORDS

mHealth; data collection; mobile apps

Introduction

In psychology and social sciences, *self-report questionnaires* are commonly used to collect data in various situations [1]. These data are predominantly collected using *paper-based* questionnaires, which are costly regarding the subsequent processing and analysis of the collected data. Furthermore, the latter has to be transferred to digital spreadsheet documents, which is a time-consuming and error-prone task, especially in the context of large-scale trials or studies. According to one estimate, approximately 50%-60% of the costs related to the collection, transfer, and processing of the data could be saved using digital instruments instead of paper-based ones [2]. Additionally, electronic questionnaires do not differ from the paper-based versions in psychometric properties [3]. Moreover, they contribute to more complete datasets compared with the ones collected using pencil and paper [4], resulting in a better data quality [5]. Finally, the digitally collected data may be enriched with contextual information [6] (eg, time and location) or sensor data [7] (eg, pulse measurement during an interview). In general, digital instruments are in increasing demand to support clinical trials or other psychological studies [8].

Over the last decade, several Web-based questionnaire apps (eg, *LimeSurvey* or *SurveyMonkey*) emerged, enabling end users to create online questionnaires themselves. Although these apps are useful, they are not suitable in certain application scenarios. Among others, Web questionnaires require permanent internet access and are usually unable to capture data from external sensors (eg, camera, Global Positioning System, or vital parameter sensors). *Smart mobile devices* (eg, mobile phones or tablets), in turn, could act as an enabler for scenarios in which Web questionnaires are not sufficient. Mobile devices have already proven their applicability in the context of various business scenarios [9], ranging from simple task management apps to sophisticated business analytics platforms to even apps supporting ward rounds in hospitals [10].

Contrary to these findings, however, mobile data collection apps are still rarely used in large-scale scenarios, like clinical or psychological trials. The following three reasons are of paramount importance in this context:

1. Researchers are unaware of the capabilities of and opportunities offered by smart mobile devices in their respective domain. This can also be traced back to the high costs of such devices, especially in the context of large-scale studies requiring multiple devices.
2. Already existing data collection apps do not adequately support researchers. There might be legal aspects that need to be considered (eg, “Where shall the data be stored?”, “Who shall be allowed to access the data?”); the mobile apps might require permanent internet access, or their advanced features (eg, use of sensors during the data collection procedure) need to be supported.
3. Implementing sophisticated mobile data collection apps usually requires considerable communication efforts between researchers and mobile app developers. This communication is further aggravated due to the fact that both groups use different *languages* (ie, terminology, or [graphical] notations) to express themselves.

It is noteworthy that there are several mobile apps proving the applicability of smart mobile devices in the context of data collection scenarios, such as *Manage My Pain* [11] or *Track Your Tinnitus* [12]. Although the participants involved in respective scenarios gave positive feedback, several shortcomings could still be observed. The latter include, for example, high development costs, the need for skilled app developers, or the common business-IT alignment gap (ie, domain experts being unable to express what developers shall realize) [13]. When relying purely on smart mobile devices for data collection purposes, specific participant groups may be excluded (eg, elderly) [14]. Furthermore, providing respective mobile app for only one mobile operating system (eg, Android or iOS) might result in biased samples as their users can differ regarding various aspects such as income, age, or education [15].

We also observed these issues in several long-running, large-scale data collection scenarios for which we had provided mobile apps (see Table 1).

Table 1. Implemented mobile data collection apps.

Data collection scenario	Country	Complex navigation[a]	Duration (years)	App versions	Collected datasets using smart mobile apps
Study on tinnitus research [17]	Worldwide	No	>5	5	≥45,000
Risk factors during pregnancy [18]	Germany	No	>5	5	≥1500
Risk factors after pregnancy	Germany	No	>2	1	≥500
Posttraumatic stress disorder in war regions [19]	Burundi	Yes	4	5	≥2200
Posttraumatic stress disorder in war regions [20]	Uganda	No	1	1	≥200
Adverse childhood experiences [21]	Germany	Yes	2	3	≥150
Learning deficits among medical students	Germany	Yes	1	3	≥200
Supporting parents after accidents of children	European Union	No	>3	6	≥5000
Overall	—	—	—	29	≥54,750

[a]No: complex navigation was not requested/required; yes: complex navigation was requested/required.

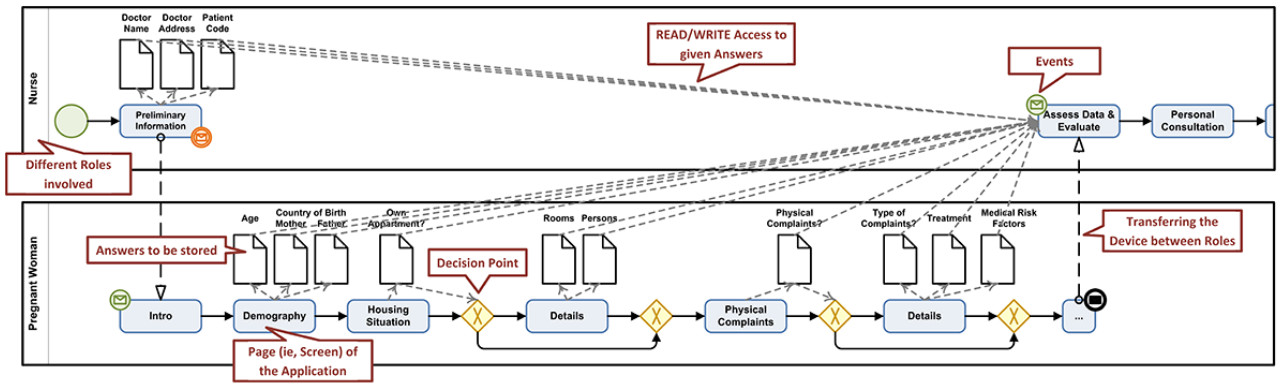
Most of these apps were explicitly tailored and implemented to support a specific application scenario. Developing such a plethora of data collection instruments enabled us to elaborate crucial requirements in this context [16]. Although the involved investigators and clinicians were satisfied with the provided mobile data collection apps, they craved for more sophisticated features over time. The latter include, for example, audio-recordings during interviews, additional notes, and real-time data analyses. Furthermore, maintaining these specifically implemented apps over time was a costly and time-consuming endeavor. In order to relieve app developers from such tasks, researchers as well as clinicians should be enabled to develop mobile apps themselves. Existing approaches [22,23] combine *WordPress*, a blogging software, and *iBuildApp*, a Web-based app builder, to create a platform supporting students from clinical psychiatry. The focus of this platform, however, is on information retrieval (eg, psychiatric guidelines). Furthermore, only limited support regarding the development of digital instruments is provided. Other projects like *MagPi* or *MovisensXS* also provide configurators using simple Web forms, allowing end users to create data collection apps. Our work significantly differs from these approaches as we focus on sophisticated data collection instruments based on advanced *process management technology*. In particular, well-established graphical notations are provided to express various aspects of such data collection instruments. Figure 1 represents an instrument using the Business Process Modeling and Notation (BPMN) 2.0 graphical notation [24] that provides a solid basis for the developed configurator. The latter, however, uses its own graphical notation in order to allow end users without expertise in process modeling to apply such techniques. The modeled instrument, in turn, may then be executed on smart mobile devices, such as mobile phones or tablets.

In general, graphical process notations comprise various elements that allow specifying and visualizing complex business processes in enterprises (eg, partners involved and their roles in the process, data elements, or temporal process constraints). When applying such a notation to the modeling of data collection instruments, several issues emerged. In particular, researchers were overwhelmed by the multitude of graphical elements as well as their semantical meaning needed to properly represent their specific data collection instrument. More precisely, dealing with data elements was especially challenging when modeling such instruments. First, the data element needs to be specified accordingly. Second, a question that produces (ie, writes) this data element must be modeled; third, the data element must be consumed (ie, read) by decisions later in order to properly control the flow of the instrument. Monitoring these aspects, while still dealing with the modeling process in general, is challenging.

To make such an expressive *modeling approach* better accessible for end users with little or no knowledge of process modeling (ie, researchers or clinicians), end-user programming techniques were evaluated. Such techniques, in turn, have proven their feasibility in a multitude of studies to support nonprogrammers. The use of a graphical programming language instead of a text-based one has been evaluated to teach children programming [25]. Their teachers reported that the simplified representation significantly improved the understanding of program code. Another approach [26] applied end-user programming techniques to support administrators in "writing" management scripts used in their daily routines. The "programming" of Web Mashups, which combines operators and functions in a graphical manner, has been previously presented [27]. Among others, these studies have proven the applicability of end-user programming approaches in their specific domain.

Taking the above issues into account, the *QuestionSys* configurator that we developed applies sophisticated end-user programming techniques to properly abstract the modeling of data collection instruments. Accordingly, QuestionSys offers a user-friendly configurator, hiding most of the complexity introduced by process modeling languages. Particularly, this configurator uses its own (graphical) modeling notation based on BPMN 2.0 in order to allow end users without any programming skills or knowledge in process modeling to graphically specify data collection instruments themselves. Therefore, there should be no need for involving IT experts anymore when developing such mobile data collection instruments [28]. To be more precise, QuestionSys particularly focuses on scenarios in which the instruments need to be frequently adapted. Especially these adaptations shall be accomplished by end users with no programming experience in order to reduce costs.

Figure 1. A data collection instrument represented as BPMN 2.0 model.



Frequent adaptations, in turn, require the continuous use of the respective configurator. Especially usability of apps that are used in a daily manner is of paramount importance. One aspect that is relevant in this context is the prior experience needed to learn the app. Following this, it is important for the usability of an app to assess learnability.

For this purpose, in a pilot study, we evaluated the QuestionSys configurator with 44 participants and obtained promising results with respect to the modeling of data collection instruments and overall usability of the configurator [29]. We found that individuals with no experience in process modeling understood how to properly use the configurator. Based on this pilot study, we conducted a larger study with a more sophisticated study design that comprised 2 testing sessions (second session 7 days after the first one) with 5 tasks (ie, modeling data collection instruments) at each session. This refined study and its results are presented in the manuscript at hand. The following research questions (RQs) were addressed with *novices* (ie, individuals with no experience in process modeling) and *experts* (individuals with experience in process modeling):

RQ1: How are the performances of novices and experts changing from the first to the last task (data collection instrument) of Session 1?

RQ2: How are the performances of novices and experts changing from the last task (data collection instrument) of Session 1 to the first task (data collection instrument) of Session 2?

RQ3: How are the performances of novices and experts changing from the first to the last task (data collection instrument) of Session 2?

RQ4: How are the performances of novices and experts changing from the first task (data collection instrument) of Session 1 to the last task (data collection instrument) of Session 2?

RQ5: How many tasks (data collection instruments) are necessary until the performance metrics of novices are as good as those of experts at the first task (data collection instrument)?

Methods

Configurator Component

The combined use of well-known technologies from end-user programming and business process management enables end users to create mobile data collection instruments on their own. The most important views of the configurator component ("Element and Page Repository View" and "Modeling Area View") are sketched in Figures 2 and 3; see [30] for more details.

Element and Page Repository View (see Figure 2). The element repository allows creating basic elements of a questionnaire (eg, texts and questions). The rightmost part shows an editor panel, where particular attributes of the respective elements may be managed. The configurator enables researchers to handle elements in multiple languages and revisions. Most importantly, the created elements may be combined to pages using drag & drop operations.

Figure 2. The QuestionSys configurator: combining elements to pages.

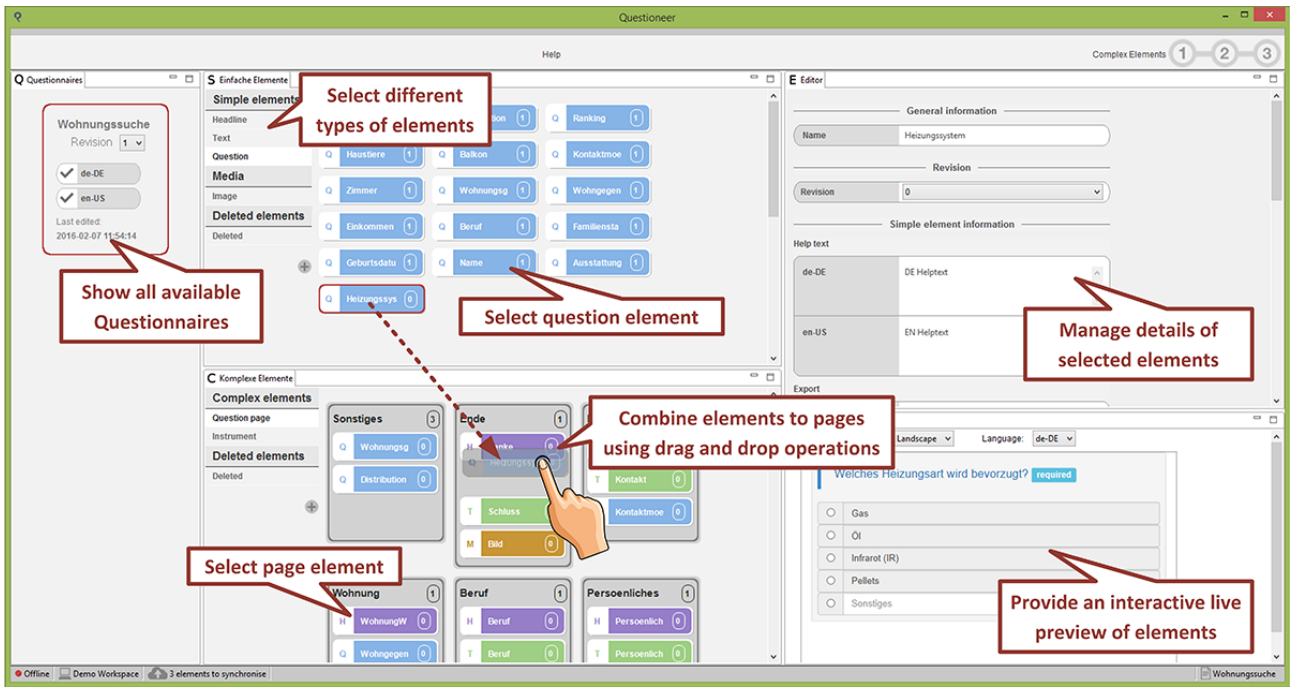
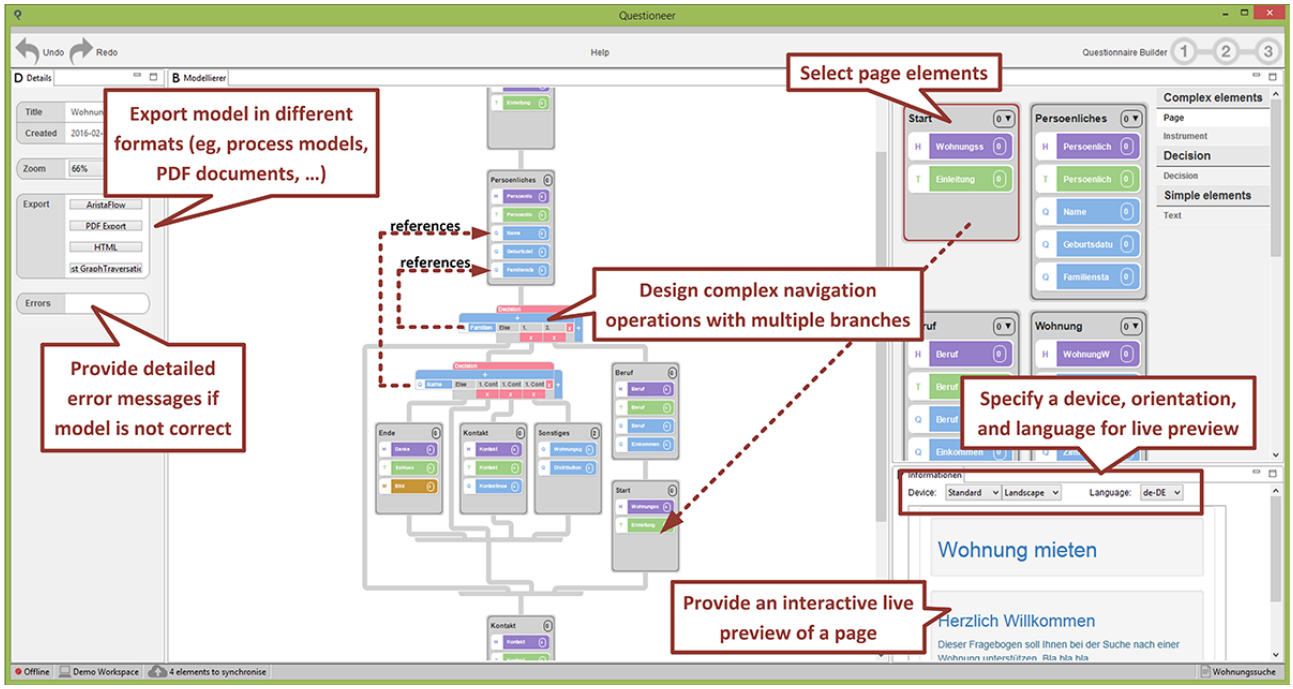


Figure 3. The QuestionSys configurator: modeling a data collection instrument.



Modeling Area View (see Figure 3). Previously created pages may be used to model the structure of the data collection instrument. Furthermore, researchers are able to model advanced navigation operations (eg, to *skip* pages depending on already given answers to previous questions) to adapt the instrument during the data collection process. The modeling view, in turn, provides guidance for untrained users; particularly, it does not allow applying *wrong* operations to the model. Note that the QuestionSys configurator applies its own (graphical) modeling notation. The latter, however, is inspired by BPMN 2.0, but significantly simplifies the modeling process for individuals having no experience with process modeling notations (eg, no explicit data flow needs to be modeled).

Altogether, the configurator component and its model-driven approach allow researchers to graphically define the elements and logic of data collection instruments.

In order to be able to automatically collect the data needed for the evaluation of the configurator component, the latter was enhanced with a *Study Mode* that enables specific features. First, it requires users to enter a *code* before using the configurator. This code, in turn, is used to store all collected data in a dedicated folder. Second, the configurator tracks the *time* when a specific *operation* (eg, adding a page to the model) was performed. Third, after performing the operation, an image of the model is stored on the computer. This allows reproducing the *process of modeling* a data collection instrument step-by-step as well as manually evaluating the *errors* in the resulting model.

Study Procedure

Participants modeled a series of data collection instruments (ie, 5 data collection instruments per session) with the QuestionSys configurator over 2 sessions (with 7 days between Session 1 and Session 2). A controlled environment was chosen for this study in order to be able to quickly react to upcoming problems.

For the study, 20 workstations, each comparable in hardware resources (eg, RAM and central processing unit cores), were prepared in a computer pool at Ulm University. Each workstation was equipped with two monitors running a common resolution. Before each of the 2 sessions, respective workstations were prepared carefully. This includes, for example, reinstalling the configurator component and placing the consent form, description of tasks, and mental effort questionnaires next to the workstation.

The procedure of the study is outlined in Figure 4. The study started with welcoming the participants and introducing the goal of the study as well as the overall procedure. Then, the participants performed 2 tests (2 min each) measuring their processing speed. Both tests are reliable and valid tests of the *Wechsler Adult Intelligence Scale* [31]. Next, we provided a tutorial (approximately 5 min) demonstrating the most important features of the configurator. Before conducting the main part of the study, the participants were asked to fill in a demographic questionnaire. Up to this point in time, the participants were allowed to ask questions. Next, participants had to model 5 data collection instruments (tasks; see Table 2) using solely the provided configurator component, followed by filling in a short questionnaire. Concluding the first session, participants had to answer a short questionnaire again. Altogether, this first session took approximately 50 min.

After pausing for exactly 1 week, the participants were reinvited for a second session. The latter, however, was much shorter as the collection of demographic data could be skipped. Participants were given 5 new tasks (ie, to model 5 new data collection instruments; see Table 2), and they had to answer the short questionnaires again.

The data, automatically recorded by the configurator, were then uploaded to a network-attached storage after each session.

Figure 4. Study design.

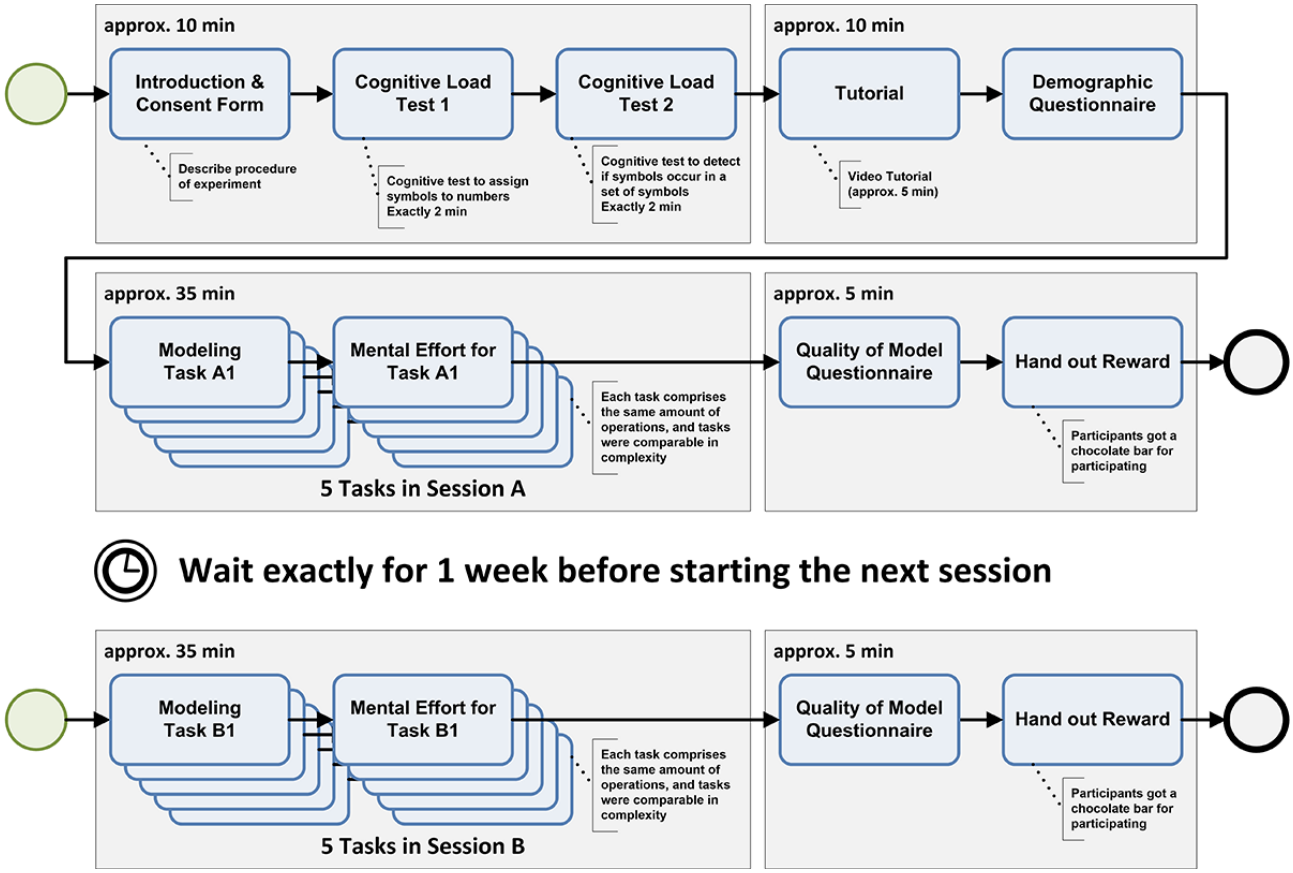


Table 2. Short description of the tasks to be modeled by participants.

#	Modeling a questionnaire	Pages	Decisions
1	...to collect information about flight passengers	5	2
2	...to help customers select an appropriate mobile phone	5	2
3	...to help collect required information for travel expense reports	5	2
4	...to order food and drinks online	5	2
5	...to support customers select a movie and book cinema tickets	5	2
6	...to help customers select an appropriate laptop computer	5	2
7	...to support customers book seats for a theater play	5	2
8	...to inform patients regarding their upcoming surgery	5	2
9	...to guide customers through the process of purchasing a new coffee machine and equipment	5	2
10	...to collect required data to conclude a contract in a gym	5	2

All materials and methods were approved by the Ethics Committee of Ulm University and were carried out in accordance with the approved guidelines. All participants gave their informed consent.

Tutorial

Before working with the configurator app, a screencast tutorial was presented directly to each participant. The latter was recorded by us; it describes how to create a very simple data collection instrument. No voice or sound was recorded; however, the screencast was annotated with small comments in postproduction.

Tasks

Each task to be modeled was presented in a textual representation that described the overall structure of the data collection instrument to be created.

When designing the tasks for the participants, we paid close attention to the fact that all 10 tasks were mutually comparable. As this study intended to measure the learnability, which is a contributory factor of the overall usability of the configurator, it was of utmost importance to keep the complexity for all modeling tasks constant. Tasks in divergent complexity, in turn, may limit the validity of the study results as a change in performance measures may be attributed to a more complex

model itself or respective learning effect. The overall complexity includes, on one hand, the complexity of the textual representation handed out to the participants and, on the other, the complexity of the resulting data collection instrument.

All tasks were designed so that a perfect instrument modeling solution would need exactly the same number of operations. Furthermore, each model contained two decision points in order to influence the further processing of the instrument based on given answers. Thematically, the models to be created were selected from various domains, ranging from a health care instrument up to a questionnaire for a food delivery service (see Table 2).

Participants

In total, 80 participants were recruited at Ulm University for the experiment. Most of them were students or research associates from various departments, like computer science, economics, chemistry, psychology, and medicine [32]. We recruited participants from these different disciplines to allow a comparison of how individuals with no experience in process modeling can learn using the configurator compared with individuals with experience in process modeling. The target group (end users from medical, psychological, or social sciences) that shall be empowered by the configurator to develop mobile data collection instruments has most probably no experience in process modeling. During the recruitment phase, we paid close attention to maintaining the balance between female and male participants. Students willing to participate were instructed according to the developed study design, which was explained to them before, and they were additionally informed that there will be 2 consecutive sessions to attend. To ensure that all participants correctly understood the tasks to be performed by them, all relevant material was handed out in German [33]. Participants who answered the prequestion (ie, a question in the demographic questionnaire) *"Do you have experience in process modeling"* with *yes* were classified as *experts*, whereas participants who answered this question with *no* were classified as *novices*. It should be kept in mind that this is only one (simplified) possibility to classify participants into *novices* and *experts*. Another possibility would be more in-depth prequestioning of participants (eg, asking about familiarity with notations such as BPMN, asking for examples of process models they have created, and asking specific questions about particular items in process modeling notations). This would lead to a spectrum of rated expertise, rather than the simplified binary approach used in this study.

Altogether, our classification resulted in 45 novices and 35 experts. Three of the recruited participants did not participate in the second session (1 novice and 2 experts). Therefore, RQs 2-4 (RQs that included data gathered in the second session) were investigated with 77 participants (44 novices and 33 experts).

Baseline Measures

To evaluate whether experts and novices differed in their cognitive abilities, we performed 2 established tests measuring their processing speed [31]. Within 2 min each, participants had to assign symbols to numbers ("Digital Symbol Coding") and detect symbols from within a set of symbols ("Symbol Search"). Differences in cognitive abilities at baseline would be a confounder as a higher cognitive ability could result in better or faster learnability of the configurator.

Questionnaires

A demographic questionnaire collecting personal information (eg, gender or education) was handed out to the participants. Specific focus was put on questions about their prior knowledge regarding process modeling, in general, or about how many process models they had read and written during the last 12 months, in particular. After completing each task, participants had to answer 5 questions regarding their mental effort when modeling the instrument. At the end of each session, they had to answer questions regarding the quality of the modeled instruments or their own competence when working with the provided configurator component.

Performance Measures

The following performance measures were collected:

Time

The moment participants started modeling their instruments, the respective timestamp was added to an Excel file stored in the configurator app's directory. Once the task was completed, another timestamp was added to the file. This allowed us to evaluate the time taken to complete the respective tasks on a fine-grained level (values were assessed in milliseconds).

Operations

Whenever participants interacted with the instrument (eg, by adding a new page), their specific operations were logged in an Excel file. In addition, the time at which the participant executed this operation was logged. Finally, the configurator took an image of the current model after performing the respective operation and stored it to the directory of the participant.

Errors

It was not possible for the configurator to automatically assess the errors in the resulting model (eg, order of branches in decision points may be switched or respective statements may be inverted). Therefore, we manually evaluated all created models based on the provided images. As the configurator provided a snapshot of the model after each operation, it was possible to recreate the modeling process of each participant. Furthermore, this allowed us to assess the models on a fine-grained basis.

Statistics

SPSS 23 was used for all statistical analyses. Frequencies, percentages, means, and standard deviations were calculated as descriptive statistics. Novices and experts were compared in baseline variables using Fisher's exact tests and *t* tests for independent samples. To test RQs 1-4, *t* tests for dependent samples were performed to investigate the change in the performance measures between the tasks (data collection instruments) specified in the corresponding RQ; these *t* tests for dependent samples, in turn, were conducted separately for novices and experts. *t* tests for independent samples were performed to evaluate RQ5, thereby performances of novices

at each task (data collection instrument) were compared with those of experts at Task 1 of Session 1 (first data collection instrument) in order to identify the tasks (data collection instruments) for which the performances of novices were not significantly different from those of experts at Task 1 of Session 1 (first data collection instrument). All statistical tests were performed two tailed; the significance value was set to $P<.05$.

Data Availability

The raw data set containing all collected data that was analyzed during this study is included in this paper (and its supplementary material).

Results

Baseline Comparison Between Novices and Experts

Table 3 summarizes the sample description and comparisons between novices and experts in baseline variables. There were more female participants in the novices' sample and more male participants in the experts' sample ($P=.003$). Moreover, the experts' sample comprised a higher percentage of participants with a bachelor degree as highest education than the novices' sample, whereas the latter comprised a higher percentage of participants with graduating high school as highest education ($P=.009$). While a higher percentage of the novices' sample studied psychology than the experts' sample, a higher percentage in the latter studied economics or computer science than in the former ($P=.001$).

Table 3. Sample description and comparison between novices and experts in baseline variables.

Variable	Novices (n=45)	Experts (n=35)	*P* value
Gender, n (%)			
Female	31 (69)	12 (34)	
Male	14 (31)	23 (66)	.003[a]
Age (years), mean (SD)	21.20 (2.63)	22.72 (2.97)	
Age category, n (%)			
<25 years	29 (64)	17 (49)	
25-35 years	16 (36)	18 (51)	.180[a]
Highest education, n (%)			
High school	13 (29)	2 (6)	
Bachelor	32 (71)	32 (91)	
Master	0 (0)	1 (3)	.009[a]
Current field of study, n (%)[b]			
Economics	14 (33)	12 (40)	
Media computer science	0 (0)	8 (27)	
Computer science	1 (2)	6 (20)	
International business	0 (0)	1 (3)	
Chemistry	2 (5)	0 (0)	
Psychology	26 (60.5)	3 (10)	.001[a]
Processing speed test 1: digital symbol coding, mean (SD)			
Correct answers	84.33 (21.76)	81.11 (21.89)	.515
Wrong answers	0.07 (0.25)	0.06 (0.24)	.864
Processing speed test 2: symbol search, mean (SD)			
Correct answers	41.93 (7.77)	38.91 (8.53)	.103
Wrong answers	1.73 (1.98)	1.63 (1.50)	.795

[a]Fisher's exact test.

[b]N=73/80 (91%) participants gave information on their current field of study.

Results for RQ1

Time

Novices (n=45): The mean time (in milliseconds) required for the first task of Session 1 (first data collection instrument) was 452,334.29 (SD 209,527.70), and the mean time required for the last task of Session 1 (fifth data collection instrument) was 135,273.89 (SD 49,861.64). This improvement reached statistical significance: t (44)=10.71; P<.001.

Experts (n=35): The mean time needed (in milliseconds) for a task significantly decreased from 405,444.89 (SD 248,497.68) at the first task of Session 1 (first data collection instrument) to 147,251.91 (SD 91,181.39) at the last task of Session 1 (fifth data collection instrument): t (34)=6.12; P<.001.

Operations

Novices (n=45): Operations significantly decreased from a mean 17.60 (SD 7.87) at the first task of Session 1 (first data collection instrument) to 11.24 (SD 3.68) at the last task of Session 1 (fifth data collection instrument): t (44)=5.23; P<.001.

Experts (n=35): Significantly less operations were needed at the last task of Session 1 (fifth data collection instrument) than at the first task of Session 1 (first data collection instrument): 17.49 (SD 11.20) at the first task of Session 1 and 11.31 (SD 3.98) at the last task of Session 1: t (34)=3.41; P=.002.

Errors

Novices (n=45): Errors nonsignificantly decreased from 1.24 (SD 2.15) at the first task of Session 1 (first data collection instrument) to 1.00 (SD 1.83) at the last task of Session 1 (fifth data collection instrument): t (44)=0.88; P=.386.

Experts (n=34, as errors were not available for one expert because of corrupted snapshot images): Errors decreased from a mean of 0.35 (SD 0.88) at the first task of Session 1 (first data collection instrument) to 0.32 (SD 0.84) at the last task of Session 1 (fifth data collection instrument). However, this change was not statistically significant: t (33)=0.16; P=.876.

Results for RQ2

Time

Novices (n=44): The mean time (in milliseconds) significantly increased from the last task of Session 1 (fifth data collection instrument) to the first task of Session 2 (sixth data collection instrument): 133,725.80 (SD 49,332.01) versus 235,291.93 (SD 167,630.02); t (43)=−3.82; P<.001.

Experts (n=33): No significant change in the mean time (in milliseconds) emerged between the last task of Session 1 (fifth data collection instrument) and the first task of Session 2 (sixth data collection instrument): 148,253.30 (SD 93,726.57) versus 222,304.67 (SD 227,425.64); t (32)=−1.76; P=.088.

Operations

Novices (n=44): Significantly more operations were observed at the first task of Session 2 (sixth data collection instrument) than at the last task of Session 1 (fifth data collection instrument): 11.11 (SD 3.61) versus 13.89 (SD 6.88); t (43)=−2.25; P=.030.

Experts (n=33): Operations did not significantly change between the last task of Session 1 (fifth data collection instrument) and the first task of Session 2 (sixth data collection instrument): 10.97 (SD 3.62) versus 12.70 (SD 5.93); t (32)=−1.46, P=.155.

Errors

Novices (n=44): Errors did not significantly change between the last task of Session 1 (fifth data collection instrument) and the first task of Session 2 (sixth data collection instrument): 1.02 (SD 1.85) versus 0.86 (SD 1.44); t (43)=0.69; P=.492.

Experts (n=33): From the last task of Session 1 (fifth data collection instrument) to the first task of Session 2 (sixth data collection instrument), errors did not significantly change: 0.33 (SD 0.85) versus 0.46 (SD 0.97); t (32)=−0.61; P=.545.

Results for RQ3

Time

Novices (n=44): The mean time (in milliseconds) significantly decreased from the first task of Session 2 (sixth data collection instrument), 235,291.93 (SD 167,630.02), to the last task of Session 2 (tenth data collection instrument), 107,957.18 (SD 54,837.64): t (43)=5.12; P<.001.

Experts (n=33): The mean time (in milliseconds) significantly decreased from the first task of Session 2 (sixth data collection instrument), 222,304.67 (SD 227,425.64), to the last task of Session 2 (tenth data collection instrument), 85,600.36 (SD 23,698.01): t (32)=3.53; P=.001.

Operations

Novices (n=44): Operations became significantly less from the first task of Session 2 (sixth data collection instrument), 13.89 (SD 6.88), to the last task of Session 2 (tenth data collection instrument), 11.55 (SD 4.86): t (43)=2.01; P=.050.

Experts (n=33): Significantly less operations were needed at the last task of Session 2 (tenth data collection instrument), 9.45 (SD 1.06), than at the first task of Session 2 (sixth data collection instrument), 12.70 (SD 5.93): t (32)=3.00; P=.005.

Errors

Novices (n=44): Errors did not significantly change between the first task (sixth data collection instrument), 0.86 (SD 1.44), and last task (tenth data collection instrument), 0.64 (SD 1.01), of Session 2: t (43)=1.26; P=.215.

Experts (n=33): No change in errors between the first task (sixth data collection instrument), 0.46 (SD 0.97), and last task (tenth data collection instrument), 0.30 (SD 0.85), of Session 2 emerged: t (32)=0.78; P=.443.

Results for RQ4

Time

Novices (n=44): From the first task of Session 1 (first data collection instrument) to the last task of Session 2 (tenth data collection instrument), the mean time (in milliseconds) significantly decreased: 456,322.02 (SD 210,215.59) versus 107,957.18 (SD 54,837.64); t (43)=11.30; P<.001.

Experts (n=33): The mean time (in milliseconds) significantly decreased from the first task of Session 1 (first data collection instrument) to the last task of Session 2 (tenth data collection instrument) 393,204.06 (SD 46,642.43) versus 85,600.36 (SD 23,698.01); *t* (32)=7.24; *P*<.001.

Operations

Novices (n=44): From the first task of Session 1 (first data collection instrument) to the last task of Session 2 (tenth data collection instrument), operations became significantly less: 17.80 (SD 7.85) versus 11.55 (SD 4.86); *t* (43)=4.98; *P*<.001.

Experts (n=33): Operations significantly decreased from the first task of Session 1 (first data collection instrument) to the last task of Session 2 (tenth data collection instrument): 17.18 (SD 11.41) versus 9.45 (SD 1.06); *t* (32)=3.83; *P*=.001.

Errors

Novices (n=44): Errors significantly decreased from the first task of Session 1 (first data collection instrument) to the last task of Session 2 (tenth data collection instrument): 1.7 (SD 2.17) versus 0.64 (SD 1.01); *t* (43)=2.09; *P*=.043.

Experts (n=33): Errors did not significantly change between the first task of Session 1 (first data collection instrument) and the last task of Session 2 (tenth data collection instrument): 0.36 (SD 0.90) versus 0.30 (SD 0.85); *t* (32)=0.30; *P*=.768.

Results for RQ5

Time

The comparisons between the time (in milliseconds) of experts at the first task of Session 1 and the time of novices at each task are presented in Table 4. It can be seen that novices were not significantly different from experts already at the first task of Session 1 (first data collection instrument) and that the time taken by novices at Tasks 3-10 was significantly less than that taken by experts at Task 1 of Session 1 (*P*=.363 comparing Task 1 of novices with Task 1 of experts; *P*=.062 comparing Task 2 of novices with Task 1 of experts; *P*<.001 comparing Task 3 of novices with Task 1 of experts; *P*<.001 comparing Task 4 of novices with Task 1 of experts; *P*<.001 comparing Task 5 of novices with Task 1 of experts; *P*=.001 comparing Task 6 of novices with Task 1 of experts; *P*<.001 comparing Task 7 of novices with Task 1 of experts; *P*<.001 comparing Task 8 of novices with Task 1 of experts; *P*<.001 comparing Task 9 of novices with Task 1 of experts; *P*<.001 comparing Task 10 of novices with Task 1 of experts).

Operations

Table 5 compares the operations of experts at the first task of Session 1 and those of novices at each task. Again, novices performed not significantly different from experts already at the first task of Session 1 (first data collection instrument). Moreover, the operations of novices at Tasks 3, 4, 5, 7, 8, 9, and 10 were significantly less than those of experts at Task 1 of Session 1. Only the difference between operations of novices at Task 6 (first data collection instrument of Session 2) and those of experts at Task 1 (first data collection instrument of Session 1) did not reach statistical significance (*P*=.957 comparing Task 1 of novices with Task 1 of experts; *P*=.373 comparing Task 2 of novices with Task 1 of experts; *P*=.002 comparing Task 3 of novices with Task 1 of experts; *P*=.027 comparing Task 4 of novices with Task 1 of experts; *P*=.003 comparing Task 5 of novices with Task 1 of experts; *P*=.101 comparing Task 6 of novices with Task 1 of experts; *P*=.007 comparing Task 7 of novices with Task 1 of experts; *P*=.004 comparing Task 8 of novices with Task 1 of experts; *P*=.020 comparing Task 9 of novices with Task 1 of experts; *P*=.005 comparing Task 10 of novices with Task 1 of experts).

Table 4. Comparisons between the time (in milliseconds) taken by experts at the first task of Session 1 and that taken by novices at each task.

Sample and task	Session	N	Mean (SD)	*P* value[a]
Experts				
Task 1	1	35	405,444. 89 (248,497. 68)	—
Novices				
Task 1	1	45	452,334. 29 (209,527. 70)	.363
Task 2	1	45	310,765. 11 (198,970. 99)	.062
Task 3	1	45	173,889. 87 (73,069. 81)	<.001
Task 4	1	45	161,358. 91 (65,405. 85)	<.001
Task 5	1	45	135,273. 89 (49,861. 64)	<.001
Task 6	2	44	235,291. 93 (167,630. 02)	.001
Task 7	2	44	126,357. 86 (59,195. 92)	<.001
Task 8	2	44	188,537. 89 (144,107. 50)	<.001
Task 9	2	44	155,625. 20 (90,902. 41)	<.001
Task 10	2	44	107,957. 18 (54,837. 64)	<.001

[a]*P* values compare experts (Task 1) with novices (Tasks 1-10).

Table 5. Comparison between the operations of experts at the first task of Session 1 and those of novices at each task.

Sample and task	Session	N	Mean (SD)	*P* value[a]
Experts				
Task 1	1	35	17.49 (11.20)	—
Novices				
Task 1	1	45	17.60 (7.87)	.957
Task 2	1	45	15.42 (9.39)	.373
Task 3	1	45	10.84 (3.05)	.002
Task 4	1	45	12.91 (4.19)	.027
Task 5	1	45	11.24 (3.68)	.003
Task 6	2	44	13.89 (6.88)	.101
Task 7	2	44	11.64 (5.33)	.007
Task 8	2	44	11.41 (3.87)	.004
Task 9	2	44	12.46 (5.92)	.020
Task 10	2	44	11.55 (4.86)	.005

[a]*P* values compare experts (Task 1) with novices (Tasks 1-10).

Table 6. Comparisons between the errors of experts for the first task of Session 1 and those of novices at each task.

Sample and task	Session	N	Mean (SD)	*P* value[a]
Experts				
Task 1	1	34	0.35 (0.88)	—
Novices				
Task 1	1	45	1.24 (2.15)	.015
Task 2	1	45	1.40 (2.33)	.008
Task 3	1	45	0.80 (1.56)	.112
Task 4	1	45	1.53 (2.07)	.001
Task 5	1	45	1.00 (1.83)	.042
Task 6	2	44	0.86 (1.44)	.058
Task 7	2	44	0.68 (1.14)	.168
Task 8	2	44	0.75 (1.28)	.109
Task 9	2	44	0.84 (1.52)	.101
Task 10	2	44	0.64 (1.01)	.192

[a]*P* values compare experts (Task 1) with novices (Tasks 1-10).

Errors

Table 6 summarizes the comparisons between the errors of experts at the first task of Session 1 and those of novices at each task. Novices made significantly more errors at almost each task of Session 1 (except for Task 3) than did experts at Task 1 of Session 1.

The errors of novices at each task of Session 2 were, however, not significantly different from those of experts at Task 1 of Session 1 (*P*=.015 comparing Task 1 of novices with Task 1 of experts; *P*=.008 comparing Task 2 of novices with Task 1 of experts; *P*=.112 comparing Task 3 of novices with Task 1 of experts; *P*=.001 comparing Task 4 of novices with Task 1 of experts; *P*=.042 comparing Task 5 of novices with Task 1 of experts; *P*=.058 comparing Task 6 of novices with Task 1 of experts; *P*=.168 comparing Task 7 of novices with Task 1 of experts; *P*=.109 comparing Task 8 of novices with Task 1 of experts; *P*=.101 comparing Task 9 of novices with Task 1 of experts; *P*=.192 comparing Task 10 of novices with Task 1 of experts).

Discussion

This study evaluated the QuestionSys configurator, which was developed to empower end users to develop mobile data collection instruments. In total, 80 participants with and without knowledge of process modeling (ie, experts and novices, respectively) took part and modeled 10 data collection

instruments at 2 sessions. Within each session (RQ1 and RQ3), a learning effect was observed: time and number of operations needed to model the data collection instruments became less in each session for novices as well as for experts. Also, across both sessions (RQ4), novices as well as experts improved their needed time and operations, adding further evidence to the mentioned learning effect. Across both sessions, novices also showed a decrease in errors from the first to the last (tenth) data collection instrument. This learning effect across sessions was not observed for experts, probably because they already had very few errors in the first data collection instrument. Yet, errors were not reduced within sessions, indicating that the learning effect regarding reducing errors took more time in novices than the learning effect regarding time and operations.

One week after Session 1 (without using the configurator component), the performances of experts did not change, but needed operations and time increased again in novices (RQ2). This might indicate that the *within-session* learning effect of novices was not as robust to an interval without using the configurator as the within-session learning effect of experts. One reason to explain this result might be that experts work with this type of app on a "day-to-day" basis, retaining some level of expertise between sessions. When novices did not use the configurator for 1 week, they needed to get themselves acquainted with the configurator again, and our results showed that novices got better or faster relatively quickly when they started using the app again. The *decay of learning* noticed within the novices' sample is a salient factor to be considered and may have practical implications, especially in scenarios requiring infrequent adaptations of instruments. However, as mentioned in the introduction, the QuestionSys configurator addresses the above scenarios in which frequent adaptations of instruments are required. Besides, even for scenarios where infrequent adaptations become necessary, the QuestionSys configurator provides an applicable approach when used by end users experienced in process modeling (ie, experts) as they did not show a decay of learning in this study. However, note that although scenarios with infrequent changes may be supported, they do not constitute the main target of the QuestionSys configurator.

Finally, RQ5 evaluated how many tasks needed to be completed by novices in order to be as good as experts at the first task. Interestingly, novices became significantly faster from the third task on. Moreover, from the third task on, novices needed significantly less operations than experts at the first task, except for Task 6. This might be attributed to the already-mentioned within-session learning effect causing novices to forget how to properly work with the configurator more quickly compared with experts.

Despite the fact that novices did not need to model many data collection instruments in order to be faster and that they needed less operations than experts at the first modeling task, novices were unable to catch up with experts regarding errors. In order to allow for more error-free data collection instruments, more training (than modeling 10 data collection instruments) might be necessary for novices. Furthermore, one could argue that experts are the sample of choice when the data collection instrument should have as less errors as possible.

Several limitations to this study [34] need to be discussed. First, the process of selecting the participants limits external validity or generalizability as mostly students and research associates were recruited for this study. In this context, however, one approach discusses that students may act as proper substitutes in empirical studies [32]. Furthermore, the classification of recruited participants into *novices* and *experts* solely based on a "yes or no" question may be oversimplified and subject for discussion. A more in-depth prequestioning of participants (eg, asking about familiarity with notations such as BPMN, asking for examples of the process models they have created) might allow analysis of how performance depends on the whole spectrum of rated expertise. However, in this study, we aimed to classify novices and experts by distinguishing between no process modeling experiences at all or being in touch with process modeling. Finally, a more elaborated classification by directly observing individuals during modeling or by inspecting the images recorded during the modeling process may be applied in future research. Next, threats to the internal validity constitute the baseline differences between novices and experts regarding gender, education, and field of study. As stated earlier, these differences were intentional as we recruited from different disciplines to be able to compare how well novices could learn using the configurator compared with experts. The target group (end users from medical, psychological, or social sciences) will most likely have no experience in process modeling. Tests measuring processing speed indicated equal cognitive abilities between both groups. Differences in cognitive ability at baseline would be a confounder as this could result in better or faster learnability of the configurator. As another shortcoming, the experts' sample consisted of less participants than the novices' sample so that the statistical power was higher in tests for the novices' sample. Another limitation of this study was that the tasks to be modeled were from various domains (see Table 2). However, the modeling concept used within the configurator is domain agnostic. In order to show the feasibility of this approach for different domains, a vast number of scenarios were modeled. Likewise, the tasks to be modeled did not include modeling of sensors that may be connected to smart mobile devices (eg, to measure vital health care parameters during an interview). In order to deal with these limitations, however, a study specifically targeting health care instruments and the integration of related sensors may be subject for future research.

Despite these limitations, the strength of the study was that we specifically focused on the learnability of the QuestionSys configurator. Note that learnability is a contributory factor to the overall usability. For example, many usability attitude scales explicitly include learnability factors. Interestingly, usability is often measured by subjective reports (eg, usability scales). In this context, studies that measure learnability not by self-reports but by performance measures are more complex and time consuming than those using opinion-based instruments (eg, *System Usability Scale* [SUS]) [35]. Therefore, measuring learnability by performance measures is often neglected in usability studies [36], although it may have an impact on the success or failure of an app [37]. Despite the fact that there exist a plethora of best practices on how to create a user-friendly app, most of them deal with the proper design of the *user interface* [38-40] or with the enhancement of the overall *user experience*

[41,42]. Note that there also exist instruments that assess these properties fairly easily (eg, SUS [35]). Although such measures are useful and have proven their applicability in various ways, they might be misleading when evaluating sophisticated apps used by end users with little (or no) IT knowledge. In such scenarios, focusing on the *experience gained* (ie, learning) when continuously working with an app that needs to be evaluated may be more conclusive. However, learning is a process that takes place over time and takes practice into account as well. It can be measured by evaluating the time and effort needed to become better at doing something [43]. Thereby, learnability can be measured using various performance metrics. However, efficiency-based metrics (eg, the *time needed*, *errors committed*, or *operations required*) during task completion are the most common ones.

In summary, the results of this study valuably replicate and extend the results of a previous pilot study [29]. The main findings show that even novices can properly use the configurator and that novices as well as experts perform better when they use the configurator more often (learning effect). Addressing the abovementioned reasons for the lack of sophisticated mobile data collection instruments in large-scale scenarios (see Introduction), the developed configurator component helps build awareness regarding the capabilities of the smart mobile devices used nowadays (see Reason 1). Furthermore, it may allow using sensors during the procedure of collecting data, which may support more complex data collection scenarios (see Reason 2). Most importantly, however, the configurator component not only allows researchers to create data collection instruments themselves but also provides a common (graphical) notation that may improve the communication between researchers and mobile app developers (see Reason 3). Altogether, QuestionSys will significantly influence the way data are collected in large-scale studies (eg, clinical trials). To the best of our knowledge, usability issues in the context of creating mobile data collection apps by researchers have not been studied at this scale previously. Furthermore, this may serve as a valuable benchmark for collecting data in general.

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Authors' Contributions

All authors analyzed the real-world projects; JS and RP conceived and designed the architecture and prototype; JS implemented the prototype and conducted the experiments; TP and WS processed and analyzed the experiment data; all authors wrote the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The tutorial screencast for the configurator.

[MP4 File (MP4 Video), 3MB - mhealth_v6i6e148_app1.mp4]

Multimedia Appendix 2

Raw data collected using the configurator.

[XLSX File (Microsoft Excel File), 60KB - mhealth_v6i6e148_app2.xlsx]

Multimedia Appendix 3

Description of one task to be modeled (translated from German to English).

[PDF File (Adobe PDF File), 233KB - mhealth_v6i6e148_app3.pdf]

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Abbreviations

BPMN: Business Process Modeling and Notation
IT: information technology
RQ: research question

SUS: System Usability Scale

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Original Paper

Digital Health Intervention for Asthma: Patient-Reported Value and Usability

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Abstract

Background: Although digital health tools are increasingly recognized as effective in improving clinical outcomes such as asthma control and medication adherence, few studies have assessed patient experiences and perception of value.

Objective: The aim of this study was to evaluate patient satisfaction, perception of usability and value, and desire to continue after 12 months of using a digital health intervention to support asthma management.

Methods: Participants were enrolled in a randomized controlled study evaluating the impact of a digital health platform for asthma management. Participants used electronic inhaler sensors to track medication use and accessed their information in a digital health platform. Electronic surveys were administered to intervention arm participants aged 12 years and older after 12 months of use. The survey assessed asthma control, patient satisfaction with the sensor device, and perception of the usability and value of the digital health platform through closed-ended and open-ended questions. Logistic regression models were used to assess the impact of participants' characteristics on survey completion, satisfaction, and perception of value.

Results: Of the 207 intervention arm participants aged 12 years and older, 89 submitted survey responses (42.9% response rate). Of these 89 participants, 70 reported being very satisfied (79%, 70/89) or somewhat satisfied (20%, 18/89) with the inhaler sensor device. Moreover, 93% (83/89) expressed satisfaction with the reports, and 90% (80/89) found the information from the reports useful for learning about their asthma. In addition, 72% (64/89) of the participants reported that they were interested in continuing to use the sensor and platform beyond the study. There were no significant differences in satisfaction with the device or the platform across participants' characteristics, including device type, age, sex, insurance type, asthma control, or syncing history; however, participants with smartphones and longer participation were more likely to take the survey.

Conclusions: Electronic sensors and a digital health platform were well received by participants who reported satisfaction and perceived value. These results were consistent across multiple participants' characteristics. These findings can add to a limited literature to keep improving digital health interventions and ensure the meaningful and enduring impact on patient outcomes.

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KEYWORDS

asthma; mHealth; surveys and questionnaires; patient satisfaction; perception; self-management

Introduction

Cost of Asthma

The health impact and economic costs of asthma are significant, with the annual direct costs approaching US $50.1 billion and indirect costs such as lost productivity contributing an additional US $5.9 billion [1-3]. Despite asthma's negative impact on health, patient self-management remains a challenge, with controller medication adherence rates of approximately 30% [4-7]. Asthma self-management requires daily work by the patient, including adherence to complex medication regimens and addressing multiple triggers of symptoms.

Digital Health Interventions for Asthma

Digital health interventions have been used increasingly in self-management interventions for asthma. For example, the development of mobile apps for asthma management doubled between 2011 and 2013 [8]. These interventions, which can include tools such as short message service, mobile apps, Web-based portals and websites, and electronic inhaler sensors, offer new ways for patients to monitor and manage their asthma. A limited but growing body of literature demonstrates the effectiveness of digital interventions in improving clinical outcomes, including asthma control, adherence, and symptom-free days [9-24].

Better understanding of how patients perceive and use digital health interventions to achieve improved outcomes is of utmost importance; however, there have only been a few studies published that focused on this topic. A recent review of digital health interventions across multiple diseases found that usability was assessed in only 33% of studies [25]. Within the asthma literature, a systematic review concluded that "patient perspectives have been largely ignored" [26]. A small number of studies have evaluated patient perceptions of asthma apps [19,24] or electronic inhaler sensors [27,28], but these have been limited to small samples over short periods of time (1-4 months). Little is known about how patients perceive the utility of combining electronic inhaler sensors with mobile apps and other digital tools. Furthermore, no studies have explored patient perceptions in a real-world setting over a sustained duration.

The study's primary objective was to evaluate participant satisfaction, perception of usability and value, and overall experience after sustained use of a digital health intervention combining sensors, a mobile app, a Web dashboard, and email communication, to support asthma management in a real-world setting. The study also aimed to explore whether these perceptions would be influenced by specific participants' characteristics such as age, gender, device ownership, insurance type, asthma control, and engagement. Improving the understanding of how diverse patients experience digital tools for asthma self-management will contribute to the success of these tools and the durability of their effects.

Methods

Digital Health Platform

Participants were enrolled in a randomized controlled study to evaluate the impact of a Food and Drug Administration–cleared digital health platform on asthma outcomes including short-acting beta-agonist (SABA) use and asthma control. The digital health platform includes electronic inhaler sensors (Propeller Health, Madison, Wisconsin) that attach to inhaled asthma medications (Figure 1). The sensor monitors the date, time, and frequency of medication use and transmits these data back to secure servers through a smartphone app or hub base station. Location data are collected on medication use among patients who have a smartphone. The sensors regularly transmit data back to the server, or sync, through the smartphone or hub. The version of the sensor that participants used in this study required them to charge their sensors every 2 weeks.

The data collected by the sensors are presented back to patients and health care providers through the digital health platform. The platform aims to promote disease awareness and self-management by enabling access to a patient's own medication use data, including daily assessments of asthma control, adherence, identified triggers, and education based on the national guidelines (NHLBI 2007). The information is shared via a number of communication channels for all users, including weekly email reports, a Web-based dashboard, and a mobile app for smartphone users. Additional digital health platform details have been described elsewhere [13,18].

Participant Enrollment

The clinical study enrolled adult and pediatric asthma patients (N=495) in parallel arms from specialty and primary care clinics at 2 sites in the Dignity Health system. Clinic staff enrolled eligible participants with the following inclusion criteria: over the age of 5 years, a provider diagnosis of asthma, presence of a SABA prescription at study inception, Spanish or English fluency, and absence of significant comorbidity such as chronic obstructive pulmonary disease. Further study detail is described elsewhere [13].

Study Design

Participants were randomly assigned to either the intervention or control group and matched on sex, age, insurance type (public vs private), and baseline asthma control status (as defined by an Asthma Control Test [ACT] score ≤19 indicating a lack of asthma control) [29]. All participants received at least one sensor to monitor their medication over a 12-month period. If a participant had a smartphone, the study coordinator assisted them in downloading the app and conducting a first sync with the sensor. If a participant did not have a smartphone, they were provided a hub base station. This study used the earliest version of the sensor, which had a 15-day battery life, and participants were instructed to charge the sensor at regular intervals. Intervention group participants (n=250) received full access to the digital health platform described previously for 12 months. Physicians from the clinics could monitor the status of these intervention patients in real time and receive notifications about SABA overuse through Web-based dashboards. The Dignity

Health Institutional Review Board reviewed and approved this study and survey (Trial Registration: ClinicalTrials.gov NCT01509183).

Survey Data Collection

Surveys were administered electronically to participants in the intervention group who were aged 12 years or older at study completion at 12 months (N=207). The exit survey assessed asthma control with the ACT [29]. The study coordinator sent participants an email invitation to complete the survey electronically, and the coordinator made a single follow-up attempt with participants who did not respond within 1 week. Participants were given the option to take a paper version of the survey and return it through the mail. The participants did not receive any incentive to complete the exit survey.

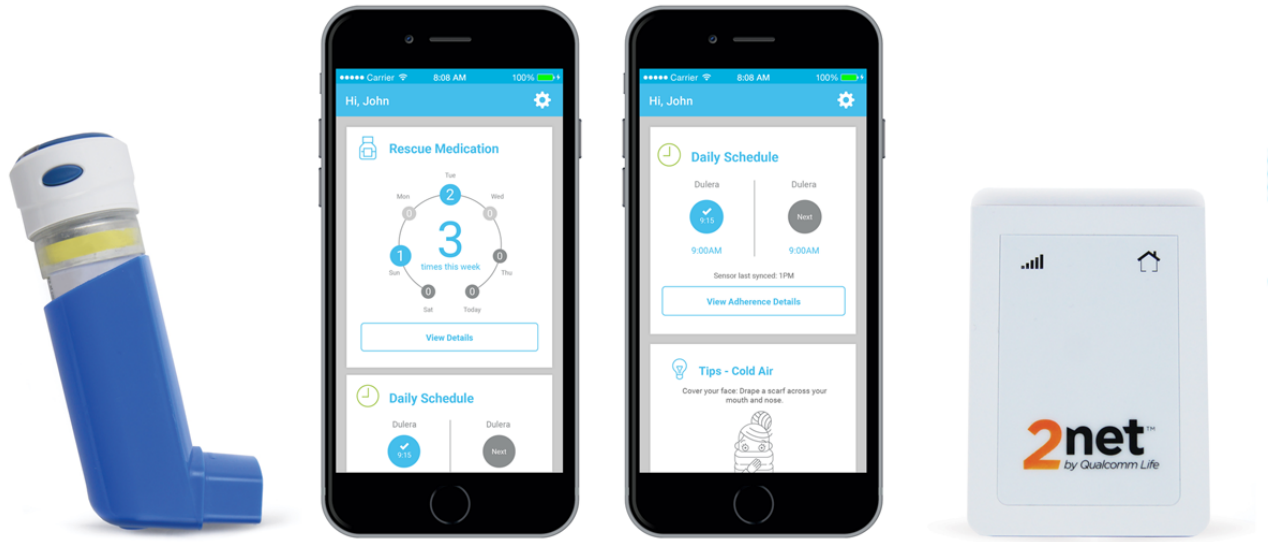
The survey consisted of open- and closed-ended questions, which evaluated satisfaction with the reports and information, satisfaction with the sensor device, learnings as a result of platform use, identified triggers, quality of communications with health care providers, suggestions for improving the reports and sensor, and interest in continued use of the platform. Detailed survey questions are included in Multimedia Appendix 1.

Data Analysis

Closed-ended questions were analyzed by determining the percentage of respondents who selected each of the possible responses. Thematic analysis of the open-ended responses in the survey followed the structured approach described by Braun and Clarke [30], where primary themes and subthemes were identified and coded according to specific usability and value topic areas. Two reviewers (KH and MB) independently assessed the open-ended questions, met to address discrepancies, and agreed on primary themes and subthemes. We report the number and percentage of participants who reported the primary themes and subthemes.

We assessed participant engagement with the platform by evaluating the mean email open rate, number of push notifications received, and number of participant sign-ins to the dashboard or app. We used a logistic regression model to evaluate if there were differences between those participants who took the exit survey compared with those who did not across the following variables: age (12-17 years vs 18 years and over), sex, insurance type (public vs private), device type (smartphone vs hub), asthma control at intake (controlled vs uncontrolled), syncing duration (time between the first and last sync), and syncing frequency (number of syncs between the first and last sync). Using a logistic regression modeling approach, we also evaluated whether these variables were associated with participants' responses to the closed-ended questions on device and report satisfaction, usefulness, and interest in continued use of the platform. Responses were grouped based on binary categories, for example, satisfied versus not satisfied, useful versus not useful.

Figure 1. Propeller Health sensor device, smartphone app, and hub base station. The Propeller sensor attaches directly to the metered dose inhaler and objectively captures the date, time, and frequency of medication use. The sensor transmits these data wirelessly via Bluetooth to a paired smartphone, where a mobile app displays the information for the user. For participants without a smartphone, a wireless hub transmits the data, which are accessible through a Web-based dashboard.



Results

Participants

Of the intervention group participants (N=250), 207 met the requirement of being aged 12 years or older at study completion to receive the exit survey. A total of 89 participants completed the exit survey (Table 1), which represented a 42.9% response rate (89/207). Among the participants who completed the survey (N=89), the average and median ages were 42.7 and 45 years, respectively; 85% (76/89) of participants were aged older than 18 years, 15% (13/89) were aged between 12 and 17 years, and 64% (57/89) of participants were female. Participants used a variety of device types to access the digital platform, including smartphones (49%, 44/89; 27%, 24/89 iOS and 23%, 20/89Android) and hub base stations for those without smartphones (51%, 45/89). In addition, 74% (66/89) of participants had private insurance and 26% (23/89) had public insurance. At the start of the study, 30% (27/89) of participants were well controlled, 61% (54/89) were not well controlled, and 9% (8/89) had an unknown control status.

Among the 207 intervention group participants, the logistic regression model identified that participants who used smartphones (P=.02), had a longer syncing duration (P<.001), and higher syncing frequency (P<.001) were more likely to take the exit survey (Table 2). There were no other significant differences across age, sex, asthma control, or insurance type between those participants who took the survey and those who did not.

Among the participants who completed the survey (N=89), on average, they synced their sensor for 361 days over the course of the study period (minimum: 264 days and maximum: 365 days). Participants synced their sensor 2149 times on average during the study or an average of 6 times per day. Participants also had a mean email open rate of 78%, received 35 push notifications, and had a mean 60 sign-ins to the patient dashboard, which represents more than 1 sign-in per week. The following results pertain to the 89 participants who completed the survey.

Satisfaction With Inhaler Sensor Device

Participants reported their degree of satisfaction with the inhaler sensor device, with 79% (70/89) of respondents reporting “very satisfied,” 20% (18/89) reporting “somewhat satisfied,” and 1% (1/89) reporting “not at all satisfied” (Figure 2). There were no significant differences in responses to this question across participants’ device type, age, sex, insurance, asthma control at intake, or syncing history (see Multimedia Appendix 2). A total of 37 participants (40%, 37/89) stated the inhaler device was “easy,” including 3 subthemes of “easy to use” (32%, 29/89), “easy to maintain” (6%, 6/89), and “easy to understand” (2%, 2/89). Moreover, 23 participants (26%, 23/89) described the size of the device as “small” and “compact” (Table 3). Of the subthemes relating to the size of the device, 10 participants (11%, 10/89) specified that it did not “obstruct” or “interfere” with their use of their inhaler and “was not bulky.” Furthermore, 17 participants (19%, 17/89) described the sensor’s convenience, with the 2 subthemes of the device being “portable” and functioning well.

The majority of the participants (56%, 50/89) made no recommendations for sensor improvements. Of the participants who reported specific ideas for improvements (44%, 39/89), the most frequent response was for a longer battery life (20%, 18/89). Participants also reported wanting a smaller size device (13%, 12/89). The remaining participants reported wanting a more secure fit (4%, 4/89) or recommended additional features such as adding a dose counter (6%, 5/89).

Table 1. Characteristics of participants who responded to the exit survey (N=89).

Characteristics of participants	n (%)
Device	
Smartphone	44 (49)
Hub	45 (51)
Asthma control	
Well controlled	27 (30)
Not well controlled	54 (61)
Unknown	8 (9)
Age (years)	
12-17	13 (15)
≥18	76 (85)
Sex	
Female	57 (64)
Male	32 (36)
Insurance	
Private	66 (74)
Public	23 (26)

Table 2. Demographic and individual predictors of whether participants completed survey or not (N=207).

Characteristics of participants	Predictors of survey completion (N=207)	
	Estimate (SE)	*P* value
Device type (smartphone)	1.154 (0.508)	.02
Age <18 years	0.157 (0.640)	.81
Syncing duration	0.063 (0.016)	<.001
Syncing frequency	0.008 (0.002)	<.001
Sex (male)	0.019 (0.438)	.97
Insurance (public)	−0.118 (0.481)	.81
Initial uncontrolled asthma	−0.686 (0.854)	.42
Initial well-controlled asthma	−0.471 (0.868)	.59

Figure 2. Participants' responses to closed-ended questions: a) "How satisfied were you with the inhaler device?" b) "Overall, how satisfied were you with the reports?" and c) "How useful were the reports in helping you learn more about your asthma?".

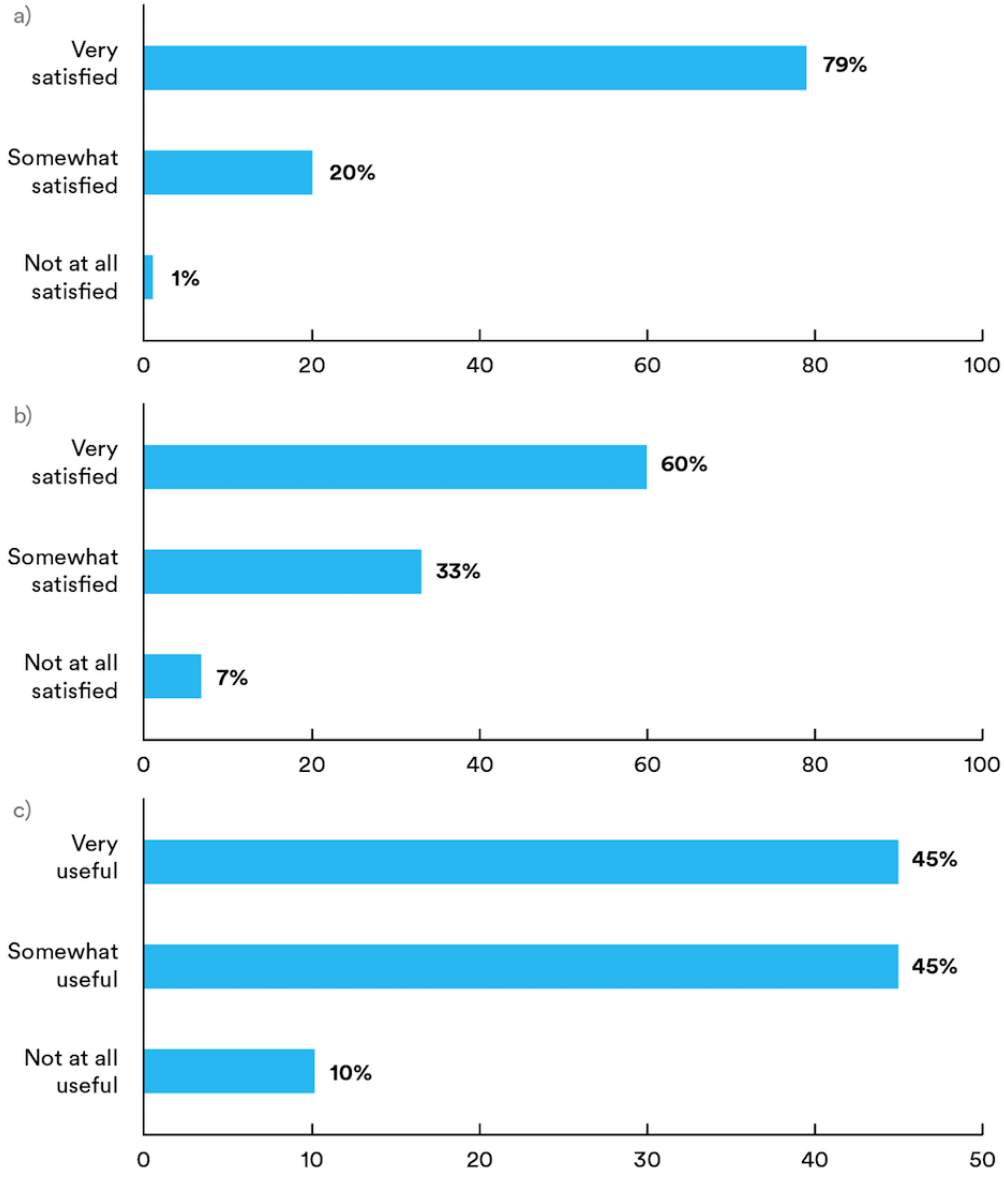


Table 3. Primary themes, subthemes, and selected excerpts from open-ended responses about participants' experience with the inhaler sensor device.

Primary and subthemes	Representative quotes
Easy	
Easy to use	• "It is easy to use." • "It was easy to operate."
Easy to understand	• "Instructions for use are pretty straight forward." • "Easy to understand."
Easy to maintain	• "Easy to attach to my inhaler." • "Easy to use [and] care for."
Size	
Small	• "Small and compact." • "Small size."
Unobtrusive	• "Didn't obstruct anything." • "Didn't get in the way." • "Not big or bulky which I liked."
Convenience	
Portable	• "Easy to keep with you. Easy to carry." • "Fits in purse."
Functioned well	• "Worked great." • "I liked that it worked wherever I went."

Perception of the Reports and Information

Participants reported on their satisfaction and perceptions of the reports' usability and value in supporting their asthma management. A total of 60% (54/89) of the participants reported that they were "very satisfied" with the reports, 33% (29/89) were "somewhat satisfied," and 7% (6/89) were "not at all satisfied" (Figure 2). There were no significant differences in responses to this question across participants' device type, age, sex, insurance, asthma control at intake, or syncing history (see Multimedia Appendix 3).

Moreover, 33 (37%, 33/89) of participants reported liking the content of the reports, including informative (9%, 8/89), actionable (6%, 5/89), and easy to understand (8%, 7/89; Table 4). They also reported that they liked the report display (10%, 9/89) and the frequency (4%, 4/89). In addition, 23 participants (26%, 23/89) shared that the reports provided new information that increased their awareness of their asthma management. Some participants did not see significant value in the reports, responding that they did not view the reports (9%, 8/89), found the reports to be only "generally helpful" (4%, 4/89), did not receive the reports (3%, 3/89), or did not have any feedback to share (9%, 8/89).

Perceived Utility and Participant Learnings

Participants responded the information was "very useful" (45%, 40/89), "somewhat useful" (45%, 40/89), or "not at all useful" (10%, 9/89) in learning about their asthma (Figure 2). There were no significant differences in responses to this question across participants' device type, age, sex, insurance, asthma control at intake, or syncing history (see Multimedia Appendix 4).

The participants reported several learnings from using the digital platform (Table 5). A primary theme focused on understanding, identifying, and managing asthma triggers (23%, 21/89). A total of 53 participants (60%, 53/89) reported identifying up to 7 new triggers. Weather, allergies, and exercise were the most commonly identified triggers, documented across 79% (42/53) of the participants who identified new triggers.

A second primary theme focused on improved self-awareness. A total of 19 participants (21%, 19/89) specifically reported learning from monitoring the timing, location, and frequency of their medication use. Moreover, 10 participants (11%, 10/89) described learning strategies for managing their asthma such as taking their controller medications and avoiding specific triggers. Furthermore, 6 participants (7%, 6/89) reported that they discovered they were not as in control of their asthma as they had believed or they confirmed that their treatment plan helped them stay controlled. In addition, 5 participants (6%, 5/89) learned that they are accountable for their self-management and have the capacity to control their asthma. Participants could opt to discuss their data with their providers; 46% (41/89) of the participants reported that they had conversations with their providers about their data.

Some participants reported not learning anything from the reports: 16 participants (18%, 16/89) reported "none," and 3 participants (3%, 3/89) reported not learning anything because they were already well controlled.

Table 4. Primary themes, subthemes, and selected excerpts from open-ended responses about participants' experience with the data reports.

Primary and subthemes	Representative quotes
Content of reports	
Informative	• "Very informative." • "They contained relevant information."
Actionable	• "Tells you about asthma so I can control it." • "Indicate to me where and when I needed to improve my surroundings to limit asthma problems."
Easy to understand	• "Easy to read and understand." • "Easy to read [and] interpret."
Display (visual)	• "Being able to see the data was helpful." • "Seeing a visual."
Frequency	• "Regular feedback." • "Timely"
New information that increased awareness	
Triggers	• "Helped me try to focus on what my triggers are." • "Kept up to date, let me know weather and pollen count."
Timing and location of medication use	• "I could see how often I was using the medication as well as the location." • "GPS [Global Positioning Systems] locations of incidents is nice."
Control	• "Tell me how well my asthma was controlled or not controlled." • "Helps to show tracking of asthma control."
Frequency of medication use	• "Knowing the actual number of time I needed meds." • "Kept me conscious of regular use of meds."
General understanding	• "Told me how I was managing." • "They just allowed me to see the general picture about my condition."

Participants were asked to provide suggestions for improving the reports or platform. A total of 59 participants (66%, 59/89) reported no improvements were needed, and 11 participants (12%, 11/89) responded with "not sure" or "no comment." The remaining responses (21%, 19/89) offered specific suggestions including more educational content on how to improve asthma, information about how to subsidize medication costs, improvements in the app login process, additional customization options for how to receive reports, changing the cadence of the reports, and extending the sensor battery life.

The final question of the survey asked participants whether they would like to continue using the digital intervention: 72% (64/89) of the participants reported that they were interested in continuing to use the sensor and platform beyond the study. There were no significant differences among those participants who were interested in continuing or those who were not based on a participant's device type, age, gender, insurance type, syncing history, or asthma control at intake (see Multimedia Appendix 5).

Table 5. Primary themes and subthemes of participant learnings as a result of the digital intervention.

Primary and subthemes	Representative quotes
Triggers	
Specific triggers	• "Worsens a lot with exercise." • "Stress can bring on symptoms."
To be aware of triggers	• "Should pay more attention to what triggers attacks." • "I pay closer attention to my triggers."
Value of being aware of triggers	• "Discovering the triggers of your asthma can better help you control it." • "By being aware of the pollen count assist in what activities to do when."
Medication use	
General awareness	• "It made me much more aware of the use of my inhaler." • "How often I was using my inhaler."
Timing and location	• "Learned that my asthma bothers me more at night and windy areas." • "I learned a lot about when and where my attacks were at."
Asthma control	
New insights	• "I learned how well my asthma was controlled through those reports." • "That it wasn't as controlled as I thought."
Confirmation of control status	• "I confirmed that my asthma is well-controlled with my current medication." • "It confirmed the combination of avoidance of known triggers and the medication keeps it well managed."
Management strategies	• "To make sure to take the preventative every time." • "How to stay away from what triggers my asthma."
Management beliefs	• "That I can control it better if I try." • "The program makes you accountable for taking the steps to control the asthma."
Ways to communicate with doctor	• "I was never sure how often I used my rescue inhaler. When my doctor asked I could not give him an accurate response and now I can." • "I learned that I need to talk to my doctor about my asthma during [and] post workouts."

Discussion

Summary of Findings

Participants were satisfied with the digital health intervention for managing their asthma and perceived value in using the technology to support their self-management. Participants reported improving their awareness, learning about trends in their medication use, identifying new triggers, and objectively monitoring how well their asthma is controlled, which they could discuss with their doctor. Participants shared helpful feedback regarding areas for improvement including interest in longer battery life and smaller size of the device.

We saw no significant differences in the degree of satisfaction and perceived usability across participants regardless of participant age, gender, insurance type, asthma control, technology adoption, and syncing duration. However, we did observe that those with a smartphone and a longer record of syncing were more likely to take the survey in the first place, which could have biased the sample toward more engaged, more technologically savvy participants. Despite this potential bias, these results add to the limited evidence exploring patient perspectives on digital health tools across diverse participants and shed light on the perceived benefits of the tools as well as opportunities for improvement.

Mechanisms for Supporting Self-Management

These findings align with and supplement the existing evidence [19,24,31], in particular adding to the literature by demonstrating participants' perceptions among a larger cohort in a real-world setting over a prolonged period of time. We explore 4 learnings that emerged from the participants' responses.

First, participants frequently emphasized ease of use for the inhaler sensor in terms of deployment, comprehension, maintenance, size, and convenience. Similarly, in a small study of adolescent asthma participants, patients cited the importance of the device not drawing any attention, being small in size, and being easily portable [28]. Furthermore, a review of previous digital health intervention studies suggested that ease of use and adaptation to an individual's personal lifestyle are essential factors for engagement and persistent use [32]. These findings align with the concept of minimally disruptive medicine, which aims to find ways to reduce patient treatment burden [33]. To support this approach, digital tools enable passive data collection of medication use, eliminating the burden of manual tracking.

By providing objective documentation of medication use, trends, and specific information about potential triggers, the self-monitoring process can become more efficient and actionable.

Second, participants in this study and others have reported that having objective data leads to increased self-awareness. This finding aligns with the self-regulation model for chronic disease and the more refined version for asthma management [24,34], in which a patient goes through a process of self-monitoring and assessing feedback to inform behavior. Participants reported gaining insights from monitoring medication use, especially the timing and location of medication use events, to identify patterns, times of worsening, and potential triggers. Almost one-quarter of patients valued learning about their asthma triggers including specific environmental conditions, such as temperature, humidity, and air quality, through the digital tool to help inform their management.

Improved confidence in one's ability to self-manage, as was seen in some of the open-ended responses, is promising, but further investigation is needed to evaluate the intervention's impact on self-efficacy. The survey design did not include specific questions to assess self-efficacy; therefore, we are unable to determine if the intervention had an impact on self-efficacy. Future studies evaluating digital interventions for asthma should thoroughly evaluate self-efficacy using validated self-efficacy measures and surveys, such as the mini-Asthma Quality of Life Questionnaire [35], Self-efficacy and Situational Barrier Survey Questionnaire (KASE-AQ) [36], and Mobile App Rating Scale [37].

Third, this study found that participants value having information they can share with their clinical providers. Almost half of all participants had spoken with their clinical provider about the data collected. A smaller subset reported using the data to request medication adjustments, therefore taking more responsibility for their management. These findings are supported in a study that found that 70% of patients wished to share their data with health teams [31].

Digital health tools can support the patient-provider relationship through shared decision making [38,39]. By enabling the sharing of data and the ability of patients to discuss specific issues as they arise, patients and providers can work collaboratively to adjust their management plan and achieve asthma control. A recent study that surveyed clinical providers about digital health tools, such as sensors, documented similar perceived benefits. Clinicians reported that objective data from sensors have the potential to enable patients to see trends and patterns in their medication use, increase accountability and confidence in their management, and support discussion with clinical providers [40].

Fourth, this study identified areas for improvement that can inform digital health tool development in the future. Participants reported wanting a longer battery life for the sensors. This feedback helped inform the development of the latest version of the sensors, which use Bluetooth low energy technology, do not require charging, and have a battery life of 12-18 months. In addition, some participants reported an interest in a smaller device, which resulted in the development of a sensor with 30% reduced volume. Participants also reported desiring more personalization and customization in the notifications and reminders and requested multiple methods of communication so that they can select the method that works best for them at the right time. Ongoing work is underway to add personalization, customization, and new communication options. There is growing evidence in this study and others [24,31] indicating how much patients value personalization and customization; however, more research is needed to determine best practices for identifying customizable features that will enhance patient satisfaction and engagement.

Limitations

First, although the participants' cohort was fairly diverse in age, insurance type, technology use, gender, and asthma control status, additional studies are needed to evaluate preferences in larger samples of different types of patients across race, pediatric versus adult, geographic diversity, and health literacy levels. For example, this survey was only administered to participants aged 12 years and older and therefore did not capture the young pediatric patient or caregiver perspective. Second, the response rate was 42.9%, and selection bias may have influenced the results. We did find that participants who used smartphones and those who remained in the program longer (defined by their sync duration) were more likely to take the survey in the first place. They may have experienced more value from a longer interaction with the intervention and reported as such on the survey. Future research should target individuals with early study attrition to ensure a more complete understanding of their perceptions of usability and satisfaction to enable scalability to all populations. Third, the infrastructure to capture more robust individual-level participant engagement data was limited, which prevented a more complete understanding of participant engagement and how this engagement may have influenced overall satisfaction and perception of utility. Fourth, the survey questions were not derived from validated measures and did not use standard Likert scales, which limited the generalizability of the results.

Conclusions

This study offers new insights about patient satisfaction, preferences, and perceptions of a digital health intervention for respiratory disease among a larger, fairly diverse cohort in a real-world setting after a prolonged period of use. Participants reported satisfaction with the sensor device and reports and particularly valued the ability to integrate the device into everyday life, the provision of accessible and meaningful information to improve self-awareness, and the enhancement of communication with health care providers. As the use of digital tools in health care expands, it will be critical to learn from patient preferences and experiences to ensure that the tools fit well into their daily life and support their self-management.

Acknowledgments

The authors would like to thank all the participants and the research coordinator responsible for administering the surveys.

Conflicts of Interest

DVS, KH, MB, JR, and DS are Propeller Health employees and receive salary and stock options. RM, RI, and JGS report no conflicts.

Multimedia Appendix 1
Survey questions.
[PDF File (Adobe PDF File), 26 KB - mhealth_v6i6e133_app1.pdf]

Multimedia Appendix 2
Participants' responses to the closed-ended question, "How satisfied were you with the inhaler device?" by demographic and individual characteristics.
[PDF File (Adobe PDF File), 27 KB - mhealth_v6i6e133_app2.pdf]

Multimedia Appendix 3
Participants' responses to the closed-ended question, "Overall, how satisfied were you with the reports?" by demographic and individual characteristics.
[PDF File (Adobe PDF File), 27 KB - mhealth_v6i6e133_app3.pdf]

Multimedia Appendix 4
Participants' responses to the closed-ended question, "How useful were the reports in helping you learn more about your asthma?" by demographic and individual characteristics.
[PDF File (Adobe PDF File), 27 KB - mhealth_v6i6e133_app4.pdf]

Multimedia Appendix 5
Participants' responses to the closed-ended question, "How interested would you be in continuing to track your asthma medication use with this program?" by demographic and individual characteristics.
[PDF File (Adobe PDF File), 27 KB - mhealth_v6i6e133_app5.pdf]

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Abbreviations

ACT: Asthma Control Test
KASE-AQ: The Knowledge, Attitude, and Self-Efficacy Asthma Questionnaire
SABA: short-acting beta-agonist

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Original Paper

Acceptability of a Mobile Clinical Decision Tool Among Emergency Department Clinicians: Development and Evaluation of The Ottawa Rules App

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Abstract

Background: The Ottawa Ankle Rules, Ottawa Knee Rule, and Canadian C-Spine Rule—together known as The Ottawa Rules—are a set of internationally validated clinical decision rules developed to decrease unnecessary diagnostic imaging in the emergency department. In this study, we sought to develop and evaluate the use of a mobile app version of The Ottawa Rules.

Objective: The primary objective of this study was to determine acceptability of The Ottawa Rules app among emergency department clinicians. The secondary objective was to evaluate the effect of publicity efforts on uptake of The Ottawa Rules app.

Methods: The Ottawa Rules app was developed and publicly released for free on iOS and Android operating systems in April 2016. Local and national news and academic media coverage coincided with app release. This study was conducted at a large tertiary trauma care center in Ottawa, Canada. The study was advertised through posters and electronically by email. Emergency department clinicians were approached in person to enroll via in-app consent for a 1-month study during which time they were encouraged to use the app when evaluating patients with suspected knee, foot, or neck injuries. A 23-question survey was administered at the end of the study period via email to determine self-reported frequency, perceived ease of use of the app, and participant Technology Readiness Index scores.

Results: A total of 108 emergency department clinicians completed the study including 42 nurses, 33 residents, 20 attending physicians, and 13 medical students completing emergency department rotations. The median Technology Readiness Index for this group was 3.56, indicating a moderate degree of openness for technological adoption. The majority of survey respondents indicated favorable receptivity to the app including finding it helpful to applying the rules (73/108, 67.6%), that they would recommend the app to colleagues (81/108, 75.0%), and that they would continue using the app (73/108, 67.6%). Feedback from study participants highlighted a desire for access to more clinical decision rules and a higher degree of interactivity of the app. Between April 21, 2016, and June 1, 2017, The Ottawa Rules app was downloaded approximately 4000 times across 89 countries.

Conclusions: We have found The Ottawa Rules app to be an effective means to disseminate the Ottawa Ankle Rules, Ottawa Knee Rule, and Canadian C-Spine Rule among all levels of emergency department clinicians. We have been successful in monitoring uptake and access of the rules in the app as a result of our publicity efforts. Mobile technology can be leveraged to improve the accessibility of clinical decision tools to health professionals.

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KEYWORDS

emergency department medicine; clinical tools; mobile apps; digital health

Introduction

Clinical decision rules attempt to reduce the uncertainty of medical decision making by standardizing the collection and interpretation of clinical data. These tools are derived from original research and incorporate 3 or more variables from clinical assessment or simple tests. These offer concrete yes/no answers and help clinicians with management decisions at the bedside [1-3].

The Ottawa Knee Rule [4], Ottawa Ankle Rules [5], and Canadian C-Spine Rule [6] are 3 internationally validated clinical decision rules that were developed to facilitate rapid detection of bone fractures upon entry into the emergency department (ED) and reduce unnecessary radiographic series. In various clinical trials, clinicians who applied the rules had a 28% reduction in ankle and 14% reduction in foot radiographic series [7]. In addition to reducing unnecessary use of diagnostic imaging services, appropriate application of the rules has been shown to improve standardization of practice and care and reduce emergency room wait times with significant health cost savings [8-10]. Although clinical decision rules such as The Ottawa Rules were developed to assist with bedside diagnostic or therapeutic decisions, some may have limited impact due to weak clinician uptake in jurisdictions [11,12].

Use of mobile technologies in the health care setting has provided clinicians with a means of rapidly and easily accessing hospital information systems and services. Mobile apps now assist clinicians with day-to-day tasks including health record maintenance, patient management and monitoring, and medical education and training. There exists an opportunity to leverage increasing use of mobile devices to support easy and efficient access to clinical decision rules.

In this study, we sought to develop and evaluate a mobile app housing 3 validated ED clinical decision rules, collectively known as The Ottawa Rules. Our primary objective was to determine acceptability of a mobile app format of The Ottawa Rules among ED clinicians (physicians, residents, nurses, and medical students) at The Ottawa Hospital (TOH), in Ottawa, Canada. The secondary objective was to evaluate the effect of publicity efforts on uptake of The Ottawa Rules app.

Methods

Mobile App Development

The Ottawa Rules app was developed natively for both iOS and Android operating systems and as a mobile-enhanced website at www.theottawarules.ca. App development was led by The Ottawa Hospital mHealth Lab located at the Ottawa Hospital Research Institute (OHRI). The Ottawa Knee Rule, Ottawa Ankle Rules, and Canadian C-Spine Rule, together known as The Ottawa Rules, were included in the app. Each rule was made available as a set of images with clear procedural guidelines. Instructional videos and links to academic resources for each rule were also included. The app was designed to include a mechanism for feedback and support where users were permitted to provide suggestions for app improvements, report bugs, and request technical assistance.

Pilot-Testing

Following internal alpha-testing, the prototype was beta-tested on 6 consenting ED clinicians at TOH. Beta testers were instructed to use the app as if they were experiencing the circumstances outlined in provided mock clinical scenarios. Scenarios involved a patient entering the ED with a suspected knee, foot, or neck injury for which the clinicians needed to use the app to determine whether the injury would require diagnostic imaging. Beta testers completed their mock scenario twice; once as new users and once after having familiarized themselves with the app for approximately 10 minutes. Semistructured interviews with beta testers were then conducted to establish further insight into what content would be appropriate for the app and any barriers to app access or perceived barriers for app use. Findings from beta-testing were then integrated into the app before its public release.

App Release

The app was publicly released on April 21, 2016, for iOS devices via the App Store, for Android devices via Google Play, through OHRI's app portal, and on the Web at www.theottawarules.ca. A press release was circulated on the same day with local and national news sources, national and international emergency medicine media, and through social media messaging on affiliate Twitter accounts. Social media posts about app release were also disseminated via affiliate Twitter accounts and Facebook pages, and announcements were made at departmental rounds.

Study Enrollment

The study was advertised through poster displays in EDs at TOH Civic and General campuses and email distribution to ED staff and medical students at the University of Ottawa. Study staff also showcased the new app at a hospital-organized digital health networking event, resident rounds, and the hospital's annual academic research day. Primary study recruitment was conducted in person by study staff. Participants were required to be over 18 years of age, work in or be on rotation in the ED, possess an institutional email (TOH, OHRI, or University of Ottawa), and own a personal or institutional iOS or Android mobile phone onto which they could download The Ottawa Rules app. Since 2011, TOH has been equipping clinicians with iPads—clinicians also had the option of downloading The Ottawa Rules app onto these institutional devices and enrolling in the study.

Inclusion criteria were assessed as part of the in-app informed consent process. Figure 1 provides screen shots of The Ottawa Rules app home screen with the "TOH Study" button for participants, informed consent screen, and 1 of the 3 in-app guidelines. From the app's home screen interface, users could select 1 of the 3 rules according to the patient's suspected injury. From the main menu, there were options to learn about The

Ottawa Rules app, link to the lead physician's Twitter account, provide feedback, and read the terms of use. With the goal of enhancing app usefulness, study participants had additional access to hospital resources within the app; these features were not available to general app users. Hospital resources included TOH's antibiotic guidelines, nursing medical directives, and triage algorithms.

Once enrolled, consenting participants had to verify their institutional email before proceeding. Participants had in-app access to the consent documents and contact information of study staff throughout the duration of the study. Participants were instructed to explore the app features and use the app as reasonable when evaluating patients with suspected knee, foot, or neck injuries. This study was approved by the Ottawa Health Research Network Science Research Ethics Board (#20150405-01H).

Data Collection

Frequency of use of The Ottawa Rules app was measured via in-app analytics and user surveys as detailed below.

Participant Survey

One-month post-study enrollment, participants were prompted via their verified institutional email to complete a usability survey to assess their perceived acceptability and usability of the app. The survey consisted of multiple-choice, 5-point Likert scale, and open-ended questions designed to ascertain participant demographics, ease of use, and intention for future use and provide the opportunity for written feedback. Participants who completed the end-study survey received an electronic coffee gift card in the amount of Can $10 (US $8).

Technology Readiness Index

The Technology Readiness Index (TRI) 2.0 was also administered in the 1-month survey. The TRI 2.0 includes 16 questions that measure an individual's innate "propensity to embrace and use new technologies for accomplishing goals in home, life, and at work." TRI questions are measured on a 5-point Likert scale ranging from 1=strongly disagree to 5=strongly agree and capture 4 dimensions. Two motivating dimensions capture qualities of individual optimism and innovativeness, whereas questions pertaining to individual discomfort and insecurity are considered inhibiting dimensions. A higher individual TRI indicates a higher likelihood to adopt new technology: TRI 2.0 = (innovativeness + optimism + [6 – discomfort] + [6 – insecurity]) / 4). Questions related to each of the 4 TRI 2.0 dimensions are provided in Multimedia Appendix 1.

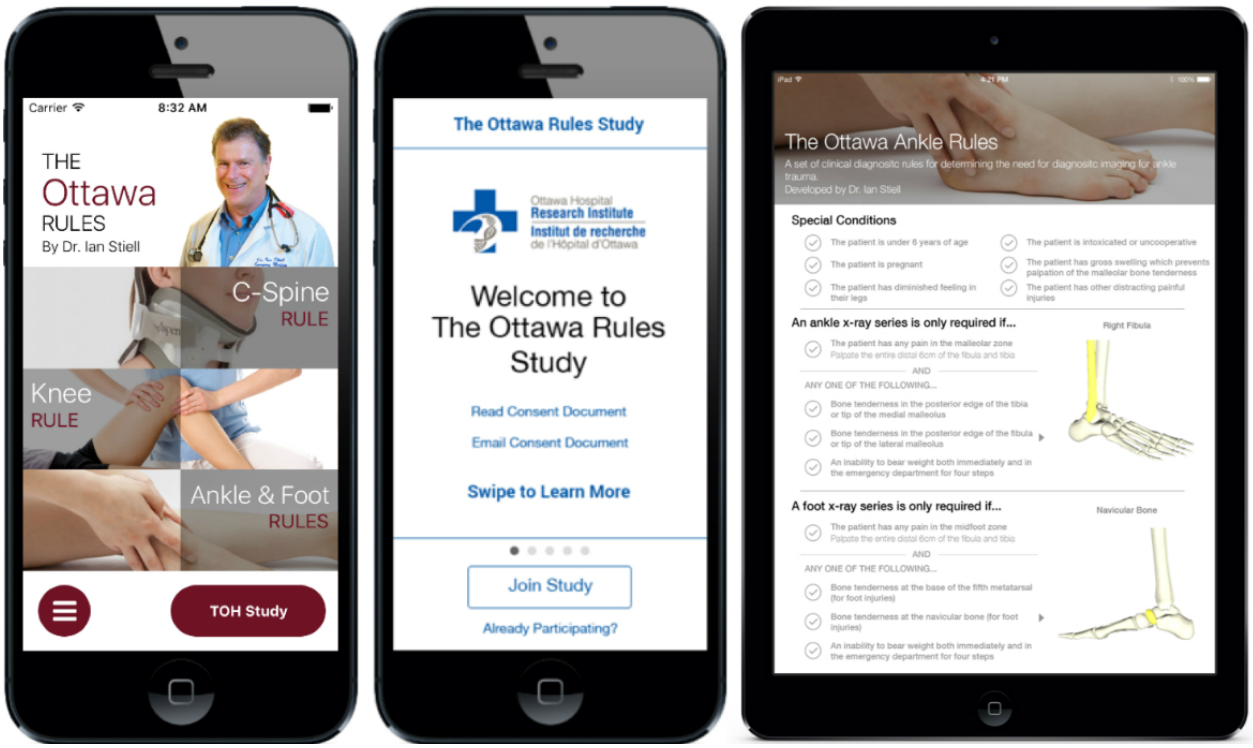
Participant In-App Activity

Analytics on participant use of the app were encrypted and sent to a secure cloud server in Canada administrated by The Ottawa Hospital mHealth Lab at OHRI. The following metrics were collected on an individual level, only identified by study ID on the server: date app was first opened, number of times each rule was accessed, number of consenting participants who did not reopen the app, frequency of rule use, number of app sessions, and number and content of submitted feedback reports.

Google Analytic Data

General anonymous usage data of The Ottawa Rules app were collected through Google Analytics and used to gauge global app uptake and success of promotional activities. Google Analytics was used to ascertain total downloads, geographical region by IP address, app screens accessed, and average time spent in the app.

Figure 1. The Ottawa Rules interfaces on Android and iOS.



Results

Study Participants

A total of 155 consenting participants provided electronic verification of their enrollment into the study, and 119 (76.8%) participants submitted usability surveys 1 month after study enrollment. Due to data quality concerns, participants who enrolled under multiple email addresses and those who did not complete the usability survey in full were excluded from analysis. The final study cohort consisted of 108 participants (Figure 2).

Nurses constituted the largest number of study participants (42/108, 38.9%), followed by residents (33/108, 30.6%), physicians (20/108, 18.5%), and medical students (13/108, 12.0%). The majority of participants were 34 years of age or younger (73/108, 68.2%) and owned iOS devices (87/108, 80.6%). Table 1 summarizes the baseline characteristics of study participants.

Usability Survey

When asked if they encountered any issues using the app, all participants reported either strongly disagree (103/108, 95.4%) or disagree (5/108, 4.6%). Self-reported frequency of use revealed the majority of participants (92/108, 85.2%) used the app at least once during the course of the study. A total of 43.5% (43/108) of participants said they used the app weekly, 38.9% (42/108) said monthly, 14.8% (16/108) said never, and 2.8% (3/108) said they used the app daily (Figure 3).

Questions on app usability revealed favorable reception by ED clinicians. A total of 30.6% (33/108) of participants indicated strongly agree or agree when asked if they used the app for the majority of the cases that required application of the clinical decision rules, 67.6% (73/108) of participants found the app useful in applying the clinical rules (strongly agree, agree), 75.0% (81/108) indicated that they would recommend the app to colleagues, and 67.6% (73/108) would continue using the app in its current form. Figure 3 summarizes usability survey data.

In addition, 56.5% (61/108) of participants provided free-form written feedback. Feedback included recommendations based on functionality, acceptability, and available features. Participants reported a desire for access to more TOH-developed decision aids, particularly the addition of the Canadian CT Head Rule and Subarachnoid Hemorrhage Risk Score. Users also indicated wanting access to more institutional resources and directives. A number of participants suggested inclusion of more interactive features, including a drop-down menu for easier and quicker navigation. Some indicated their preference for other medical mobile apps that housed more comprehensive or interactive lists of medical directives and decision rules. Lastly, participants highlighted the potential benefits of the use of the app among early learners or community physicians who might be less familiar with The Ottawa Rules.

Figure 2. Study flow diagram.

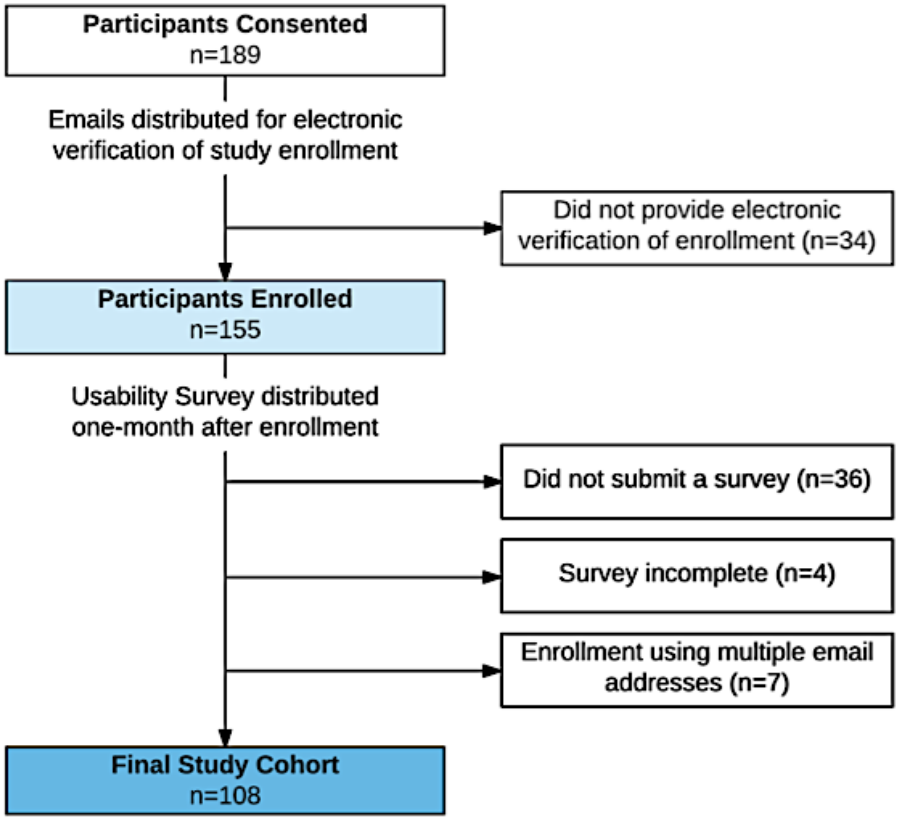


Table 1. Summary of participant characteristics (n=108).

Characteristic	Value
Age[a] (years), mean (SD)	33.7 (9.9)
Age range (years), n (%)	
18-24	9 (8.4)
25-34	64 (59.8)
35-44	14 (13.1)
45-54	14 (13.1)
55-64	6 (5.6)
Sex, n (%)	
Male	49 (45.4)
Female	59 (54.6)
Level of training, n (%)	
Medical student	13 (12.0)
Nurse	42 (38.9)
Resident	33 (30.6)
Physician	20 (18.5)
Years of service, mean (SD)	6.85 (7.8)
Years of service, n (%)	
0-4	61 (56.4)
5-9	22 (20.4)
10-14	7 (6.5)
15-19	7 (6.5)
20-24	4 (3.7)
>25	7 (6.5)
Mobile operating system used, n (%)	
iOS	87 (80.6)
Android	21 (19.4)

[a]One participant did not report a valid age; this person's age data is not reported.

Technology Readiness

After the exclusion of 6 incomplete surveys, the median TRI score was 3.56 (interquartile range [IQR] 0.62) out of a maximum score of 5, suggesting a slightly higher than average (3.02) propensity for technological adoption among participants. Examination of TRI scores across ED staff role (nurse, physician, resident, medical student), age (<35 or ≥35 years), by self-reported frequency of app use, and by response to usability questions revealed no association between TRI scores and patient demographics or user satisfaction and use of The Ottawa Rules app. The distribution of participant responses to survey questions ascertaining propensity to adopt new technologies overall and by participant subgroup are provided in Multimedia Appendix 1.

In-App Activity

Study participants accessed the app a total of 762 times between April 21 and August 30, 2016 (Table 2). Server data showed that of the 108 participants, 13 (12.0%) participants did not venture beyond the app home screen to use specific app features, confirming patterns of self-reported use. Nurses were the most active users of the app features (responsible for 37.8% [288/762] of activity), followed closely by ED residents (32.5% [248/762] of activity). Of the 3 Ottawa Rules hosted in the app, the Canadian C-Spine Rule was the most frequently accessed overall (20.1% [153/762] of app events), followed by the Ottawa Ankle Rules (134/762, 17.6%), and Ottawa Knee Rule (128/762, 16.8%). TOH guidelines and algorithms accounted for 45.5% (347/762) of app events overall and were among the most accessed tools across all participant subgroups.

Figure 3. Usability survey responses.

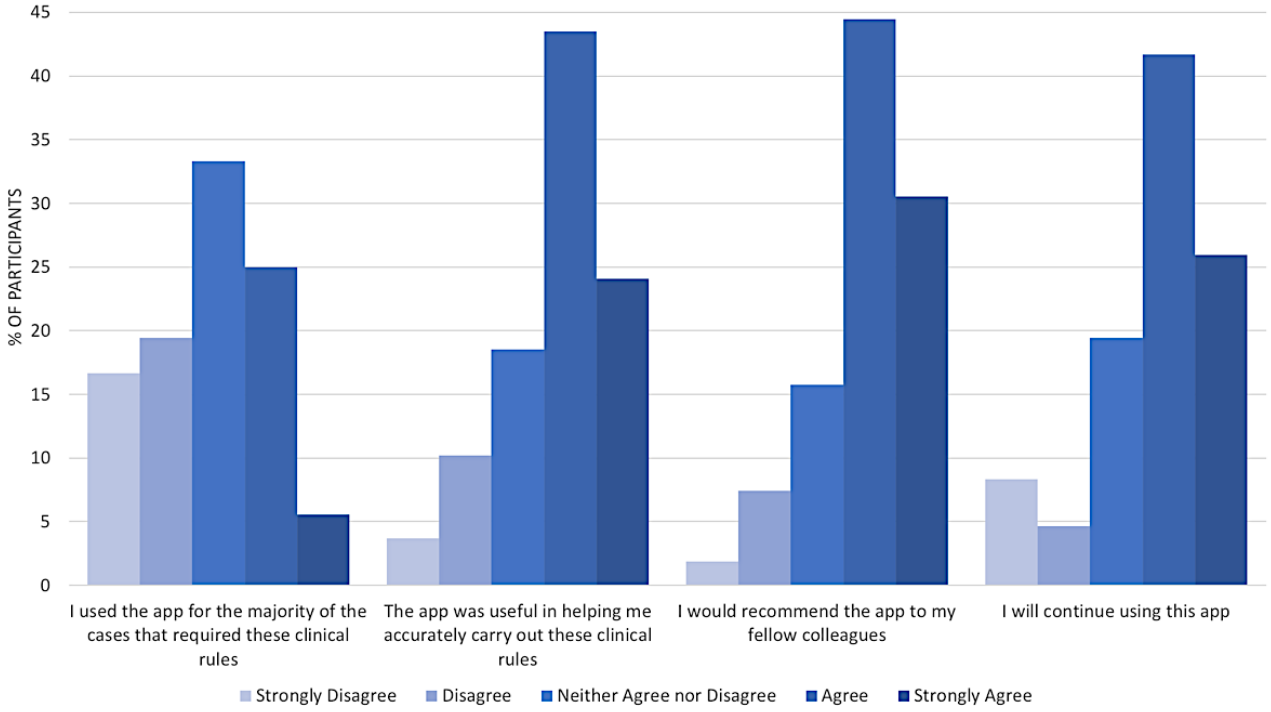


Table 2. In-app activity of study participants overall and by clinician role.

	Overall, n (%)	Students, n (%)	Residents, n (%)	Nurses, n (%)	Physicians, n (%)
Total number of app events	762 (100)	121 (15.9)	248 (32.5)	288 (37.8)	105 (13.8)
Ankle Rules events	134 (17.6)	21 (17.4)	46 (18.6)	49 (17.0)	18 (17.1)
Knee Rule events	128 (16.8)	22 (18.2)	37 (14.9)	48 (16.7)	21 (20.0)
C-Spine Rule events	153 (20.1)	26 (21.5)	46 (18.6)	47 (16.3)	34 (32.4)
Other TOH[a] resources	347 (45.5)	52 (43.9)	119 (47.9)	144 (50.0)	32 (30.5)

[a]TOH: The Ottawa Hospital.

Table 3. App activity from April 21, 2016, to June 1, 2017.

Metric	Amount, n (%)
Total downloads (n=3863)	
iOS	1853 (47.9)
Android	1638 (42.4)
Other	372 (9.7)
Downloads by country (n=3863)	
Canada	1234 (31.9)
United States	953 (24.7)
Spain	347 (8.9)
Other	1329 (34.5)
In-app events (n=7747)	
Ottawa Ankle Rules	2066 (26.7)
Ottawa Knee Rule	1991 (25.7)
Canadian C-Spine Rule	1904 (24.6)
Additional features[a]	1786 (23.0)

[a]Additional features includes other screens accessible from the app homepage or main menu (eg, Terms of Use, About).

A summary of global app use and in-app activity since public release is shown in Table 3. As of June 1, 2017, The Ottawa Rules app had been downloaded nearly 4000 times across 89 countries. Users in Canada accounted for the largest number of downloads (1234/3863, 31.9%), followed by users in the United States (953/3863, 24.7%) and Spain (347/3863, 8.9%). The Ottawa Ankle Rules were accessed 2066 times, followed by the Ottawa Knee Rule (1991 times) and Canadian C-Spine Rule (1904 times).

Uptake of the app across 89 countries worldwide may reflect success of promotional efforts of our team for The Ottawa Rules app. Such efforts included media releases [13], a local morning televised news broadcast, and dissemination of the work through academic and clinical channels. We observed an increase in app downloads following circulation of a press release on May 9, resulting in 202 daily downloads. The period between September 23-30, 2016, saw 171 new downloads in Spain. Other potential reasons for global success may be app usefulness spread through word of mouth between clinicians and interactions or presentations at national and international conferences.

Discussion

Principal Findings

Mobile apps can be leveraged to improve the accessibility of clinical decision rules in the ED. Pilot-testing of The Ottawa Rules app among ED workers produced useful feedback that can be used to optimize the platform for our users. Overall, survey data suggest the app was useful in guiding clinical decision making and is a tool that clinicians would use in the future and recommend to others. A preference for single-source access to clinical resources and inclusion of additional decision rules and center-specific directives were among the most frequently cited feedback responses. Users also indicated that the platform could be improved by inclusion of interactive features.

The Ottawa Ankle Rules, Ottawa Knee Rule, and Canadian C-Spine Rule were developed to reduce unnecessary radiography for ankle/foot, knee, and cervical spine injuries without jeopardizing patient care. The rules have been widely validated across numerous international patient and hospital settings [14-17] and have been shown to reduce department crowding and patient length of stay [18] and save on hospital resources [19]. Dissemination, uptake, and implementation of the rules have not been optimal, however, even with educational strategies [12,20].

Health care has been impacted by advances in mobile technology. Whereas previously pagers and personal digital assistants were commonplace, mobile phones and tablets are now the preferred computing devices for health care professionals [21]. Ownership and use of smart devices is particularly high among the health care community, who report using medical apps on personal devices for both clinical activities and continued education [22,23]. Health care professionals increasingly rely on electronic resources to support patient management decisions, and there are numerous apps available that help provide information on diagnosis, treatment, and standard clinical formulas [24]. Other mobile apps, similar to the one evaluated in this study, have been designed to help clinicians identify the most appropriate scans or tests to order, thereby increasing efficiency of use of hospital resources [24]. Medical apps, although convenient, must be viewed with caution, however. Despite the high rate of adoption of health apps among young health care providers, medical professional involvement in the development of such apps is notably limited [23]. As a result there is a paucity of literature for reference on the rate of adoption, satisfaction, and use scores for apps used by health care providers. With the number of such tools becoming publicly available, the source of information upon which medical apps and electronic resources have been developed must be considered. Standards for the evaluation and validation of medical apps are warranted to ensure that the recommendations and outputs from these tools are reliable and safe [25].

Strengths and Limitations

This study has important strengths and weaknesses. Strengths include close involvement of clinicians in the development of The Ottawa Rules app, user testing among all levels of ED staff, the use of surveys to capture both closed and open-ended feedback on the app system, and a high response rate (119/155, 76.8%). The successful completion of this study with over 100 ED workers of varied educational training, duration of employment, and age demonstrated an openness of the clinical community to trying new technology in the workplace. Our ability to leverage 3 separate data collection mechanisms to capture user-level (study participants) and aggregate-level (all app users) app activity is also a notable strength. Self-reported use of The Ottawa Rules app by participants, validated by server analytics data, confirmed that 12% to 15% of participants did not actively use the app despite having it downloaded on their phones. Through server analytics, we were able to identify the most frequently accessed app features and resources. Google Analytics data further permitted review of in-app activity among all users of the app, beyond the study cohort. Through Google Analytics, patterns of download across geographies and by type of devices were available for review, and trends in app activity following promotional efforts could be assessed. The primary weaknesses of this study were the small sample size, self-selecting nature of participant recruitment, and our single-center approach. This study also took place at a tertiary care hospital in an urban center where there was a high degree of familiarity with The Ottawa Rules among ED workers. As highlighted by some participants, evaluation of receptiveness to the app among medical trainees, general practitioners, and community physicians may be warranted, as these groups are less likely to be familiar with the rules.

Conclusion

As we seek to optimize The Ottawa Rules app based on feedback to improve the user experience, interactive modalities will be provided. Importantly, inclusion of new clinical decision rules and other resources will be incorporated to provide a more comprehensive tool to our users. Work in this field would benefit from ongoing clinician involvement in the development and evaluation of health apps to ensure app quality, reliability, and

user satisfaction. Future work should aim to assess the impact of health apps such as The Ottawa Rules on the quality and cost effectiveness of patient care and hospital resources. In sum, The Ottawa Rules app stands to provide health care professionals an efficient, reliable, and user-friendly means of accessing clinically validated decision rules shown to reduce health care costs and improve quality of patient care.

Acknowledgments

We would like to acknowledge the research participants for their constructive feedback on The Ottawa Rules app. App development and evaluation was supported by the Innovation Fund of the Alternative Funding Plan for the Academic Health Sciences Centres of Ontario.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Survey questions and response data.

[PDF File (Adobe PDF File), 38KB - mhealth_v6i6e10263_app1.pdf]

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Abbreviations

ED: emergency department
IQR: interquartile range
OHRI: Ottawa Hospital Research Institute
TOH: The Ottawa Hospital
TRI: Technology Readiness Index

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Original Paper

The Prescription of Mobile Apps by Primary Care Teams: A Pilot Project in Catalonia

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Abstract

Background: In Catalonia, the Fundació TIC Salut Social's mHealth Office created the AppSalut Site to showcase to mobile apps in the field of health and social services. Its primary objective was to encourage the public to look after their health. The catalogue allows primary health care doctors to prescribe certified, connected apps, which guarantees a safe and reliable environment for their use. The generated data can be consulted by health care professionals and included in the patient's clinical history. This document presents the intervention and the major findings following a five-month pilot project conducted in the Barcelona area.

Objective: The objective of the pilot study was to test, in a real, controlled environment, the implementation of AppSalut. Specifically, we tested whether (1) the procedures corresponding to the prescription, transmission, and evaluation of the data functions correctly, (2) users interact successfully and accept the tool, and (3) the data travels through existing pathways in accordance with international standards. The evaluation is not based on clinical criteria, but rather on the usability and technological reliability of the intervention and its implementation in the context of primary care.

Methods: The project was presented to the Primary Care Team participants to encourage the involvement of doctors. The study involved at least 5 doctors and 5 patients per professional, chosen at their discretion and in accordance with their own clinical criteria. An initial consultation took place, during which the doctor discussed the pilot project with the patient and recommended the app. The patient was sent a text message (SMS, short message service) containing an access code. When the patient arrived home, they accessed their personal health record (PHR) to view the recommendation, download the app, and enter the access code. The patient was then able to start using the app. The data was collected in a standardized manner and automatically sent to the system. In a second visit, the patient looked at the data with their doctor on their clinical station screen. The latter was able to consult the information generated by the patient and select what to include in their electronic health record. In order to assess the performance of the system, three focus groups were performed and two ad-hoc case-specific questionnaires, one for doctors and one for patients, were sent by email. Response was voluntary.

Results: A total of 32 doctors made 79 recommendations of apps to patients. On average, the patients uploaded data 13 times per prescribed app, accounting for a total of 16 different variables. Results show that data traveled through the established channels in an adequate manner and in accordance with international standards. This includes the prescription of an app by a doctor, the patient accessing the recommendation via the PHR, app download by the patient from the official app stores, linking of the patient to the public platform through the app, the generation and visualization of the data on the primary care workstation, and its subsequent validation by the clinician.

Conclusions: First, the choice of apps to be used is fundamental; the user's perception of the utility of the proposed tool being paramount. Second, thorough face-to-face support is vital for a smooth transition towards a more intense model of telemedicine. Last, a powerful limiting factor is the lack of control over people's ability to use the apps.

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KEYWORDS

mobile apps; apps; mHealth; primary health care; telemedicine; telemonitoring

Introduction

Background

As part of the Catalan Ministry of Health, the *Fundació TIC Salut Social* (the ICT Social Health Foundation) works to promote the use of information and communication technologies (ICT) in the field of public health and social welfare. Its main tasks include the observation of new trends, monitoring of emerging initiatives and the provision of services to certify products, systems and apps. In this context, the mHealth Office was created in early 2016 with the aim to bring patients closer to health and social mobility services so that they can interact with the health system in a trouble-free, personal way. The Office created a website featuring mobile apps in the field of health and social care for medical professionals and members of the public, a mechanism for accrediting apps, the development of mobility standards and a means to monitor experiences with health-related apps. As part of the framework of services that meet the corresponding interoperability standards, the Digital Health Platform (DHP) acts as a repository for this information. It also facilitates interactions between members of the public (providing the user with the information they have generated through the use of one or more recommended apps) and doctors (providing support in monitoring the patient's status and allowing the treatment to be personalized and adaptable to their needs).

App Catalogues - The AppSalut Site

Easy to get, easy to use and insanely cheap. The use of mobile apps for health management has been promoted both by independent reviews and public initiatives [1]. In the former, the app stores themselves (Google, Apple, Windows, Amazon, Blackberry) rank the apps in their catalogs according to the opinions of expert or user ratings [2] [3]. Nevertheless, they are unable to avoid significant heterogeneity in their quality [4] and safety standards [5].

Likewise, countless leading websites feature health apps, either exclusively, such as iMedicalApps and *Fundación iSYS's* iSYScore [6], or only as one of their numerous areas of interest (Android Authority, ForbesTech). As for catalogues aimed at the public sector, we find fewer initiatives: for example, the United Kingdom promotes its "Digital Apps Library," which is still at the design stage; at the regional level, the Andalusian Health Service maintains its "Catalogue of mobile health apps" recipients of its *AppSaludable* label, its own accreditation process.

In Catalonia, the *Fundació TIC Salut Social'* s mHealth Office created the AppSalut Site as a central, wide-reaching project. It is intended as a showcase of mobile apps in the field of health and social services with its primary objective being to encourage members of the public to look after their health. All of the apps on the website, which are available for both iOS and Android devices for free in leading app stores, need to have passed the Foundation's own quality control process, which guarantees a safe and reliable environment for their use. In addition, doctors in Primary Care Teams can recommend the apps to their patients in their surgery, thus complementing the follow-up of the patients' condition by monitoring the data generated, which can be consulted by health care professionals and included in their clinical history, with the patient's permission. In the future, the plan is to extend access to professionals from other specialties.

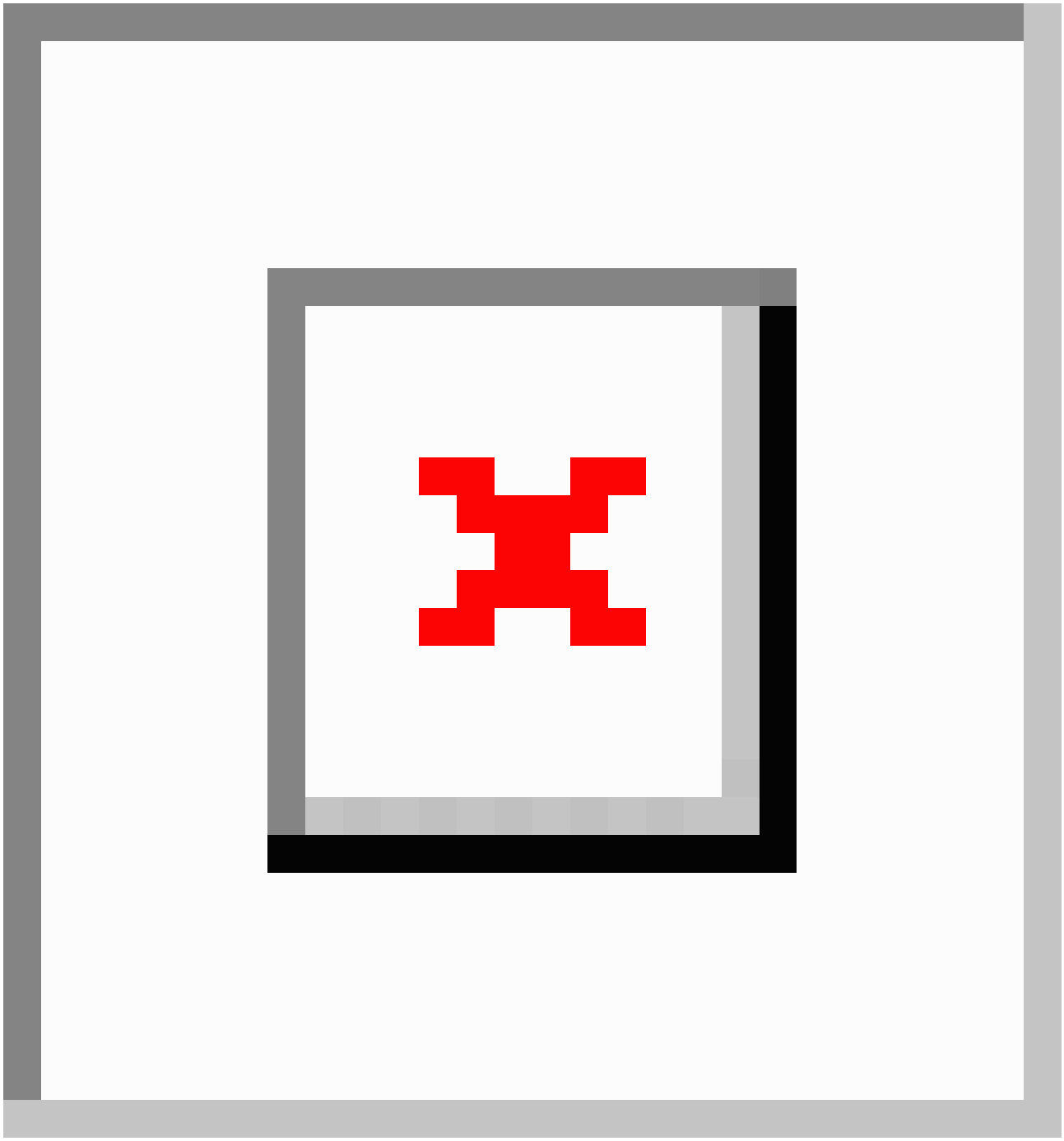
After conducting various tests in the preproduction environment, the need arose to carry out a controlled pilot study with doctors and real patients to ensure the system worked correctly from a technological point of view. This document is intended to present its significant findings, generating pioneering evidence for the integration of mHealth technologies with Primary Care systems in a public setting [7,8].

Objectives of the Pilot Project

The overall objective of the pilot project was to test, in a real, controlled environment, the implementation of AppSalut. Specifically, the three objectives that were to be evaluated are the following: (1) that procedures corresponding to the prescription, transmission and evaluation of the data functions correctly (Figure 1), (2) users interact successfully and accept the tool, and (3) the data travels through existing pathways in accordance with international standards.

The evaluation of the pilot project is not based on clinical criteria but rather the usability and technological reliability of the intervention and its implementation in the context of primary care.

Figure 1. The AppSalut Site recommendation process.



Methods

Preliminary Design

The project was presented to the Primary Care Team (PCT) participants to encourage the involvement of doctors. Once they were recruited, together with their corresponding patients, the following three steps were taken. First, an initial consultation took place, in which the doctor was able to explain to the patient what the pilot project consisted of, provide them with the necessary documentation, and recommend the app to them. The patient was sent a SMS text message (short message service, SMS) containing an access code, and the recommendation of the app was registered on the system. Second, when the patient arrived home, they accessed the *La Meva Salut* (My Health, MH) Personal Health Record to view the recommendation, download the app and enter the activation code they were sent by SMS to link the app to the platform. The patient was then able to start using the app. The data was collected in a standardized manner and automatically sent to the system. Lastly, in a second visit, the patient looked at the data with their doctor on their screen. The latter was able to consult the information generated by the patient and select what to include in their Electronic Health Record.

Participant Recruitment

The agents involved in the execution of the pilot project are presented in Table 1.

The following four PCTs participated in the study and belong to the South Metropolitan Territorial Management (province of Barcelona): Vinyets PCT (Sant Boi de Llobregat), Sant Andreu de la Barca PCT, Cubelles-Cunit PCT and Sant Ildefons PCT (Cornellà de Llobregat). For each team, the involvement of at least 5 PCT doctors and 5 patients per professional was requested and chosen at their discretion and according to their own clinical criteria. Thus, the objective recruitment population was 20 doctors and 100 patients. Patients were selected according to the following inclusion criteria: the patient's expressed their willingness to participate, and proof that they were over the age of consent and gave written authorisation. Since the object of the study was the implementation of the process rather than the evaluation of any clinical outcomes, the intervention was not assigned in a randomized manner. Consequently, potential biases (medium-advanced users of mobile technology) can be assumed to be present and caution should be exercised in the extrapolation of the results.

Mobile Apps

Three mobile apps were used (see Table 2). They were chosen for their potential in providing continuity of care for the conditions they address, and their ability to adapt to the requirements that were identified during the pilot study. The integrated apps were required to perform specific technical adaptations to conform to the specific doctor-patient context effectively. The three of them could be downloaded free-of-charge.

Duration

The planned duration was initially 3 months. However, due to the decrease in the use of the platform during the summer holidays (July and August) it was extended to 5 months from the time the PCT candidates for participation in the pilot were identified, until the last recommendation was made. The variables sent by the app continued to be recorded in November to include information from users recruited during the end of October. Thus, the period covers June 1 to November 30, 2017.

Follow-Up and Monitoring

To initiate the pilot study, presentations were organized to introduce the doctors to the project and to train them in the prescription and use of the apps. Once started, the timing of periodic follow ups was established, accompanied by training for the doctors to ensure the processes were clear and to deal with any doubts. After detecting problems in various phases of the recommendation of the apps, it was decided to occasionally assist the professionals in the prescription process and the patients in downloading, registering, and configuring the app.

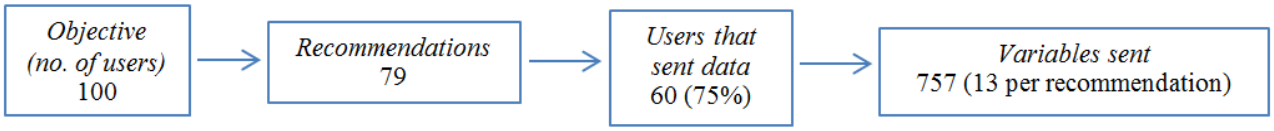
Table 1. The roles of organizations participating in the study.

Organization	Role
Fundació TIC Salut Social (ICT Social Health Foundation)	Coordinated the entire pilot phase, training the doctors, monitoring the project, dealing with any incidents which arose, and the utilization and evaluation of the results
Four Primary Care Teams belonging to the South Metropolitan Territorial Management Directorate of the Catalan Health Institute	Clinicians are the users of the eCAP, the main clinical management software used by primary care clinicians in the public system
The *Dirección Asistencial* ICS (ICS Health Care Directorate)	Participated in the validation of the process and provided training to the professionals involved
The Catalan Personal Health Record *La Meva Salut* My Health (MH)	The functional and technical managers established the AppSalut Site service within MH and provided access to the participating providers in the pilot study
IN2, an app and web developer	Offered support for technological incidents

Table 2. Apps used in the pilot project.

App	Health indication	App description
AsmaProcare	Asthma	An app which serves as an instrument for sending information from asthma sufferers to their physician. The daily readings of *PeakFlow* measurements are introduced via the app, as well the use of any rescue medication; the data can be displayed visually in the apps' interface. In addition, the user is able to see the ongoing treatment introduced in the *backoffice* by their doctor.
ExpertSalud	Chronicity	An app that allows the monitoring of the pharmacological adherence to a treatment. It is designed to help manage the intake of medications, the setting of reminders and the monitoring of variables such as weight and glucose levels.
Sideal	Alcohol consumption	A self-help system for people with alcohol dependence that offers advice aimed both at reducing intake and abstinence and which allows monitoring both of consumption and therapeutic compliance based on the objectives that the person sets or agrees with their doctor.

Figure 2. Participant attrition diagram.



The recommendation was made to the patient in the doctor's surgery, while the process of downloading the app, registering the patient on the platform and configuring the relevant variables was carried out in an adjoining surgery by the Foundation's staff. In this way, the most critical period within the process was reduced, where the highest rate of loss of patients was identified: when the user connects with the platform and needs to configure the variables. These follow-ups were an important aspect in the development of the project since they allowed to gain personal experience from the problems which arose and to implement corrective measures and additional training. The following Figure 2 summarizes the evolution of the project's adherence.

Results

Usage of the Instrument

A total of 32 doctors made 79 recommendations of apps to patients, representing 160% of doctors and 79% of recommendations compared to what was expected during the design of the pilot project. Of the recommendations, 75% (60/79) of patients used the app, sending a total of 757 variables to the system (Table 3). In general, the main reasons for non-use were connection errors with the platform, problems with accessing the app (incorrect configuration, failing to activate alerts and problems with the confirmation email), and dropping out (mainly due to the study coinciding with the summer holidays and loss of motivation).

The amount of prescriptions made to patients was heterogeneous along the intervention period. As shown by Figure 3, the reduction occurred from the second half of July to the first half of September, coinciding with the doctors' vacation period, bringing out one of the major design drawbacks. The aforementioned heterogeneity can also be noted by the number of recommendations made by the doctors. A first subgroup has made only one, while at the other extreme many doctors made five or more. It can be seen, therefore, that the shortfall in meeting the objective concerning patient recruitment is primarily due to the first subgroup of less-motivated doctors.

Table 3. Physician recommendations, messages, and data-uploads sent per primary care team.

Primary care team	Physician recommendations per primary care team, n	Patients who sent data per primary care team, n (%)	Total messages sent per primary care team, n	Messages per patient per primary care team, n (%)
Cubelles-Cunit	12	10 (83)	206	21 (10.2)
Cornellà de Llobregat	16	12 (75)	165	14 (8.5)
Sant Andreu de la Barca	22	14 (64)	92	7 (7.6)
Sant Boi de Llobregat	29	24 (83)	294	12 (4.1)
Total	79	60 (75)	757	54 (7.1)

Figure 3. Monthly recommendations and number of recommendations per professional.

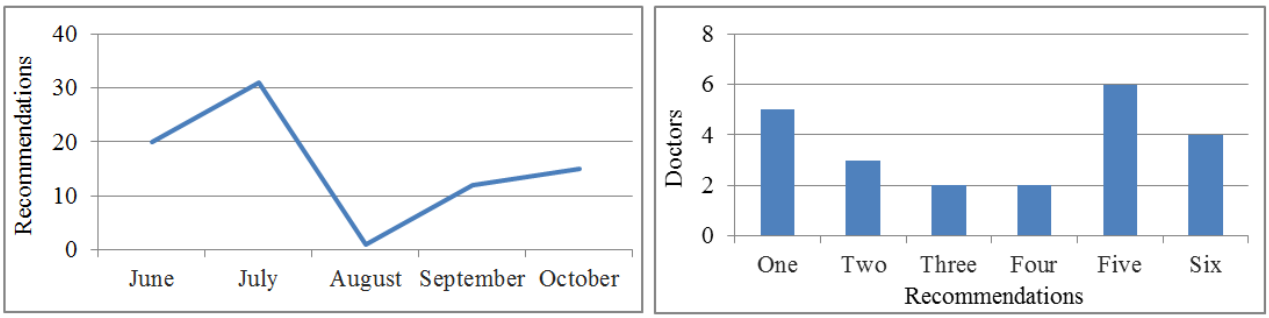


Table 4. Apps use by patients.

App and variable upload	Number of patients used (n=79), n (%)
AsmaProcare	9 (11)
ExpertSalud	67 (85)
Sideal	3 (4)

Uploading of Data

Regarding which apps were likely to be prescribed (Table 4), ExpertSalud was the most-used by the patients (67/79, 85%). According to the results of the focus groups and the periodic follow-ups, this could be due to the full range of variables that the app can handle (glycemia, blood pressure, weight, pain, stress, pulse, dizziness). Very few patients used the AsmaProcare app (9/79, 11%), while prescription of the Sideal app was negligible (3/79, 4%).

On average, the patients uploaded data 9.6 (757/79) times per prescribed app, accounting for a total of 16 different variables. Weight was the most used (28/79, 35%) upload, followed by systolic and diastolic blood pressure variables (21/79, 26%) uploads, and heart rate (11/79, 13%) uploads. Other variables such as temperature, alcohol intake and dizziness levels were not used as much, with migraine being the least used variable. To ensure a consistent exchange of the apps' variables, the mHealth Office and the Foundation's *Oficina de Estándares e Interoperabilidad* (Standards and Interoperability Office) employed a subset of codes for mHealth variables using controlled vocabulary that guarantee their unique identification: Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) is the reference vocabulary used in the subset, but other classifications and terminologies, such as International Statistical Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Statistical Classification of Diseases, Tenth Revision (ICD-10), Logical Observation Identifiers Names and Codes (LOINC), *Anatomical, Therapeutic, Chemical* Classification System (ATC), and International Classification of Primary Care (ICPC), were also considered and then transformed into SNOMED CT.

Usability Evaluation

Two ad-hoc case-specific questionnaires, one for doctors and one for patients who had participated in the pilot study were sent by email during the first week of November (the deadline for making new recommendations, but while data was still being sent). They were completed on a voluntary basis. A total of 17/32 (53%) responses from doctors and 30/79 (38%) from patients were received.

Doctors' Questionnaire

Information was collected from the doctors as to the app recommendation process, the use of the data, and the general characteristics of the platform. The main ideas derived from each of these issues are described in the following. First, making a recommendation is not an easy task (since it lengthens the consultation) and the patient is not autonomous in its management: they must receive support. Second, visualizing the data is easy and is carried out before, during and after consultation with the patient, indicating the success of the integration model in patient-doctor environments.

Table 5. Incidences by type.

Source	Incidence (N=34), n (%)
AsmaProcare (app)	
User training	1 (2.9)
ExpertSalud (app)	
Sign up email	6 (17.6)
Make of smartphone	2 (5.9)
AppSalut (site)	
SMS[a] code	16 (47.1)
Error connecting with platform	3 (8.8)
Problems connecting patients	6 (17.6)

[a]SMS: short message service.

Third, with respect to the platform, the doctors would like to be able to create alerts based on the data they have received. In general, they value the usefulness of the AppSalut Site as part of the health care process (3.4, on average, on a scale of 1 to 5, 5 being "Very useful").

Patients' Questionnaires and Focus Groups

Regarding the users, the questionnaire collected information on three topics: the recommendation process, the use of the Personal Health Record, and the use of the app. In relation to the first, the patients' experience confirms the difficulties identified in linking the app with the professional's prescription. Nevertheless, the added value that is expected both from the patient's ability to use the app autonomously and from the doctor's ability to access the information is very high. With respect to My Health (MH), in spite of the difficulties patients faced in terms of access, the prescription of the app was closely associated with access to the patient's Personal Health Record (two out of three patients used it). Finally, regarding the usage of the app, patients would consider recommending it to other patients with the same medical condition and generally see it as very simple to use. In general, they rate the AppSalut Site as "very interesting" (4.5, on average, on a scale of 1 to 5).

To complement this qualitative vision, three focus groups were established (two consisting of doctors, one of patients) with a minimum of three participants, with a professional from the Foundation acting as moderator with a script and prepared questions. Both the script and the full summary of the three sessions can be found in the Multimedia Appendix 1 and

Multimedia Appendix 2, confirming the ideas collected by the questionnaire's approach.

Incidents Detected During the Use of the Platform

During the pilot project, 34 incidents were registered (see Table 5). Two types stand out. First, those related to the AppSalut Site, such as the SMS being sent with a missing or invalid activation code or incidents related to connection and upload errors. Second, those related to the user's connection with the app (for example, not receiving the confirmation email to be able to use the app).

Concerning the duration of the pilot study, initially, problems were detected related to users getting lost on the platform and their access to the website, requiring a two-day halt in the prescription process. In general, incidents were detected regarding the connection and access to the AppSalut Site that will need to be reviewed during an additional technical audit.

Discussion

Principal Findings

In terms of the specific objectives, the execution of the pilot study has shown that, despite the aforementioned incidents, the platform operates continuously and safely: Therefore, it represents a significant experience in the prescription of health apps and the integration of its information in primary care practitioners' workstation in a public setting. It was observed that it is generally usable although critical issues have been identified in the user experience, which indicates room for improvement. The pilot study showed that the data travels through the established channels in an adequate manner and in accordance with international standards.

The results validate, in a controlled environment with real participants, the entire process. This includes the prescription of an app by a doctor, the patient accessing the recommendation via their Personal Health Record, download of the app by the patient from the official app stores, linking of the patient to the public platform through the app, the generation, visualization of the data on the primary care workstation, and its subsequent validation by the clinician. The following are the major findings. First, shortcomings in terms of the usability of the tool are largely associated with the user linking to the platform using the code sent by SMS, which the patient needs to activate the app. In many instances, the user registration within some of the apps is not intuitive, an issue which is also found when the patient registers with the AppSalut Site using the SMS code: some users are unable to follow the process. Once this barrier is overcome, the process is smooth in terms of sending and viewing data. Second, the patients have a very high opinion of the service while the doctors feel they need to carefully manage its implementation so as not to overload themselves: for the former it is an additional service, for the latter an added burden. Related to this, the registration process within the app and signing up with the platform is perceived as much more critical for the doctors than for the patients, who are less concerned about the difficulties. For both groups, the integration of the data generated in their usual interfaces is a key factor in its acceptance. Third, there is a steep learning curve associated with the entire process of the use of such mobile technologies; in many cases the doctors ask for additional training for the apps, both for themselves and for the patients, potentially people aged over 65, where the digital divide is present. Fourth, the recurring need for reviews and support for doctors and patients indicates that support elements are needed at least in the early stages of the intervention. Finally, in relation to the information sent by the patients, the doctors feel that it would be more useful if alerts were received within the professional work interface.

Conclusion

By way of a recommendation, three factors can be identified which would improve similar experiences. First, the choice of apps to be used is fundamental; the user's perception of the utility of the proposed tool being paramount. Second, thorough face-to-face support is vital to a smooth transition towards a more intense model of telemedicine. Last, a powerful limiting factor is the lack of control over people's ability to use the apps.

Acknowledgments

We would like to thank the clinicians and patients for their participation in the pilot study. This study was conducted with the support of the Secretary of Universities and Research of the Department of Business and Knowledge at the Generalitat de Catalunya.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Guide to the focus groups.

[PDF File (Adobe PDF File), 15KB - mhealth_v6i6e10701_app1.pdf]

Multimedia Appendix 2

Summary of focus groups.

[PDF File (Adobe PDF File), 26KB - mhealth_v6i6e10701_app2.pdf]

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Abbreviations

ATC: Anatomical, Therapeutic, Chemical Classification System
DHP: Digital Health Platform
ICT: information and communication technologies
ICPC: International Classification of Primary Care
LOINC: Logical Observation Identifiers Names and Codes
MH: My Health (Catalan Personal Health Record)
PCT: Primary Care Teams
SMS: short message service
SNOMED CT: Systematized Nomenclature of Medicine–Clinical Terms CIM

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Original Paper

Mobile Decision Support Tool for Emergency Departments and Mass Casualty Incidents (EDIT): Initial Study

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Abstract

Background: Chemical exposures pose a significant threat to life. A rapid assessment by first responders and emergency nurses is required to reduce death and disability. Currently, no informatics tools exist to process victims of chemical exposures efficiently. The surge of patients into a hospital emergency department during a mass casualty incident creates additional stress on an already overburdened system, potentially placing patients at risk and challenging staff to process patients for appropriate care and treatment efficacy. Traditional emergency department triage models are oversimplified during highly stressed mass casualty incident scenarios in which there is little margin for error. Emerging mobile technology could alleviate the burden placed on nurses by allowing the freedom to move about the emergency department and stay connected to a decision support system.

Objective: This study aims to present and evaluate a new mobile tool for assisting emergency department personnel in patient management and triage during a chemical mass casualty incident.

Methods: Over 500 volunteer nurses, students, and first responders were recruited for a study involving a simulated chemical mass casualty incident. During the exercise, a mobile application was used to collect patient data through a kiosk system. Nurses also received tablets where they could review patient information and choose recommendations from a decision support system. Data collected was analyzed on the efficiency of the app to obtain patient data and on nurse agreement with the decision support system.

Results: Of the 296 participants, 96.3% (288/296) of the patients completed the kiosk system with an average time of 3 minutes, 22 seconds. Average time to complete the entire triage process was 5 minutes, 34 seconds. Analysis of the data also showed strong agreement among nurses regarding the app's decision support system. Overall, nurses agreed with the system 91.6% (262/286) of the time when it came to choose an exposure level and 84.3% (241/286) of the time when selecting an action.

Conclusions: The app reliably demonstrated the ability to collect patient data through a self-service kiosk system thus reducing the burden on hospital resources. Also, the mobile technology allowed nurses the freedom to triage patients on the go while staying connected to a decision support system in which they felt would give reliable recommendations.

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KEYWORDS

triage; mass casualty incidents; decision support tools; mobile technology; biomedical informatics; human-computer interaction

Introduction

Biomedical informatics is an interdisciplinary field that deals with the storage, retrieval, sharing, and optimal use of data and knowledge for problem-solving and decision-making. Historically, Health Information Systems (HIS) and the medical community, in general, have been slow to adapt to new technologies [1]. However, healthcare institutions are now seeking to develop integrated computer-based information

management environments with various informatics tools that aid care-givers in decision-making [2].

One area of healthcare that could benefit from an integrated decision support system is the hospital emergency department (ED). The ED typically operates under a set of conflicting main objectives. On the one hand, the ED system aims to process patients promptly, and on the other hand, the most optimal treatment of patients relies on a collection of detailed information from patients, which is time-consuming. The net effect of these competing objectives results in a compromise in one of the two main objectives. Under extreme circumstances like mass casualty incidents (MCIs) where the ED is inundated with many patients, additional constraints are imposed by overwhelmed hospital resources. Adaptation of modern technology can assist in diminishing the degree of compromise during the normal ED operations, and ED operations under MCI conditions.

Over the past few years, a limited set of software products have been presented spanning mobile devices, desktop computers, and Web-based services. Relevant to this study, the National Library of Medicine has created the Wireless Information System for Emergency Responders (WISER) [3], which allows emergency personnel to identify a list of possible chemical substances based on observed patient signs and symptoms. The US Department of Health and Human Services has developed another software tool, the Chemical Hazards Emergency Medical Management-Intelligent Syndromes Tool (CHEMM-IST) [4], which aims to identify a possible syndrome based on observed patient symptoms. Although such software makes significant strides in assisting the process of emergency care, they are not designed for a hospital ED. Therefore, the software efficiency, especially during MCI events, has not been well established [5].

In this report, we present the Emergency Department Informatics Computational Tool (EDICT), a comprehensive tool for processing, management, and triage of patients during an MCI. EDICT is designed to assist with the process of seamless data collection, aggregation, and dissemination using mobile technology to facilitate a client-server transaction model. EDICT has also been designed to include a recommendation decision support system, which we have utilized its potential for chlorine exposure. In this report, we present the EDICT software package and demonstrate its efficiency and agreement among nurses in application to a simulated reenactment of a 2005 chlorine spill that took place in Graniteville SC.

Methods

Background on Triage Systems

Triage is used to define how patients are categorized in the ED based on the severity of their condition. A triage nurse typically assigns a triage level with little information and in a short amount of time. Therefore, an effective triage requires a complex clinical decision based on small amount of data with a very limited margin for error. Given the complexity of the pragmatic cost of mistakes in patient assessment, triage-nurses typically favor over-triaging patients to guarantee patient care. Triage bias may be tolerable during normal ED operations, but over-triaging patients during an MCI event can place an unnecessary burden on already taxed hospital resources and reduce patient outcome [6,7].

Over the years, many models have been developed for triaging patients at the scene of the incident (field-triage) and in the hospital system (hospital-triage). Most of these models either use a three-tiered color system such as Sort, Assess, Lifesaving Interventions, Treatment or Transport (SALT) [8] or a five-tiered numeric system such as the Emergency Severity Index (ESI) [9]. The ESI algorithm is one of the most commonly used triage systems and is found in over 70% of large hospitals across the United States [10]. Triage algorithms are simplistic to train ED personnel quickly and simplify the decision-making process. However, the simplistic nature of these triage systems is not a reflection of their ability to optimize patient outcome. In fact, the effectiveness of these triage models to accurately triage patients in an MCI is widely unproven [11-13].

A modern triage system should incorporate existing mobile technology to reduce the cost of data collection and improve efficiency by providing rapid and accurate decision support. In the following sections, we outline a prototype for a patient management triage system that can provide decision support for ED personnel during a chemical MCI. This innovative tool utilizes mobile technology, giving staff the freedom to move about the ED, provides secure data collection with redundant features, and deploys artificial intelligent (AI) algorithms to provide clinical decision support.

EDICT: Emergency Department Informatics Computational Tool

EDICT was designed to improve patient outcomes during a chemical MCI through the utilization of mobile technology and incorporation of AI. To achieve its objectives, the EDICT software package integrates three main components: (1) fast and accurate data collection through aggregation and dissemination of information; (2) re-engineering of the patient processing protocol; and (3) a clinical recommendation system. Each of these components is described in the following sections.

Component 1: EDICT Data Collection, Aggregation, and Dissemination Platform

The EDICT software package was engineered to seamlessly facilitate data collection, aggregation, and dissemination during an MCI event. EDICT employs a Client-Server model that allows safe and fast bidirectional communication of data between mobile devices and a data storage server. The data-storage and AI servers can be located offsite to ensure additional data security. In addition to the centralized server, each client device creates and maintains its local database. This concurrent model of distributed and centralized data storage provides data redundancy that ensures data integrity against hardware failure. Recovery from a server-crash can be accomplished through aggregation of all the local data distributed across the client's local database. In return, local data can be reconstituted from the central server in the case of accidental damage to a client device.

Another critical feature of EDICT is providing situational awareness to all the pertinent members of the ED personnel. The current implementation distributes relevant information to all mobile devices such as the number of patients admitted, number of critical and noncritical patients, and geographical distribution of admitted patients. It is easy to envision future expansions of this feature to include a list of available ED resources and occupied resources as part of the global situational awareness report.

The current version of the application allows the proper function of each device to be selected through a login and setup process (Figure 1). A super-user can select between two distinct modes of operation: patient mode and nurse mode (Figure 2). The ability to switch between the two modes provides a dynamically adaptive system that can mitigate the effects of a surge at any point of the patient processing pipeline. Each of the two modes of operation will be described in sections below.

EDICT's Mobile App: Kiosk Mode

The kiosk mode enables a kiosk system that facilitates the process of collecting data from patients and divides into two operational submodes: assisted and nonassisted. The nonassisted mode will initiate the kiosk data collection module and can be operated by a patient. The assisted mode is identical, with the exception that the login identification of the assistant ED personnel is recorded.

When patients interact with the kiosk system, they are greeted with a welcome screen and asked to scan their barcode (Figure 3). Instructions are given on how to correctly align the barcode inside the scanner window. Under some abnormal conditions, the barcode scanning may fail or take too long. To mitigate such instances, patients and nurses have the option of entering the numeric value of their barcode to bypass the scanning process.

Figure 1. Triage app home screen.

Figure 2. App navigation and set-up.

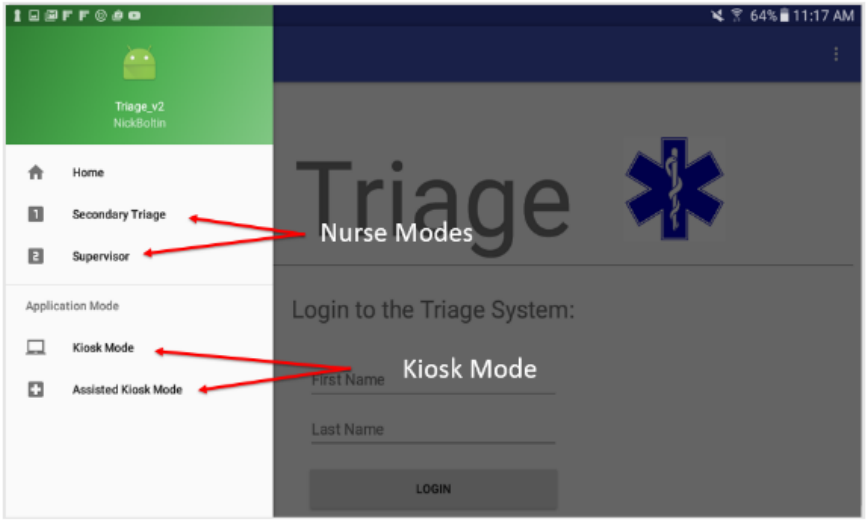


Figure 3. Kiosk barcode scanner.

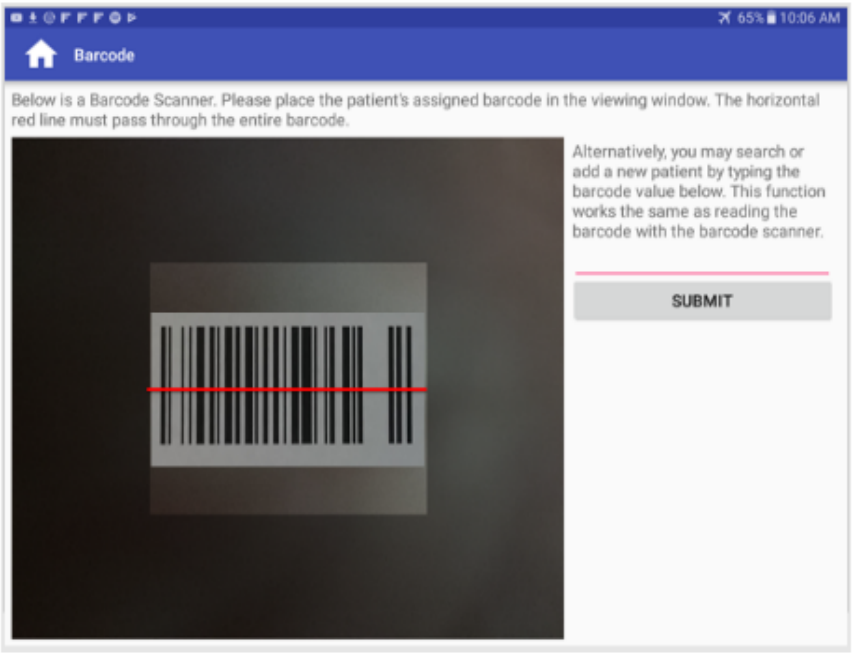
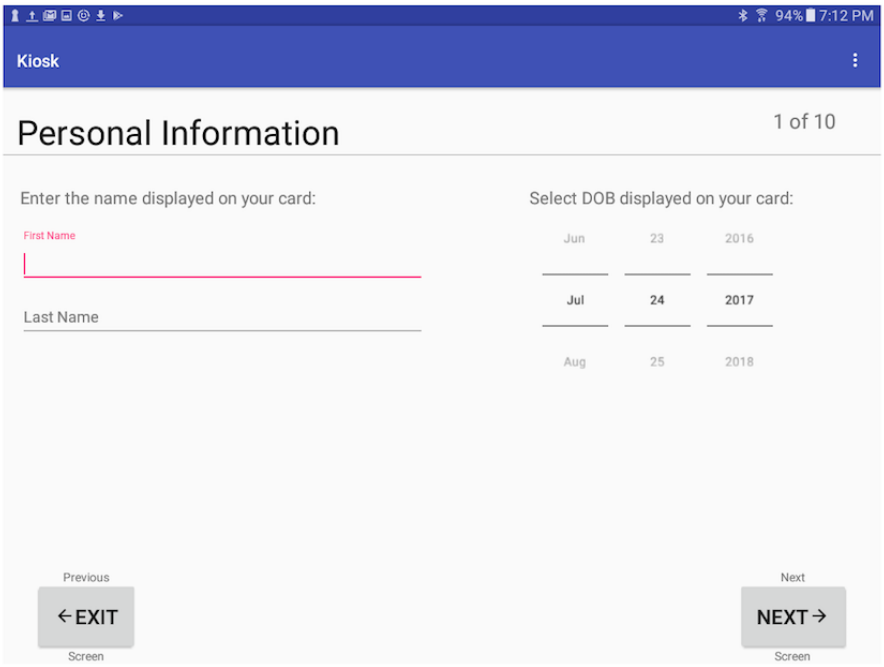


Figure 4. Kiosk demographic screen.



On the patient's initial entry into the system, the central server creates an instance of a new record based on barcode values. Patients then proceed linearly through a series of screens that collect information on their demographics including name, and date of birth (Figure 4). Information related to their symptoms and chief complaint (Figure 5) are also collected. Additional features of the kiosk system include collecting pulse rate and oxygen saturation values using a pulse oximeter (Figure 6). The geographic location where a patient first experienced their signs or symptoms (Figure 7) is also collected. Google maps Application Programming Interface [14] facilitates the location and can accept a street address, a manually placed marker, or longitude and latitude.

EDICT's mobile application: Nurse Mode

The nurse mode provides more diverse subfunctions when compared to kiosk mode. One example is the information related to global awareness of the MCI event. The situational awareness view (right panel, Figure 8) gives an overview of the event by displaying the number of patients in the system and a breakdown of triage levels currently assigned. The spatial view (Figure 9) helps establish the geographical scattering of patients within the event which is critical when determining if incoming patients have been exposed to the MCI event.

Figure 5. Kiosk sign/symptom screen.

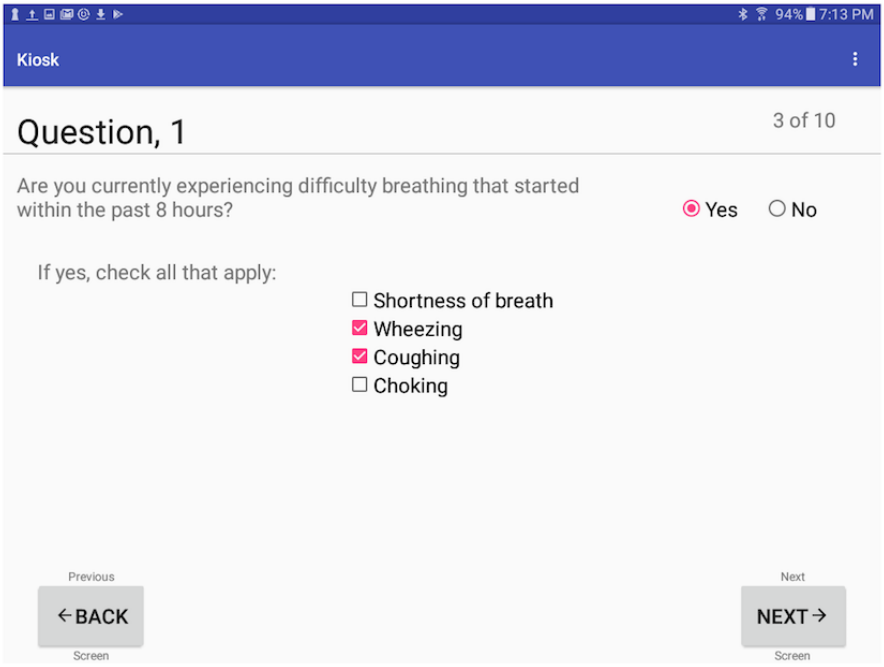


Figure 6. Kiosk patient vitals screen.

Figure 7. Kiosk google map screen.

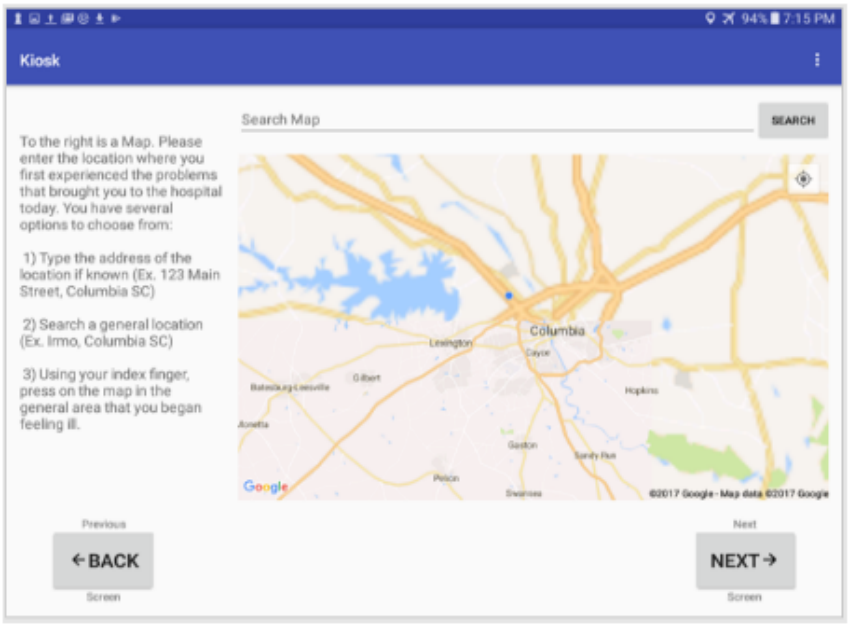


Figure 8. Nurse global view screen.

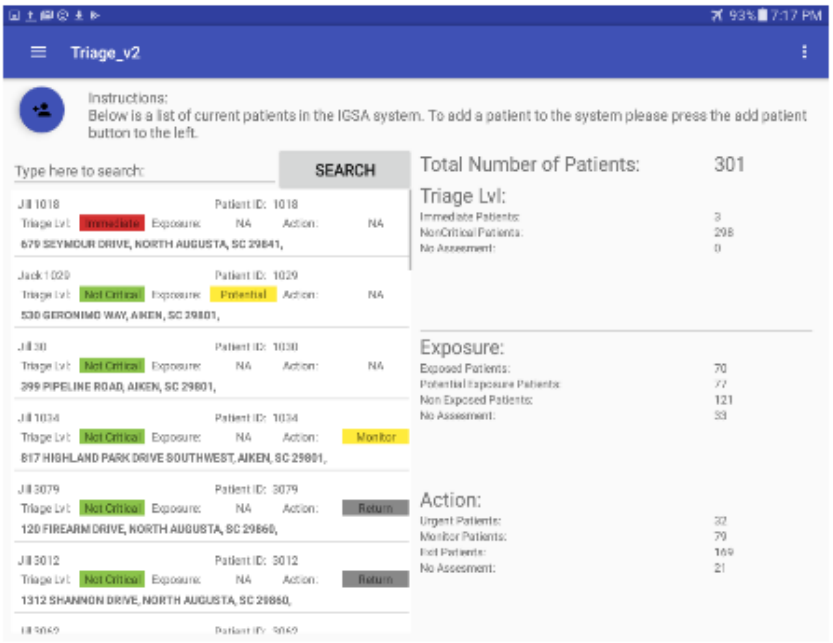


Figure 9. Nurse google map screen.

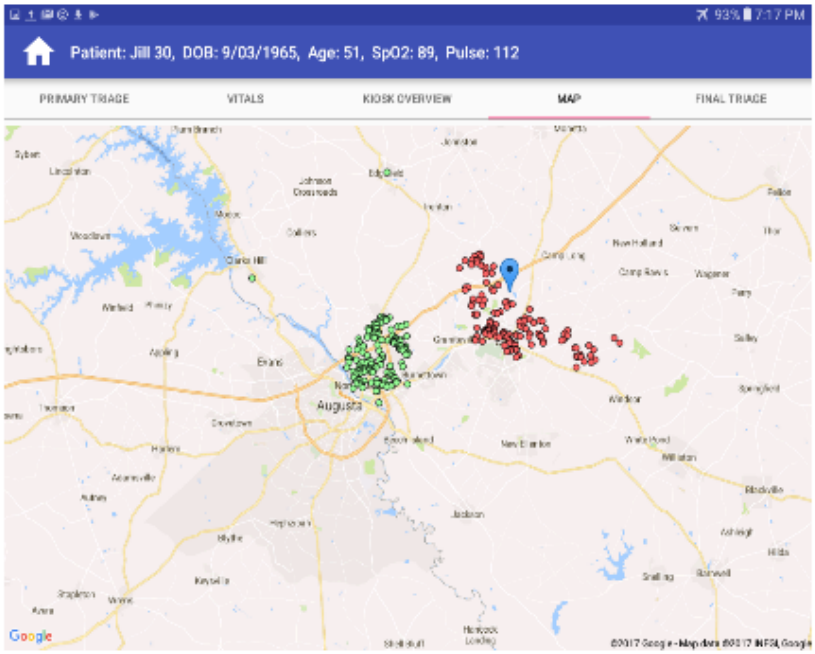
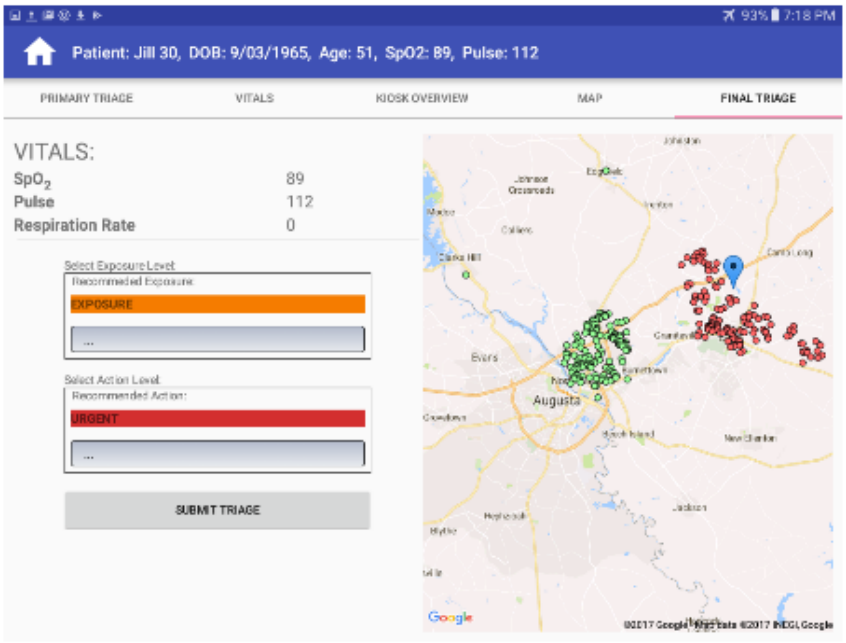


Figure 10. Detailed patient information screen.

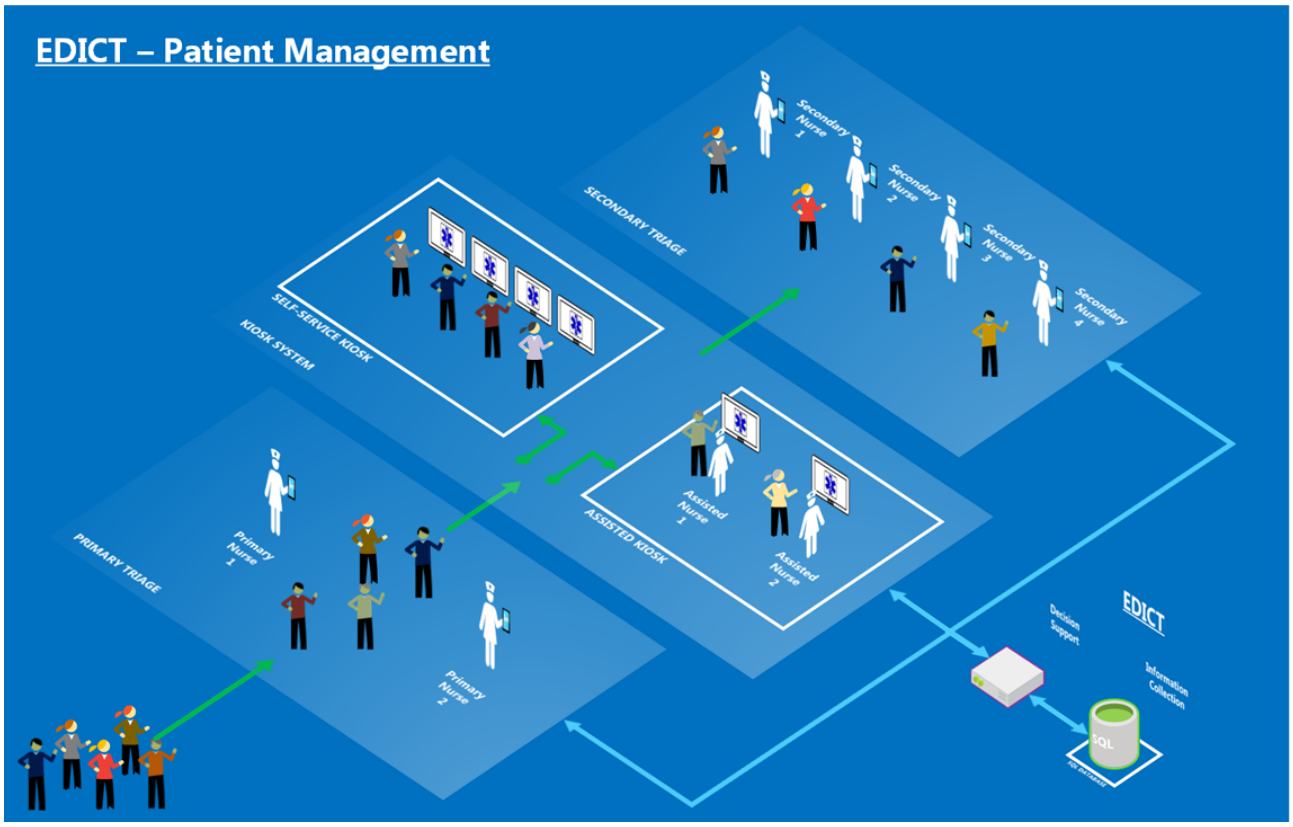


The nurse mode can also be used to view a comprehensive list of patients currently in the system and a summary of collected information (left panel, Figure 8). Detailed information can be displayed by selecting an individual patient in one of three ways: (1) manually navigating the list of patients, (2) using the search dialogue, or (3) scanning a patient's barcode. Figure 10 illustrates an example of the detailed patient information screen. Additional functions are available through different functional tabs at the top of the screen and include: review or update patient data such as geographical location, signs and symptoms or initial triage category. Tabs are also available for reviewing AI recommendations for each patient (subject to availability of sufficient data), and the evaluation screen, where nurses assign the final triage classification. EDICT's system menu (top left corner Figure 8) allows easy navigation to other modes or screens.

Component 2: Re-engineered Patient Processing Pipeline

An improved patient management system can benefit from establishing order during the chaos that takes place during an MCI. Here we propose a patient processing pipeline that helps improve patient management while facilitating a faster mechanism for collecting data and tracking patients. The patient tracking system will consist of three main stages shown in Figure 11. The three stages are denoted as the "primary triage," "kiosk system," and the "secondary triage" phases, which are described in the following sections.

Figure 11. EDICT, a mass casualty incident–specific triage tool used to map data gathered by the mobile application to the Irritant Gas Syndrome Agent algorithm. Information gathered in the primary triage, the kiosk system and secondary triage is used to determine a patient's specific exposure level and action.



Primary Triage

The main objective of primary triage is to identify the patients who need immediate care. Functionally, ED personnel can engage the arriving patients in a variety of ways. For our research, we assume patients will be given a wristband with a barcode that will serve as the patient's unique identification for the remainder of their virtual existence within the EDICT system. In addition to receiving a wristband, patients will be evaluated by a primary triage nurse if necessary and receive a triage category of "Immediate" if assessed to have a life-threatening problem and sent directly for treatment. All remaining patients are initially categorized by default as "not critical" and directed to the kiosk area for further acquisition of information.

Kiosk System

The kiosk system is designed to interactively collect individual information such as name, date of birth, and other demographics from patients initially categorized as "not critical." Additional information is obtained to help define the location of the incident using an applet like Google maps. Data is also collected on signs and symptoms of the presenting condition, and chief complaint. The kiosk stage is partitioned into assisted and nonassisted sections, where patients can complete the registration process independently or with the help of designated ED personnel. The patient information is gathered concurrently by multiple mobile devices and can, therefore, contribute to rapid data collection and patient processing.

Information collected from patients is aggregated into a central database and analyzed by the AI system to understand the nature of the incident better and provide decision support for triage recommendations. The aggregated information is also disseminated throughout the system to all registered ED personnel as a means of providing a global view of the event. After patients have completed the data collection process, they are given instructions to proceed to the final stage of the patient management system, secondary triage.

Secondary Triage

At Secondary Triage, nurses are tasked with providing the most appropriate triage category to optimize patient outcomes. EDICT assists secondary triage nurses by providing decision support specific for each patient. EDICT offers a complete information profile and a system triage recommendation based on the AI analysis of each patient. The secondary-nurse can scan the patient's barcode to retrieve information collected, which eliminates errors related in the miss-identification of patients. The nurse can view recommendations from the central server on a patient's possible chemical exposure, and the appropriate course of action for each patient. The nurse provides the final triage category by agreeing or disagreeing with the decision support system recommendation and providing a rationale when they disagree. The AI recommendation system is described in the following section.

Table 1. Summary of the decision logic for the triage recommendation system. Nurses are given recommendations by the decision support system based on information provided by patients in the kiosk system.

Category	Outcome
Exposure	
Exposed	Patient has been exposed to an IGSA
Potentially exposed	Patient has potentially been exposed to an IGSA
Not exposed	Patient has not been exposed to an IGSA
Action	
Exit	Retriage using a nonchemical related algorithm
Monitor	Monitor the patient for up to 8 hours for latent symptoms
Urgent	Seek immediate medical treatment

Component 3: Triage Decision Support System for Irritant Gas Syndrome Agent Exposure

EDICT is designed to provide clinical decision support for each patient based on available information. EDICT offers a summary of all data acquired for each patient as they proceed through the patient processing pipeline. When sufficient information is gathered for a given patient, the central AI engine in EDICT provides inferred recommendations regarding a patient's exposure level, and the most effective course of action for each patient. The patient exposure feature is designed to separate patients who visit the ED uninvolved in the MCI event and therefore do not need to be subjected to the chemical triage process.

The current recommendation system of EDICT is optimized for exposure to an Irritant Gas Syndrome Agent (IGSA; Figure 1) [15]. However, in principle, EDICT could house a comprehensive collection of possible triage mechanisms from which the optimal procedure could be selected for each MCI. Table 1 describes the categories for exposure and the recommended actions that are provided by the central AI engine in EDICT based on the IGSA mechanism.

Test and Evaluation Process

In April of 2017, a large-scale exercise was conducted utilizing over 500 emergency responders and nursing students. For this exercise, a chemical MCI event was simulated to replicate a derailed train accident that took place in 2005, releasing chlorine gas into the town of Graniteville, South Carolina. Participants were separated into 4 groups: patients, assisted kiosk helpers, primary triage nurses, and secondary triage nurses. EDICT was used for patient management, data collection, and decision support.

During the exercise, 15 tablets were used to study the effectiveness of the patient management system. The tablets were partitioned into 3 functional groups based on the app's operational mode: assisted-kiosk mode, non-assisted-kiosk mode, and nurse mode. EDICT was evaluated on its efficiency in triaging patients and the agreement with the decision support system. Information related to each of the participant groups and EDICT users is found in the following sections

Emergency Department Patients

Two hundred ninety-six students from USC's nursing program participated as ED patients. Of the participants, 95% were female and 90% were 18-24 years old. ED patients were split randomly into 2 patient populations. The first group consisted of 198 patients that were part of the chlorine exposure event. Data used for this group was gleaned from de-identified medical records of patients from the 2005 train derailment. The second group consisted of 100 patients suffering from ailments unrelated to the MCI event. The data for this group was acquired from de-identified medical records of patients with flu-like symptoms who visited the same hospital in 2016. As part of the exercise, students randomly received a patient card (Figure 12), for either a victim of the first group or a flu patient from the second group. The cards outlined specific information related to their visit to the ED, vitals, and a location where they first felt sick. Students used the information displayed on their card to interact with the kiosk system and proceed through the patient processing pipeline. Students had no pre-exercise access to their patient data or the EDICT software until they entered the simulated ED.

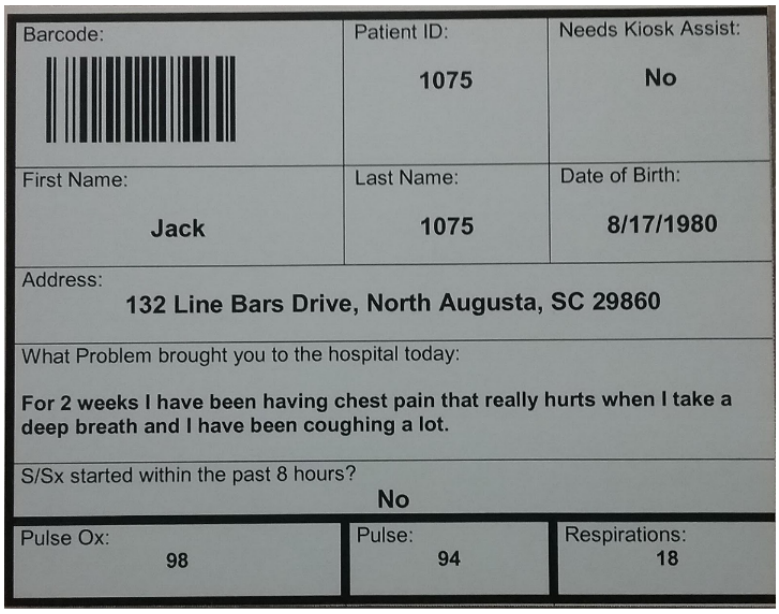
Kiosk Helpers

Five assisted kiosk stations were set up for the April 2017 exercise. Each station was assigned a kiosk helper tasked with assisting patients with entering information into the kiosk system. The helpers were all female between the ages of 29-59. They received 1 hour of individual training before the exercise with a member of the app development team who guided them with navigating through the kiosk system and entering patient information.

Triage Nurses

Thirteen registered nurses and emergency responders were assigned to evaluate patients in the secondary triage stage. There was 1 male nurse, and 12 female nurses between the ages of 30-69. Each received 1 hour of training before the exercise with a member of the app development team on how to use the nurse-interface. They also received instruction on how to review patient information using the app and how to assign triage categories based on the IGSA algorithm. In addition, secondary-nurses were given an information packet describing the IGSA algorithm and the MCI scenario.

Figure 12. Example of a patient card given to participates in the chemical mass casualty incident exercise. Participates were asked to enter information and answer questions in the kiosk system based on the cards they received.



Data Exclusion

Two categories of data were excluded from our analysis of EDICT's performance. The first consisted of records that contained No Available (NA) information. Some NAs were identified as "Immediate" patients who required instant attention and were removed from the patient pipeline or patients who were able to bypass a section of the registration process. The latter cause is currently under investigation by the development team and will be resolved in a future iteration of the app. In total, an insignificant number of NA instances were observed (214/5096, 4% of database transactions) and therefore have little impact on our outcomes.

The second criterion for data exclusion was based on the implausibility of data values (outliers). Outliers were identified using the Tukey's method described in Equation 1 below, where q is a tabulated score [16], w is the range of the normal distribution and s is the standard error of the sum of the means. The Tukey's test uses the interquartile range (IQR) defined in Equation 2 below to identify outliers and removing points +/-1.5*IQR. Outliers were identified for each of the questions in the kiosk, the time spent at the kiosk, the time patients spent waiting to enter secondary triage and the time spent in secondary triage. The exclusion of this category of data is justified by students who may have received a phone call or engaged in a chat discussion on their cell phone during the exercise. Other more relevant exclusions are based on patients who may have needed to pause the registration process for personal reasons (eg, bathroom break).

Results

Component 1: EDICT Data Collection, Aggregation, and Dissemination Platform

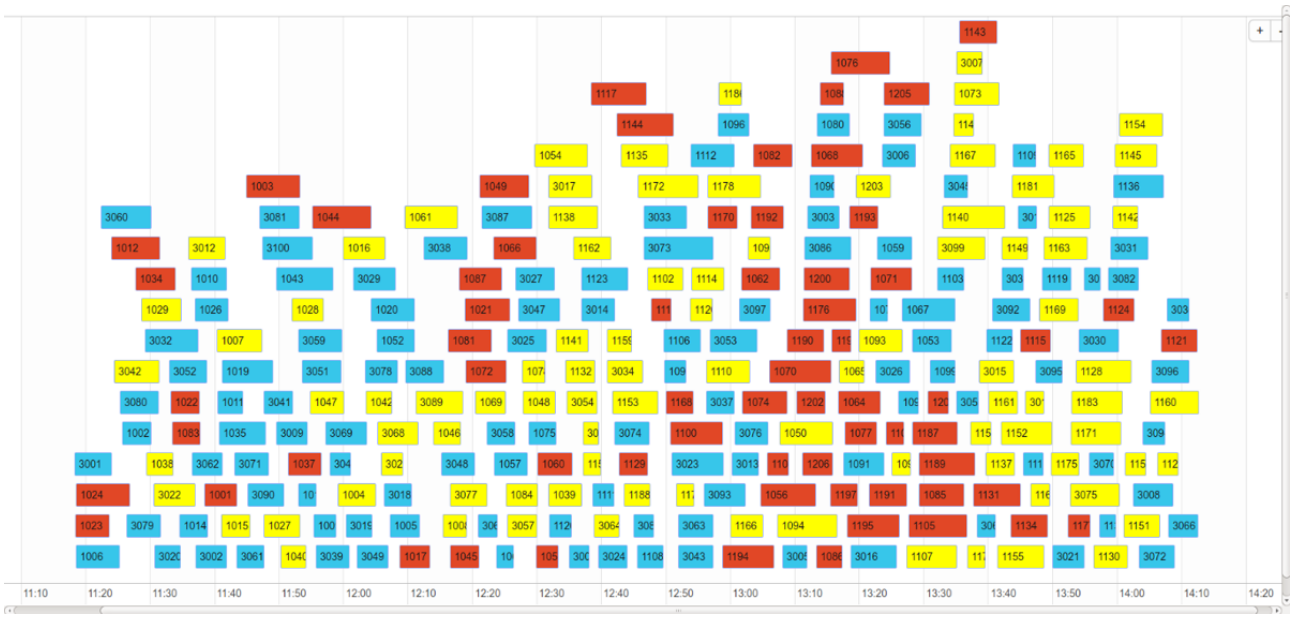
During the April 2017 exercise, every item of submitted data and its corresponding timestamp was captured in EDICT's central database. The information included: patient demographics, answers to all the Kiosk questions, vitals, illness onset location, the central server's recommended triage, and triage levels assigned by nurses, to name a few. In summary, the EDICT software package captured 5471 data transactions for the April 2017 exercise.

The patient management utility of EDICT processed 296 patients within a window of less than 3 hours. This results in an average of 36 seconds per patient to complete the initial triage, information collection, waiting to be seen by a secondary-triage nurse, and the final triage assessment. The information acquired by the data aggregation mechanism of EDICT can provide a global view of the event as illustrated in Figure 13. In this figure, each block represents the interval of time required to process each patient. The blue, yellow and red cells in Figure 13 correspond to patients categorized by EDICT as not exposed, potentially exposed, and exposed respectively.

Component 2: Re-engineered Pipeline of Patient Processing

The second component of EDICT aims to improve individual patient's processing time and patient management. Timestamps captured by EDICT have been used to assess the efficiency of each step and identify outliers. By analyzing the outliers found at each of the data points we could identify areas of concern and investigate technical or usability issues. The following sections provide results related to each of the three components of the patient processing pipeline.

Figure 13. Overall triage results from the April 2017 exercise. Blue cells indicate patients EDICT recommended as not exposed. Yellow cells indicate patients EDICT recommended as potentially exposed and red cells indicate patients EDICT recommended as exposed. The length of the cells describes the amount of time the patient spent in the patient management system.



Kiosk System

The efficiency of the kiosk system and its discrete question components were measured using timestamps from patients as they progressed through the questionnaire screens. Table 2 summarizes the results of our analysis with and without outliers. In this table, the first column corresponds to the different questions asked in the kiosk system. The second column indicates the number of excluded patients from the 296 created patient IDs. Figure 14 shows the average time spent by patients answering each question in the kiosk system. Of the 296 created patient IDs, 288 completed the kiosk after removing outliers. On average, patients required 3 minutes, 22 seconds to complete the patient kiosk system. The longest and shortest completion times consisted of seven minutes, 12 seconds and one minute, eight seconds respectively. Question 1 required the longest completion time with an average of 92.9 seconds closely followed by the Google map with an average of 46.9 seconds. Questions with only checkboxes (Questions 2-6) required the least amount of time to complete with question 6 being the shortest average of 3.7 seconds.

Secondary Triage

Efficiency in the secondary triage stage was measured by examining two factors: the wait time separating the kiosk and the secondary triage stages, and the duration of the secondary triage stage. Table 3 summarizes the average, maximum, and minimum time required by patients to complete various portions of the triage process. The triage completion time in Table 3 corresponds to the time it took patients to complete the entire process, starting from the first entry into the system until the exit from the secondary-triage stage.

Component 3: Triage decision support system for Irritant Gas Syndrome Agent Exposure

While patient processing speed is an essential aspect of a patient management system, it should be at no cost to improving patient outcome. Therefore, it is as equally important to review the performance of the AI recommendation system. The app's decision support system was quantified by examining the agreement and disagreement between secondary nurses and the decision support system regarding patient exposure and triage action (Tables 4 and 5). The data shows that 286 of the starting 296 patients (96.6%) completed the triage process and received recommendations from EDICT. In summary, EDICT's exposure and action recommendation exhibited 91.6% (262/286) and 84.3% (241/286) agreement with nurses' assessments, respectively. It is worth noting that in the critical subcategory of patients requiring Urgent care, there was 100% (11/11) agreement between EDICT's recommendation and nurses' assessment.

Table 2. Summary of data outliers' (N=296) time spent with each question. Strict rules were developed by identifying outliers at each step of the triage process. These outliers were then investigated further to see if a user or technical error could be determined.

Step	Outliers, n (%)	Mean of Outliers (sec)	Mean with Outliers (sec)	Mean without Outliers (sec)
Q1	2 (1)	240.50	94.04	92.95
Q2	19 (7)	30.89	10.31	8.76
Q3	20 (8)	26.45	7.05	5.63
Q4	14 (5)	16.57	5.71	5.17
Q5	6 (2)	15.83	4.42	4.18
Q6	11 (4)	13.18	4.03	3.67
Vitals	19 (7)	65.26	21.86	18.82
Map	10 (4)	166.90	51.07	46.93
Waiting	25 (12)	1095.84	156.84	45.58
Time in kiosk	1 (1)	593.00	203.76	202.41
Time in secondary	14 (7)	202.50	77.79	69.56

Figure 14. Time comparison of questions asked in the patient kiosk system.

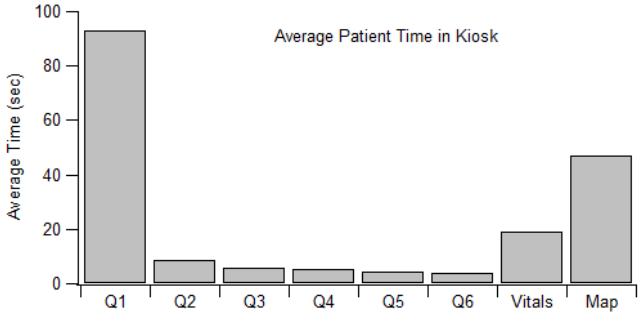


Table 3. The mean, maximum, and minimum amount of time a patient spent waiting to be seen by a nurse, in secondary triage and the overall time to be triaged using EDICT.

Stage	Mean (sec)	Min (sec)	Max (sec)
Wait time	45	0	117
Secondary triage time	69	19	168
Triage complete time	334	152	646

Table 4. Exposure agreement among secondary triage nurses and the decision support system for the Irritant Gas Syndrome Agent triage.

Nurse Input	Computer Recommendation		
	Exposed (n)	Potential (n)	Not Exposed (n)
Exposed (n)	65	8	1
Potential (n)	1	80	0
Not Exposed (n)	2	12	117

Table 5. Action agreement among secondary triage nurses and the decision support system for the Irritant Gas Syndrome Agent triage.

Nurse Input	Computer Recommendation		
	Urgent	Monitor	Exit
Urgent	11	10	11
Monitor	0	57	23
Exit	0	1	173

Discussion

During the April 2017 exercise, kiosk helpers and triage nurses each received 1-hour of training. This was necessary to achieve familiarity with the system. The current version of EDICT was designed to focus on efficiently triaging patients related to an IGSA. Future development will look to create decision support for additional MCI scenarios and deploy EDICT during normal hospital operations. Everyday use of EDIT by caregivers would minimize the amount of training necessary for its deployment during an MCI.

Principal Findings

The utility of EDICT evaluated during a large-scale mock exercise demonstrated many successful aspects of the system. The efficiency of such an approach has the potential to substantially improve patient management during chaotic situations, improve patient outcome, and provided a research platform for data collection, data-mining, and modeling during an MCI related triage. In Table 2 we have presented information related to outliers in each stage of the patient triage process. While in this work we have used these temporal anomalies to further investigate the functionality of the app, during an actual deployment of this app, this feature can be used to monitor patient progress. For example, a patient who may exhibit a long waiting time or does not have an exit timestamp may be traced and any problems rectified. The fast analysis of complex data by computers allows for incorporation of sophisticated triage processes, which will inevitably lead to improved patient outcomes.

Two components of EDICT have contributed substantially to accelerating patient processing. The first component harnesses the organization and improved efficiency of a pipeline mechanism during an MCI event. The utility of a pipeline to improve productivity has been exploited significantly in designing current computer hardware [17] and predates to as far back as Henry Ford's Model T production [18]. The second contributing factor takes advantage of the concurrency in gathering data and processing patients which demonstrates dynamically adaptive nature of EDICT. This was accomplished by using several mobile devices— as many as eight at times—to gather patient data in the kiosk system and triage patients in the secondary triage stage. Since a given mobile device can function in either kiosk or nurse mode, the utility of the devices can be altered to accelerate the slowest segment of the patient processing pipeline. For instance, during our exercise, from between 12:30 pm and 2:00 pm (Figure 13), a rush of patients inundated the kiosk stage of the pipeline. In response, two additional tablets were switched into kiosk mode and added to the patient processing pipeline to resolve a potential bottleneck. This feature of the app allows for real-time modification to the system to satisfy the most demanding portion of the triage process.

Limitations

Future iterations of EDICT will look to resolve important obstacles identified during our analysis. First, despite a 97.1% (5174/5328 transactions) data completeness, some patients were able to bypass sections of the software by using the app in unintended ways (eg, exiting the app and reopening it). Second, during the exercise, we identified some instances where the final submission button was not clicked by the user (nurse or patient). These instances were the primary contributors to anomalous times. To resolve these issues, future developments of the app may include automatic time-out features.

A key aspect of developing a triage system is the identification of bottlenecks or areas in which the patient processing might be slowed down. By quantifying the time patients spent at different sections, we were able to identify and remedy these bottlenecks for future iterations of EDICT. For example, patients spent more time on question 1 in the kiosk system than any other question. The expertise of a human-computer interaction researcher can help design better approaches to the limitations imposed by the cumbersome use of the on-screen keyboard. Advances in Natural Language Processing can also be of immense help in this category.

During the April 2017 exercise, we anticipated two additional limitations: battery life, and internet availability. Although both issues are current limitations for any mobile development, they can be resolved in numerous ways. During the exercise, we provided redundancy in our system by having power-packs ready for use if necessary. A backup laptop server with 10 hours of battery life and a battery operated mobile Wi-Fi system was also prepared to handle any possible power failure. Theoretically, with the use of solar panels, one could deploy our independent integrated system in any remote location.

Conclusions

Analysis of the data from the 2017 drill allowed us to quantify user behavior and measure the performance of the decision support system. The data shows that the kiosk system design performed well during the exercise regarding patient management related to a chemical MCI. Of 296 patient users, 97.3% (288/296) were able to complete the kiosk system either on their own or with an assistant, which suggests very few usability issues. This is substantial considering that participants using the kiosk without an assistant had no training or prior experience using the app.

The data also showed strong agreement among nurses regarding EDICT's decision support system. Overall, nurses agreed with EDICT 91.6% (262/286) of the time when it came to choosing an exposure level and 84.3% (241/286) of the time when selecting an action. EDICT reliably demonstrated the ability to collect patient data through a self-service kiosk system, thus reducing the burden on hospital resources. Also, the mobile technology allowed nurses the freedom to triage patients on the go while staying connected to a decision support system which they felt would give reliable recommendations. This work has set a precedent for the way patients will be triaged in the future and is a testimony that mobile technology can be a viable resource, even in an environment as chaotic as a hospital ED during a chemical MCI.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Chemical triage algorithm for detecting an Irritant Gas Syndrome (IGSA). The algorithm requires that decisions be made regarding a patient's exposure level and action to correctly assign a triage category.

[PNG File, 276KB - mhealth_v6i6e10727_app1.png]

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Abbreviations

ED: emergency department
EDICT: Emergency Department Informatics Collection Tool
EHR: Electronic Health Record
ESI: Emergency Severity Index
HIS: Health Information Systems
ID: identifier
JIT: Just-In-Time Training
MCI: mass casualty incident
NIH: National Institutes of Health
NLM: National Library of Medicine
NSF: National Science Foundation
SALT: Sort, Assess, Lifesaving Interventions, Treatment/Transport
START: Simple Triage and Rapid Treatment

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Original Paper

Patient Experiences Using a Self-Monitoring App in Eating Disorder Treatment: Qualitative Study

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Abstract

Background: The Recovery Record smartphone app is a self-monitoring tool for individuals recovering from an eating disorder. Unlike traditional pen-and-paper meal diaries, which are often used in eating disorder treatment, the app holds novel features, such as meal reminders, affirmations, and patient-clinician in-app linkage, the latter allowing for clinicians to continuously monitor patients' app data.

Objective: To explore patients' experiences with using Recovery Record as part of outpatient eating disorder treatment.

Methods: A total of 41 patients from a Danish eating disorder treatment facility were included in the study. All 41 patients participated in participant observations of individual or group treatment sessions, and 26 were interviewed about their experiences with using the app in treatment. The data material was generated and analyzed concurrently, applying the inductive methodology of Interpretive Description.

Results: The patients' experiences with Recovery Record depended on its app features, the impact of these features on patients, and their specific app usage. This patient-app interaction affected and was affected by changeable contexts making patients' experiences dynamic. The patient-app interaction affected patients' placement of specific Recovery Record app features along a continuum from supportive to obstructive of individual everyday life activities including the eating disorder treatment. As an example, some patients found it supportive being notified by their clinician when their logs had been monitored as it gave them a sense of relatedness. Contrarily, other patients felt under surveillance, which was obstructive, as it made them feel uneasy or even dismissing the app.

Conclusions: Some patients experienced the app and its features as mostly supportive of their everyday life and the eating disorder treatment, while others experienced it primarily as obstructive. When applying apps in eating disorder treatment, we therefore recommend that patients and clinicians collaborate to determine how the app in question best fits the capacities, preferences, and treatment needs of the individual patient. Thus, we encourage patients and clinicians to discuss how specific features of the applied app affect the individual patient to increase the use of supportive features, while limiting the use of obstructive ones.

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KEYWORDS

feeding and eating disorders; anorexia nervosa; bulimia nervosa; mental health; psychiatry; mHealth; mobile applications; self-monitoring; blended treatment; eating disorder treatment

Introduction

Blended Treatment in Health Care Settings

Since the launch of mobile phones in 2007, the development of mobile phone apps has rapidly increased within health care settings; by 2017, more than 325,000 health-related apps were available to the large population of mobile phone users worldwide [1]. Correspondingly, "blended" treatment, namely, the mixture of digital tools and traditional face-to-face treatment, is becoming more common, although highly underresearched [2]. In many countries, digitized health care is encouraged politically because it is expected to bring about several benefits, such as a wider geographical outreach and reduced costs [3,4]. Additionally, several digital health tools aim at engaging patients in their treatment by performing self-monitoring activities, which is often helped by in-app nudging features [5-7].

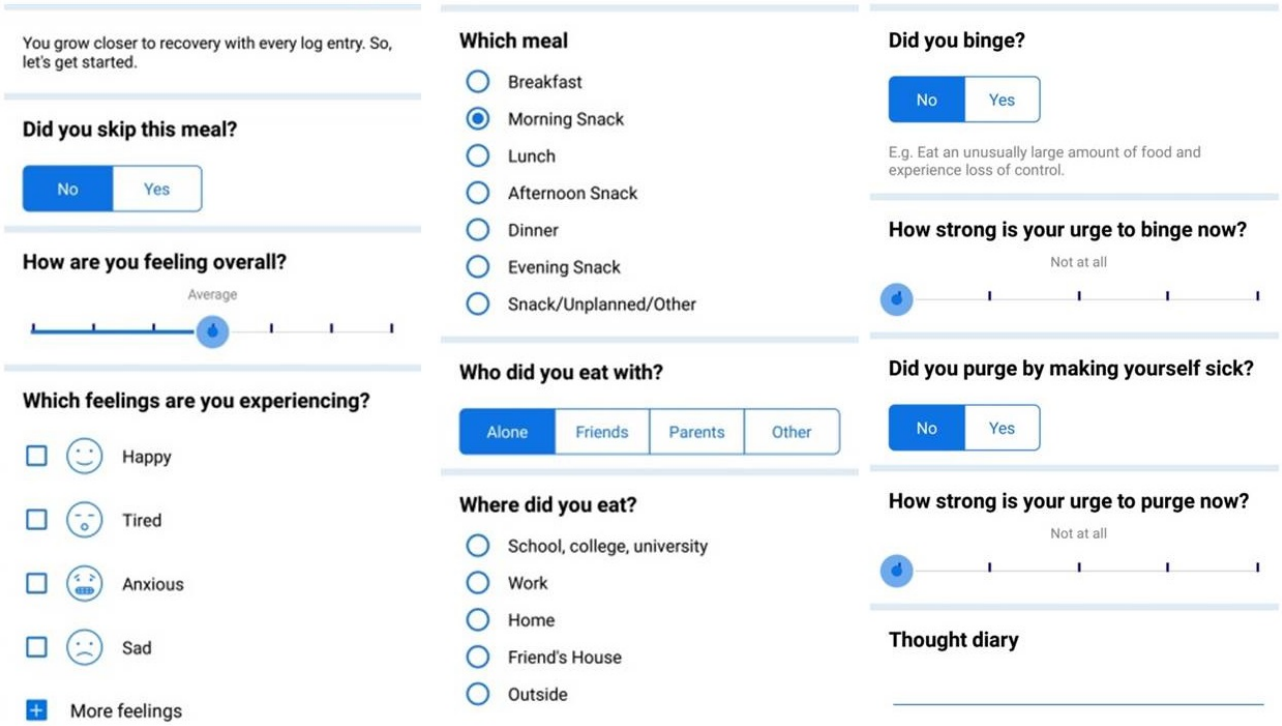
Eating Disorders and Self-Monitoring

Self-monitoring apps have been developed for several mental disorders, including eating disorders (EDs) [8]. EDs can have severe physiological and psychosocial consequences, for example, osteoporosis, infertility, depression, and social isolation [9,10]. The main EDs are anorexia nervosa, bulimia nervosa, and binge ED (BED). Anorexia nervosa entails self-inflicted underweight due to restrictive dieting, whereas bulimia nervosa involves episodes of binge eating. In both these EDs, different weight loss measures are applied, for example, excessive exercising and fasting in the restrictive subtype or vomiting and the use of laxatives and diuretics in the purging subtype. BED also includes binge eating but no regular compensatory weight loss behaviors [11]. In worst cases, EDs can be lethal [12], and standard mortality ratios are elevated, especially for anorexia nervosa [13,14]. Thus, effective ED treatment is crucial, although only 40%-70% fully recover, relapse is common [10], and treatment dropout rates are high, ranging from 29% to 73% in outpatient settings [15]. Normalizing patients' eating patterns and weight is prioritized, especially in the initial treatment phases [16]; often, cognitive-behavioral therapy (CBT) is applied because it has been found to be effective for this purpose [17-19]. CBT also aims at patients gaining an understanding of what triggers and relieves their ED symptoms [20]. For these purposes, CBT in ED treatment employs self-monitoring activities where patients register information on their meals and their emotions, behavior, and thoughts related to each meal and their ED in general [20]. Normally, clinicians review the patient's diary in the beginning of each treatment session to integrate it in the session [20]. However, effective CBT, including self-monitoring, is challenged by the high dropout rates in ED treatment [15]. These might be explained by patients' ambivalence toward dismissing the ED [21], patient-reported inadequate amounts of clinician support [2,22], and a lack of patient buy-in to treatment, that is, patients disagreeing with the rationale of the given ED treatment [23]. Additionally, filling in a pen-and-paper diary and bringing it to treatment sessions seems to be outdated, which is supported by patients requesting digital alternatives [24,25].

Recovery Record: An App for Eating Disorder Management

Recovery Record (RR) is an example of a self-monitoring app for ED management [26]. It works as a self-management tool or as a part of treatment where clinicians employ the clinician interface of the app [26]. Similar to the recognized ED treatment regimens [27,28], RR issues log questions on the user's meals, behavior, feelings, and thoughts (Figure 1).

Figure 1. Examples of log questions in Recovery Record. The screenshots are from a Samsung Galaxy S7 (SM-G930F) running Android 7.0.



It also includes nudging features, that is, meal reminders and affirmations following a meal log, prompting users to self-monitor and eat regularly [26]. RR encompasses other novel features, such as personalized goals and coping strategies, and in-app meal photos intended to increase the user's incentive to adhere to the app and standard clinical recommendations. RR also contains gamification, that is, game-like principles in a nongame-like setting [29]. In RR, users are rewarded with a piece of a puzzle for every meal log, eventually resulting in a full puzzle linking to a song of their preferred genre [26]. If employed in a treatment program, RR allows for patient-clinician in-app linkage, enabling clinicians to monitor patients' app data between treatment sessions and providing patients with in-app notifications when their logs have been reviewed [26]. Linking also allows for direct patient-clinician in-app messaging. However, this feature is not permitted in the Danish public health care system because clinicians' means of digitally contacting patients are restricted [30]. Nevertheless, RR may increase patients' adherence to ED treatment, including self-monitoring activities, due to its customizable features and digital format, which individuals tend to prefer to pen-and-paper self-monitoring [8,31,32]. In addition, the incidence of EDs is peaking among 15- to 19-year-old individuals [33], which is a tech-savvy age group [3,34]. Finally, patients may prefer in-app meal logging because it is likely to be more discrete than pen-and-paper.

Apps in Eating Disorder Treatment

Despite their increasing popularity, concerns have also been raised regarding the use of ED treatment apps because it is still uncertain how the quality of psychological treatment is affected when partially disseminated digitally [35]. Additionally, it has been suggested that treatment facilities are prematurely adopting apps out of eagerness to work with novel tools, although their effectiveness and utility remain unclear [36]. However, studies have identified patient-reported benefits of ED management apps; in qualitative studies conducted by Basterfield et al (N=15) and Juarascio et al (N=11), and a usability study with qualitative elements conducted by Nitsch et al (N=9), participants found ED management apps to be convenient and easy to adopt [37]. They also appreciated the option of adjusting the apps to fit their individual needs [24] and found in-app social support from peers and professionals to be helpful in recovery [24,25,37]. However, these findings were based on small samples, in 2 studies, participants without clinically diagnosed EDs were included [25,37], and in the third study, participants did not use but simply discussed a suggested app [24]. Therefore, to ensure an optimal usage of ED management apps facilitating patients' recovery by engaging them in treatment, we still need knowledge on patients' experiences and preferences with these apps. Thus, the aim of our study was to explore patients' experiences using RR (eg, helpfulness, ease of use, and intrusiveness), including their experiences with the app itself and its influence on treatment and everyday life.

Methods

Setting

Participants were recruited from a specialized 2-centered ED treatment facility at Aarhus University Hospital receiving around 500 annual referrals. The facility treats patients with moderate to severe EDs in inpatient or outpatient programs. It employs 53 clinicians working in multidisciplinary teams consisting of psychiatrists, psychologists, dietitians, nurses, and physiotherapists, all with a minimum of a bachelor's degree. The regular treatment of patients with anorexia nervosa depends on the individual patient's age and situation, for example, living situation and comorbidity. However, typically, it involves family-based treatment or a weekly session altering between group and individual sessions and the latter including family members, if relevant [16]. Regular bulimia nervosa treatment consists of 10 weekly manualized group sessions followed by an additional group or individual treatment, if needed [38]. Nonresponders are offered additional treatment in the day hospital consisting of 3 weekly days of treatment for 16 weeks. In special cases, patients are offered individually tailored programs, for example, in case of severe comorbidity. The facility has been employing a Danish translation of RR since 2014, although not in a standardized way. At the time of data generation, clinicians had received approximately 2 × 2 h of group training on how to use RR in treatment and introduce it to patients, which was carried out by the first author with a clinician-facilitator ratio of about 10:1. Furthermore, clinicians had access to written and illustrated training material and were encouraged to request additional individual training, if needed.

Interpretive Description

We applied the qualitative methodology of Interpretive Description because it fits the explorative aim of our study and has the objective of informing and improving clinical practice, preferably by discovering "something new" [39]. According to Interpretive Description, field work, including observation sessions, is important to detect the impact of contextual events on the matter being studied. Interpretive Description applies the notion that social influences are formed by people and form people and their actions; on the other hand, it also seeks a nuanced understanding of the individual's perceptions of the phenomenon of interest [39]. Thus, the methodology draws on selected parts of ethnography, grounded theory, and phenomenology but also differs from the listed traditions by stressing the value of a "research logic," permitting the researcher to apply and combine the methods needed to fully answer the research question. This flexibility of Interpretive Description is practical when exploring a field, where unexpected findings may occur requiring an adjusted strategy. In Interpretive Description, the validity and relevance of the study are pursued partly by conducting the data generation and analysis simultaneously and partly by keeping a detailed audit trail [39]. The former allows for the early analysis to inform the subsequent data collection that may be adjusted accordingly and vice versa, whereas the latter keeps a track of the preliminary findings and methodological decisions made during the study [39].

Theoretical Framework

According to Interpretive Description, a theoretical framework may be applied to help set the study in motion [39]. Consequently, because RR is founded upon it, we employed the rationale of CBT focusing on the relationship between physical state, behavior, thoughts, and emotions [20]. We also applied the self-determination theory (SDT) describing how individuals' actions depend on their personal convictions and the degree to which their psychological needs for competence, autonomy, and relatedness to others are fulfilled [40]. We combined the two because SDT accounts for the individual's experience of how it is impacted by its context, for example, social setting, to a higher degree than CBT. The theoretical framework influenced the data generation by inspiring the development of the interview and observation guides (Tables 1-2). However, it did not determine the data analysis, in which inductive findings were still allowed [39].

Data Generation

Ethical Considerations

Eligible patients were invited to participate in the study after the initial treatment assessment by the clinician performing the assessment or by the first author. The clinician or the first author provided oral and written information on the study purpose and methods as well as the participants' right to withdraw at any time without any treatment consequences. After 4-8 weeks, patients who had neither agreed nor declined to participate were reminded of the invitation by their primary clinician. If they agreed to participate, they signed an informed consent form, which was also signed by the legal guardian(s) if the patients were under the age of 18 years. The data material was anonymized and kept confidential. The study was approved by the Danish Data Protection Agency (case ID: 1-16-02-313-15) and conducted according to current legislation [41,42].

Table 1. Semistructured interview guide. The guide was adjusted to fit the number of interview participants, who were asked additional follow-up questions as needed, and the order of subjects (in bold) was flexible. The theoretical inspiration column identifies which part of the theoretical framework the questions were inspired by.

Interview guide	Theoretical inspiration
Patients' usage of Recovery Record (RR)	
Please tell me about the way you use RR on a "normal" day without treatment sessions, for example, when in school or with your friends? Do your friends or family members know about RR?	SDT[a]
Which RR features do you use? Why? Are there features you have stopped using? Why?	—
Does RR affect your eating and your thoughts and feelings about eating? Is it different for you to log a meal accompanied by eating disorder (ED) symptoms (eg, binging) than to log a meal without ED symptoms? How?	CBT[b]
What is it like to log your ED behavior, feelings, and thoughts in RR?	CBT
Do you use other apps relating to EDs or diet or calorie counting? Does RR affect how you use these other apps or vice versa? How?	SDT
Usage of RR in the patient-clinician collaboration	
Please tell me about the way you and your clinician adapted RR to your symptoms, that is, when selecting what to monitor? Did you and your clinician agree on what was important to monitor? Why or why not? If disagreeing, how did you and your clinician proceed?	CBT and SDT
How does it feel knowing that your clinician has access to your app data? Do you consider this when logging? Why or why not?	CBT and SDT
Are you experiencing that RR affects what you and your clinician discuss during treatment sessions? How?	CBT and SDT
How does your clinician use RR in your course of treatment, for example, during sessions? Which features does your clinician apply? How do these features make you feel (eg, notifications informing you that clinicians have reviewed your logs)?	SDT
What does it make you feel or think when your clinician has or has not used your logs in RR to prepare your sessions?	CBT
Usability of RR	
How was the process of downloading, setting up, and beginning to use RR for you? Did you need help from anyone, for example, your friends or clinician?	SDT
If you have previously used a pen-and-paper meal diary, how do you like using RR in comparison? What is different? Why is that better or worse?	SDT
Do the features, text, images, and menu setup in RR make sense to you? Why or why not? What do you think about them? How do they make you feel?	CBT
Potential alterations of RR	
In your opinion, how could RR be improved, for example, by additions or alterations?	—

[a]SDT: Self-determination theory.

[b]CBT: Cognitive-behavioral therapy.

Table 2. Observation guide. Field notes were recorded discretely during or immediately after the observations. The theoretical inspiration column shows which part of the theoretical framework the topics were inspired by.

Observation guide	Theoretical inspiration
Situation	
Who is present (participants)? • What is the patient-clinician ratio? • Clinicians: Which clinical professions are represented? • Patients: How many are present? How long have they been in treatment? What eating disorder diagnosis do they have? • Others: Are others present, such as relatives (eg, parents), partners, friends, medical students, or others?	SDT[a]
Participants	
How do participants (patients, clinicians, and others) appear? • Mimicry: Which emotions do participants appear to display? • Verbal communication: What is the tone of voice and choice of words of participants? • Nonverbal communication: What body language are participants using? Do participants have eye contact? Does participants' body language change markedly during the session?	CBT[b]
Interactions	
How do participants interact in relation to Recovery Record (RR)? • How, why, and by whom is RR brought up during the treatment session? • How is the patient-clinician relationship seemingly affected by RR in the session? Do the participants' mimicry, verbal, and nonverbal communication change when using RR?	SDT
Activities	
Which activities in relation to RR are taking place? • Which specific RR activities are taking place? Do activities differ in individual versus group settings? Are specific RR features talked about differently in individual versus group sessions? • Who initiates the specific activities relating to RR? • How does RR influence any other activities taking place?	CBT and SDT

[a]SDT: Self-determination theory.

[b]CBT: Cognitive-behavioral therapy.

Sample Size and Composition

We recruited patients aged 15 years or older with anorexia or bulimia nervosa. The age limit of 15 years was chosen because younger patients are offered manualized family-based treatment [43] (or other treatment substantially involving the family), which is incompatible with patient self-monitoring [43]. Because patients with BED were not treated at the facility, they were excluded, as were inpatients, because they are continuously monitored by the staff. Patients with psychotic or developmental disorders were also excluded to ensure a participant sample with the cognitive resources needed to perform self-monitoring activities. A total of 41 patients, counting 3 males, were included (Table 3). All 41 were a part of the participant observations, and 34 were invited to an interview, of whom 26 accepted the invitation (Figure 2). Interview participants were sampled purposefully with the aim of obtaining a sample of patients with varying characteristics [39]. In all, 20 participants were interviewed individually, 4 in a focus group, and 2 in a dyadic interview. The dyad took place because 2 additional participants did not show up as planned. Initially, more focus groups were planned with patients attending the same group sessions to capture their perspectives on using RR in group settings, for example, their experiences with clinicians formulating themes across patients using their app data. However, this plan was abandoned because gathering participants outside of treatment sessions was difficult; some were busy with other activities, and others declined because their therapist would be absent. Because ED treatment is often lengthy, we wanted to gather information on the potential changes in patients' experiences with RR over time. Thus, 5 participants were individually interviewed twice with approximately 6 months in between. These participants were selected purposefully to represent different ED diagnosis, treatment programs, and genders (Table 3). We invited 15 participants for a second interview, but by then, most of the patients had been discharged and no longer wished to participate.

Data Material

The first author conducted 25 individual interviews (average: 57 min, range: 45-95 min), 1 focus group (94 min), and 1 dyadic interview (83 min), applying a semistructured interview guide to ensure the coverage of subjects relevant to the study aim [39]. To stimulate the discussion in the focus group and dyadic interview, an exercise inspired by Halkier was applied [44]; participants were given printed screenshots of each RR feature and were asked to discuss and comment on the relevance of the features to their treatment. Interviews were conducted at the treatment facility, except for individual interviews of participants who preferred being interviewed at home (n=11).

Table 3. Characteristics of participants. Data were collected at the time of the first interview or participant observation session (whichever came first) from self-report questionnaires and medical records.

Variable	Participants (N=41)
Age in years, mean (SD), range	24.0 (5.9), 15-41
Body mass index, mean (SD), range	20.0 (3.5), 15.2-27.6
Previous eating disorder treatment[a], mean (SD), range	1.3 (1.6), 0-6
Recovery Record usage in months, mean (SD), range	5.5 (6.4), 1-24
Type of participation, n (%)	
Observation sessions	41 (100.0)
Interviews	26 (63.4)
Second interview[b]	5 (12.2)
Age groups, n (%)	
15-20	14 (34.1)
21-25	15 (36.6)
26-30	8 (19.5)
≥31	4 (9.8)
Grouped body mass index, n (%)	
15.0-18.4	18 (43.9)
18.5-19.9	5 (12.2)
20.0-24.9	12 (29.3)
≥25.0	6 (14.6)
Grouped previous eating disorder treatment, n (%)	
0	16 (39.0)
1	11 (26.8)
2	6 (14.6)
≥3	7 (17.1)
Grouped Recovery Record usage in months, n (%)	
1-2	14 (34.1)
3-4	14 (34.1)
5-6	4 (9.8)
≥7	9 (22.0)
Eating disorder diagnosis, n (%)	
Bulimia nervosa	19 (46.3)
Anorexia nervosa restrictive type	18 (43.9)
Anorexia nervosa binging-purging type	4 (9.8)
Treatment program, n (%)	
Regular bulimia nervosa	15 (36.6)
Regular anorexia nervosa	11 (26.8)
Individual	9 (22.0)
Day hospital	6 (14.6)
Psychiatric comorbidity[c], n (%)	

Variable	Participants (N=41)
None	14 (34.1)
Depression	12 (29.3)
Anxiety	7 (17.1)
Personality disorder	5 (12.2)
Attention deficit hyperactivity disorder	1 (2.4)
Daily occupation, n (%)	
Student	17 (41.5)
Working	12 (29.3)
Sick-leave	8 (19.5)
Other[d]	4 (9.8)
Living situation, n (%)	
Alone	16 (39.0)
With parents	13 (31.7)
With romantic partner	9 (22.0)
With roommate	3 (7.3)
Relationship status, n (%)	
Single	28 (68.3)
In a relationship	10 (24.4)
Married	3 (7.3)

[a]Defined as the number of previous separated courses of eating disorder treatment in public or private facilities.

[b]Characteristics of participants interviewed twice: bulimia nervosa (n=2), anorexia nervosa restrictive type (n=2), anorexia nervosa binging-purging type (n=1); treatment program: regular anorexia nervosa (n=1), regular bulimia nervosa (n=2), individual (n=2); male (n=1).

[c]Some patients had 2 to 3 additional psychiatric diagnoses (n=8).

[d]The term "Other" includes maternity leave and job training arranged by the municipality.

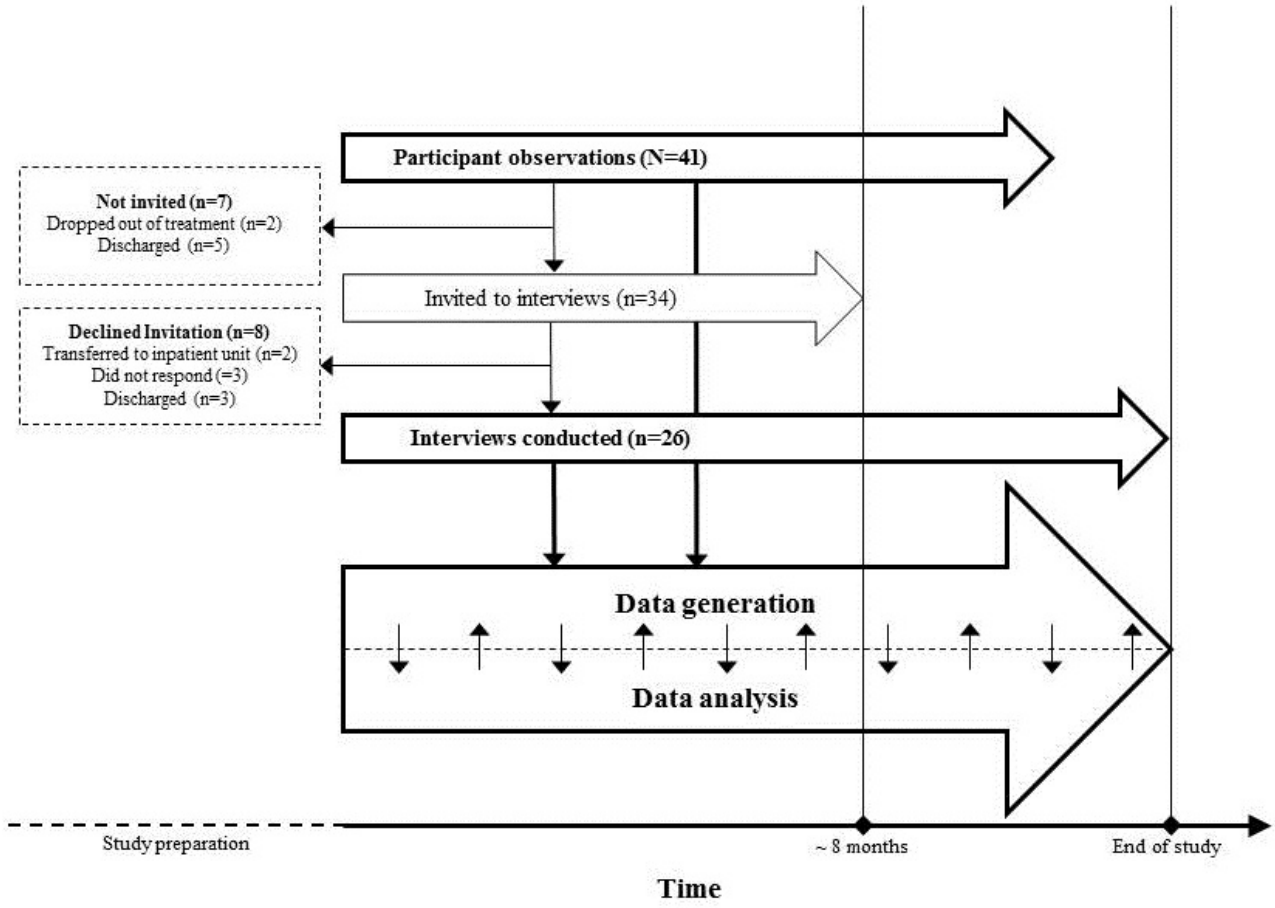
The audio from each interview was digitally recorded and transcribed verbatim by a student worker who had received thorough instructions, for example, on how to mark participants' tone of voice in the transcripts. The first author evaluated the transcripts by comparing random parts of every fourth manuscript to the corresponding audio recording. Besides minor errors, which were corrected, the transcripts were satisfying.

Because individuals' verbal statements on their behavior may differ from their actual behavior [39], the interviews were supplemented with participant observations performed by the first author of the individual or group treatment sessions (approximately 160 h) [44]. An observation guide was employed to ensure that the different aspects of patients' usage of RR and the patient-clinician interaction concerning the app were detected and documented as field notes. Besides exploring participants' observed behavior in addition to the interview statements, the participant observations inspired the further development and adjustment of the interview guide. The data material was generated in the years 2016-2017.

Data Analysis

Interview transcripts and field notes were continuously added to and ordered in NVivo 11® [45]. Although the data analysis was a creative and iterative process repeated as new data material was generated, it can, for the sake of clarity, be described as a 4-step procedure [39]. First, we performed a systematic and broad initial coding constantly shifting between the process of coding and taking "a step back" to gain perspective of the data material as a whole. Second, we discarded irrelevant data, namely, data on technical or aesthetic aspects of the app, while retaining the data contributing to our study aim [39]. Third, we described and discussed themes grounded in the remaining data. If we disagreed on or doubted their trustworthiness, we repeated the broad coding to ensure that the themes did indeed derive from the original data material, and that we had not overlooked any contradictory data [39]. Thus, we addressed any inconsistencies both within and between the interview transcripts and field notes. Finally, we described the critically assessed themes [39].

Figure 2. Illustration of participant flow and the concurrent data generation and analysis process. Specified in the boxed are the reasons why some participants were not invited to an interview or declined said invitation.



Results

Dynamic Patient Experiences

We found that the individual patients placed each RR feature along a continuum from supportive to obstructive of their everyday life activities, including school, work, hobbies, social events, and the ED treatment. Thus, patients perceived some features of RR mostly as supportive, for example, affirmations improving their treatment adherence, while experiencing other features primarily as obstructive, for example, meal reminders pinpointing their illness to them when otherwise engaged, for instance, in school work. We found that the various patient experiences with RR depended on A) its features, B) the impact of these features on patients, and C) patients' app usage, that is, the specific manner in which each patient used RR (Figure 3). This patient-app interaction affected and was affected by patients' changeable D) contexts, which made their experiences with RR dynamic. Three groups of app features appeared particularly significant to patients' experiences of RR as mostly supportive or obstructive, that is, features related to logging, nudging, and patient-clinician linkage. Below, we elaborate on the patient-app interaction, but first, we briefly outline the patient-reported contextual factors of importance when using RR.

Contexts Affecting the Patient-App Interaction

The contexts described by patients as significant to their experiences with RR were physical location (eg, in school), time of day and week (eg, nights and weekends), social setting (eg, with friends), and current treatment program (eg, group treatment). Besides influencing the patient-app interaction, contextual factors affected the patients' placement of specific RR features along the supportive-obstructive continuum. Using the social setting context as an example, some patients perceived meal reminders as supportive when alone but obstructive when with friends. Moreover, the patient-app interaction could change over time, for example, as patients' treatment progressed; then, some patients gradually found RR to be more supportive, possibly due to increased treatment buy-in, that is, an elevated acceptance level of treatment guidelines, which may have validated the content of various RR features to patients.

The Patient-App Interaction

Logging: To Log or Not to Log?

Two aspects of the log questions posed by RR were important to patient experiences, namely, their focus and preset format (Table 4). Some patients found it supportive to log because the preset format made them confront the parts of their ED that they would otherwise ignore. This was especially the case after becoming accustomed to the app over time and encouraging continuous logging, as recommended by clinicians.

Figure 3. Illustration of results. The figure depicts the patient-app interaction, ie. the interaction between A) the Recovery Record features, B) the impact of these on patients, and C) patients' specific app usage. This patient-app interaction (dotted circle) affected and was affected by D) patients' contexts (outer box), ie. physical location, time of day/week, social settings, treatment program, and the course of time.

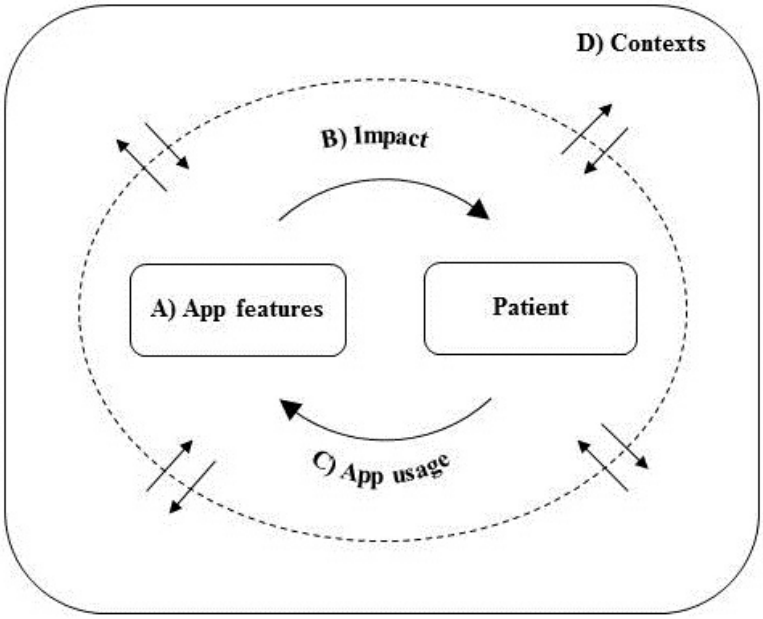


Table 4. Patients' experiences with the Recovery Record (RR) meal log features. The table summarizes the individual patient-app interaction, that is, the specific features related to meal logs, the impact of these on patients, and patients' specific app usage supported by interview quotes.

App features and impact	App usage	Interview quotes
Preset log questions		
Supportive		
Confronting the eating disorder	Continuous logging	"If you're struggling with binging and purging, you're kinda forced to log it, 'cause you're asked about it. Previously, it was easier to avoid talking about it if you didn't feel like it."
		"I've been able to see a relationship between not eating enough or at the right time of day, and having an urge to binge. So, in that way, logging makes a lot of sense to me."
Obstructive		
Pointless if no distress	Avoiding to log	"If I'm doing well at a meal and moving forward, I don't need it [logging]. If I believe I've been eating what I'm supposed to, I don't see a reason to log."
Maintaining the eating disorder	Obsessive logging	"There's this thing in me that wants to keep track of everything. It [logging] was overwhelming and quite intrusive, 'cause it had to be a certain way, and I couldn't change the format. That bothered me a lot, 'cause then I felt like the app controlled me."
		"Sometimes, logging gives me ideas. When it [RR] asks me if I've been exercising, I hate answering no. I never replied no in the other [fitness] app. So it gives me an urge to exercise."
Focus of log questions		
Supportive		
Liberating	From obsessive to constructive logging	"I had to follow a meal plan and log it. And stop weighing myself and counting calories. It was so scary and stressful, but also extremely liberating."
Obstructive		
Enslaving	Obsessive logging	"I counted calories using this other app. But then I had to use this [RR] too, so I had to use two apps. It was too much and became strenuous."

However, other patients found it unnecessary or even obstructive to log if a meal had not caused any significant distress. Then, these patients felt like they were logging simply for the sake of logging, which was considered as pointless and time-consuming. Instead, they would prefer not logging altogether.

Prior to adopting RR, several patients had become habituated to using apps focusing on weight loss or fitness-related content. Some found these apps to be addictive because they made calorie tracking easy, which provided immediate stress relief by reducing their fear of gaining weight. Then, when commencing ED treatment, some patients experienced a similar addiction to logging but this time in RR; although not encouraged in the app, they logged their meals in excessive detail to keep monitoring their calorie consumption. This made some patients log obsessively in RR, which they experienced as obstructive because it partly maintained their ED by making them uphold or resume harmful habits developed when using fitness-related apps. Similarly, the preset log questions, for example, on exercise or purging, could instigate urges to exhibit these behaviors in some patients. Consequently, some succumbed to these urges, whereas others experienced distress due to ongoing deliberations on whether to pursue the urges. To avoid these potentially triggering stimuli, these patients tended to avoid logging. On the other hand, others were relieved by replacing fitness-related apps with RR. Here the log questions focus on emotions and behavior related to each meal and not on calories and weight. Thus, several patients found it liberating to monitor their food intake in a broad sense as opposed to having a strict focus on calories and weight, as is the case in many fitness-related apps. Therefore, some patients therefore experienced logging in RR as supportive because it helped them transform their previously adverse app usage into a recovery-oriented one. However, other patients did not feel ready to solely use RR because the thought of completely abandoning their calorie records in fitness-related apps increased their anxiety levels. Thus, some used RR and a fitness-related app, especially in the initial phases of the ED treatment. This obsessive "double bookkeeping" was experienced as obstructive by patients by being highly time-consuming and enslaving.

Nudging: Guidance or Nuisance?

Two nudging features, meal reminders and affirmations, were significant to the patients' experiences of RR (Table 5). Several patients found the meal reminder feature to be supportive because it provided a structure guiding them to eat and to log the number of meals recommended by clinicians. Other patients experienced meal reminders as nuisances occurring at inconvenient times, for example, when socializing with friends. To some patients, receiving meal reminders was overwhelming because it confronted them with their illness and treatment need when they wanted to focus on other things instead. In addition, others found meal reminders to be ignorant of the core symptom of ED; patients were not simply forgetting to eat but explicitly avoiding it. Finally, meal reminders were experienced as condescending by some patients feeling like they were being treated as incompetent individuals incapable of structuring meals and remembering to eat on their own. Thus, for different reasons, some patients mostly experienced the meal reminder feature as obstructive, making them turn it off or avoid RR altogether.

Receiving an affirmation after a meal log was experienced as supportive by several patients; they felt rewarded for complying with treatment guidelines, which encouraged continued app and treatment adherence. However, other patients found the feature to be negligent of the seriousness of EDs because they considered the feature to be built on the assumption that precomposed messages would speed up their recovery. Moreover, some patients found that the feature addressed them as if they were children, which they experienced as condescending. This was obstructive, especially to patients whose ED had led them to regress in terms of maturity, for example, by moving back in with their parents depending on their support.

Linking: Safety or Surveillance?

RR linking features important to patients were data sharing with clinicians, review notifications received when clinicians had checked patients' logs, and clinicians' usage of patient-app data in treatment sessions (Table 6). Overall, several patients found the patient-clinician linkage feature to be supportive by making them feel safe; patients expected clinicians to monitor their logs and interfere, if necessary, for example, if they unintentionally neglected any treatment guidelines. Thus, the linkage feature encouraged these patients to log continuously, enabling clinicians to track their treatment progress and interfere if needed. However, the linkage feature caused distress in other patients who felt exposed; not only were their ED symptoms documented in an app but the data were also visible to clinicians. The distress was especially prominent in patients with ED symptoms that they perceived as shameful, for example, binging and purging. Thus, some patients logged their meals leaving out the shameful symptoms, whereas others avoided logging altogether. To these patients, the linkage feature was mostly obstructive due to additional distress.

Several patients found the review notifications to be helpful by reminding them that they were not alone in their recovery efforts; their clinician was "out there." Thus, by inducing a sense of relatedness in between treatment sessions, the review notifications were supportive to some patients, encouraging them to log continuously and work on their recovery. Yet, the review notifications caused discomfort in other patients who felt being under surveillance, particularly when notifications arrived at unexpected times, for example, on another weekday than expected. This was obstructive to some as it entailed speculations as to why clinicians had reviewed the logs at that specific time. Some patients also had intrusive thoughts about their clinicians' opinion about their logs, worrying that clinicians were judging or making fun of them when viewing the app data. Subsequently, some patients censored their logs or were discouraged from logging.

Table 5. Patients' experiences with the nudging features of Recovery Record (RR). The table summarizes the individual patient-app interaction, that is, the specific nudging features, the impact of these on patients, and patients' specific app usage supported by interview quotes.

App features and impact	App usage	Interview quotes
Meal reminders		
Supportive		
Structuring	Continuous logging	"I feel like it [RR] is helping me quite a lot. When I started eating according to the meal plan, it was a good way to make sure that I was actually following the plan. I need that structure in my life in order to eat what I'm supposed to."
Obstructive		
Reminder of illness and treatment need	Avoiding to log or turning off feature	"Actually, the app is quite challenging. First, you have to eat. And when you've eaten, you have to log it. So you're reminded that you've eaten. Again. And you just wanna move on."
Condescending	Avoiding to log or turning off feature	"It's not like my problem is that I forget to eat, but that I sometimes don't want to."
Affirmations		
Supportive		
Encouraging and rewarding	Continuous logging	"It's affirmations like 'I wanna be kind and loving to myself today'. It's so basic, but then you think, I haven't been kind to myself all day. Or maybe the entire week. And the more times you get those hints, the more they stick with you."
Obstructive		
Condescending	Avoiding to log	"It seems like it's supposed to be fun logging all this stuff, but for me, it's a serious thing that I need to get used to [logging]. It becomes too much fun and games." "And it's like 'here's a treat for you, since you've been good'. And that makes you feel less inclined to recover. It's a bit childish and condescending. When you have this [eating disorder], it's like you're becoming a kid again, 'cause you can't eat on your own. That's reinforced by the app treating you like a child."

Some patients found it invasive, yet helpful, when clinicians explicitly used the app data in sessions, for example, by highlighting patients' attempts to resist the urges of ED. Patients felt that they were taken seriously when they got the impression that their clinician had thoroughly prepared the session using the app data, which encouraged them to keep logging. Nonetheless, others found it obstructive to know that clinicians could use their app data in session; it made them worry about their clinician's judgment prior to each session. Consequently, some patients excluded information that they expected their clinician to disapprove. Other patients would prefer if clinicians only viewed their logs during sessions as opposed to before, allowing them to have a dialogue about and explain what was logged. Most patients had experienced clinicians not employing any app data in session, which was disappointing because they had made an effort logging, partly with the aim of the logs being commented on. Some patients felt like their clinicians were neglecting their professional responsibilities when seemingly not reviewing patient logs and utilizing them in session. Consequently, some patients lost trust in their clinicians. Thus, it was primarily obstructive when clinicians did not incorporate the app data in treatment sessions.

Table 6. Patients' experiences with the patient-clinician linkage feature in Recovery Record (RR). The table summarizes the individual patient-app interaction, that is, the specific linkage features, the impact of these on patients, and patients' specific app usage supported by interview quotes.

App features and impact	App usage	Interview quotes
Data sharing		
Supportive		
Feeling safe	Continuous logging	"It provides some kind of security knowing that someone is keeping an eye on me. It makes me feel safer."
Obstructive		
Feeling exposed	Avoiding to log or Logging with clinicians in mind	"I wasn't always honest about it [exercising]. Often, I'd just log 'no'. I was embarrassed to admit it to my clinician."
		"I cheat quite a lot. Those days when I don't log, it's because I feel bad about not eating what I was supposed to."
Review notifications		
Supportive		
Feelings of relatedness	Continuous logging	"I like them [review notifications]. It's part of treatment. It reminds me that I'm doing this [eating disorder treatment]. And they [clinicians] are here to help."
Obstructive		
Feeling under surveillance	Avoiding to log or Logging with clinicians in mind	"It makes me wonder why they've been looking at my logs at that specific time. If it's in the middle of the week and my appointment isn't until a week later, then I start wondering why they're looking."
		"It makes me worry. Like, are they laughing at me? Or judging me. It makes my heartbeat rise."
Clinicians using logs in sessions		
Supportive		
Encouraging	Continuous logging	"They'll check if you've lost or gained weight [using a scale]. And then they confront you saying look at your app data. You haven't been eating like you should. It's kinda intrusive, but also really helpful getting that push. You need it."
		"It makes me so proud when I succeed and they [clinicians and other patients] see it."
Obstructive		
Concerned about confrontation	Logging with clinicians in mind	"It was kinda like she had to control that I had been doing things correctly. It made me wonder what would happen if I had done something wrong, or hadn't been doing well enough."
		"I'd rather she'd just look, when we meet face-to-face, so I can say something."
Clinicians not using logs in sessions		
Obstructive		
Feeling neglected	Avoiding to log	"She said she'd go through my logs before our sessions, but I feel like that didn't actually happen. There were no consequences. If I'd logged something specific, she didn't ask about it, although I was expecting it. Then it's like it doesn't really matter what I do."
		"If they wanna use it [RR], it should be obvious to them that they should comment on my logs. If they don't, I don't mention it. I don't wanna seem needy."

Discussion

Minimally Disruptive Medicine

In this study, we found that patients' experiences with RR were dynamic and depended on the individual patient-app interaction. Some patients primarily experienced the RR features as supportive of their everyday life activities, including the ED treatment, for example, by supporting a regular eating pattern and by inducing a sense of relatedness to clinicians. In contrast, other patients mostly perceived the app or its features as obstructive of day-to-day life, for example, when feeling being under surveillance or when transferring obsessive logging behavior from other apps to RR. Thus, our findings add to the field by highlighting the complex diversity of patient experiences using an app such as RR and with that the importance of adjusting technological treatment tools to fit the individual patient.

The concept of minimally disruptive medicine may explain part of our findings; it aims at offering effective treatment that also fits the individual patient's preferences and daily life [46]. In minimally disruptive medicine, managing the workload, that is, tasks and responsibilities, associated with long-term treatment requires substantial patient capacities, for example, individual and contextual resources [46]. If the treatment workload exceeds the patient's capacities, they feel burdened and may reduce their adherence to treatment, thereby decreasing its effectiveness [47]. Thus, clinicians and patients need to collaborate to reach a patient workload-capacity balance [46]. Transferred to our study, some patients might have experienced RR mostly as obstructive of daily life because the workload accompanying the app exceeded their overall capacities or conflicted with their preferences. Thus, patients and clinicians need to assess the various app features together, while taking patients' day-to-day life activities, preferences, treatment needs, and capacities into account. Consequently, the supportive app features may be applied further, whereas the obstructive ones may be avoided. However, this patient-clinician collaboration may be challenging because tools assessing patient capacities and preferences are lacking [47]. Furthermore, the patients' perception of treatment workload may depend on their abilities to counteract the ED pathology in general; in ED treatment, a common challenge is the egosyntonic nature of some ED symptoms and patients' ambivalence toward some treatment activities, for example, weight gain [48]. Finally, the clinicians' reception of the training on how to use RR and with that their specific RR usage [49] may also influence the patients' experiences of treatment workload. Thus, minimally disruptive medicine might be especially complicated to apply in ED treatment. Still, we recommend clinicians to focus on how self-monitoring apps may best fit the individual patient's preferences and treatment needs.

Clinical practice is in need of explicit guidelines on the usage of apps in ED treatment [49]. Although the specific content and design of such guidelines require more research, our study outlines possible recommendations. Overall, patients and clinicians need to explicitly discuss how to apply a specific app in treatment and the patient's everyday life. Specifically, we recommend a discussion of (1) the degree of helpfulness of app features to determine which should be applied and how, (2) the parties' expectations to one another regarding the usage of app data in and outside treatment sessions, including who is responsible of introducing the data in session, (3) specific issues related to possibly harmful, obsessive logging, and (4) each patient's specific reasons for potentially not logging. We recommend these points to be discussed continuously during the course of treatment because the individual patient's needs and preferences might change over time. Finally, we encourage app developers to ensure that the apps are flexible, allowing for specific features to be easily selected or deselected in accordance with the preferences and treatment needs of individual patients. Besides further research on the content of clinical guidelines, our findings pinpoint the need for studies investigating the treatment effect of RR and similar apps, the positive and negative effects of specific app features on patient sub groups, and predictors of app usage, for example, patient characteristics.

Strengths and Limitations

To our knowledge, our study is the first to explore in-depth the patient experiences using an ED treatment app in a naturalistic ED treatment setting, which is an important step toward filling the gap in the literature. By generating data in individual and group settings, we have covered the aspects affecting the patient-app interaction on both these levels. However, the group dynamics of relevance when using RR in group treatment might have been elaborated on further, if more group interviews had been feasible. It is also important to consider the potential impact of the cultural setting on the study participants and with that the findings; in Denmark, public health care is free of charge, which might reduce the influence of social and financial resources on treatment experiences, as found in other countries [50]. The dismissal of the in-app messaging feature could also have biased our results toward more negative patient experiences with RR, for example, by limiting their feelings of relatedness. Moreover, our findings might have been skewed by the fact that some participants declined or did not respond when invited to an interview. Nevertheless, because the remaining participant sample is rather diverse in terms of patient characteristics, we expect having portrayed significant experiences of various patient groups. Although our novel approach of interviewing participants twice provided some understanding of the perspectives on using RR over time, more than 5 participants would likely to have benefited our study. Finally, there are several RR features that we have not dealt with in this paper because patients did not point them out as significant. However, rather than patients not finding these features as important, their disregard of some features might be associated with the nonstandardized clinician app usage at the ED treatment facility, or a lack of clinician training or technological abilities in some clinicians. Thus, ED treatment facilities and clinicians should keep in mind that the remaining app features might still benefit patients if applied appropriately.

Conclusions

Patients' experiences with RR in ED treatment varied and depended on their individual app interaction and contextual factors. Some patients experienced RR mostly as supportive of

their everyday life and ED treatment, whereas others experienced the app and its specific features primarily as obstructive. Thus, when applying apps in ED treatment, we recommend that patients and clinicians collaborate to clarify how the app in question best fits the individual patient's capacities, preferences, and treatment needs. Similarly, we encourage app developers to build flexible apps that may easily be adjusted to fit individual patient's preferences and treatment needs.

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Conflicts of Interest

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Abbreviations

ED: eating disorder
BED: binge eating disorder
CBT: cognitive-behavioral therapy
SDT: self-determination theory
RR: Recovery Record

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Original Paper

Testing a Smartphone App (Young with Diabetes) to Improve Self-Management of Diabetes Over 12 Months: Randomized Controlled Trial

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Abstract

Background: Young people often struggle to self-manage type 1 diabetes during the transition from childhood to adulthood. Mobile health (mHealth) apps may have the potential to support self-management, but evidence is limited and randomized controlled trials are needed.

Objective: We assessed whether the mHealth app "Young with Diabetes" improved young people's self-management measured by glycated hemoglobin (HbA_{1c}) and three self-reported psychometric scales.

Methods: Young people (14-22 years) with inadequate glycemic control and their parents were enrolled in a randomized controlled trial and assigned either to Young with Diabetes and usual care (Young with Diabetes group) or to usual care alone (control). Young with Diabetes use was monitored; functions included a chat room, contact the health care provider, reminders, tips, information about the diabetes department and type 1 diabetes topics, carbohydrate counting, and a parents' section. Outcomes included HbA_{1c} and three self-reported psychometric scales: Perceived Competence in Diabetes Scale; Health Care Climate Questionnaire; and Problem Areas In Diabetes care survey. Data were collected at baseline and at 2, 7, and 12 months.

Results: A total of 151 young people were randomized (Young with Diabetes group=76, control=75) and 49 parents agreed to participate. At 12 months, HbA_{1c} was significantly higher (4.1 mmol/mol; 0.4 %) in the Young with Diabetes group, compared to the control group (P=.04); this finding did not occur when comparing app users (Young with Diabetes use ≥5 days) with nonusers. Young people used Young with Diabetes on a mean of 10.5 days. They spent the most time chatting about alcohol and searching for information about sex. Most young people and half of the parents reported that Young with Diabetes helped them. More than 80% would recommend Young with Diabetes to peers.

Conclusions: Young with Diabetes did not improve HbA_{1c}, but it may be a useful complement to self-management. Qualitative evaluation is needed to explore benefits and shortcomings of Young with Diabetes. Health care providers should address young

peoples' knowledge about sensitive topics, provide them with peer support, and be aware of parents' need for information about how to support

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KEYWORDS

mHealth; randomized controlled trial; self-management; diabetes; young people; transition

Introduction

Background

As young people with type 1 diabetes (T1DM) grow up, they are expected to assume responsibility for their disease self-management [1]. This includes daily insulin dosage, glucose measurements, and carbohydrate counting to meet the recommended target for glycemic control [2]. However, young people often struggle to achieve adequate glycemic control [3], risking early onset of long-term complications [4]. Parents are key players in supporting young people in self-managing T1DM, but they are often faced with stress and frustration [5] and request guidance on how to support their children [6].

Self-management is defined as an individual's ability to manage the symptoms and the consequences of living with a chronic condition, including treatment, physical, social, and lifestyle changes [7]. In young people, self-management is a gradual process of acquiring necessary skills and knowledge, with parents as consultants [1].

Mobile health (mHealth) apps present unique opportunities to engage young people in self-management by providing information and optimizing communication with health care providers [8]. Recent studies among adults show promising results. A systematic review assessed the effectiveness of self-management apps in long-term conditions and found that six of nine studies significantly improved outcomes [9]. Another systematic review of 12 randomized controlled trials (RCTs) demonstrated a significant reduction of glycated hemoglobin (HbA_{1c}) in adults (particularly with type 2 diabetes) allocated to app-based interventions to support diabetes self-management [10].

However, limited evidence exists that mHealth apps can improve young peoples' self-management [11]. Only three mHealth apps for young people with T1DM have been evaluated. Frøisland et al [12] tested a digital diabetes diary in a three-month prospective cohort study. At a mandatory consultation, the diary was discussed, and patients and providers reflected on its recordings (n=12; ages 13-19). Berndt et al [13] tested an app to collect data and provide clinical support in a four-week RCT (n=68; ages 8-18). Finally, Goyal et al [14] tested an mHealth app in a 12-month RCT (n=92; ages 12-15). The app facilitated feedback on the transfer of blood glucose readings from a glucometer, rewarding action. The three studies found no improvement in HbA_{1c} compared to the control group. However, one study [14] found a statistically significant association between increased self-monitored blood glucose and improved HbA_{1c}. Unfortunately, comparability is limited by the small number of existing studies and differences in intervention design. As the number of mHealth apps rapidly increases, a pressing need arises for more RCTs to assess the impact of mHealth apps among young people and their parents [15].

Young with Diabetes - The mHealth App

The mHealth app, Young with Diabetes (YWD), was developed in 2014 and 2015 in a mixed-methods design based on a participatory approach, with the aim of supporting young people and parents in T1DM self-management. Usability was tested in think-aloud tests and by a mail panel, and feasibility was tested for five weeks by young people and health care providers. The development is detailed elsewhere [16]. YWD is based on the premise that providing a platform for young people to access information and support from peers, parents, and health care providers will improve their self-management skills. YWD comprises eight main functions (Multimedia Appendix 1) described in the following: (1) *My Page* enables users to contact their health care provider and write notes, (2) *My Department* provides information about the diabetes department, (3) *Chat Room* is an opportunity to chat with peers, (4) *Carbohydrate Counting* provides information on how to count carbohydrates, (5) *Information about…* provides information about multiple T1DM-topics, such as obtaining a drivers' license, (6) *Tips Package* enables users to receive daily T1DM tips, (7) *To Parents* provides parents with information about how to support their teen, and (8) *Reminder Function* allows users to set reminders for self-management tasks.

The aim of this study was to test whether YWD improved self-management, measured by HbA_{1c} and three psychometric scales, among young people with T1DM, compared with usual outpatient care.

Methods

Design, Sample, and Setting

A 12-month, open, parallel RCT was conducted. Young people were eligible for the study if they satisfied the following conditions: (1) they had been diagnosed with T1DM for more than one year, (2) received diabetes care at one of three pediatric or three adult outpatient clinics (Multimedia Appendix 2), (3) were 14 to 22 years of age, (4) had a HbA_{1c} ≥64 mmol/mol (8%) at their last visit and an average HbA_{1c}>58 mmol/mol (7.5%) at the last three visits prior to invitation, (5) did not attend appointments with a psychiatrist or psychologist, (6) they spoke and understood Danish, and (7) did not participate in other diabetes intervention studies. Parents were invited to

participate if their child was randomized to the YWD group and if they spoke and understood Danish.

Recruitment Procedures

Young people and parents were recruited from November 2015 to March 2016. They received an invitation letter, followed by a phone call to answer any questions. If young people were interested, a one-hour meeting was scheduled to complete written consents and randomization. Participants were digitally randomized in a 1:1 allocation ratio either to YWD and usual care (YWD group) or usual care alone (control). They were stratified by department in random permuted blocks of two and four. Blinding was not possible.

Intervention

After randomization, young people and parents downloaded YWD on their smartphone or tablet during a 10-minute initial face-to-face or telephone guidance session provided by the first author. The parents received the same version of YWD except for the *Chat Room*, which was only available for young people. Young people were encouraged to use YWD as a stand-alone resource and in collaboration with their parents and health care providers. They received no prompts to use YWD. The control group received only usual outpatient care, which consisted of quarterly clinic visits (measuring HbA_{1c}, adjusting insulin and receiving guidance on carbohydrate counting).

Physicians, nurses, and dieticians provided the YWD intervention as part of usual outpatient care and saw participants from both the YWD and control groups. No extra time was allocated for the YWD intervention. Health care providers attended YWD training: a one-hour introduction to the app followed by two roleplaying scenarios with a colleague or the first author acting as young patients [16].

The first author offered monthly visits to health care providers to address technical issues and refresh training in app use; a telephone hotline was available for technical difficulties. The app content did not change during the study.

Outcome Measures

Outcomes data were collected at baseline and two months, seven months, and 12 months after YWD use began. The primary outcome of HbA_{1c} was measured by a single automated glycohemoglobin analyzer (Tosoh) at Nordsjællands Hospital. Three psychometric self-reported scales measured the secondary outcome of the development of self-management skills. Perceived competence at managing diabetes was measured by the five-item Perceived Competence in Diabetes Scale (PCD) [17]. The degree to which participants experienced their health care provider to be autonomy-supportive in providing general treatment was measured using the five-item Health Care Climate Questionnaire (HCCQ) [17]. The perceived burden of diabetes-related problems was assessed using the 20-item Problem Areas in Diabetes care survey (PAID-20) [18]. Severe hypoglycemic episodes (low blood glucose levels requiring assistance from another person) and acute diabetes-related hospitalizations were self-reported.

Sociodemographic Items and Young with Diabetes-Specific Questions

Sociodemographic characteristics (gender, age, height, weight, age at diabetes onset, occupation, family structure, comorbidity, insulin regime, weekly blood glucose measurements, transfer to adult care, smoking, and alcohol use) were self-reported. Responses to YWD-specific questions, such as “Has YWD helped you?” and “Would you recommend it to peers?” were self-reported using yes/no response options.

The psychometric scales, sociodemographic items, and YWD-specific questions were compiled into an electronic questionnaire. Face validity was tested in six young people before the trial start; no changes were required.

YWD users were defined as those who had used YWD on at least five days. The cutoff of five days was set to be sure the participants used the app more than the four times where they were paid a visit from the data collector (baseline, 2, 7, and 12 months). YWD use was documented by log data as time, date, and action (view, update, create, delete). Page hits were defined as the number of “clicks” within a function. Technical issues were noted.

Power Estimation

Sample size estimation was based on HbA_{1c}. A minimum of 52 participants per group was necessary to detect a difference of 5.5 mmol/mol (0.5 %) in HbA_{1c} at 80% power with 5% significance level, a standard deviation in the outcome variable of 0.5, and a 2-tailed significance test. To compensate for potential dropouts, a 25% adjustment was made, resulting in a target sample size of 65 subjects per group.

Statistical Analysis

Baseline data were described by mean and standard deviation (continuous variables) and frequencies and proportions (categorical variables). In accordance with the CONSORT guidelines [19], hypothesis tests for baseline differences were not performed.

The primary intention-to-treat analysis, comparing groups at 12 months, was performed by a linear regression model adjusting for baseline values and diabetes department. Due to stratified randomization, the department was included in the regression model as a categorical covariate [20].

The effect of YWD depends on use. Consequently, the CONSORT-EHEALTH checklist [21] recommends a sub-group analysis comparing users with nonusers, equivalent to an as-treated analysis. YWD use is a post-randomization variable, and the possibility that several unmeasured factors affected both the probability of noncompliance with the intervention and glycemic control confounds the as-treated analysis. We, therefore, focused on estimating the complier average causal effect of YWD [22]. The analysis compared the effect of the intervention among compliers (the observed YWD users and those from the control group who would have been YWD users had they been assigned to the YWD group) and non-compliers (the observed YWD non-users and those from the control group who would have used YWD less than 5 days had they been assigned to the YWD group) [22]. The causal effect of YWD

on HbA_{1c} at 12 months among compliers was estimated by the expectation-maximization algorithm assuming normally distributed outcomes in each of the principal strata under one-sided noncompliance. This estimate was adjusted for baseline HbA_{1c} and department. Baseline variables were included as covariates for the probability of compliance with the treatment allocation in a latent logistic regression model.

Secondary analyses of outcomes (HbA_{1c}, PCD, HCCQ and PAID) over time were performed using a constrained mixed model incorporating all measurement periods [23]. Confidence intervals were calculated using normal approximation. The number of acute hospitalizations and severe hypoglycemic episodes was compared by logistic regression after dichotomizing outcomes into zero or one or more events.

Analyses were performed by a statistician blinded to group assignment using R version 3.3.3 and Mplus7. A value of $P \leq .05$ was considered to be statistically significant.

Ethical Considerations

YWD complies with regulations for protecting personal health information. A code was required to access YWD in addition to user name and password. Written informed consent was obtained from young people and parents, and parental consent was required for participants younger than 18 years. The study was approved by the Danish Data Protection Agency (no. 04015 NOH-2015-031) and performed in accordance with ethical recommendations of Helsinki Declaration. Ethical approval by Research Ethics Committee was not necessary (Ref.no. 14013934). The study is registered at ClinicalTrials.gov (NCT02632383). The RCT is reported in accordance with the CONSORT-EHEALTH guidelines for improving and standardizing evaluation reports of Web-based and mobile health interventions (Multimedia Appendix 3 shows the CONSORT-EHEALTH checklist [21])

Results

Overview

A total of 852 young people were assessed for eligibility, of whom 701 were excluded (Figure 1). In total, 126 young people declined to participate because they were too busy (n=64), were not interested in the research project (n=29), did not want to focus on diabetes (n=11), did not feel they needed the app (n=10), had no reason (n=9), or due to illness (n=3). A total of 151 young people (54% female) were randomized to the YWD group (n=76) or control group (n=75); of these, 148 (YWD=75, control=73) completed follow-up assessments, yielding a retention rate of 98%.

Participants were enrolled at their homes (n=121), school (n=10), hospital (n=9), café (n=4) or by phone (n=7).

Baseline Characteristics

Participants' mean age was 17.6 (SD 2.6) years, and their mean duration of T1DM was 8.0 (SD 4.5) years (Table 1). One third (n=42, 28%) had at least one comorbidity, and half (n=70, 46%) of the participants' parents were divorced. A total of 49 parents participated, representing 40 (53%) young people in the YWD group.

Outcome Measures

Glycated Hemoglobin

Mean baseline HbA_{1c} (Figure 2 and Table 2) was 81.1 mmol/mol (SD 18.0) or 9.6% (SD 1.6) in the YWD group and 76.2 mmol/mol (SD 14.9) or 9.1% (SD 1.4) in the control group. This difference was not significant (P=.07). At the 12-month follow-up, mean HbA_{1c} was 81.4 mmol/mol (SD 18.8) or 9.6% (SD 1.7) in the YWD group and 73.9 mmol/mol (SD 12.6) or 8.9% (SD 1.2) in the control group. The intention-to-treat-analysis, comparing the two groups at 12 months, showed a significant difference in glycemic control (P=.04), with the control group having a 4.1 mmol/mol (95% CI 0.3-7.9) or 0.4% (95% CI 0.0-0.7) lower mean HbA_{1c} after adjusting for baseline values. After including all follow-up periods in the mixed model, this difference was 4.3 mmol/mol (95% CI 0.7-8.0) or 0.4% (95% CI 0.1-0.7, P=.02). Despite randomization, the YWD group included more females. This difference was not significant (P=.37); adjusting for gender in the intention-to-treat analysis did not change the results.

Effect of App Use on Glycated Hemoglobin

The as-treated analysis, comparing YWD users with nonusers, yielded a non-significant difference in HbA_{1c} at 12 months (P=.67), with the control group having a 0.9 mmol/mol (95% CI –3.1 to 4.9) or 0.1% (95% CI –0.3 to 0.4) lower mean HbA_{1c}. The complier average causal effect of YWD, comparing the effect of the intervention among compliers and non-compliers (please refer to the Statistical Analysis section for further details), yielded a non-significant difference of 3.9 mmol/mol (95% CI –0.7 to 8.9) or 0.4% (95% CI –0.1 to 0.8, P=.11) in HbA_{1c}, favoring the control group. No baseline covariates were significantly associated with the probability of compliance with the treatment allocation (Multimedia Appendix 4). However, a negative effect on the probability of compliance to the treatment allocation was related to comorbidity, divorced parents, severe hypoglycemic episodes during the previous 12 months, forgetting insulin, smoking, alcohol-drinking intake and skipping school. A positive effect on the probability of compliance with the treatment allocation was related to the number of glucose measurements last week, acute hospitalizations, insulin pump and the female gender.

Self-Reported Self-Management of Type 1 Diabetes

As shown in Table 2, no significant effects on PCD (P=.39), PAID (P=.13), or HCCQ (P=.53) were observed.

Hypoglycemia and Hospitalizations

Between-group differences in acute diabetes-related hospitalizations and severe hypoglycemia were not statistically significant. Seventeen (22%) participants from the YWD group and 8 (11%) participants from the control group were hospitalized for an acute event at least once during the 12-month study period. The control group had 54% lower odds (odds ratio [OR] 0.46, 95% CI 0.17-1.15, P=.10) of acute hospitalization after adjusting for acute hospitalizations during the 12 months

prior to enrollment. A total of 34 (45%) participants in the YWD group and 29 (39%) in the control group experienced at least one episode of severe hypoglycemia. The control group had 13% lower odds (OR 0.87, 95% CI 0.43-1.75, *P*=.70) of severe hypoglycemia, compared to YWD group, after adjusting for hypoglycemic episodes during the year prior to the study.

Figure 1. Participant flow diagram.

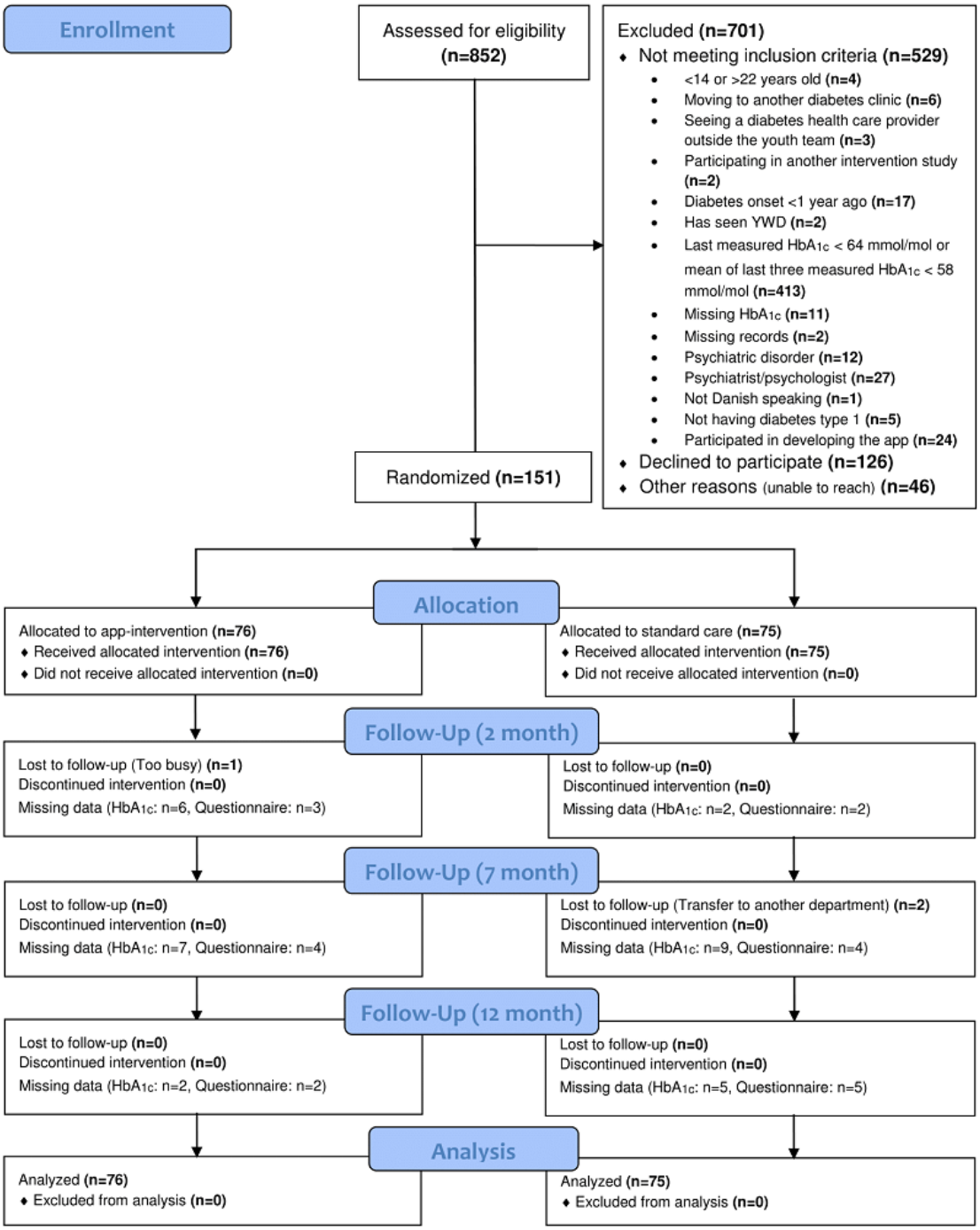


Table 1. Sample characteristics.

Characteristics	YWD[a] (n=76)	Control (n=75)
Female, n (%)	44 (58)	37 (49)
Age in years, mean (SD)	17.6 (2.6)	17.6 (2.7)
Age at diabetes onset in years, mean (SD)	9.2 (4.3)	9.9 (4.9)
Diabetes duration in years, mean (SD)	8.3 (4.3)	7.7 (4.7)
Baseline HbA_{1c}[b] (mmol/mol), mean (SD)	81.1 (18.0)	76.2 (14.9)
Baseline PCD[c] score, mean (SD)	27.4 (6.0)	27.5 (6.2)
Baseline PAID[d] score, mean (SD)	26.7 (19.3)	24.0 (16.1)
Baseline HCCQ[e] score, mean (SD)	28.2 (6.8)	25.4 (8.4)
≥1 acute diabetes-related hospital admission[f], n (%)	19 (25)	13 (17)
≥1 episodes of severe hypoglycemia, n (%)	27 (36)	23 (31)
SMBG[g] per week, mean (SD)	24.4 (12.8)	25.8 (15.5)
Forget to take insulin, n (%)		
Every day	5 (7)	10 (13)
One to four times a week	24 (32)	24 (32)
One or more times a month	25 (33)	22 (29)
Never or almost never	22 (29)	19 (25)
BMI[h], kg/m^2, mean (SD)	22.1 (3.2)	23.3 (3.4)
Smoking cigarettes ≥1 time in the last month, n (%)	23 (30)	25 (33)
Drinking alcohol ≥1 time in the last month, n (%)	50 (66)	50 (67)
Insulin regimen, n (%)		
Multiple daily injections of insulin	40 (53)	40 (53)
Pump	36 (47)	35 (47)
Living with both parents, n (%)	34 (45)	32 (43)
Divorced parents, n (%)	38 (50)	32 (43)
Education, n (%)		
Danish public school (grade 0-10)	28 (37)	26 (35)
Continuation school	2 (3)	2 (3)
Secondary education[i]	15 (20)	14 (19)
University	6 (8)	7 (9)
Other schools[j]	12 (16)	10 (13)
Not attending a school at the moment	13 (17)	16 (21)
Pediatric site, n (%)		
Pediatric and Adolescent Department, Nordsjællands Hospital, Hillerød	12 (16)	13 (17)
Pediatric and Adolescent Department, Herlev	26 (34)	26 (35)
Pediatric Department, Roskilde	7 (9)	7 (9)
Adult site, n (%)		
Department of Cardiology, Nephrology and Endocrinology, Nordsjællands Hospital, Hillerød	6 (8)	6 (8)
Steno Diabetes Center	20 (26)	20 (27)
Department of Endocrinology, Køge	5 (7)	3 (4)
Transfer to adult care, n (%)	7 (9)	5 (7)

Characteristics	YWD[a] (n=76)	Control (n=75)
Comorbidity, n (%)	22 (29)	20 (27)
Learning disability and/or mental health condition	6 (8)	2 (3)

[a]YWD: Young with Diabetes.

[b]HbA_{1c}: glycated hemoglobin.

[c]PCD: Perceived Competence in Diabetes Scale.

[d]PAID: Problem Areas in Diabetes Scale.

[e]HCCQ: Health Care Climate Questionnaire.

[f]Acute hospital admission caused by hyperglycemia, ketoacidosis or hypoglycemia.

[g]SMBG: self-monitored blood glucose.

[h]BMI: body mass index.

[i]Secondary education: Gymnasium, Higher Preparatory Examination, Higher Commercial Examination Program, Higher Technical Examination Program.

[j]Other schools, such as taking a bachelor in nursing or attending a school of crafts.

Figure 2. Mean glycated hemoglobin (HbA_{1c}) levels in control and Young with Diabetes (YWD) groups at 2, 7, and 12 months.

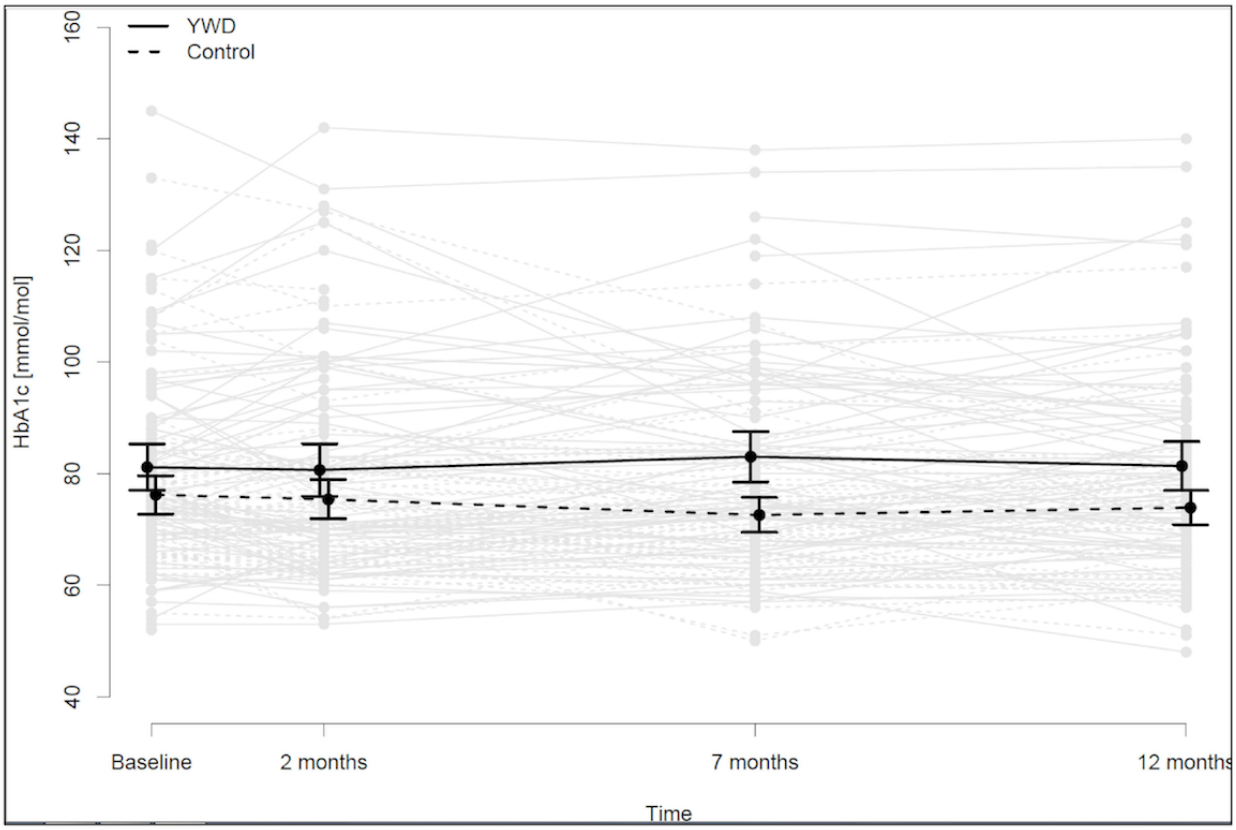


Table 2. Between-group differences in outcomes.

Outcome	Adjusted mean at baseline	Control versus YWD[a], mean difference (95% CI)			
		2 months	7 months	12 months	*P* value[b]
HbA_{1c}[c], mmol/mol	78.9	–2.8 (–5.4 to –0.3)	–6.2 (–9.5 to –2.9)	–4.3 (–8.0 to 0.7)	0.02
HbA_{1c}[c], %	9.4	–0.3 (–0.5 to 0.0)	–0.6 (–0.9 to –0.3)	–0.4 (–0.7 to 0.1)	0.02
PCD[d] score[e]	28.18	0.27 (–1.50 to 2.03)	–0.53 (–2.55 to 1.50)	–0.79 (–2.56 to 0.98)	0.39
PAID[f] score[e]	23.68	–2.64 (–6.17 to 0.88)	0.96 (–3.00 to 4.91)	–3.14 (–7.22 to 0.95)	0.13
HCCQ[g] score[e]	27.10	–0.05 (–2.44 to 2.35)	0.04 (–2.52 to 2.61)	–0.73 (–2.98 to 1.52)	0.53

[a]YWD: Young with Diabetes.

[b]Significance level of difference at 12 months follow-up.

[c]HbA_{1c}: glycated hemoglobin.

[d]PCD: Perceived Competence in Diabetes Scale.

[e]Range for PCD and HCCQ is 5-35 and the range for PAID is 0-100.

[f]PAID: Problem Areas in Diabetes.

[g]HCCQ: Health Care Climate Questionnaire.

Young with Diabetes-Specific Questions

Fifty-nine (78%) young people and 25 (51%) parents reported that YWD had helped them at least once. Most young people (n=65, 85%) and parents (n=41, 84%) reported that they would recommend YWD to peers.

Young with Diabetes Use

Young people used YWD on a mean of 10.5 days (range 1-64), while parents used YWD on a mean of 5 days (range 1-21). A total of 53 (70%) young people and 19 (39%) parents used YWD on at least 5 days, while 7 (9%) young people and 13 (27%) parents never used YWD after the introductory session. Figure 3 depicts weekly YWD activity.

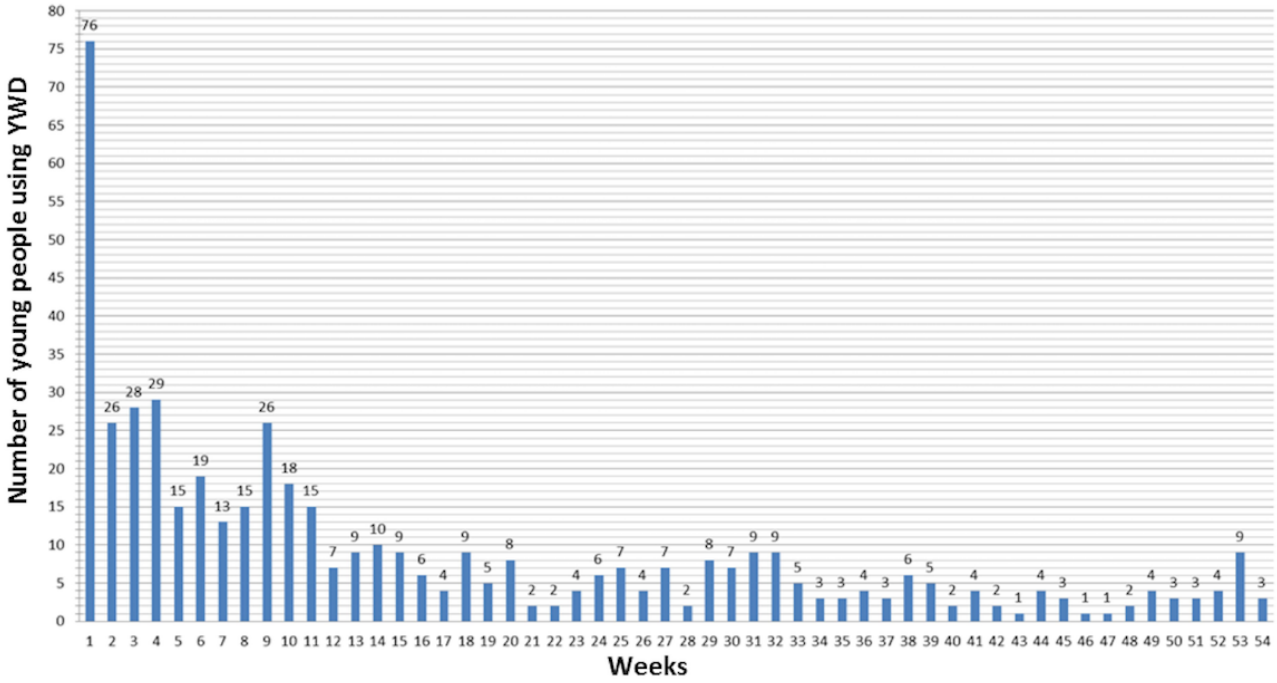
In total, 71 messages were sent to 14 (36%) health care providers by 15 (20%) young people. The messages were primarily used to schedule visits (n=25), ask treatment questions such as about insulin dose (n=24); discuss challenges such as eating disorders and feeling alone (n=9); and provide ongoing support such as feedback on glucose measurements (n=13).

A total of 103 chat-room comments were posted by 28 (37%) young people (Multimedia Appendix 5). The majority of chat time was spent on *Alcohol*, *Sport*, and *Fuck Diabetes*. Fifteen (20%) young people created reminders, and 46 (61%) activated tips packages. The carbohydrate-counting quiz was initiated 68 times by 46 (61%) young people. Only 7 (9%) young people watched animations, while 18 (24%) clicked on video self-portraits. The most popular main functions were *Chat Room* and *My Page* (Multimedia Appendix 6), and the most popular information topics were *Sex*, *What is Diabetes?*, *Driver's License*, and *Alcohol and Party* (Multimedia Appendix 7). Among parents, the most popular main functions were *Information about …* and *To Parents* (Multimedia Appendix 6). Parents primarily approached *How to Support My Teen*, *When My Teen turns 18*, *Alcohol and Party*, and *Being Young with Diabetes* (Multimedia Appendix 7).

Technical Issues

Four major platform-specific technical issues occurred and were resolved: (1) January 2016, Android. Starting carbohydrate-counting-quiz resulted in log-off (duration=10 days, n=1), (2) March 2016, iOS. YWD could not open on some iPhone-software versions. Required re-installation (duration=10 days, n=7), (3) September 2016, Android. Unable to upload photos (duration=40 days, n=1), and (4) January 2017, iOS. YWD could not open due to update. Needed re-installation (duration=10 days, n=14). In addition, participants reported minor technical issues, such as having lost the YWD app due to new or broken phones (young people=26, parents= 2). A total of 43 (57%) young people and eight (16%) parents reported technical issues.

Figure 3. Number of young people who used Young with Diabetes (YWD) during the study.



Discussion

Principal Findings

To the best of our knowledge, this is the largest RCT to date evaluating the effect of an mHealth app supporting self-management in young people with T1DM and their parents. YWD did not improve glycemic control, and the app use declined rapidly. Interestingly, most of the participants reported that YWD was helpful and that they would recommend it to others.

We can only speculate as to why HbA_{1c} did not improve in the YWD group. A large difference was observed between the results from the as-treated analysis and the estimate of the complier average causal effect (0.9 mmol/mol vs. 3.9 mmol/mol, respectively). This may indicate the existence of unmeasured confounding variables influencing HbA_{1c} and YWD use. Health care providers play a significant role in supporting young people to self-manage [24]. However, not all health care providers feel confident using mHealth apps [25], and some may feel uncomfortable engaging with young people through technical means [26,27]. This could have influenced the effect of YWD. Unfortunately, we neither registered the young people's health care provider nor stratified at the level of the health care provider. Also, YWD training for health care providers was very brief; further training may optimize health care providers' ability to use YWD as a platform for collaborating with young people and parents. Furthermore, the use of YWD declined rapidly during the RCT (Figure 3), which may be one of the main reasons why the intervention lacked improvement of self-management. Since the participants did not use YWD for long, a mediation analysis would have been highly relevant. However, the study was an RCT designed and powered for assessing the difference in HbA_{1c} and therefore, we did not pursue a post-hoc analysis. This is important to address in the design of future studies.

A qualitative study by Klasnja et al [28] found that most people diagnosed with diabetes, face acute need for information about their disease and that this need becomes more intermittent afterwards. It would have been highly relevant to test YWD in a group of people newly diagnosed with T1DM. Unfortunately, HbA_{1c} differs and changes a lot during the time around diagnosis depending on how long (days, weeks, or months) people have had diabetes before it is diagnosed and depending on the degree of the eventual honeymoon phase. Since HbA_{1c} was our primary outcome, we had to be sure that we only included patients with "stable" diabetes to better identify the effect of the intervention. This challenge could be addressed in future studies by qualitative evaluation of self-management apps in people just diagnosed with diabetes.

We were unable to measure participants' eHealth skills, which may have influenced YWD use and subsequent HbA_{1c} levels since it is related to improved outcomes [29-31]. Furthermore, baseline HbA_{1c} was higher in the YWD group, which may indicate poor motivation and lack of self-management skills, which would affect the ability to use YWD and improve HbA_{1c}[32]. Finally, it is arguable whether a randomized trial is the optimal way to evaluate YWD. Diabetes care should be individualized [33], and mHealth apps, which evolve and are updated over time, are often incompatible with a rigid RCT study design. Furthermore, Campbell et al [34] raise doubts about RCTs as an evaluation method targeting young people in transition from childhood to adulthood due to the complex, patient-centered, evolving, and multidisciplinary nature of care. Alternative methods may be preferable, such as qualitative evaluations and interrupted time series [35].

Further qualitative evaluation [36] is needed to understand why most young people reported being helped by using YWD, despite failing to improve glycemic control and maintain app use. Also, successful adoption of self-management apps is hard to achieve without additional strategies for enhancing patient motivation and engaging health care providers [37]. Finally, simply knowing how often and how much young people engage with YWD by opening the app and clicking around may not be enough. Understanding and observing "effective engagement" [38,39] with mHealth apps is much harder to do, and better ways need to be worked out. This should be taken into account in future studies.

Notably, the most popular app function among young people was the *Chat room*, where they shared experiences. The most popular topics were *Alcohol* and *Fuck Diabetes*. While few participants posted comments, most read about others' experiences. This is consistent with previous findings [40,41] and underscores the importance of online peer support to complement education and provide reassurance that lived experiences are common [42].

In contrast, more sensitive topics, such as sex, were not discussed in the chat room but were the most popular topic searched privately. Wiley et al [42] explored young adults' experiences with T1DM education and found that health care providers did not address sensitive topics such as sex. Our findings and those of Wiley et al highlight the unmet needs of young people and parents, which should be solicited and addressed regularly in clinic visits. They underscore the importance of acknowledging young peoples' need for sharing experiences with peers and providing them with opportunities to engage with peer networks. The findings also emphasize parents' need for guidance in supporting their child and the importance of addressing sensitive topics regularly.

Strengths and Limitations

Our study has several strengths. A rigorous design tested YWD in an RCT over a lengthy study period, and YWD use was logged and available for analysis. Our study had both a large sample size and a high retention rate. The high retention rate could be a result of the flexibility to collect data at young peoples' choice of place and time of day and should be considered a way to ensure high retention rates in future studies with young people.

Limitations should also be considered. It was not possible to conduct a blinded RCT [43,44]. Not all young people had participating parents. No clear criteria were defined for how health care providers should deliver YWD. Also, we cannot exclude the possibility of a spillover effect because the same health care professionals provided both the YWD intervention and usual care. Finally, a concern is whether HbA_{1c} and the three psychometric questionnaires (PCD, HCCQ, PAID-20) captured changes in self-management as intended. Our choice of scales was limited by lack of validated self-management instruments in Danish and also by the ages of the participants, spanning below and above 18 years. The outcomes were chosen based on the self-management definition [1,7] and because they have been used in similar populations testing self-management interventions [45,46], increasing the comparability of our study.

Conclusion

The mHealth app YWD did not improve HbA_{1c}, but it may be a useful tool for complementing self-management in young people with T1DM. Qualitative evaluation is needed to further explore and address benefits and shortcomings of the intervention [36]. Alternative evaluation methods should be considered when testing self-management mHealth apps among young people. Our findings highlight the importance of supplementing self-management care with peer support. Health care providers should routinely address sensitive topics and be aware of parents' need for guidance as to how to effectively support their child during the transition from childhood to adulthood.

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Conflicts of Interest

YWD was developed in cooperation with the IT enterprise Mobile Fitness A/S and the project group (including the authors). The project group owns the national rights.

Multimedia Appendix 1

Detailed description of the mHealth application Young with Diabetes.

[PNG File, 715KB - mhealth_v6i6e141_app1.png]

Multimedia Appendix 2

Diabetes departments participating in the RCT.

[PNG File, 102KB - mhealth_v6i6e141_app2.png]

Multimedia Appendix 3

CONSORT-EHEALTH checklist (v1.6.1).

[PDF File (Adobe PDF File), 102KB - mhealth_v6i6e141_app3.pdf]

Multimedia Appendix 4

Association between baseline covariates and compliance.

[JPG File, 943KB - mhealth_v6i6e141_app4.jpg]

Multimedia Appendix 5

Use of chat room groups.

[JPG File, 1MB - mhealth_v6i6e141_app5.jpg]

Multimedia Appendix 6

Use of main functions by young people and parents.

[JPG File, 921KB - mhealth_v6i6e141_app6.jpg]

Multimedia Appendix 7

Use of information topics by young people and parents.

[JPG File, 1MB - mhealth_v6i6e141_app7.jpg]

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Abbreviations

HbA $_{1c}$: glycated hemoglobin
HCCQ: Health Care Climate Questionnaire
OR: odds ratio
PAID: Problem Areas in Diabetes
PCD: Perceived Competence in Diabetes
RCT: randomized controlled trial
T1DM: type 1 diabetes
YWD: Young with Diabetes

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Original Paper

Self-Management of Chronic Diseases Among Older Korean Adults: An mHealth Training, Protocol, and Feasibility Study

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Abstract

Background: Most training programs for self-management of chronic diseases in Korea currently involve face-to-face interactions primarily in a health care setting. Therefore, older Koreans living in the community continue to seek other training opportunities for the management of chronic diseases. This has led to the development of new training methods, such as mobile health (mHealth) care, which are valuable in community centers and homes.

Objective: This feasibility study (1) developed an mHealth training protocol to empower community-dwelling elderly individuals to manage their chronic diseases; (2) examined the feasibility of delivering this mHealth training protocol to elderly individuals through mobile tablets and applications (apps); and (3) discussed the contextual and methodological challenges associated with the development of this protocol.

Methods: The mHealth training protocol was developed based on the eHealth Enhanced Chronic Care Model and comprised of four phases. Phase 1 included standardized technology (mobile tablets) training using guidebooks, demonstrations, and guided practice. Phase 2 included provision of standardized information about disease management that was obtained from governmental and professional health care organizations. Phase 3 included provision of training on the use of high-quality mHealth apps that were selected based on individual diagnoses. Phase 4 included encouraging the patients to practice using self-selected mHealth apps based on their individual needs. Quantitative descriptive statistics and qualitative content analyses of user evaluations were used to assess the feasibility and user acceptance of this protocol.

Results: Of the 27 older adults included in this study, 25 completed all 4 weeks of the mHealth training. The attrition rate was 7% (2/27), and the reasons included time conflicts, emotional distress, and/or family discouragement. The men required little or no training for Phase 1, and in comparison with men, women seemed to depend more on the mHealth trainers in Phase 3. Gender, level of education, and previous experience of using smartphones were associated with the speed of learning, level of confidence, and overall competence.

Conclusions: A tailored and personalized approach is required to develop mHealth training protocols for older adults. Self-management of chronic diseases via mHealth training requires careful consideration of the complex nature of human behavior, emotional responses, and familial influences. Therefore, integration of a theoretical, clinical, and technical approach is necessary for the successful development and implementation of an mHealth training program that targets older adults with chronic diseases in a community setting.

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KEYWORDS

mobile health; feasibility study; chronic disease; eHealth Enhanced Chronic Care Model; elderly; community health service

Introduction

Chronic diseases such as cancer, heart disease, diabetes, chronic lower respiratory disease, liver disease, hypertension, and cerebrovascular disease were some of the leading causes of death in Korea in 2014 [1]. According to the Ministry of Health and Welfare report (2014), 90.4% of elderly Koreans exhibited at least one of the chronic diseases listed above, of which 18.2% were diagnosed with one disease, 22.8% with two, and 49.4% with three or more chronic diseases [2]. Statistics Korea (2016) reported that the life expectancy at birth in 2015 was 82.1 years [3], and this differed from the disability-adjusted life expectancy (ie, 70.72 years) by approximately 10 years. This can be attributed to advances in treatment strategies for chronic diseases or long-lasting disabilities for an extended period in late adulthood [4].

Self-management of chronic diseases is essential to minimize their negative influence on the patient's health status. Therefore, it is imperative to emphasize the importance of active disease management and maintenance of proper health behaviors that promote a better quality of life among older adults [5,6]. To encourage the younger individuals to engage in healthy behaviors at an early stage, it is important that the characteristics of elderly individuals be taken into consideration when designing training protocols to achieve sustainable self-management outcomes [5]. Therefore, there is a considerable need to diversify self-management training protocols to overcome methodological limitations and the effects of aging [7].

However, promoting self-management of chronic diseases among elderly Koreans is challenging. The majority of self-management programs for chronic diseases currently available involve face-to-face interactions through group-based teaching sessions, where general information on diseases is provided by health care providers [7,8]. However, this information-focused approach has not been effective in changing health behaviors [9]. Moreover, most of these programs are only provided for a short period of time (4-12 weeks), and are intensively centered on delivering information about the disease and medication using a one-way communication approach that is directed from the health care providers to the patients [7]. This standardized approach has limitations in that it does not provide a tailored and personalized training experience, despite the fact that most elderly individuals exhibit different levels of progression with regard to their chronic diseases [8,9].

Mobile health (mHealth) training, defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices, [10]" is a newly-developed method of enhancing self-management of diseases [10-12]. It enables users to utilize resources through network services and diverse technological apps in a timely manner and eliminates the need for physical travel [10,12,13]. Furthermore, mHealth services have the potential to empower users to become active to participate in health care practices through interactive communications with health care providers [12]. These mHealth interventions help individuals identify their health care needs, facilitate access to health services, and provide assistance with solving problems related to their illnesses [12,13]. Some studies have reported that mHealth interventions are associated with potential increases in adherence to treatment and disease management, which lead to better patient outcomes across the chronic disease trajectory [10,13].

However, there are significant gaps in the literature focusing on the manner in which mHealth training may assist elderly individuals in self-management of their chronic diseases [10,13-19]. Past studies have emphasized the efficacy of disease-centered training that focuses on a single disease group and is delivered through mobile communication, including telephone calls and short message services, rather than multi-factorial training sessions that integrate apps and Web-based interactive programs [10]. Moreover, there is limited information on how these mHealth training protocols are developed, and whether they have taken key challenges faced by community-dwelling elderly individuals into consideration [10,13,20]. Moreover, there are no theory-based studies that have aimed to develop specific components of mHealth training tailored to elderly Koreans with diverse chronic diseases. Therefore, it is necessary to conduct a feasibility study to evaluate the training protocol prior to conducting any experimental studies [21]. Consequently, we (1) developed an mHealth training protocol to empower community-dwelling elderly individuals to manage their chronic diseases; (2) examined the feasibility of delivering this mHealth training protocol to elderly individuals through mobile tablets and apps; and (3) discussed the contextual and methodological challenges associated with the development of this protocol.

Methods

Study Design

This study consisted of two parts: (1) a methodological section that describes the development of the mHealth training protocol, and (2) a descriptive section focusing on evaluation provided by users (N=27) who participated in the mHealth training.

Developing the mHealth Training Protocol

The eHealth Enhanced Chronic Care Model (eCCM) [22] was used to guide the development of the mHealth training protocol described in this study and to evaluate its feasibility. It explains how adults with chronic diseases become active, educated, engaged, and empowered while working with their health care providers, communities, and social networks in actual and virtual communities along with health care systems [22]. Because the management of chronic diseases in Korean adults is currently centered in health care settings, our mHealth strategies

encouraged those living in the community to enhance their integrative knowledge and practice of self-management when dealing with chronic diseases on a daily basis.

The current mHealth training protocol, which focused on the self-management and mHealth training components of the eCCM, included multiple phases: (1) phase 1: standardized technology training; (2) phase 2: provision of general information about chronic diseases; (3) phase 3: mHealth training using pre-selected mobile apps related to individual chronic diseases; and (4) phase 4: active use of self-selected apps based on daily health care needs. Each of these phases has been described below.

Phase 1 used an iPad mini 2 retina (Apple Inc, California, USA) display to provide standardized training to all study participants. This device has several advantages: (1) its size and weight are suitable for carrying around; (2) it has high pixel density in high quality images, which is key for elderly individuals with vision difficulties; and (3) it allows the user to access a diverse range of apps developed internationally [10,11,20,23].

The strategies employed to protect patient anonymity and confidentiality were carefully designed and described to the participants [13,20]. As per the recommendations for ethical conduct of internet, computer, and technology research proposed by the Association of Internet Research [24], a unique code was assigned to each participant for data collection and entry into the database. An anonymous user identification number and password was created by a research assistant, and the participants were provided these to allow them to log into the mHealth device.

Technology training included provision of mobile device guidebooks, standardized demonstrations by the mHealth trainers, guided practice, and 24/7 telephonic trouble-shooting services. After allowing the participants to practice for one week, the mHealth trainers evaluated their proficiency in using the mobile devices independently [20]. In addition, the participants also self-reported their level of confidence in using the mobile tablets [20]. Once the participants were evaluated as being both proficient and confident in using the device, they progressed to Phase 2. However, if participants were not deemed proficient, confident, or comfortable enough with the device, they were asked whether they were willing to continue the training. In case they expressed willingness to continue, additional training was provided by the mHealth trainers a maximum of two more times.

In Phase 2, the mHealth trainers provided information retrieved from the Korean Center for Disease Control [25], Ministry of Health Welfare [26], Korean Academy of Medical Sciences [27], and Korean Diabetes Association [28] on healthy diets, exercise, lifestyle modifications, prevention and management of complications secondary to primary diseases, and medication. This information was retrieved on the basis of the following criteria: (1) the information should focus on a single or multiple chronic disease(s) in a specific individual; (2) the information on the risk factors and consequences of chronic diseases should be evidence-based; (3) the information should be written at a sixth grade or lower level of literacy [29]; and (4) the information should be designed such that it can be efficiently delivered using diverse types of multimedia, including webpage script, video streaming, workbooks, and pictures.

In Phase 3, following assessment of the type of chronic disease, health status, individual needs, and mHealth proficiency of each participant by the mHealth trainers, specific mobile apps including blood pressure measuring tools, fingertip glucose monitoring, tracking log, and interactive games were selected. Only apps that could operate both online and offline were chosen so that users with no internet access could use them freely [10]. Neither the mobile tablet provided nor the apps selected required the participants to enter their personal information. Moreover, all participants were instructed that they were required to log out after using their personal email or other apps on the provided device.

In Phase 4, the feasibility was examined by asking the participants to use the selected apps for at least 30 minutes daily for one week [11]. Participants were free to explore additional apps and download them with the help of the mHealth trainers, if necessary. Upon completion of the mHealth training, equipment was sanitized, inspected for safety, and retested as per the manufacturer's recommendations and the research protocol before being given to the next participant. Web pages and apps that were not part of the mHealth training program and were used by the participants were not examined in order to protect the participant's privacy [13,20].

Feasibility Test

Study Participants

A convenience sample of 30 elderly Korean individuals was selected from two community centers. Inclusion criteria were as follows: (1) age ≥60 years; (2) ability to understand Korean; (3) living at home in a community setting; and (4) living with at least one chronic disease, including cardiovascular disease, diabetes mellitus, hypertension, and cerebrovascular disease, which are the most prevalent among elderly Koreans [2]. Those with cognitive impairment, depressive mood, or psychiatric disorders (assessed using the Korean versions of the Mini-Mental Status Examination, MMSE-K [30]; the Geriatric Depression Scale-short form, SGDS-K [31]; and self-reports) were excluded. Following the exclusion of 3 ineligible volunteers, 27 participants commenced with our mHealth training, of whom 25 completed it.

Measures

For screening purposes, the MMSE-K and SGDS-K were used to assess cognitive impairments and emotional distress, both of which are barriers to health training. The MMSE is a 30-point scale that is internationally used to assess cognitive function in older adults [32]. The Korean version has been shown to be valid, reliable, and culturally equivalent to the English version, with regard to diagnostic, concurrent, and discriminant validity [30]. The SGDS is a 15-item measure that is used internationally to assess geriatric depression with scores on a range from 0 to 15 [33]. The Korean version has also been shown to be valid, reliable, and culturally equivalent to the English version, in terms of internal consistency and discriminant validity [31]. MMSE scores lower than 24 and SGDS-15 scores higher than 11 indicate significant cognitive impairment and depressive

mood, respectively, and these were used as the exclusion criteria for this study [20].

At baseline, all participants completed the questionnaires, including all socio-demographic, clinical, and computer-related questions after screening. Socio-demographic characteristics included age, gender, education, marital status, living status, and employment, whereas the clinical information included the number and types of chronic diseases and comorbidities exhibited, disease duration, and history of medications. Computer-related information included questions on whether the participants had previously used computers, smart devices, or the internet. A user self-reporting evaluation form and a proxy-report checklist of essential tasks was developed based on previous literature [11,34]. After completing Phase 1, the participants reported their level of confidence in using the mobile devices, and a research assistant used a standardized checklist to observe their basic skills in using the devices. At the end of Phase 4, the participants were asked to answer several questions addressing their levels of subjective confidence with, satisfaction in, and perception of usability of the mHealth training protocol (Multimedia Appendices 1 and 2).

Data Collection

The two local community centers from which the participants were selected were similar in terms of socio-demographic and economic factors and the proportions of older adults. The study purpose, protocol, and strategies for protection of anonymity were explained to the nurses working in the community centers. Participants were recruited through advertisements posted on bulletin boards or through word-of-mouth. Community nurses working at each center assisted with recruiting and screening study participants (eg, cognitive function and psychiatric illnesses). The data were collected using standardized self-reporting questionnaires, observation notes, and unstructured 5-minute interviews conducted between May 2016 and January 2017. To minimize bias from the community nurses, anonymous questionnaires were collected at separate places. Data collection typically took less than 30 minutes, and the participants received a small gift worth US $5 for their time and effort.

Data Evaluation

Based on the feasibility evaluation criteria [21], this study focused on (1) evaluating the users' subjective appraisal of the training and study procedures and (2) identifying strategies to implement the training protocol. Therefore, both contextual and methodological considerations were identified to assist the researchers in understanding the associated barriers to be considered in future studies. Qualitative analyses of data from the structured interviews and observations were carried out, while quantitative data were reported as frequencies (%) and mean values (SD). Given the exploratory nature of this feasibility study, the statistical significance of differences between those who completed the 4-week mHealth training (n=25) and those who did not (n=2) were not tested. All statistical analyses were performed using IBM SPSS Version 23.0.

Ethical Considerations

The study protocol was approved by the Institutional Review Boards of College of Nursing, Yonsei University. In addition, all participants were provided with information on the voluntary nature of the study, their freedom to withdraw their enrollment, and the strategies that would be adopted to protect their anonymity and confidentiality, following which written informed consent was collected.

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Results

Description of Study Participants

The demographic, clinical, and technological profiles of the 27 study participants have been shown in Table 1. The mean age of the study sample was 73.33 (SD 5.98) years, and the majority of the participants were female (67%, 18/27), married or partnered (70%, 19/27), living with family members (70%, 19/27), and unemployed (96%, 26/27). Only 15% (4/27) were educated to college level or higher. The mean number of diseases exhibited by the participants was 2.07 (SD 1.21), and the mean duration of illness was 11.68 (SD 11.32) years. The majority of the participants were taking medication (70%, 19/27) to manage their chronic diseases, and approximately two thirds of the participants had previously used computers (59%, 16/27) and smartphones (67%, 18/27).

Attrition

The attrition rates were used to evaluate the acceptability of mHealth training. The participants were classified as having completed the training if they had been through all of the phases as well as the pre- and post-evaluation. All other participants were classified as dropouts. The attrition rate for the 27 participants who took part in our mHealth training program for 4 weeks was 7% (2/27). Two dropouts (both females, less educated, widowed, living alone, diagnosed with cardiovascular diseases and exhibiting significantly depressed mood) occurred during Phase 1, and their reasons included time conflicts, emotional distress, or family discouragement.

Assessment of Confidence and Proficiency

Phase 1 consisted of delivering group sessions, and the participant's confidence and proficiency in using the mobile tablets were determined. The confident and proficient status indicated that the older adults could perform all eight key operating skills easily and expressed that they were "confident" or "strongly confident" without any assistance. Although participants had the opportunity to receive device training up to three times, the majority only required 1 session (88%, 22/25), and only 12% (3/25) required additional training. Twenty-five participants became proficient in completing key tasks when using the selected device and apps (mean 3.68, SD 1.75) after receiving our training (mean 3.44, SD 2.39).

Table 1. Characteristics of study participants.

Characteristics	Participants (N=27)
Age, mean (SD)	73.33 (5.98)
Korean version of Mini-Mental Status Examination (MMSE-K), mean (SD)	27.70 (1.73)
Korean version of Geriatric Depression Scale-Short Form (SGDS-K), mean (SD)	3.67 (3.55)
Period of living with chronic diseases, mean (SD)	11.68 (11.32)
Number of chronic diseases, mean (SD)	1.56 (0.89)
Number of comorbid conditions, mean (SD)	2.07 (1.21)
Duration of computer use (n=16, unit: month), mean (SD)	6.69 (6.18)
Duration of smartphone use (n=19, unit: month), mean (SD)	44.84 (22.49)
Gender, n (%)	
Male	9 (33)
Female	18 (67)
Education, n (%)	
Less than middle school	9 (33)
Middle to high school	14 (52)
College or more	4 (15)
Marital status, n (%)	
Married or partnered	19 (70)
Widowed	8 (30)
Living status, n (%)	
Living with family members	19 (70)
Living alone	8 (30)
Employed, n (%)	
Employed	1 (4)
Unemployed	26 (96)
Chronic disease present (multiple answers were allowed), n (%)	
Cerebrovascular disease	5 (19)
Ischemic heart disease	4 (15)
Diabetes mellitus	9 (33)
Hypertension	14 (52)
Medication, n (%)	
Yes	19 (70)
No	8 (30)
Computer use, n (%)	
Past or current	16 (59)
Never	11 (41)
Smartphone use, n (%)	
Past or current	18 (67)
Never	9 (33)
Internet access at home, n (%)	
Yes	14 (52)
No	13 (48)

Table 2. Most frequently used apps in this study.

Name of app	Provider	Major purpose	Feature participants liked most
Cardiio	Cardiio, Inc (Cambridge, USA)	Monitoring heart rate in daily life	Suggestions of exercise programs based on heart rate variability
iCare	iCare Fit Studio (Missouri, USA)	Measuring heart rate, blood pressure, vision acuity and field, lung capacity, or mood	Alarms responding to abnormal results or dramatic changes in measured data
Hypertension Protector	DONGWHA Pharm Co (Seoul, Republic of Korea)	Tracking trends in blood pressure and body weight	Personalized information based on levels of blood pressure, provided in an easy and readable manner
Diabetes Guide	Innova Think, Corp (Seoul, Republic of Korea)	Providing stepwise and diverse information on diabetes mellitus	Promotion of self-care through diet control, exercise, foot care, and infection control
Diabetes Note	Minister of Health and Welfare (Seoul, Republic of Korea)	Tracking trends in daily glucose levels	Depiction of daily, weekly, and monthly trends of blood glucose
Noom Coach	Noom, Inc (Seoul, Republic of Korea)	Facilitating lifestyle modification	Diverse types of lifestyle modification suggestions addressing sleep, stress management, prevention of depression, diet, or exercise

The mean reported confidence level for these participants, measured using a 5-point Likert-type scale where the higher scores indicated more confidence, was 3.76 (SD 1.17). The number of confident participants increased from 44% to 52% after Phase 1 training.

Men and those with higher education were more likely to learn how to use the devices and apps quickly and easily compared to women and those with lower education. Those who had used computers or mobile devices prior to this study required less training compared to the no-experience group. Previous users of Android mobile devices (72%, 18/25) required more time and information to become accustomed to Apple's operating system.

Users' Satisfaction With the mHealth Device

User satisfaction was self-reported using a 5-point Likert type scale (1=*strongly disagree*, 5=*strongly agree*) for various items. Device training was considered helpful before participants initiated the mHealth training (mean 4.36, SD 1.04), and it was also found to be appropriate for health promotion (mean 4.44, SD 1.00). The device was easy to carry (mean 3.76, SD 1.27) and use (mean 3.80 SD 1.19), and the participants would recommend the device training to others (mean 4.04, SD 1.06). In addition, using the mHealth device was deemed to be less likely to interfere with their daily lives, including any concerns associated with privacy (mean 1.12, SD 0.84).

Participants' Preference With Regard to Selecting and Using Specific Mobile Apps

The participants requested a tailored and personalized approach toward selecting appropriate apps that took their individual health care needs into consideration from Phases 2-4. Therefore, the ratio of the number of mHealth trainers to participants became essential during Phases 3 and 4. During phases 3 and 4, one mHealth trainer assisted 2-3 participants in providing instant feedback.

Most participants preferred using interactive apps instead of those with one-way information delivery systems. For example, participants frequently used an app measuring blood pressure from the fingertip, and responded to its evaluation and instructions for lifestyle modification. In addition, they also visited websites of authorized organizations to acquire disease information; however, they very rarely revisited these pages. The favored apps among participants were those related to exercise, including tracking records, video streaming, or personalized recommendations. Table 2 summarizes the apps most frequently used by our participants. In addition, the participants also received weekly follow-up calls or text messages as reminders and reported that this contact was useful and allowed them to ask questions concerning technical problems and explore more diverse types of apps on an 'as-needed' basis.

Discussion

Principal Results and Comparison with Previous Evidence

Our protocol assisted elderly individuals participate in an mHealth training program for the self-management of chronic diseases in a community setting, where there is limited staff and resources [6,35,36]. The findings of this study revealed that acceptable feasibility of an mHealth training protocol was associated with the participants' subjective perception, efforts to overcome barriers, and personalized approach tailored to the older adults' characteristics [13,20]. Therefore, this study provides detailed information on the users' experiences when implementing an mHealth training protocol among older adults. Consequently, the conceptual and methodological lessons learned are discussed to aid the development of resources and strategies for provision of mHealth training to community-dwelling older adults dealing with chronic disease management.

The emotional responses of participants at the primary stages are key factors that play a role in the successful implementation of mHealth training. Although mHealth training is considered useful, the participants that dropped out from this study or

required additional mHealth training were likely to report higher depressive scores or feelings of stress. The respondents' level of confidence is also critical for the assessment of their level of emotional distress and their ability to learn new health care training skills [10,20]. Previous studies have identified the major factors influencing successful outcomes from mHealth interventions among older populations as being independence, understanding, and confidence in accessing complex interventions [13,20]. Tracking features during periodic training and regular follow-ups are essential for the provision of positive feedback regarding progression based on objective data obtained during the mHealth training [11,35].

Furthermore, a tailored and personalized approach is necessary to ensure high levels of adherence, specifically during Phases 3 and 4 [37,38]. The mHealth trainers in this study provided health coaching rather than merely delivering information about chronic diseases [9], and the participants' health care needs were carefully assessed before selecting apps. Strong interest in and autonomy of selection based on individual needs are a driving force facilitating any mHealth training or intervention [20]. In this study, the participants were mainly seen to utilize physiological monitoring, information-based training, and self-management app, and these findings were consistent with those of another study examining older adults in Taiwan [34]. Common features of the selected apps included recording individual data such as blood pressure and providing personal guidance and alerts based on the information provided. It appears that personalized data and timely responses enhance mHealth engagement in older adults [11,13]. Personalized information computer and technology (ICT) is one of the preconditions of achieving person-centered ICT care to manage chronic diseases [39].

In addition, a gray digital divide was seen to exist, that is, disparities using ICT device or programs in older adults. The group sessions were carefully constructed, taking into consideration the following factors: (1) mixed gender to facilitate peer learning; (2) participants exhibited similar levels of education; and (3) participants had similar previous experience of using smart devices. Adults of an advanced age required more training to become accustomed to using the device itself [10,13]. Furthermore, the mHealth trainer often had to adjust some features such as text size, brightness, and volume to overcome possible sensory and functional impairment barriers associated with the participants' diseases or disabilities [13,20]. Gender differences, as previous studies have discussed [10,13], were identified during training and when choosing specific types of apps. There was an unintentional increase in the proportion of older and female participants in our study. Previous evidence suggests that special instructions should be provided to subgroups with low levels of literacy or e-literacy [10]. In addition, it is necessary to assess end-user's physical conditions and preparedness prior to implementing mHealth training or intervention [40]. Moreover, clinicians should be prepared to meet all clinical and technical needs of elderly individuals receiving mHealth care. Consequently, organizational support and an interdisciplinary team approach are necessary when implementing mHealth training programs or interventions in community settings [40].

Successful self-management of chronic diseases requires empowerment and the support of informal caregivers [6] who make daily decisions regarding the patients' health care [9]. When older adults require technical support while using smart devices and mHealth training, they are more likely to receive instant help or feedback from a significant other or a family member [38]. As demonstrated in previous studies, new devices and tasks are frequently discussed with family members, who influence the older adults' intent to use the intervention [34,38]. Therefore, family attitudes toward telecare are a critical factor affecting the patients' willingness to continue using the services [34]. For example, the low technical support group mentioned that their family felt pressured to learn new skills or perform additional tasks when dealing with mHealth devices or trainings [41]. Similar to older adults, family caregivers reported experiencing a greater burden when they were not fully prepared to assist the older patients with receiving mHealth care [41]. Therefore, mHealth training programs for chronic diseases must integrate goals that should be discussed with the patients and their families and health care providers [6,40]. In addition, family members should also learn how to assist older adults in using mHealth training and provide them with effective feedback [38].

Technical assistance should be provided at any phase of mHealth training. The participants of this study expressed some degree of negativity toward the use of technology in their daily practice of health care. The most common difficulties experienced by the participants were technical challenges such as unfamiliarity with using highly sensitive touch screens, the completion of technology training, or with diverse mobile apps. Many of the older adults expressed concern regarding incorrect operation of the devices or misunderstanding due to their lack of knowledge and experience [10,20,34,38]. In this study, participants received multiple device training sessions that were adjusted to their level of progress; they also received technical support for continuous use of mHealth care, as suggested by a previous study [20]. Participants were able to avail this benefit throughout the tailored and personalized approach where the technical support met their unique characteristics and needs [38].

Implications for Current Research and Practice

This study focuses on mHealth training protocols and provides detailed information on how to develop similar training programs for older adults with chronic diseases. It is essential to ensure consistency in the initial device training to reduce any threat to internal validity [20], as limited ability to use the mHealth devices may increase the measurement error of the clinical effect [11]. Furthermore, exploring diverse retainment strategies is key in preventing dropout and providing better mHealth training [42]. Consequently, special attention should be provided to women, those who are older, and those that are not well-educated when attempting to retain older adults in mHealth training studies and practices. This study provided information about the participants' concerns, and these should be taken into consideration when implementing evidence-based mHealth training to reduce the subjective burden [20].

The strengths of a tailored and personalized approach include provision of individualized health care services, reduction of

health care expenditures, and improvement of the quality of life [43,44]. Although an mHealth care service cannot be a complete replacement for traditional face-to-face training or clinic-based treatments, it can facilitate tailored and personalized care across various settings [13]. This study provides fundamental information about mHealth training and effective delivery methods to aid clinicians caring for older Koreans living with chronic diseases. The barriers identified by this feasibility study offer opportunities for improvement to app developers, who need to consider the consumers' perspectives of health care services.

Policymakers should consider the potential of mHealth care to meet the needs of older adults living with chronic diseases. Public service and reimbursement should be established by considering the scientific evidence [13], as mHealth training can provide diverse routes, through which health care services can be delivered to community residents [10,36]. Moreover, community centers need to disseminate mHealth technology to vulnerable populations with greater needs with regard to chronic disease management [20,36]. Future policies and public services should be equipped to take into consideration gray digital divide groups when providing mHealth services to ensure health equity.

Study Limitations

Despite being the first feasibility study to develop an mHealth training protocol for older Korean adults, this study had several limitations. Firstly, the sample was small and had been recruited from two community sites only. Future feasibility studies should include larger sample numbers and control groups as this would enable identification of factors influencing dropouts. This, in turn, would aid clinicians in developing evidence-based strategies to enhance completion of or adherence to mHealth training [45]. Second, this study mainly used apps, websites, and video streaming, and further studies should consider expansion to other features such as text messaging, teleconferencing, and real-time feedback [10].

Conclusions

Self-management of chronic diseases through mHealth training requires the integration of a theoretical, clinical, and technical approach, particularly when targeting older adults in a community setting. This study provided detailed information on how to develop an mHealth training protocol for self-managing chronic diseases in a community setting. The older adults exhibited a strong interest in learning how to use mHealth training devices with careful assistance from professionals. A tailored and personalized approach based on the individual characteristics and needs of the patients is necessary when implementing mHealth training protocols for older adults.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Confidence and proficiency in using mHealth devices.

[PDF File (Adobe PDF File), 183KB - mhealth_v6i6e147_app1.pdf]

Multimedia Appendix 2

User satisfaction with mHealth device and training: evaluation form.

[PDF File (Adobe PDF File), 199KB - mhealth_v6i6e147_app2.pdf]

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Abbreviations

eCCM: eHealth Enhanced Chronic Care Model
mHealth: mobile health
MMSE-K: Korean versions of Mini-Mental Status Examination
SGDS-K: Korean version of Geriatric Depression Scale-Short Form

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Review

Smartphone Apps for Mindfulness Interventions for Suicidality in Asian Youths: Literature Review

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Abstract

Background: The advent of mobile technology has ushered in an era in which smartphone apps can be used as interventions for suicidality.

Objective: We aimed to review recent research that is relevant to smartphone apps that can be used for mindfulness interventions for suicidality in Asian youths.

Methods: The inclusion criteria for this review were: papers published in peer-reviewed journals from 2007 to 2017 with usage of search terms (namely "smartphone application" and "mindfulness") and screened by an experienced Asian clinician to be of clinical utility for mindfulness interventions for suicidality with Asian youths.

Results: The initial search of databases yielded 375 results. Fourteen full text papers that fit the inclusion criteria were assessed for eligibility and 10 papers were included in the current review.

Conclusions: This review highlighted the paucity of evidence-based and empirically validated research into effective smartphone apps that can be used for mindfulness interventions for suicidality with Asian youths.

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KEYWORDS

suicidality; Asian youths; smartphone applications; mindfulness

Introduction

Suicide rates increase with age from adolescence to young adulthood [1,2], with corresponding heightened rates of suicidal ideation and attempts [3]. Both Western and Asian studies have highlighted the prevalence of youth suicidality, and youth suicide rates have been rising faster compared to other age groups [4,5], with a peak in those between 15 and 24 years of age [3,6,7]. In a recent large study on Asian suicide attempters in Singapore, a prominent peak in suicide attempts over a 3-year period was observed in youths aged between 15-24 years, as compared to other age groups [4].

In recent decades, the advent of smartphone technologies has transformed the mode of delivery of psychological treatment [8] for patients suffering from chronic medical illnesses [9,10] and psychiatric illnesses [11], as well as their caregivers [12]. The demand for electronic health apps across the world is mirroring larger societal trends wherein consumer acceptance of technology has grown [13,14].

Common psychiatric illness such as depression are associated with high direct and indirect costs [15]. Psychiatric illnesses result in functional impairment, leading to lost wages and work impairment, with related personal, societal, and economic burdens [16,17]. Smartphone apps have the potential to reduce health care costs for treating psychiatric illnesses in Asia [18,19]. In comparison to Western countries, there is a shortage of mental health professionals in Asia, yet a high penetration of mobile phone usage throughout Asia [20]. Over 50% of the Asian population uses smartphones, with Singapore alone reporting that smartphone adoption rates far exceeded the population [21].

There is a critical need for comprehensive research to inform the development of evidence-based smartphone apps that can be made widely available for the public, to ameliorate symptoms and improve well-being in Asian populations.

As younger demographics are more likely to access online information related to mental health problems [22-24], mobile technologies can enhance patient-centered care for youths in an increasingly technology savvy society [25], highlighting a growing need to offer electronic interventions [26,27]. The evidence base for the use of smartphone apps has been demonstrated in many areas [28-33], and Internet-based interventions have been found to be efficacious for mental health issues [34] in young adults [23,26,35] to enhance support [36], help them to cope, and to aid in recovery [37,38]. Positive outcomes were shown in overall motivation [39] and with ethnically diverse populations [40]. Smartphone apps have been used to deliver therapies that are relevant to young adults, such as cognitive behavior therapy [10], addiction treatment [41], and virtual reality therapy [42]. These findings hold promise for mental health professionals who are not technical experts to develop smartphone apps as an alternative platform to deliver interventions, in view of the recent advances in technology [43]. However, it should not be assumed that smartphone apps delivering interventions demonstrated to be effective in Western cultures will be similarly effective in Asian cultures [44]. Cultural adaptations may be needed for Asian youths [45].

Some clinics in Australia have implemented conjunctive treatment modalities in guided programs such as Cognitive Behavioral Therapy and psychoeducation apps alongside face-to-face therapy sessions [40]. One example is the Dialectical Behavioral Therapy Coach, which was an app that was designed after extensive feedback from experts [46]. The app aimed at cultivating emotional regulation skills to change negative emotions [47]. The users gave ratings and identified the current emotion, after which users were directed to specific coaching [47].

Such developments are currently lacking in Asia. As aforementioned, it should not be assumed that interventions demonstrated to be effective in Western cultures will be similarly effective in Asian cultures, especially those concerning suicidality. Culture plays an important role in determining risk and protective factors for suicidality, which informs targeted assessment and intervention strategies [44]. Asian suicide attempters are more likely to overdose on prescribed and over-the-counter medications instead of using firearms in their suicide attempts [48], as compared to Western samples, and Asian suicide attempters also endorse different views on the lethality of suicide methods [49].

Mindfulness interventions have been used to treat various psychological problems such as anxiety and depression [50-52]. Mindfulness practice reduces psychological distress while optimizing psychological functioning among young adults [53] by enhancing positive affect and lowering negative affect [51]. Large scale empirical research investigating the evidence base for mindfulness interventions in Asian samples seems to have gained momentum in the last few years [52]. Depression is a common psychiatric illness in Asia. Asians suffering from depression often experience maladaptive ruminations [54] and would be suitable for mindfulness-based therapies, which have been shown to contribute to significant reductions in maladaptive rumination [55]. Furthermore, youths are often affected by problems including low self-esteem [56], poor weight control [57], eating problems [58], Internet addiction [59], and chronic diseases including dermatitis [60] and asthma [61]. Mindfulness-based therapy shows evidence in improving self-esteem [62], weight control [63,64], eating problems [65], Internet addiction [66], and chronic diseases in Asian youths [67], and holds promise for use with Asian youths to enhance their overall wellbeing and resilience and reduce their vulnerability to suicidality [45]. Recent studies have drawn links between resilience, suicidality [44,68], and mindfulness practice for Asian populations [45,68]. In Asia, the stigma related to mental illness and suicidality may hinder help-seeking behavior in youths. This issue further increases their vulnerability to suicide risk [4]. These at-risk youths might prefer to access community interventions such as self-help on electronic platforms delivered using smartphone apps [20] rather than face-to-face therapy. Such apps offer an alternative delivery medium that is also cost effective [53]. The accessibility of such apps may enhance our efforts in primary prevention, and mental health promotion, aligned with recent research in Singapore. A recent study in Singapore highlighted the need for mental health promotion to reduce stigma related to psychiatric illnesses and enhance psychological wellbeing [45]. Recent research indicates that preventative mental health care involves enhancing resilience and promoting protective factors, which includes mindfulness-based interventions for emotional regulation [44,45,53].

There are many smartphone apps currently available that are marketed as mindfulness apps. A search using the search term “mindfulness-based iPhone Applications” from November 2013 yielded 808 results. This number is consistent with earlier research informed by a search for “mindfulness” conducted on iTunes and Google Applications for mindfulness training [36]. Such apps were reviewed by experts. However, the utility among Asian youth consumers remains unclear. Widespread implementation of self-help mindfulness interventions could be premature without salient evidence and scientific scrutiny for use by the intended population [69]. Youths can be impressionable consumers, and principles of rigorous scientific enquiry should be applied to explore therapeutic benefits of such apps [70]. Unfortunately, the utility of such apps for suicidality in Asian youths remains largely unexamined. Research aimed at examining low-cost smartphone apps that are efficacious as a therapeutic tool for suicidality in Asian youths would add significantly to the current literature [71]. Considering the heightened suicide risk uncovered by recent research with Asian youths [4], and the need for early prevention [45], research is needed to explore alternative ways to deliver effective interventions that are also cost effective and easily accessible. The aim of this paper is to review research relating to the evidence base for smartphone apps that can be used for mindfulness intervention for suicidality in Asian youths.

Methods

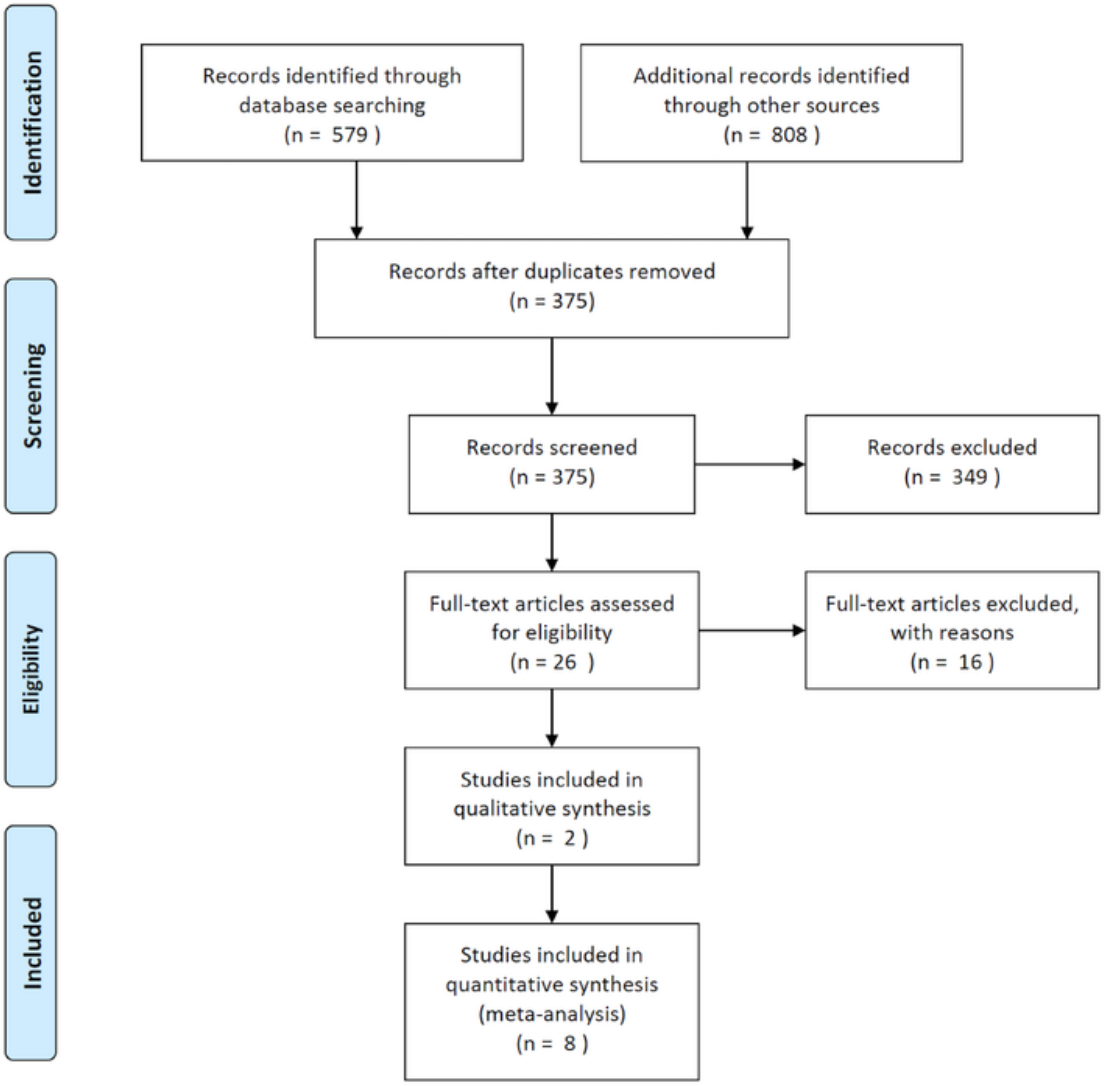
The inclusion criteria for this review were: publications in peer-reviewed journals from 2007 to 2017 with usage of search terms namely "smartphone application" and "mindfulness." Databases included PSYCINFO, SCOPUS, Google Scholar, and PubMed. The papers were retrieved if they related to interventions via smartphone apps for mindfulness interventions. The structured proforma for evaluating eligibility for inclusion involved the following: recent papers that contain original work published in peer-reviewed journals after the year 2007; papers related to usage of a smartphone app by clinicians for therapeutic purposes and considered by an experienced Asian clinician to be of clinical utility with suicidal youths in Asia.

The focus was on recently published papers in peer-reviewed journals that fit the inclusion criteria and were relevant to smartphone apps that can be used for mindfulness intervention for suicidal youths in Asia. The main reason for the exclusion of articles was the fact that papers did not refer to the use of smartphone apps by clinicians for therapeutic purposes.

Results

The *PSYCINFO* database was initially used to identify peer-reviewed papers with the inclusion criteria named above; this yielded 375 results when all search terms were used. From the original search results, the abstracts were screened, and 14 full text papers from peer-reviewed journals were then downloaded and assessed against the inclusion and exclusion criteria. See Figure 1 for the PRISMA flow chart [72]. Ten recent papers deemed to be suitable were included in the current review, with a focus on papers published in the last 5 years. The results of the review are presented in Multimedia Appendix 1. A review of papers in Multimedia Appendix 1 shows a lack of convincing evidence of the efficacy of smartphone apps that can be used for suicide interventions for Asian youths.

Figure 1. PRISMA flow diagram.



Discussion

In summary, a review of papers presented in Multimedia Appendix 1 shows a lack of convincing evidence of the efficacy of smartphone apps that can be used for suicide interventions for Asian youths. A review of 15 randomized controlled trials, including 4 mindfulness-based interventions, indicates that mindfulness interventions significantly improve levels of mindfulness and depressive symptoms [69]. However, effect sizes were small to medium. There were high drop-out rates and few trials were adequately powered. Another recent study examined an app with Spanish features with a large sample size but employed statistical analyses that did not produce convincing evidence [73]. Other studies only reviewed apps [13,53,74] and did not test them on the intended users. Another study that examined mindfulness-based interventions found significant effects on well-being, stress, anxiety, depression, and mindfulness, but had a low representation of Asian youths [75]. Another study found significantly increased positive affect and decreased depression but no statistically significant difference in satisfaction with life or negative affect, and again this study had low representation of Asian youths in the sample [76]. A study on Chinese youths [77] found that an online mindfulness intervention had a significant effect on overall mental well-being and mindfulness with no specific mention of suicidality. Except Larsen et al [13], the apps in other studies were developed to address symptoms of mental disorders related to suicidality. These symptoms included depression and anxiety. In summary, the extent of generalizability of such findings to suicidality in Asian youths remains questionable.

The research reviewed in Multimedia Appendix 1 indicated that considerations for future research should include interventions lasting more than 10 days that had more than one postintervention measurement [76]. To reduce drop-out rates, reminders should be sent to users [69]. Researchers should carefully consider power and sample size and ensure robustness in statistical analyses.

There is currently a lack of interactive self-care apps available to Asian users that incorporate explicit delineation of the scope or initial screening for suitability, or offering targeted guidance, regarding management of suicidal crises [74]. Few of the apps currently on the market included content aimed at encouraging professional help-seeking or had an explicit mention of the theoretical or empirical basis of interventions. This gap needs to be addressed by partnerships between scholars, software engineers, and specialists in biomedical informatics to develop, test, and refine appropriate interfaces and apps. When designing such a mindfulness app, features to be considered include: the evidence base supporting use of mindfulness techniques in Asia; and the consideration of all the aforementioned issues, such as inclusion of explicit delineation of the scope or initial screening for suitability, targeted guidance, linking users with professional help-seeking, or explicit mention of the theoretical or empirical basis of mindfulness interventions. Specifically, mindfulness features in the app may include: breathing, body scanning, sitting meditations, walking meditations, loving kindness meditations, thoughts and emotion focus, mountain meditation, lake meditation, and 3-minute breathing spaces [53]. The content of apps for suicidality should contain at least one interactive suicide prevention feature (eg, safety planning, facilitating access to crisis support) and contain at least one strategy consistent with the evidence base or relevant best-practice guidelines [13]. Potentially harmful content, such as listing lethal access to means or encouraging risky behavior in a crisis, should be carefully screened and eliminated. Psychoeducational components to reduce the stigma related to suicidality and mental illnesses could be incorporated [44], together with monitoring of moods and stressors or other suicide triggers [45]. Youths are adversely affected by many psychosocial stressors, such as interpersonal stress which triggers suicidal ideation [78]; such triggers should be carefully assessed and addressed [4].

Another consideration is that suicidal Asian youths are not a homogenous group [4]. Suicide risk assessment needs to be conducted with consideration of risk and protective factors [45]. Therapeutic needs must be considered before clinicians decide on suitability for the use of a mindfulness app with their patients. Clinicians should carefully examine the prevailing code of ethics in working with suicidal clients to ensure best practices are observed [4,44]. This approach may include a comprehensive suicide risk assessment before deciding on the best intervention for the client [45]. Other factors to consider include defining the primary therapeutic goal and outcome (eg, reduced intensity or frequency of suicidal ideation, reduced lethality [4,44], or reduced frequency of repeated suicide attempts [45]) and monitoring the therapeutic gains progressively. It is unclear if suicide risk screening and monitoring using a smartphone app could replace face-to-face assessment conducted by an experienced clinician, but the prevailing code of ethics and professional best practices do not currently support this [4,44,45], especially when the evidence base is not clearly demonstrated.

A limitation of the review stems from the inconsistencies of the study types included in the review. Narrative reviews were included to inform the context but should be excluded because they are challenging to compare across study types. This issue further highlights the paucity of research in this area. Future research could focus on empirical studies and randomized controlled trials with Asian samples that conform to CONSORT guidelines [79]. Further research is also needed to examine the parametrization of the characteristics of the apps and their quantitative analysis with Asian samples. In addition, it is unclear if discrepancies exist between Asian samples from developing and developed countries, which could be explored in future research. The strengths of the review include the investigation of an important clinical issue and highlighting the need for more research on this pertinent topic.

In conclusion, there is consensus that suicidal risk in youths is a rising concern, especially in Asia in recent years [4]. The potential use of smartphone apps in the delivery of mindfulness interventions tailored for suicidality in Asian youths remains promising, but the evidence base to support their use is lacking. More research is needed to address the current gaps in knowledge and to provide an evidence base for the implementation of smartphone technologies. Developing mobile tools for young suicidal users requires careful ethical

consideration regarding the patient-practitioner relationship, the logic of self-surveillance, prevailing codes of ethics, and overall best practices. More rigorous research and evaluations are needed to ascertain the efficacy of, and establish evidence for, best practices for the usage of such smartphone apps [40].

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of evidence.

[PDF File (Adobe PDF File), 36KB - mhealth_v6i6e139_app1.pdf]

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Original Paper

The Crush the Crave Quit Smoking App and Young Adult Smokers: Qualitative Case Study of Affordances

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Abstract

Background: Mobile phone apps have emerged as a promising way to reach young adult smokers, given their high mobile phone ownership rates and openness to receiving cessation support via digital technologies. Although emerging evidence indicates that quit smoking apps are an effective way to reduce smoking among young adults, lacking is formative evaluative research that captures the perspectives of end-users.

Objective: The objective of this study was to contribute insights toward understanding how young adults interact with the Crush the Crave (CTC) app, and how this interaction shapes young adults' smoking cessation experiences and practices, with consideration of the influence of gender.

Methods: Semistructured interviews were conducted with 31 young adult CTC end-users. Guided by sociomateriality theory and an affordances approach, data were inductively analyzed to derive thematic findings in relation to the impacts of CTC on quit efforts, and to expose the underlying affordances (mechanisms) that lend to these outcomes. Findings were grouped according to the 4 design components of CTC: credibility, social support, task support, and dialogue support.

Results: The credibility component of CTC played an important role in harnessing the trust of young adults because it afforded them promise in relation to its potential effectiveness in assisting them with quitting smoking. The social support component lent to various end-user practices and experiences that rendered this aspect as the weakest component in supporting quit efforts. Although most functions situated in the task and dialogue support components were found to be helpful, there were a few affordances in CTC that resulted in negative experiences, notably weaning from smoking. Gender-related influences were also evident. For example, young men preferred to control and self-manage their quitting and, therefore, did not engage with functions that afforded journaling or reminding to stay on track. Women, in contrast, were more likely to benefit from these affordances.

Conclusions: An affordances approach is productive for gaining an in-depth understanding of how mobile apps interact with end-users to lend to particular outcomes. The study findings have implications for developing and improving apps for helping young adults quit smoking, as well as apps that target other health behaviors. Productive affordances may also serve as a framework for leveraging apps for smoking cessation.

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KEYWORDS

smartphone; smoking cessation; young adult; qualitative research; social theory

Introduction

Background

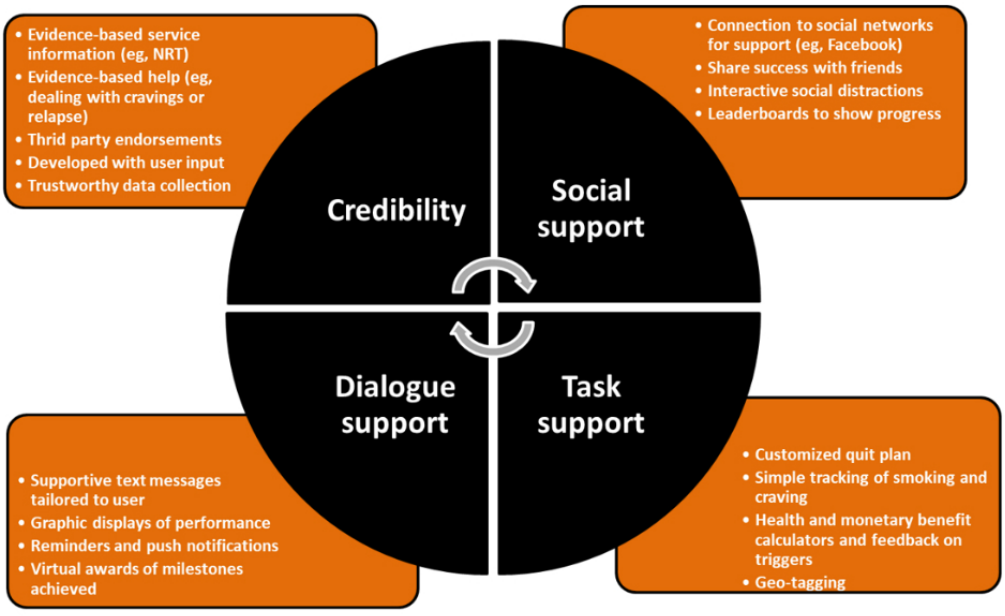
Finding effective strategies to assist young adults with quitting smoking is a priority in light of their high smoking rates [1,2] and low uptake of available cessation resources [3]. Given young adults' ubiquitous presence in the mobile phone market [3], many researchers have turned their attention to mobile phone apps as a promising way to reach young adult smokers [4]. There are now over 500 smoking cessation apps available between the Apple iOS and Google Play App stores, which have been met with enthusiasm by health care consumers according to the large number of downloads [5]. Young adults particularly indicate a desire for cessation support via apps compared with other interventions [6-8].

In the Crush the Crave (CTC) randomized controlled trial (RCT) [9], the CTC mobile phone app, which aims to help young adults quit smoking, was evaluated. CTC was developed in 2012 by a multi-sectoral team as an evidence-informed quit smoking app for young adults aged between 19 and 29 years. Underpinned by the US Clinical Practice Guidelines for quitting smoking [10] and principles of persuasive technology for behavior change [11], CTC includes 4 key design components: credibility (eg, backing by credible agencies), social support (eg, a Facebook community), task support (eg, tracking of cravings and smoking habit), and dialogue support (eg, virtual awards that credit performance toward reaching goals; Figure 1). The RCT compared CTC with a control condition (smoking cessation print materials) to assess efficacy of the app for helping young adults quit smoking. This study focuses on a qualitative exploration of the experiences of trial participants who interacted with the CTC. Trials evaluating smoking cessation apps are emerging, with recent systematic reviews summarizing preliminary evidence that smoking cessation apps are effective [12,13]. Although this quantitative evidence is important, qualitative data that capture end-users' perspectives are lacking. Given that these interventions are situated in the daily lives of smokers, understanding end-users' perspectives and the mechanisms by which these apps may promote behavior change is critical for adjusting and leveraging future apps focused on quitting smoking [14,15]. In addition, despite established evidence that gender-sensitive approaches are needed for smoking cessation interventions, and that electronic health (eHealth) cessation interventions that include gender-sensitive approaches positively influence receptivity to and use of the interventions [16-18], the empirical base regarding the influence of gender-related factors or ways to incorporate a gender-sensitive approach into mobile-based smoking cessation interventions is under developed.

Objectives

The purpose of this study was to contribute insights toward understanding how young adults interact with the CTC app, and how this interaction shapes young adults' smoking cessation experiences and practices, with consideration of the influence of gender.

Figure 1. Crush the Crave design components. NRT: nicotine replacement therapy.



Methods

Design

This study complemented the RCT that was underway to evaluate the CTC app where data were collected at baseline, 3 months, and 6 months [9]. Young adults who had been assigned to the intervention group were recruited in this study. Ethics approval for this study was obtained from the University of British Columbia (Okanagan campus) Behavioral Research Ethics Board (certificate #H15-00466).

A qualitative case study design [19] was chosen, with CTC as the case. In addition to being paradigmatically flexible [20], this approach enables flexible boundaries around what entails the case, is ideal for investigating phenomena on which little is

known, and promotes a commitment to intense, contextually minded, and the holistic study of a case. Given that the app functions and is influenced by young adults' contextually laden day-to-day lives, the case study was an ideal method for investigating the interactions between CTC and young adult end-users. Congruent with this methodology, data collection was qualitative in nature, and analysis followed the framework approach, which aims to draw descriptive and explanatory conclusions clustered around themes [21].

Participants

Using a purposive sampling strategy, young adults aged between 19 and 29 years, who used CTC and were either recent quitters or still smoking, were sought. Recruitment included young adults participating in the RCT who completed the 6-month questionnaire and selected *yes* to receiving information about this qualitative companion study. These participants provided their contact information (email and phone number) and, therefore, recruitment was conducted via email, phone calls, and text messaging. Altogether, 31 young adults provided informed consent and participated in this study. Participants were between 20 and 29 years (mean 24, SD 2.72), a little less than half were female at 42% (13/31), they were predominantly white at 71% (22/31), and from the province of Ontario at 48% (15/31). Most completed some postsecondary or college education at 67% (21/31), followed by high school at 13% (4/31), less than high school at 10% (3/31), and a University degree at 10% (3/31). Most participants (24/31, 77%) were still smoking at 6 months after using the CTC app.

Regarding end-user experiences with CTC (see Table 1), when using the app, the majority of participants used the app 1 to 3 times per month. However, only 23% (7/31) were still using CTC at the time of interview. In addition, 45% (14/31) of the sample reported being satisfied with the app. All features of the app were used, except 2 (online resources and my map). The majority of participants reported using the cigarette and craving tracking features the most. The crave community features (Facebook and Twitter) were the least used and least liked.

Data Collection

Data were collected using semistructured individual telephone interviews with young adults. The interviews were guided by sociomateriality theory in that interview questions aimed to uncover the actionable items that CTC enabled or constrained to reach the goal of quitting smoking. In this regard, interview questions were focused on *how* CTC enabled or constrained their quit smoking goals (eg, *Please tell me about a time or times that you used [function used] and how it helped you in your quit efforts.*).

All interviews were audiotaped and lasted between 30 and 80 minutes. Study participants received an honorarium (Can $50 per interview) to acknowledge the time spent on the study.

Theoretical Approach

To guide this study, Leonardi's [22] sociomateriality theory was employed. This theory was developed in response to observations that qualitative research on the use of digital technologies tends to focus on end-user perceptions, although the technological aspects of these innovations remained unexamined [23,24]. Sociomateriality offers a way to overcome established opposition between social and material determinism, considering both technological tools (material agency) and individuals (social agency) as 2 components of the same underlying phenomenon [25].

Operationalized through the concept of affordances, Leonardi's sociomateriality theory foregrounds actionable items (affordances) that result from the interactions (also called imbrication—joining together) between humans and technological tools. Although an app can do many different things (material agency), what it does do is only provoked through an end-user (human agency), and this may vary according to the context of an end-user. Therefore, an affordance is an underlying mechanism as a result of a sociomaterial relationship (eg, an app's functions and a young adult), which subsequently lends to particular experiences and actions. In this regard, productive and unproductive affordances of a mobile-based health intervention for a population may be revealed through a sociomateriality lens. Using sociomateriality, affordances of CTC are highlighted in what follows to explain Canadian young adults' experiences and practices in relation to quitting smoking with CTC.

Data Analysis

Data collection and analysis were conducted simultaneously, so that emerging themes could be further investigated in subsequent interviews. Sampling continued until data were repeated and representative coverage of emergent themes were saturated [26]. Findings repeated by 6 or more interviews served as the starting point of saturation [27]. To guide data analysis, the framework approach by Ritchie and Lewis [21] was employed, which is hallmarked by a series of interconnected stages (familiarization, identifying an analytic framework, indexing, charting, and mapping and interpretation) that enable the researcher to move back and forth between the data until a coherent account of the phenomenon is developed [28].

The interviews were first transcribed verbatim and uploaded in the qualitative data analysis software program NVivo version 10 (QSR International Pty Ltd, Burlington, MA, USA). Data from interviews with young women were kept as a separate dataset from those with young men to enable the lead author to compare and contrast young women's and men's experiences and identify notable gender-related influences in the datasets and findings. After a detailed reading of the transcripts in their entirety to become familiar with the data, a preliminary coding framework was developed using data from the first 4 interviews with young women and young men. In addition to coding young adults' descriptions of how and why they used the app, the coding framework was informed by sociomateriality theory, in which codes and categories were inductively derived for young adults' practices and experiences in using CTC, and then the affordances that lent to them. The frameworks for each dataset were then reviewed and approved by all authors. Indexing was accomplished by coding major themes and subsequent subthemes in relation to the analytical framework in NVivo, which was revised or added to as new data were collected.

Table 1. Crush the Crave (CTC) end-user experiences.

CTC usage item	Response, n (%)
Frequency of use	
Never	2 (6)
1-3 times per month	23 (74)
Once a week	2 (6)
2-3 times per week	2 (6)
Daily	2 (6)
Overall satisfaction	
Not at all satisfied	9 (30)
Not very satisfied	7 (23)
Somewhat satisfied	7 (23)
Satisfied	5 (16)
Very satisfied	3 (10)
Would use CTC again	
Yes, still using it	7 (23)
Yes, but not using it now	11 (35)
No	13 (42)
Features used	
Cigarette tracker	14 (45)
Craving tracker	11 (35)
Distractions page	3 (10)
Awards page	6 (19)
My progress page	12 (39)
Health calculators page	9 (29)
My map feature	0 (0)
Leaderboard	1 (3)
My quit plan page	5 (16)
Information pages	3 (10)
Online resources	0 (0)
Quitline	1 (3)
Crave community (Facebook, Twitter)	1 (3)
None of the above	6 (19)
Most helpful features	
Cigarette tracker	10 (32)
Craving tracker	6 (19)
Distractions page	2 (6)
Awards page	2 (6)
My progress page	5 (16)
Health calculators page	4 (13)
My map feature	0 (0)
Leaderboard	0 (0)

Charting was accomplished by developing summaries of the interview data in tables and figures. The final stage of analysis, mapping and interpretation of the data, involved comparing the interviewee's responses within each assigned category and

subcategory. At this time, finalized themes and subthemes were established. This final analytical framework was then transferred into a table. Representative quotes were selected to illustrate key themes and subthemes.

Results

Young Adult's Use of Crush the Crave

Young adults described being motivated to use the app because it was a novel quit support, with CTC being the first cessation app that most of them had interacted with. Young adults often expressed exhaustion with the lack of success or negative side effects associated with using other quit strategies and welcomed CTC as a new alternative. In addition, participants described alternative quit aids, namely, nicotine replacement therapies, Champix, and acupuncture as unfulfilling because they targeted one aspect of smoking, primarily nicotine addiction, and they described needing an intervention that addressed the habitual nature of smoking in their daily lives. CTC was, therefore, described as a much-needed, relevant quit support.

In relation to their use of the app, participants said that they primarily used the app to reflect on their smoking behavior at the end of the day or week when they had "down time." Despite the app being designed to intercept cravings and smoking in real time, young adults described their day-to-day life as not always amenable to having their mobile phone constantly with them. Therefore, even if they had cravings or smoked cigarettes throughout the day, they were not always able to document and reflect on these events until they had some free time.

Young adults also described waning engagement with CTC, where they used it most intensely when it was first downloaded, but their usage diminished over time. Young adults described 3 reasons for this: first, it aligned with their quit smoking trajectory—the less they smoked, the less they engaged with the app, particularly those who opted to quit cold turkey; second, they became disinterested in the app because of technological glitches and usability issues (eg, freezing, only functions with an Internet connection, and resources often located outside the app), offsetting the convenience of having the app at their side; and third, they abandoned their quit attempts.

Affordances of Crush the Crave

In this section, affordances that resulted from young adults' interactions with each component of CTC (credibility, social support, task support, and dialogue support) and young adult's subsequent experiences and practices in relation to quitting smoking are presented. Table 2 presents representative quotes to support the findings. Differences reflected in young women's and men's conversations are highlighted throughout.

Credibility

The credibility design component of CTC related to the app being developed and supported by credible agencies and research institutions. Knowing that the app was supported by these agencies afforded young adults promise—CTC was a quality quit smoking resource worthy of young adults' trust. As a result of this affordance, participants described trusting the app's intent to help them quit smoking, as well as its potential to influence a positive smoking cessation outcome.

Social Support

The social support design component refers to the parts of the app that aimed to provide young adults with opportunities to harness support from new and existing social networks. Interviews revealed that the social support aspects in the app were least helpful with smoking cessation. Young adults' experiences were the result of the following affordances: *constrained identity protection; competition with others;* and *constrained coparticipation*, which shed light on their low usage rates of the crave community features.

Constrained Identity Protection

The features and functions that aimed to provide social support, particularly the social media components of CTC, were described by participants as discordant with how they wanted to harness social support for quitting smoking. Although they did want support with cessation, they explained that posting on the "open" group Facebook page would reveal their smoking status and efforts to quit to others, especially to those in their personal networks. Young adults often spoke about changing social norms that increasingly reflected an intolerance of smoking to justify decisions to conceal their smoking and protect themselves from others' judgment. Furthermore, they said that if they posted about quitting, pressures to succeed would mount, and if they were not successful, then they feared being further judged as failing or weak.

In keeping with their efforts to protect themselves, young adults primarily practiced "lurking" and avoided posting on the social media channels made available through CTC. The few young adults who were open to posting about their quit smoking efforts on Facebook said that they would only post about successes in their quit smoking efforts when they were confident about their smoke-free status.

Inhibited Competition

The leaderboard function was discussed as a function that inhibited productive competition with other CTC end-users, in that the competition embodied defeating each other rather than getting to know and support each other. As a result, participants found the competition discouraging, as well as divisive, which was magnified by the anonymous nature of the leaderboard, inhibiting being able to connect with each other.

Constrained Coparticipation in Quitting

The CTC function to encourage end-users to find a "quit buddy" was confusing to most participants. They did not know if it should be a fellow smoker who was also trying to quit. As most young adults did not have access to someone who was also ready to quit, they often bypassed this function in the app. Young adults who did try to use the support of a quit buddy said that it was not helpful because the quit buddy was often not quitting the same way that they were.

Table 2. Representative quotes.

Design component and affordance	Young adults' experiences and practices
Credibility	
Promise	Trust in app intent: *It made it seem more legit. Like it was actually something making you try to quit smoking instead of, you know, maybe the other ones have ads in them and they try to make money off them. But this one clearly isn't. It's a little more genuine, you know? (male, nonsmoker, P24)*
Social support	
Constrained identity protection	Feelings of vulnerability: *And if you don't [quit] like people might get on you and nag you or be disappointed. I don't need that. I'll be disappointed in myself, that's enough. (male, smoker, P21)*
	Selective posting: *You know, I'm gonna kinda keep it to myself and work away at it. And then, once I have quit for good, then maybe I can go and say like, this is where I'm at this point in the app. I've quit smoking completely, or it's been 100 days or whatever the case may be if I wanna share my milestone or something like that. But [its]…nothing I would use on a regular basis for sure. (female, smoker, P26)*
Inhibited competition with others	Discouraging and divisive: *Someone whose successful and quit smoking isn't any better than someone that's struggling with it. Like, no, I didn't-I don't like that aspect… it just makes someone feel bad. (male, nonsmoker, P10)*
Constrained co-participation	Unhelpful: *I tried to do the quit buddy thing but the people that I was having as quit buddies were not as serious about quitting as I was so. (male, nonsmoker, P17)*
Task support	
Visibility of the benefits of quitting	Perception shift – health implications became relevant: *Yeah, I would check that one a lot because it would keep coming up and like showing I'm this close to being…back to like a nonsmoker for this aspect of my health, or this aspect...I guess it was more of a motivation to quit because some of them it takes like years to get back to a non-smoker health state and that just really made me think about what I was doing. (female, smoker, P14)*
Documentation of smoking behavior	Raised awareness of smoking habit: *I thought I knew how much I was smoking but this [smoke button] gave me a reality check….it was neat to see how much I was actually smoking. (male, smoker, P23)*
Mapping out smoking behavior	Irrelevant information: *For me, it's definitely not geographic triggers that make me wanna smoke. It's more like…like day-to-day triggers of either stress, or commuting traffic, and like bad news. You get bad news broken on you or you had a bad day it's like, yeah I'd be more tempted to pick up that cigarette. Those type of things. More than the, oh like I'm located at 24 Sussex here and, I have a temptation. (male, smoker, P3)*
Journaling about smoking behavior	Unhelpful (men): *No [I wouldn't put in my triggers]. I would just put the craving in but the triggers, my main triggers were coffee, which I have quite a few a day, friends, drinking, after a meal.. It's the first thing I wanna do. (male, smoker, P4)*
	Proactive about triggers (women): *I loved…how you could go in and track [journaling] what your triggers were so I could actually start to notice my triggers and stay away from them. I'm craving when I'm with friends drinking, or you know, my son's acting up, and stuff like that. So I could see what was actually causing me to want to smoke and I could actually try and change them. [For example], it was my friend's birthday party and I knew we were all going to be in the same house and she smokes in her house. So I had to come prepared. I brought gum, I brought mints, I brought everything I could think of because that was one of my main times when I smoke a lot…when I'm drinking. (female, smoker, P25)*
Weening from smoking	Procrastination: *I actually think that that's [quitting abruptly instead of weening off smoking] the way that it has to be done….Like it's almost like exercising and diet. You can't say you're gonna start next week. It's really like right now or never…. Like that's one thing that I think was the flaw in CTC. (female, smoker, P28)*
Counseling through cravings	"Backpocket" support: *I didn't personally call [the quit line] but it was just—I think it was more of just knowing that like, if at any time, if I didn't have someone to talk to or if there wasn't a feature on the app that I could use, [the quitline] was kind of like in my back pocket right? Like if I absolutely 100% needed to make a call, I could. (male, nonsmoker, P17)*
Dialogue support	
App reminding	Irritating: *I completely ignored them [notifications]. Actually, I'm pretty sure I had the notifications that were from the app all turned off. It just felt like a pop up, like another thing for me to click close on throughout the day. I completely paid no attention to it. (male, nonsmoker, P10)*
	Motivation to quit (men): *I found it [notification reminders?] was almost like having my girlfriend there, in a good way. So you're like, oh I haven't done this in two days, I didn't even realize, but my phone just reminded me. Better keep it going. (male, smoker, P3)*

Design component and affordance	Young adults' experiences and practices
Recognition of ability	Confidence boost: *It [what??] was just a reminder just to say like how good you're doing. And if there's nobody physically around you to be like, oh you're doing such a great job, then [the app] did it for you. Like yeah, keep up the good work, you've been this many days without a craving or whatever else. It was kinda like a motivational boost. (female, smoker, P11)*
Visibility of quit efforts	Motivation to quit: *It [what?] was like a visual of my day of smoking. And every day, you'd look at it, it went down and down and down, like it got better every day. So it was like a motivational thing to just look, like positive reinforcement. (female, smoker, P11)*
	Discouragement: *If you're having a bad day or a couple of bad days, seeing it on [the app] as a reflection [of your bad days] just like kicks you in the face even more, you know? (female, smoker, P22)*

Task Support

The task support functions were essentially aimed at supporting young adults in accomplishing their "task" of quitting smoking (eg, through tracking their behavior and identifying their triggers). Overall, young adults were enthusiastic about the helpfulness of the task support functions. Various experiences and new ways of dealing with their smoking behavior were achieved through the following affordances: *visibility of the benefits of quitting, documentation of smoking behavior, journaling quit smoking experiences, counseling through cravings, entertainment, and weening from habit.*

Visibility of the Benefits of Quitting

Participants described how the calculating functions in the app afforded them context to the benefits of quitting smoking. They described a shift in their perceptions about the impact of smoking on their health when, eg, they could actually see with one of the app calculators the amount of cigarette tar in lungs decreasing as fewer cigarettes were smoked. They explained that seeing improvements that were otherwise invisible (eg, tar in lungs) made them realize that smoking is a relevant concern for them, rather than something they do not have to worry about until later on in life.

Documentation of Smoking Behavior

Documentation of smoking behavior was afforded via the smoke and crave buttons. Although using this feature enhanced awareness of smoking patterns, some young adults, particularly young men, were not as inclined to document their smoking behavior as women, often describing it as "cumbersome" to have to manually enter their data.

Mapping Smoking Behavior

Although the map function was intended to geographically map out where smoking or cravings occurred, young adults did not see this feature of the app as helpful or relevant. They explained that geography in and of itself was not a trigger and that their smoking triggers were situational.

Journaling Quit Smoking Experiences

Journaling, whereby young adults were prompted to reflect on their behavior when they smoked in response to triggers, was afforded through the feedback function. In relation to this aspect of the app, young men were adamant that the triggers feedback function lacked benefit because they smoked when they chose to smoke, not because they were triggered. As they already knew what prompted them to smoke, recording their triggers was perceived as unhelpful. Young women, however, described how journaling lent to a more proactive approach toward dealing with cravings. They learned how to anticipate when and where they would have a craving and would implement measures to prevent smoking in these situations.

Counseling Through Cravings

Access to quitline counseling through the app was constructed by end-users as a "last resort." Although most indicated they would not likely use counseling, this feature was described as "nice to have" in the app if they "really" needed it. Despite comfort in knowing quitline counseling was available, actual use of the quitline was associated with discomfort. Many stated that they did not want to get on the mobile phone with someone they did not know. The few who did consult with the quitline, spoke despairingly about their experiences. Although it did help them overcome their craving, one young women (smoker) stated that talking to a quitline counselor made her "feel like an addict," and a young man (nonsmoker) complained about being "warned about how bad smoking is for you" from the quitline counselor.

Entertainment

The craving distractions in the app afforded young adults' entertainment during moments of boredom that prevented them from smoking. Although there were several types of distractions in the app (games, videos, music, and social media), young adults preferred games because they "kept their hands busy." On the other hand, young adults found YouTube videos and music less effective, because their hands were available to hold a cigarette and smoke while they watched a video or listened to music.

Weening From Habit

Although most young adults chose to quit cold turkey (particularly young men), there were a few who chose to use the quit plan laid out in the app. However, the weaning afforded via the quit plan was primarily described as something that promoted procrastination in relation to becoming smokefree. Young adults who chose to quit cold turkey stated that they avoided the quit plan for the same reason.

Dialogue Support

The dialogue support design component related to aspects of the app that aimed to positively reinforce the decision to quit smoking. Interviews with young adults revealed that, overall, the dialogue support features lent to positive experiences by young adults, as they engaged in quitting smoking with a few

exceptions. These experiences were the result of the following affordances: *app reminding*, *personalized reminding*, *recognition of ability*, and *visibility of progress.*

App Reminding

Reminders about quit smoking progress and the benefits of quitting, afforded via the push notifications, were described by most end-users as a source of irritation because every app now has push notifications. To avoid having to "swipe away" notifications to keep their mobile phone "clean," some end-users simply turned off the notifications feature. Reminding via the push notifications was well received by a few men but not women. Several men asserted that the notifications helped to keep them motivated in relation to their quit smoking goals.

Personalized Reminding

Reminders of personal motivations to quit were afforded via the personalization functions in the app (eg, providing end-users with the option to upload personal photos and quotes to motivate them in their cessation efforts). Young women found this method of reminding as motivational. Young men, however, described a general disinterest in customizing apps and technological platforms in general.

Recognition of Ability

Many participants reported that the awards offered through the app afforded them recognition of their quit smoking efforts, which was described as a "confidence boost." The receipt of an award affirmed that they were able to reach cessation milestones and essentially enhanced their confidence in accomplishing their ultimate goal of quitting smoking. Women, however, sometimes found the awards discouraging when they were struggling to reach them.

Visibility of Quit Efforts

Young adults described the visibility of their quit smoking efforts via the progress page in the app, whereby a graph displays cravings and cigarettes smoked month to month, week to week, day to day, and hour by hour, as motivational. Seeing a decrease in their cravings and smoking was an incentive to keep going. A few young women and men, particularly women, however, experienced discouragement and guilt on seeing this page when they were not making steady progress.

Discussion

Principal Findings and Implications

In this qualitative study, we examined the interaction between young adults and CTC for quitting smoking through an affordances lens, a relatively novel approach to mobile health (mHealth) research. This approach enabled a detailed understanding of the underlying affordances that influenced young adults' quit smoking efforts while using CTC. Both productive and unproductive affordances for aiding in young adults' quit smoking efforts were identified. Although all affordances in relation to the social support component of the app were unproductive, with a few exceptions, the other components of the app were largely productive. These findings serve as a strong foundation for identifying practical steps that can be taken to modify and strengthen CTC and smoking cessation apps more broadly.

The gaps in knowledge in relation to the underlying mechanisms of mobile-based health interventions, particularly in the area of tobacco control, are what motivated the use of sociomateriality theory and an affordances approach. Although the use of sociomateriality theory and an affordances approach is a relatively novel approach to mHealth research, its use in examining CTC enabled a detailed understanding of the underlying mechanisms (affordances) of the sociomaterial relationship (CTC app and young adult) that influenced young adults' quit smoking efforts. Researchers have described this knowledge as a "black box" because most eHealth evaluations are focused on outcomes rather than the underlying factors and mechanisms [29-31]. As demonstrated in the findings of this study, the specificity and depth that such an approach provides are of utmost value for understanding how to move these interventions forward. This is because the underlying mechanisms of these interventions that lend to both positive and negative experiences and practices in relation to health behavior change are brought forward—articulating practical and tangible ways in which these interventions may be modified to strengthen effectiveness and be scaled up. In relation to CTC, productive affordances can be capitalized upon to enhance uptake and impact (eg, visibility of quit smoking benefits, recognition of end-user efforts, and reminding of end-users' progress), and unproductive affordances of these interventions can be addressed (eg, developing CTC for gradual quitting). In short, the use of sociomateriality theory and an affordances approach removes a lot of guesswork in relation to linking up end-users' experiences and practices to improvements in an eHealth intervention.

By focusing on affordances (action possibilities that result from imbrication between an app and a population) rather than on the app's features and functions, mechanisms that result from the interaction between the app and an individual are highlighted. In this regard, the success of an app does not lie in the features in and of themselves but in the potential action possibilities that the features and functions embody for health behavior change. An affordances approach reveals which action possibilities of an intervention have the most positive effect in relation to ongoing end-user engagement, end-user appeal, and the target behavior change. Once productive affordances are identified, then features and functions can be designed to capitalize on these affordances. Indeed, the productive affordances revealed in this study may serve as a framework for improvement of existing smoking cessation apps and development of future apps.

Productive Affordances

Productive affordances identified in this study provide useful directions for capitalizing and scaling up some aspects of CTC, as well as other apps for smoking cessation. A few noteworthy affordances should be considered. For example, backing by credible agencies resulted in affording young adults promise that the app would indeed help them quit smoking. Despite hundreds of quit smoking apps being available, CTC had an edge among the young adult population because of its backing.

It is, therefore, recommended that those who are developing evidence-informed apps make the institutions that support the app explicit in their marketing.

Also noteworthy is the affordance of documentation of smoking behavior (eg, cigarettes smoked or cravings experienced), which enabled young adults to be more self-aware of their smoking and craving patterns. Young adults' desire to track their behavior was reflected in their high use of the app's tracking features. The popularity of tracking features in smoking cessation apps is also supported in the literature and has been identified as a key reason by end-users to stay engaged with smoking cessation apps [32,33]. The importance of affording young adults with the ability to document their smoking behavior is brought forward in light of recent suggestions that successful behavior change is dependent on engagement with an intervention [34,35]. Considering promising developments for affording "smart" documentation via sensors and wearables, this productive affordance may be leveraged to strengthen engagement, while at the same time reducing end-user data input burden.

Affording young adults' visibility of quit benefits through the health calculators, which provided tailored information about the health benefits of reducing and stopping smoking, countered some optimism bias in relation to the predicted effects that smoking had on them. This optimism bias among young adult smokers is recognized in the literature [31-33]. For example, in an evaluation of the potential use of health-related factors to motivate smoking cessation among college students, it was found that almost half of smokers thought that their health was better or the same as their nonsmoking counterparts, almost all of the smokers did not think that their health was affected by smoking, and nearly half thought that quitting would bring little to no benefit to their health [36]. More recently, young adult smokers were found to demonstrate optimistic bias in relation to their risk perception and health-related behaviors for cancer, respiratory disorders, and cardiovascular diseases [37]. In a qualitative study about how young adults initiate smoking, young adults could not recall the health risks of smoking, struggled to assess the likelihood of developing health problems from smoking, and rarely saw health risks as personally relevant, often citing the tobacco industry's argument that the role of smoking in disease could not be easily delineated [38]. The findings of this study reveal how affording visibility in relation to the benefits of quitting via physiological markers (eg, lung improvement) is a breakthrough accomplishment of mobile-based interventions in young adult smoking cessation, and smoking cessation in general, and may be leveraged as embodied motivation for cessation.

Although affording end-users' visibility of their quit efforts and recognition via the gamification features of the app (eg, awards and progress statistics) was effective in motivating young adults to continue with their smoke-free efforts, some young adults found these functions discouraging when they struggled or relapsed. The literature indicates that although points, statistics, and badges are an important element of gamification features for motivating behavior change, motivation is only 1 of the 3 important elements of gamification for health behavior change [39]. In addition to motivation, capability and behavioral triggers must also be considered and integrated into gamification features (eg, through problem solving, storytelling, and fantasy) [40]. Given that quitting smoking is a process known to frequently encompass struggles and relapse [41], the importance of enhancing self-efficacy for cessation and awareness of smoking triggers should be understood as key. Unless an individual is on a straightforward success trajectory, which is seldom the case, it is possible to see how a focus on gamification to strengthen motivation is unreliable as a sole influence for smoking cessation. This is consistent with recent research indicating that an exclusive focus on points, rewards, leaderboards, or badges has an unreliable impact on behavior change because it only strengthens motivation [39]. The findings of this study extend knowledge in this area by highlighting how the affordances of visibility of quit efforts and recognition for gamification features are important but insufficient.

Unproductive Affordances

Unproductive affordances identified provide useful directions for improving the CTC app. Although the social support component of the app was designed to provide young adults with opportunities to harness social support, in keeping with previous findings [37], wherein the CTC Facebook posts were primarily posted by a CTC moderator rather than a young adult smoker, young adults seldomly posted on the CTC Facebook page. The findings of this study indicate that this component afforded constrained identity protection, inhibited productive competition, and constrained coparticipation. Preservation of and efforts to promote a positive self-presentation pervaded young adults' discussions in relation to the social support design component of the app, especially in relation to the CTC Facebook page. Young adults' avoidance of posting on the CTC Facebook page aligns with literature, describing health communication on social media as being at odds with the need to present oneself as a positive, appealing community member [42,43]. According to researchers who examined self-presentation strategies employed by young adults on Facebook [43], this platform is widely used to enhance one's self-presentation versus derogate oneself (eg, presenting struggles or negative events). Interestingly, however, Bereket-Bojmel and colleagues [43] found that those who did engage in self-derogation were rewarded with social network support (demonstrated through increased numbers of likes and comments). In a study that examined outcomes of positive versus honest presentation on Facebook, it was found that honest self-presentation had an indirect effect on well-being through perceived social support [44]. Although a private (vs the public CTC Facebook page) Facebook group or forum may address some concerns and promote more honest self-presentations, more research is needed to understand how to effectively provide opportunities for social support in the context of young adult smoking cessation via eHealth.

The influence of normative pressures also appeared to be a factor in young adults' avoidance of the social support functions in CTC. Shifting social norms, whereby smoking has become increasingly stigmatized, underpinned reluctance to harness support for cessation efforts within their own networks as well as on the CTC Facebook page. Unintended consequences of tobacco control initiatives include stigmatization of smokers

[45,46]. It is well recognized in the literature that smoking stigma leads to social isolation, decreased self-esteem, shame, perceived negative judgment, and increased stress [47]. The findings of this study suggest that the effects of smoking stigma extend into mobile environments, creating a barrier to the use of social media as a social support tool in apps for cessation. Engaging end-users in future app development is needed to ensure social support features are acceptable to end-users, reflecting their needs and preferences for identity protection, rather than risking reinforcement of smoking stigmas.

The quit buddy function did not afford coparticipation in quitting smoking and was, therefore, also unsuccessful. Young adults cited issues with finding someone who also wanted to quit at the same time, already having an established support network, and discomfort in harnessing support through a quit buddy. Similar difficulties were reported with a text messaging–based intervention for young adults that included a quit buddy component (quit buddy was another intervention participant) [8]. End-users reported problems with their buddy's availability, including being in different stages of the quitting process, on different schedules or in different time zones, already having established support, or being uncomfortable with the idea of a quit buddy [8]. Although evidence suggests that a buddy system works well in the context of a smokers' clinic [48], this study's findings add to emerging evidence that a buddy system has yet to effectively translate to mobile cessation interventions, and specifically brings attention to coparticipation as the key mechanism for this type of social support to effectively work.

Affording weening from smoking through a gradual quit plan was also unproductive, with young adults primarily opting to quit abruptly once they downloaded the app without any gradual reductions in smoking. This finding complements Ubhi and colleagues' [49] insights, with 50% of their sample consisting of young adults, who found that most (84%) participants opted to quit on the date of their registration versus gradual quitting using the Smokefree28 app. The young adults in this study found that gradual quitting made them procrastinate about actually quitting and may explain emerging evidence that quitting abruptly is better suited to those ready to quit, whereas gradually quitting aids those who are not ready to quit [50]. Future developers of cessation apps for young adults should include an option for quitting abruptly and work with end-users to identify tools and resources to support this approach to quitting.

Gender-Related Influences

There were important differences in young women's and men's preferences in relation to affordances. Young women expressed an appreciation for affordances that helped them become more self-aware and develop new coping skills (eg, journaling) and personal reminders about why they wanted to quit smoking. In contrast, most young men explained that they did not need reminding about why they should stop smoking and did not feel the need to journal about their smoking. Men's preference for app features that reinforced autonomy and ability to quit on their own appeared to reflect masculine norms and ideals (eg, men are strong and independent) [51], and therefore provide promising directions for developing apps that appeal to young men who smoke.

The CTC health calculators afforded women and men meaningful and impactful information about the health effects of smoking. This finding is particularly important in relation to men who often ignore health-related information, rendering them a hard-to-reach population to engage in health behavior change [52]. The "visibility" into personal health afforded via the data presented by health calculators, however, seemed to capture men's attention and interest in improving their health by offering objective measures by which men could track their progress. Perhaps, these personal health data play into men's preferences for autonomy and self-monitoring and management to support behavior change. Mobilizing masculinities for positive health behavior change has recently become a focus in men's health research [53,54]. Although more research is needed, affording visibility of personal health data presents as a promising way to mobilize positive health practices in men via mobile phone apps.

Limitations

There are limitations in using self-report to capture young adults' interactions with the CTC app in their everyday lives. There may be affordances and constraints that were not captured during the interviews. Some young adults were interviewed up to a year after they entered the RCT study, potentially limiting their ability to recall their experiences. To minimize this limitation, reflective questions were posed during interviews to assist participants in recalling events and experiences. Although the sample included individuals who successfully quit smoking as well as those who did not, the latter were the largest group. Further research is needed to determine if affordances identified in this study are directly linked to the app's efficacy in supporting cessation. In addition, the sample was primarily white, limiting the applicability of the findings to other population groups. Given the similarities between this study sample and the RCT sample [9], however, this study findings appear to hold strong transferability to the young adult smokers' sample included in the RCT study and, therefore, Canadian young adult smokers in general.

Finally, although the speed of technology and changes in the sophistication of end-users are challenges in claiming the application of eHealth research to future interventions, the focus on affordances lent through the app versus the actual features of the app provides a strong grounding from which to improve existing and future innovations. For example, affording visibility of quit smoking benefits is likely to remain an important goal even as eHealth and end-user sophistication progresses. Although new affordances will emerge with new innovations and new contexts, the productive and unproductive affordances found in this study will remain ever-important considerations in future mobile-based smoking cessation interventions targeting young adults.

Conclusions

This is one of the first studies in the area of eHealth research to employ sociomateriality theory. As such, this study makes a significant contribution to addressing the "black box" of

knowledge in relation to how and why aspects of eHealth interventions succeed or fail. Through this study, both productive and unproductive affordances of CTC for young women's and men's quit smoking efforts were revealed. The productive affordances identified in this study can serve as a beginning framework for improving CTC and developing scalable health behavior change apps.

Conflicts of Interest

None declared.

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Abbreviations

CTC: Crush the Crave
eHealth: electronic health
mHealth: mobile health
RCT: randomized controlled trial

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Original Paper

Effective Behavioral Changes through a Digital mHealth App: Exploring the Impact of Hedonic Well-Being, Psychological Empowerment and Inspiration

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Abstract

Background: New mobile health (mHealth) software apps are emerging and are providing the foundation to radically transform the practice and reach of medical research and care. For this study we collaborated with Quit Genius, a cognitive behavioral therapy (CBT) based mHealth app that helps users quit smoking, to explore the effective design of a digital mHealth app; one that delivers important benefits to its users and helps them change their behaviors for a healthier lifestyle.

Objective: The specific aims of this study were to (1) explore the key role of CBT program progress, (2) examine the gamification design app elements that deliver significant benefits (ie, empowerment, well-being, inspiration) to users, (3) explore the effectiveness of these app elements to help users quit smoking or reduce the number of cigarettes smoked, and (4) identify and describe any potential drivers and hindrances arising from the app design elements.

Methods: We developed an online survey and sent an email invitation to 4144 individuals, who had previously or were at the time using the Quit Genius mHealth app, to encourage participation in the study. We matched the online survey data with objective app usage data of the study participants.

Results: A dataset of 190 completed responses was used. At the time of the survey, respondents had completed an average of 60% of the CBT program in the Quit Genius mHealth app. Of the respondents, 36.3% (69/190) noted to have quit smoking successfully after using the Quit Genius app. As for those who remained smokers after using the app (N=121), the number of cigarettes smoked per day was significantly reduced by 59.6%. The ability of the app to enhance users' hedonic well-being and psychologically empower them in their daily lives was identified as being key in helping users quit smoking. Specifically, the results show that users whose well-being was enhanced through the app were 1.72 times more likely to quit smoking successfully. Moreover, a one-unit increase on a 7-point Likert scale in the app's ability to empower smokers in their daily lives led to a reduction of cigarettes smoked per day of 53%. The app's inspiration to users, however, was negatively associated with quitting success and the reduction in cigarette smoked per day.

Conclusions: The findings offer important insights for the effective design of digital mHealth apps. Specifically, we find that perceived psychological empowerment and enhanced hedonic well-being from the mobile solution may be a more impactful way to support the effectiveness of mobile cognitive behavioral therapy for smoking cessation than eliciting strong inspiration.

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KEYWORDS

mHealth; gamification; cognitive behavioral therapy; empowerment; well-being; inspiration; mobile app; behavior change and prevention; digital

Introduction

These days, many people look at their phone hundreds of times per day [1] and it is digital services such as Instagram or WeChat that extensively permeate peoples' lives [2-4] and dramatically affect their personal well-being, either positively, by connecting people, or negatively, by creating stress and anxiety [5]. This very high engagement level with one's smartphone offers an opportunity for mobile health (mHealth) apps to help people lead healthier lifestyles and engage in positive health behaviors such as quitting smoking.

Gamification, defined as "the use of game design elements in non-game contexts" [6], can serve as a natural bridge between the existing innate nature of play, and repurposing games to enhance people's health. Tailoring motivational affordances or "gamification tactics" to a task has been noted to be critical to successful gamification [7,8]. Goal-setting, for instance, has been noted as an effective tool for enhancing self-motivation [9]. Moreover, enhancing self-motivation incites the "wanting to do it oneself" psychology that is present from childhood and integral to an individual's concept of self [10]. It is worth noting that individuals proactively seek play, something that gamified experiences theoretically automate [11,12]. With the advent of digital multimedia and resulting virtual worlds, there has been a surge in multidisciplinary interest in the short-term and longer-term applications of gamification [13,14].

Gamification revolves around a complex interaction between physical (eg, vision or motion), psychological and social domains. These domains can be understood to be driven by an intrinsic motivation to satisfy human needs [15]. Gamification elements act as affordances to enhance intrinsic motivation, leading to different psychological states such as arousal, excitement, and contentment [15,16]. In turn, these may drive behavior change. Gamification is increasingly used as a design strategy when developing behavior change support systems in the healthcare domain [17]. For instance, studies have shown that aspects of gamification and program progress in gamified applications can be twice as effective in frequency of self-monitored exercise for weight loss programs compared to a standard paper diary [17]. Ultimately, applications that incorporate behavior change techniques and program progress thereof tend to be associated with increased intervention effectiveness [18,19].

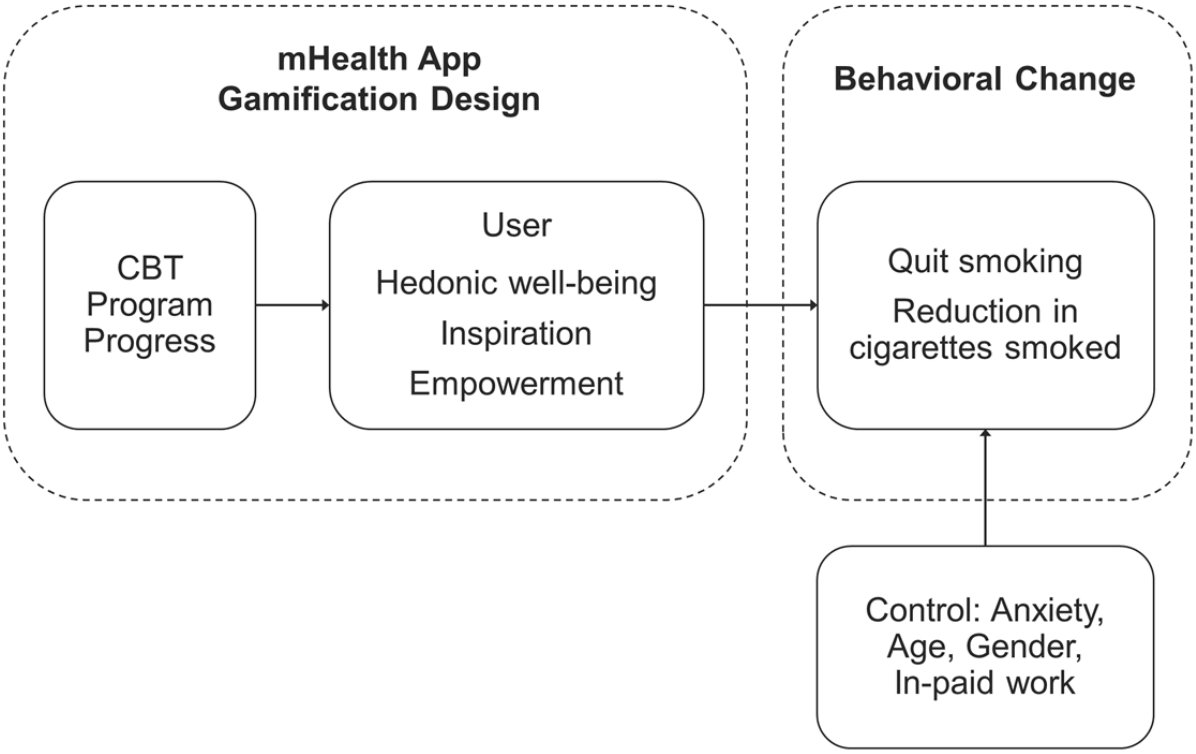
In this study, we examined how various gamification tactics affect behavior change by psychologically empowering users, enhancing their well-being, and giving them inspiration. We identified challenge–ability balance, meaningful framing, personalization, fun or user-centric design as key gamification tactics for our study based on prior research [16,18]. Such gamification tactics, among others, have been identified to elicit behavioral change within the health and healthcare settings, yet there is no clear pattern as to the type of behavioral change strategy that is most effective [8,18].

We complement and extend prior work by testing to what extent, if at all, mobile health (mHealth) solutions can positively impact an individual's well-being [20]. In our study, well-being is defined as the ability of the mHealth app to contribute to users' happiness, increase their overall life satisfaction, and help them become more productive at work [21,22].

Specifically, building on and extending prior research that studied behavioral change in the context of gamification [18,23], our research asks whether inspiration (the extent to which the mHealth app, through a gamified journey, motivates users to be the person they want to be, and inspires users to live a healthier life) can be achieved through gamified app design and explores its impact on behavioral change. Based on prior work on psychological empowerment, empowerment is defined as intrinsic motivation that manifests in four cognitions; meaning, competence, self-determination, and impact [24,25]. In the context of our study, we tested the extent to which the gamification design of an mHealth application helps users think of behavioral change differently, realize that mobile apps can improve their health, increase willpower and ultimately change their behavior.

For this research, we conducted an online survey with users of a cognitive behavioral therapy (CBT)-based mHealth app that helps them quit smoking to (1) explore the key role of CBT program progress, (2) examine the gamification design app elements that deliver significant benefits (ie, empowerment, well-being, inspiration) to users, (3) explore the effectiveness of these app elements to help users quit smoking or reduce the number of cigarettes smoked, and (4) identify and describe any potential drivers and hindrances arising from the app design elements. Figure 1 illustrates the research model that guides this work. A set of confounding variables is also controlled for, given that demographics and anxiety have been found to influence the effectiveness of behavioral change [19].

Figure 1. Research model. CBT: cognitive behavioral therapy; mHealth: mobile health.



Methods

Description of the mHealth App

We worked together with Quit Genius (QG), an mHealth intervention that delivers a digital CBT program to help people quit smoking. The digital CBT program is split into four stages consisting of 39 steps. The steps are made up of audio sessions, animated videos, reflective exercises and quizzes, which focus on identifying and altering the thoughts and behaviors that keep people smoking. Figure 2 illustrates QG's gamification tactics; eg, challenge—ability balance, meaningful framing, personalization, fun and user-centric design. The protocol of this research received ethical approval by Imperial College London.

Procedure

We designed and conducted an online survey, which was sent out to QG users via email in November and December 2017. To incentivize participation, we offered a free membership to the premium features of the QG app. This included access to additional relaxation techniques, post-quit date support and a social community to interact with other smokers. Furthermore, as part of the premium membership users have access to trained Quit Smoking Coaches who analyze their smoking patterns and share personalized tips to help app users with triggers that make them want to smoke and to help keep them motivated to quit smoking. Individuals received access to the premium features of the app after they completed the survey. Of 4144 survey recipients, 217 (5.24%) individuals responded to the survey. QG also provided the objective program progress data of respondents to the survey, following users' consent. For each respondent, we matched the survey response data with program progress data (% completion rate of the app's various steps as part of the quit smoking journey). Responses with excessive missing values were omitted, which resulted in a dataset of 190 completed responses.

Online Survey

Whenever possible we employed multi-item scales from published work. Specifically, to capture hedonic well-being, we adapted three items from Ryff's seminal work on psychological well-being [21] and Guevarra and Howell's published hedonic well-being scale [22]. To capture psychological empowerment, we adapted four items from Dahl et al [25] and Park et al [26] published psychological empowerment and enablement scales, respectively. We measured inspiration and anxiety by adapting two items from Park et al [26] and Eisingerich et al [27] published work, respectively. To avoid respondents' fatigue and manage response rate and quality, we kept the online survey as short as possible. Table 1 shows the detailed measurement items employed in the survey. The reliability of two item-measures was tested by assessing Pearson correlation coefficients; while the reliability of measures with more than two items were tested by examining the measures' Cronbach's alpha (Table 1).

Figure 2. Screenshots of Quit Genius app.

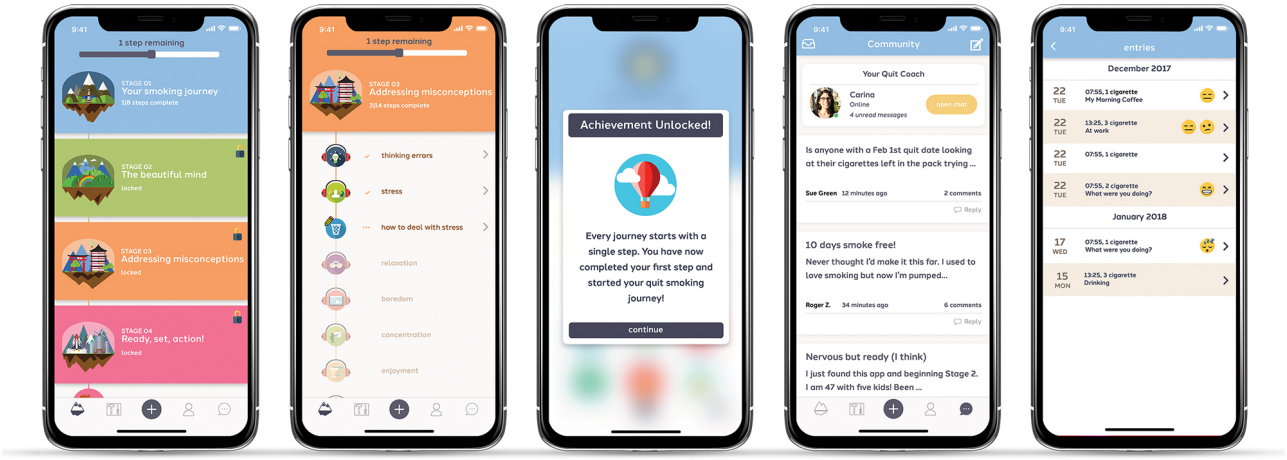


Table 1. Measurement items and reliabilities.

Constructs and items *(1=not at all, 7=very much)*	Reliabilities
Hedonic well-being	α=.88
Quit Genius contributes to my happiness today.	
Quit Genius has increased my overall life satisfaction.	
Quit Genius has helped me to be more productive at work.	
Psychological empowerment	α=.90
Quit Genius has helped me think about smoking in a different way.	
Quit Genius has helped me change my behavior.	
Quit Genius has helped me increase my willpower to quit.	
Quit Genius has helped me realize that mobile apps can improve my health.	
Inspiration	*r*=.82
Quit Genius motivates me to be the person I want to be.	
Quit Genius inspires me to live a healthier life.	
Anxiety	*r*=.50
I am worried that Quit Genius won't work for me.	
I am afraid that Quit Genius could be a waste of my time and effort.	

Statistical Analysis

We used the SPSS 24.0 software package for regression analyses. Binary logistic regression analyses were conducted to estimate the probability of being smoke-free after using the QG mHealth app. Furthermore, we explored the reduction in number of cigarettes smoked by regressing this variable on both program completion and the app gamification design elements, after having used a log transformation. Additionally, we set out to test to what extent progressing with the QG program equipped app users with a sense of well-being, empowerment and inspiration, thereby leading to these behavioral changes; ie, (1) success rate of being smoke-free and (2) number of cigarette reductions per day. Our first step was to examine the characteristics of the sample. Furthermore, we investigated QG's gamification design and whether it provided three critical psychological benefits, namely empowering its users, enhancing their well-being, and inspiring them. This effect was compared between users who paid for the app and those users who used the free version of the app. The paid version of the app offers additional and personalized information. In addition, success rates of being smoke-free and reduction in cigarettes smoked per day were examined, respectively, by considering the ability of the app to empower users, boost their well-being, and inspire them, together with control variables including user anxiety, age, gender, and employment status.

Results

Characteristics of the Sample

Progress of the program was examined by obtaining the objective usage data from QG. Specifically, for each respondent, the exact percentage of completion of the digital CBT program was obtained in relation to the number of steps of the program they had completed. The QG app has a total of 39 steps. Thus,

if respondents completed all 39 steps at the time of the survey, they were assigned a score of 100% for completion. Figure 3 shows the number of users for each program progress at the time of survey. The largest group (67 of 190 respondents, 35.3%) of program completion were users who had completed the full program (100%). Of note, 26% of program completion is the second largest group (48 of 190 respondents, 25.3%) as this marks the end of the app's free trial. A small group of respondents (14 of 190 respondents, .1%) had no record for program completion because they used different email addresses when they signed up for the survey and when they signed-up for the app.

The descriptive statistics for the final sample are reported in Table 2. In brief, respondents were on average 36 years old. Of the respondents, 52.6% (100/190) were female and 67.9% (129/190) were currently employed. On average, respondents had completed 60% of the digital CBT program in the QG app. Respondents had smoked an average of 15 cigarettes a day and had been smoking for an average of 17 years before using the QG app. Most of the respondents had tried to quit smoking before using the QG app (142/190, 74.7% tried to quit smoking up to 10 times; 19/190, 10.0% tried to quit smoking more than 10 times).

After using QG, 36.3% (69/190) of respondents noted to have quit smoking successfully. As for those remaining smoking after using the app (N=121), the number of cigarette reduced significantly by 59.6% (M_{before} 16.15, SD 7.89 vs M_{after} 9.63, SD 6.28; t_{120}=10.97, P<.001). Correlation results of all noted variables are shown in Table 3.

Relationship Between Program Completion and Psychological Benefits Offered by the App

As a first step, we regressed three potential psychological benefits offered by the app (empowerment, well-being, and inspiration) on program completion. The results (N=176) showed that the percentage of program completion of the app both significantly predicted enhanced user empowerment ($F_{1, 174}$=13.87, beta=.27, t=3.72, P<.001) and user inspiration ($F_{1, 174}$=5.91, beta=.18, t=2.43, P=.02). Users' well-being afforded by the app was marginally associated with the percentage of program completion ($F_{1, 174}$=3.60, beta=.14, t=1.90, P=.06).

Relationship Between Users of the Paid vs Free Version of App and Psychological Benefits Offered by the App

As a second step, a set of t-tests was performed, which revealed that there was a significant difference between users of the paid vs the free version of the app in all three psychological outcomes afforded by the app. This included well-being (M_{paid} 4.26, SD 1.44 vs M_{free} 3.73, SD 1.59; t_{174}=2.26, P=.03), empowerment (M_{paid} 5.55, SD 1.23 vs M_{free} 4.78, SD 1.44; t_{174}=3.74, P<.001), and inspiration (M_{paid} 5.33, SD 1.43 vs M_{free} 4.83, SD 1.49; t_{174}=2.22, P=.03). Thus, the results suggested that users of the paid version were more likely to receive the psychological benefits offered by the app, compared to users of the free version of the app.

Successfully Quitting Smoking After Using the App

A binary logistic regression was performed to estimate whether the probability of being smoke-free after using the app (1=remaining a smoker, 2=being smoke-free) was associated with the different app benefits. Specifically, the results (see Table 4) demonstrated that both well-being (P=.01) and inspiration (P=.05) made a significant contribution to predicting the likelihood of quitting smoking.

When hedonic well-being was strengthened by one unit (1-point scale out of 7-point scales) the odds ratio was 1.72 times as large, and therefore respondents whose well-being was enhanced were 1.72 times *more* likely to quit smoking successfully. Interestingly, when inspiration was raised by one unit, the odds ratio was .66 times as small and thus a respondent who felt inspired by the app was 1.51 times more likely to remain a smoker (1/.66).

Figure 3. Cognitive behavioral therapy program completion at the time of the survey.

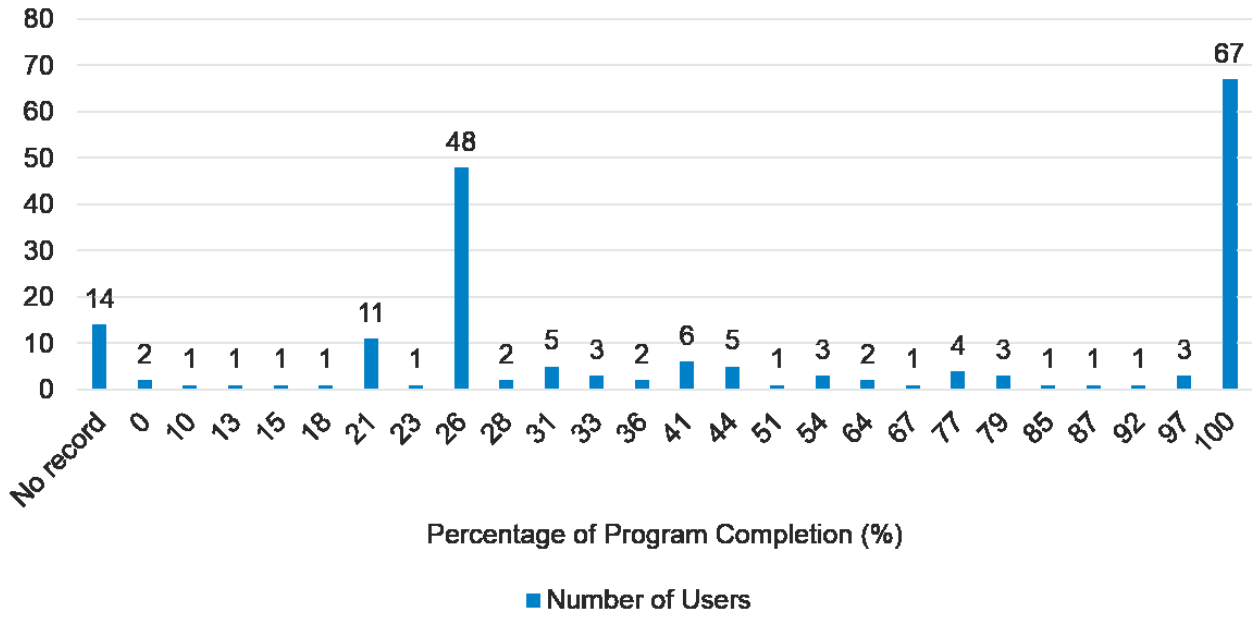


Table 2. Survey respondents: descriptive statistics. Likert scale anchors for users' well-being, empowerment, inspiration, anxiety was from *1=not at all to 7=very much*.

Description	Mean (SD)
(1) Percentage of program completion	60.31(35.34)
(2) How many cigarettes did you smoke a day?	15.44 (8.47)
(3) How many years had you been smoking for?	16.92 (10.55)
(4) Enhancement of user well-being	4.13 (1.56)
(5) Empowerment of users	5.28 (1.38)
(6) Inspiration of users	5.18 (1.49)
(7) User anxiety	2.77 (1.38)
(8) Age	36.69 (10.23)
(9) Gender (1=*male*, 46%; 2=*female*, 53%; 3=*other*, 1%)	1.55 (.52)
(10) Are you currently in paid work? (1 =*no*, 32%; 2=*yes*, 68%)	1.68 (.47)
(11) Have you tried to quit in the past? (1=*no*, 15%; 2=*yes*, 85%)	1.85 (.36)
(12) Are you currently smoke-free? (1=*no*, 64%; 2=*yes*, 36%)	1.36 (.48)

Table 3. Correlation table.

Variable	1	2	3	4	5	6	7	8	9	10	11	12
(1) Program completion	1.00											
(2) How many cigarettes did you smoke a day?	-.04	1.00										
(3) How many years had you been smoking for?	.12	.33[a]	1.00									
(4) Have you tried to quit in the past? (1=*no*, 2=*yes*)	.02	.06	.03	1.00								
(5) Are you currently smoke-free? (1=*no*, 2=*yes*)	.11	-.11	-.08	-.06	1.00							
(6) Enhancement of user well-being	.14	.11	.07	-.09	.38[a]	1.00						
(7) Empowerment of users	.27[a]	.09	.09	-.02	.31[a]	.75[a]	1.00					
(8) Inspiration of users	.18[b]	.04	.07	-.07	.17[b]	.66[a]	.79[a]	1.00				
(9) User anxiety	-.12	-.07	-.03	.11	-.28[a]	-.52[a]	-.46[a]	-.30[a]	1.00			
(10) Age	.15[b]	.26[a]	.76[a]	.07	-.01	.03	.08	.05	.06	1.00		
(11) Gender (1=*male*, 2=*female*, 3=*other*)	.08	.17[b]	.16[b]	.01	-.09	-.08	.04	-.02	.06	.22[a]	1.00	
(12) In paid work? (1=*no*, 2=*yes*)	-.04	-.08	-.09	-.03	.11	-.07	-.004	-.04	.04	-.01	-.02	1.00

[a]Correlation is significant at the .01 level (2-tailed).

[b]Correlation is significant at the .05 level (2-tailed).

Table 4. Quitting smoking successfully after using the app (χ^2_7=40.4, N=190). App benefits and anxiety scored from 1 for *not at all* to 7 for *very much*. Gender scored 1 for *male*, 2 for *female*, 3 for *other*. In-paid work scored 1 for *no*, 2 for *yes*. Importantly, as shown in Table 5, a 1-unit increase on a 7-point Likert scale in the app's ability to *empower* smokers in their daily lives led to a *greater reduction* in number of *cigarettes smoked* by 53% (beta=.53, *t*=3.26, *P*=.001). Moreover, the results showed that a 1 unit increase on a 7-point Likert scale in the app's ability to *inspire* smokers led to a *weaker reduction* in the extent of cigarette reduction by 37% (beta=-.37, *t*=-2.58, *P*=.01).

Predicator	β (SE)	OR[a]
App benefits		
Well-being	.54 (.19)	1.72[b]
Empowerment	.41 (.25)	1.50
Inspiration	-.41 (.21)	.66[c]
Control		
Anxiety	-.16 (.15)	.85
Age	.00 (.02)	1.00
Gender	-.31 (.35)	.73
In-paid work	.73 (.38)	2.07
Constant	-3.23 (1.39)	.04[d]

[a]OR: odds ratio.

[b]*P*<.01.

[c]*P*=.05.

[d]*P*<.05.

Table 5. Reduction in number of cigarettes smoked for remaining smokers (R^2=.21, $F_{7, 113}$=4.28, *P*<.001).

Predictor	β (SE)	*t*
App benefits		
Well-being	.18 (.04)	1.36
Empowerment	.53 (.05)	3.26[a]
Inspiration	-.37 (.04)	-2.58[b]
Control		
Anxiety	.05 (.03)	.52
Age	.06 (.01)	.69
Gender	.07 (.08)	.77
In-paid work	-.08 (.08)	-.90
Constant	.05 (.28)	.17

[a]*P*<.001.

[b]*P*<.05.

Remaining a Smoker after Using the App

For those who remained smokers (N=121), any changes in the number of cigarettes they smoked was explored. Firstly, we normalized the number of cigarette reduction by using log transformation and then regressed this outcome variable on both program completion and app elements. As shown in Table 5, a significant regression equation was observed ($F_{7, 113}$=4.28, *P*<.001) with an $R^2$of .21.

Mediation Analyses

A set of mediation tests were conducted to examine: (1) program completion, three psychological benefits, number of cigarette reduction; and (2) program completion, three psychological benefits, probability of being smoke free by using syntax *binary mediation* in Stata 14.2 which allows either continuous or dichotomous outcome variables together with multiple mediators. Table 6 shows the detailed mediation test results.

Table 6. Mediation test results. Model 1 tests the mediational role of well-being, empowerment, and inspiration as mediating the relationship between program completion (as independent variable) and number of cigarette reduction per day (as dependent variable). In addition to the indirect effects, a direct effect of program completion on cigarette reduction was reported. Model 2 tests the mediational role of well-being, empowerment, and inspiration as mediating the relationship between program completion (as independent variable) and the probability of being smoke-free (as dependent variable). In addition to the indirect effects, a direct effect of program completion on the probability of being smoke-free was reported.

Mediator variable and model	R^2	F (df)	χ^2(df)	β (SE)	t	Z	95% CI
(1) Cigarette reduction							
Mediator variable model							
Predicating well-being							
Program completion	N/A[a]	N/A	N/A	.00 (.01)	1.32	N/A	N/A
Predicating empowerment							
Program completion	N/A	N/A	N/A	.01 (.01)	2.88[b]	N/A	N/A
Predicating inspiration							
Program completion	N/A	N/A	N/A	.01 (.01)	1.34	N/A	N/A
Dependent variable model							
Predicating cigarette reduction							
Program completion	.00	.03 (1, 113)	N/A	.00 (.00)	.17	N/A	(-.00 to .00)
Dependent variable model							
Predicating cigarette reduction							
Program completion	.15	6.18 (4, 110)[e]	N/A	-.00 (.00)	-1.11	N/A	(-.00 to .00)
Well-being	N/A	N/A	N/A	.05 (.04)	1.21	N/A	(-.03 to .13)
Empowerment	N/A	N/A	N/A	.18 (.05)	3.33[b]	N/A	(.07 to .29)
Inspiration	N/A	N/A	N/A	-.11 (.04)	-2.62[c]	N/A	(-.20 to -.03)
(2) Probability of being smoke-free							
Mediator variable model							
Predicating well-being							
Program completion	N/A	N/A	N/A	.01 (.00)	1.90[d]	N/A	N/A
Predicating empowerment							
Program completion	N/A	N/A	N/A	.01 (.00)	3.72[e]	N/A	N/A
Mediator variable model							
Predicating inspiration							
Program completion	N/A	N/A	N/A	.01 (.00)	2.43[c]	N/A	N/A
Dependent variable model							
Predicating being smoke-free							
Program completion	N/A	N/A	2.10 (1)	.01 (.00)	N/A	1.44	(-.00 to .02)
Dependent variable model							
Predicating being smoke-free							
Program completion	N/A	N/A	28.93 (4)	.00 (.01)	N/A	.59	(-.01 to .01)
Well-being	N/A	N/A	N/A	.54 (.18)	N/A	2.93[b]	(.18 to .90)
Empowerment	N/A	N/A	N/A	.47 (.25)	N/A	1.87[c]	(-.02 to .96)
Inspiration	N/A	N/A	N/A	-.48 (.21)	N/A	-2.28[c]	(-.89 to -.07)

[a]N/A: not applicable.

[b]P<.01.

[c]$P<.05$.
[d]$P<.10$.
[e]$P<.001$.

Discussion

Key Findings

Figure 4 summarizes the key findings of this study. Thus, in the context of an mHealth app that helps users quit smoking, we show that 36% of QG users were self-reported to have successfully quit smoking, and of those who remained smokers, the number of cigarettes was reduced significantly by 59.6%. In addition, we found that progress in QG's mHealth program was associated with enhanced user hedonic well-being (contributing to their overall life satisfaction, happiness, and helping them to be more productive at work).

Furthermore, progress in QG's mHealth program was associated with enhanced user empowerment (helping them think about smoking in a different way, increasing their willpower to quit, and changing their behaviors, and realizing that mobile apps can improve their health). Moreover, the results showed that progress in QG's mHealth program was associated with enhanced user inspiration (motivating them to be the person they want to be, inspiring them to live a healthier life).

A key finding of the current research is that the success rate of users quitting smoking was significantly enhanced through gamification designs that boosted their hedonic well-being, whereas user inspiration by the gamification designs was negatively associated with quitting smoking successfully. Additionally, the results demonstrated that mHealth gamification design that empowered app users was associated with a greater reduction in cigarettes smoked per day, whereas, surprisingly, inspiration was negatively associated with a reduction in cigarettes smoked per day.

Extending Extant Knowledge

The findings of this study offer relevant and potentially provocative insights into the effective design for digital mHealth apps [17,18]. The findings related to which elements of app design are more conducive to smoking cessation are intriguing and extend current knowledge about the design of evidence-based smoking cessation mHealth apps in important ways [18]. Contrary to common intuition, the inspiring element of the app was *negatively* associated with both the probability of successfully quitting smoking as well as the reduction in cigarettes smoked per day.

While inspiration can motivate and encourage individuals to keep going [23,24], it can also reduce an individual's sense of self-responsibility at times. As prior research notes [26], inspiration is not the same as positive affect. People who enter an inspired state (by thinking of a moment when they were inspired) reported lower levels of volitional control, controllability, and self-responsibility for their inspiration. This ties in with the notion that smoking is not simply a bad habit—it is an addiction which is often derived from the fact that smokers desire to escape the reality [28-30]. When the inspiring elements of an mHealth app come into play, such a psychological state can be taxing to the extent that individuals are potentially encouraged to smoke to comfort themselves.

In addition to the app design elements that were shown to positively or negatively affect smoking cessation, progress in the QG's gamified program journey was identified as a significant means to enhance users' hedonic well-being, psychological empowerment, and inspiration. These finding shed light on the impact that completing the program has on behavioral change and underscores the role played by empowerment, inspiration and well-being afforded by the gamification design elements of the app.

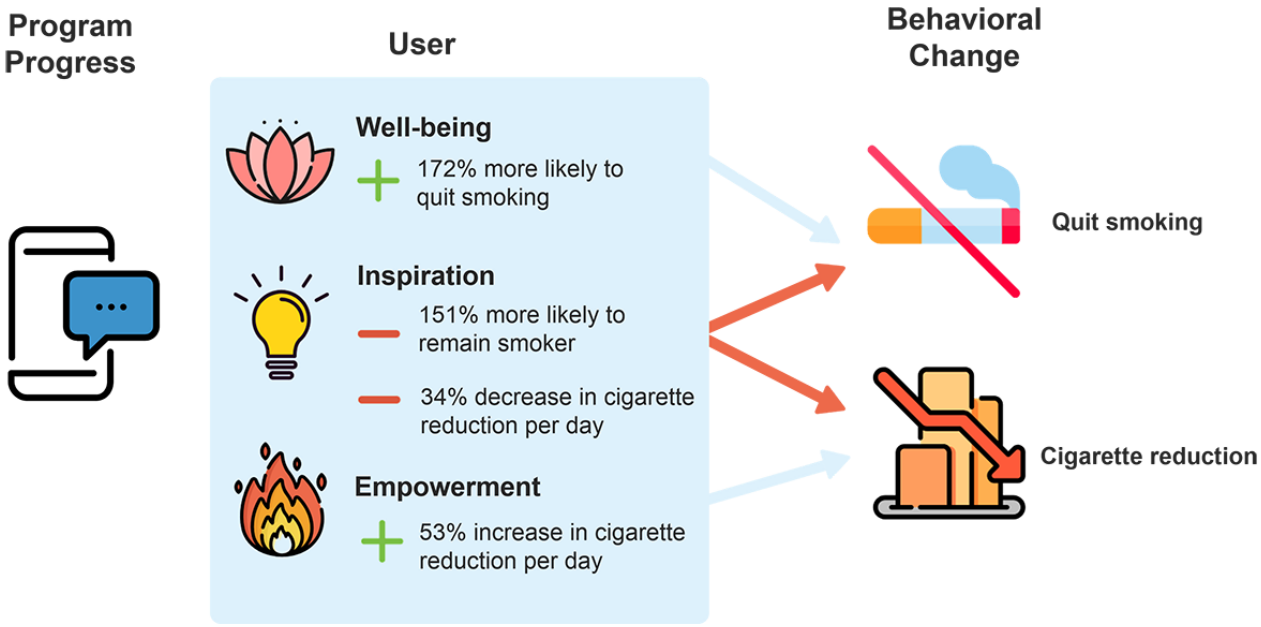
The results of this study further extend prior gamification design research of mobile apps for smoking cessation [18,31-33], showing how the design of mHealth apps is highly relevant for exploring new methods and facilitating new ways of encouraging a healthy lifestyle. In line with the literature [29,34-36], the success or failure of digital services such as a mobile phone app that tries to encourage a healthier lifestyle is highly dependent on the app's efficacy in achieving behavioral change. Based on research exploring game-based health interventions [18,19], as well as theories and practice of designing for change [19], our findings suggest that in the context of smoking cessation, psychological empowerment through the gamified design of an mHealth app significantly predicts users' ability to quit smoking successfully.

To date, most of prior work has focused on the usability and feasibility of mobile apps as mHealth interventions for self-guided care in smoking cessation [30-33]. Our focus differs from this approach, as we investigate a more psychological side of effectiveness in addition to behavioral therapy. Building on work which highlights the important role played by psychological benefits to the self of individuals [34-39], our goal was to explore and extend current work on various mHealth app design elements to maximize the effectiveness on behavioral outcomes [40-42].

Limitations and Future Research

The current findings need to be viewed with the following limitations in mind. First, the self-report method of tracing back users' previous smoking behavior (eg, how many cigarettes they smoked before and after using the app) could result in an estimation bias. We encourage additional work to investigate users' actual behavioral change in the context of digital health across longitudinal studies using biological measures. Moreover, due to the lack of data we could not account for the time since participants had their last cigarette. Future research that also captures participants' time intervals between smoking cigarettes and their last cigarette smoked (eg, hazard ratio model) can help shed additional light on the current findings.

Figure 4. Main findings of this research.



Second, we note the potential of response bias, as the users who were more motivated and engaged with the app might be more likely to complete the survey. While the response rate of this research is in line with other work based on online surveys [43,44], we invite future research to strengthen confidence in the generalizability of the current results by replicating the study with a larger sample and a higher survey response rate.

Third, to achieve a parsimonious conceptual model and to keep the online survey short to manage response rate and quality, we did not include other measures that could inform our analyses of user-app engagement and efficacy. The negative association between inspiration elements of the app and success rate of quitting smoking, as well as reduction in cigarettes smoked per day is curious. One wonders about potential process mechanisms at play here. Why does inspiration hinder and not help in the context of smoking cessation? When, if at all, does inspiration help smokers quit? How does inspiration impact one's willpower to quit smoking and their desire for relief? We invite future research to address these intriguing questions.

Fourth, we conducted this study in one context (smoking cessation) and future research that extends our work to other contexts (weight loss, reducing alcohol consumption, pornography, shopping, gambling addiction, as well as addiction to social media such as Instagram, Tinder, Facebook, and more) in which mobile health interventions could be used is richly deserving. Fifth, we invite future research to test the effectiveness of digital mHealth apps against current interventions (eg, nicotine replacement therapy) in smoking cessation, which might help drive culture change and openness to different mHealth solutions.

Finally, given the real potential of digital transformation of human life in the future [45] and individuals' current willingness to exert significant energy (emotional, time, money, and more) online [46], we call for more research to study the effects of digital applications on human well-being. As day-to-day experiences and casual observation suggest, more and more people appear to get "hooked" on digital devices and their apps and cannot imagine their lives without these [47]. Developing apps that truly improve a person's well-being is undoubtedly an ambitious goal (just as is spotting the rainbow unicorn in the start-up scene), and thus we encourage additional research to join this important effort. Let us create a future where digital solutions do not enslave humans but help them be more productive, increase overall life satisfaction, and help lead healthier, more fulfilling lives.

Conclusions

The results of this research highlight that progress in QG's mHealth program was associated with stronger user hedonic well-being, greater empowerment, and enhanced user inspiration. Furthermore, the results show that users' ability to quit smoking successfully was significantly enhanced through QG's gamified mHealth elements that strengthened their well-being. In contrast and curiously, inspiration offered by the QG app was negatively associated with quitting smoking successfully. Possibly, in the context of smoking cessation inspiration adds to the level of stress and anxiety of smokers rather than helping them in their efforts to quit. Thus, taken together the current findings offer critical implications to the effective design of mobile health solutions, such as digital apps geared towards improving users' health. In the context of smoking cessation, we find there is real value in helping users think about smoking in a different way (empowerment) and increasing their overall life satisfaction (a sense of well-being).

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Conflicts of Interest

YS, MA, and SS are co-founders of Digital Therapeutics, Inc. CTS is an employee of Digital Therapeutics, Inc. YS, MA, SS and CTS had no role in the data analyses and decision to publish the current results.

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Abbreviations

CBT: cognitive behavioral therapy
mHealth: mobile health
QG: Quit Genius

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Original Paper

How New and Expecting Fathers Engage With an App-Based Online Forum: Qualitative Analysis

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Abstract

Background: Breastfeeding is important for infants, and fathers are influential in supporting their partner in their decision to breastfeed and how long they breastfeed for. Fathers can feel excluded from traditional antenatal education and support opportunities but highly value social support from peers. Online health forums can be a useful source of social support, yet little is known about how fathers would use a conversation forum embedded in a breastfeeding-focused app. Milk Man is a mobile app that aimed to increase paternal support for breastfeeding using a range of strategies, including a conversation forum.

Objective: The aim of this study was to examine how fathers used a breastfeeding-focused conversation forum contained within a mobile app throughout the perinatal period.

Methods: A qualitative analysis of comments posted by users in the online forum contained within the Milk Man app was conducted. The app contained a library of information for fathers, as well as a conversation forum. Thematic analysis was used to organize and understand the data. The NVivo 11 software package was used to code comments into common nodes, which were then organized into key themes.

Results: In all, 208 contributors (35.5% [208/586] of those who had access to the app) posted at least once within the forum. In total, 1497 comments were included for analysis. These comments were coded to 3799 individual nodes and then summarized to 54 tree nodes from which four themes emerged to describe how fathers used the app. Themes included seek and offer support, social connection, informational support provision, and sharing experiences. Posting in the forum was concentrated in the antenatal period and up to approximately 6 weeks postpartum.

Conclusions: These data show that fathers are prepared to use a breastfeeding-focused online forum in a variety of ways to facilitate social support. Fathers can be difficult to reach in the perinatal period, yet engaging them and increasing social support is important. This research demonstrates the acceptability of an innovative way of engaging new and expecting fathers.

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KEYWORDS

mHealth; mobile app; breastfeeding; fathers; online communities

Introduction

Breastfeeding

Breastfeeding is of key importance to public health. The World Health Organization recommends that babies are exclusively breastfed to 6 months and for breastfeeding, supplemented with appropriate complementary foods, to continue for 2 years and beyond [1]. There are numerous, well-evidenced health benefits for infants and mothers, including a reduction in risk of a number of infections, sudden infant death syndrome and obesity in later life for infants [2,3], and protection against ovarian and breast cancer and improved bone remineralization in mothers [3,4].

Despite the recommendations and the benefits of breastfeeding, only about 15% of Australian infants are exclusively breastfed to 5 months of age [5]. There are many factors that impact breastfeeding [6,7], including the support of fathers. Targeting breastfeeding interventions toward fathers can positively impact breastfeeding duration [8]. Although research shows most fathers are supportive of their partners breastfeeding [7,9], there are a number of factors that impact the support they can offer [10-12]. These include the following:

1. Social support: fathers not receiving enough social support with pregnancy and early parenting
2. Knowledge: fathers want more knowledge about breastfeeding, pregnancy, and early parenting
3. Empowerment: a lack of understanding and recognition of the paternal role in breastfeeding
4. Barriers: specific barriers such as public breastfeeding and bonding postponement.

Social Support Via Online Health Forums

Increased levels of social support can have benefits for participants in terms of their mental and physical health [13]. The facilitation of social support via online health communities (OHCs) is an area of increasing research interest [14]. Seeking social support can be a key reason that people participate in OHCs, and there are benefits for those who receive social support online [15]. One of the benefits of OHCs is that participants can use them in different ways and that access to the information is available whenever the user wants. Some participants will use an OHC to actively connect with others, whereas others will prefer to simply observe and receive the information [16].

Participation in OHCs can offer both benefits and drawbacks to users. The availability of access whenever the user requires, as well as the ability for online forums to facilitate bringing people together who may share an interest or health issue but are geographically distant, can be a significant benefit [17]. Social networks can also offer a level of anonymity, which may make it easier for people to seek support, especially in circumstances where they may not feel comfortable talking to people they know [18]. People seeking to lose weight, for example, could join a support group of people from around the country or even worldwide that share their specific goal. Same sex attracted young adults in rural communities could find peers online. Parents struggling with their children's behavior could find others in the same situation.

Although there are positive aspects of connecting people, technology also comes with risks. The anonymity which can enable sharing can also provide opportunity and impunity for people to attack and bully others [19]. In terms of health information seeking, some studies report it can also lead to misinformation being sourced and shared [20]. However, other studies have found community-moderated OHCs can maintain a high quality of health information [21].

In their analysis of a large, popular breast cancer OHC, Wang et al found participants used the forum in a number of different ways [14]. Informational support, including seeking and providing information, was the most popular way support was facilitated. Companionship, which is the discussion of other issues rather than the actual health issue, was the key factor in retaining engagement in the online community over time [14].

Reaching New Fathers Via Online Forums

In Australia, the penetration of mobile devices has been increasing exponentially and offers opportunity to reach people with health interventions. In 2016, Deloitte estimated that approximately 84% of Australian adults owned a smartphone, which represents a nearing of peak market saturation [22]. A recent survey of Australian smartphone users (n=14,000) found that 40% of respondents used their mobile phone for a minimum of 3 hours each day, and an additional 47% used it for between 1 and 2 hours a day [23].

Some of the benefits offered by online forums are particularly pertinent when developing social support opportunities for fathers. Social support has been shown to have a buffering effect on parental stress [24]. In preparing for the birth of their child, fathers can feel isolated and feel that antenatal education is not inclusive of them [10]. In the perinatal period, fathers highly value social support, and support from peers is particularly sought after [12].

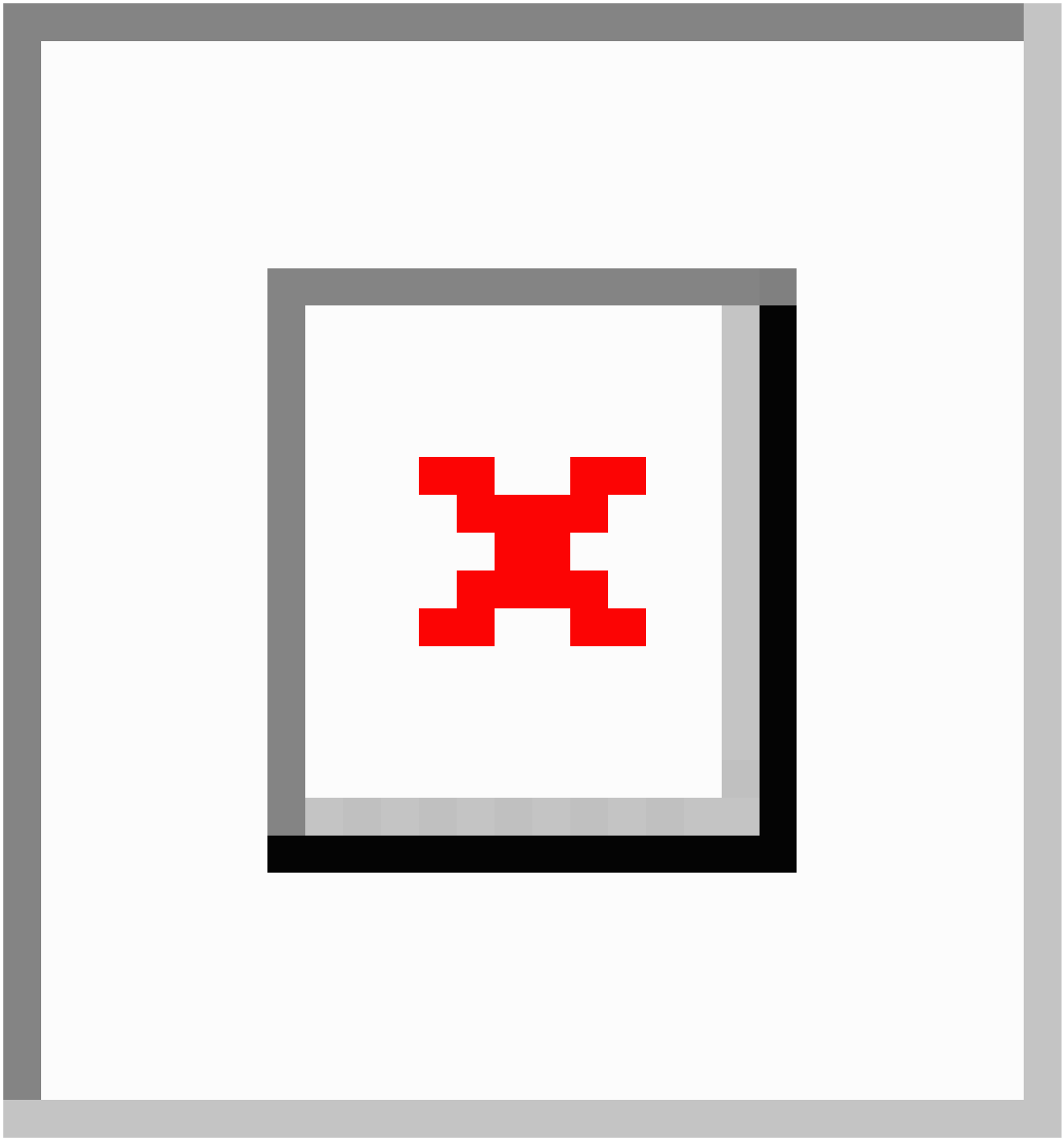
Participants in the Fathers Infant Feeding Initiative study, a fathers-focused randomized controlled trial that aimed to increase paternal support for breastfeeding, identified barriers to their access to support services [10,11]. These included accessibility and flexibility (particularly the need to balance work commitments), and the use of information technology was one recommendation to overcome these barriers. As fathers have reported feeling disempowered about their role in breastfeeding [25,26], the relative anonymity associated with online forums may further facilitate fathers actively participating in conversations about breastfeeding.

Milk Man App

The Milk Man app was designed to engage fathers in information and conversation about breastfeeding, with an aim to increase the support they offered to their breastfeeding partners. The development and trialing of the Milk Man app has been previously described [27,28]. A key component was the *conversation*, a facilitated forum whereby participants were posed questions via a series of topics and provided opportunities to comment. Figure 1 shows an example of a conversation topic

within the forum. When fathers first signed up to use the app in the antenatal period, they were grouped depending on when their baby was due.

Figure 1. Example of a topic posed within the conversation forum.



This enabled time-relevant questions to be posed and for the opportunity to talk to other fathers at a similar stage of pregnancy or early parenthood. New content was added to the app from when fathers signed up until their babies were approximately 26 weeks of age. The topics were designed to be either timely in relation to infant milestones in the perinatal stage or to focus on community building—that is, providing light content designed to encourage men to communicate with others. The purpose of these topics was to deliver small items of relevant information to participants in an engaging manner and to encourage them to share information and support their peers by participating in the conversation. New content was added to the app twice a week, coinciding with a push notification being sent out to alert users.

Study Aim

The aim of this qualitative study was to describe the way new and expecting fathers used the breastfeeding-focused conversation forum provided in the Milk Man app.

Methods

Sample

This study was part of a randomized controlled trial, the Parent Infant Feeding Initiative (PIFI; ACTRN12614000605695), which has been previously described [28]. The PIFI aimed to investigate the impact on breastfeeding duration of two different interventions, a male-facilitated antenatal class and the Milk Man app, both in isolation and combination. The project was approved by the Curtin University Human Research Ethics Committee (HR 82/2014; 14 May 2014).

Participants were recruited to the study through antenatal classes at maternity hospitals in Perth, Western Australia from August 2015 to December 2016. In total, 1426 couples were recruited to the study, with 681 couples being randomly assigned to an intervention arm that gave them access to Milk Man. Of these, 586 (86.0% [586/681]) went on to download the app. Reason for participants choosing not to participate in the PIFI study was not recorded.

Procedures

After the study was explained, participants were issued a consent form, and upon consenting, were informed of the group they had been randomized into. As fathers signed up to the app on a rolling basis, conversation groups were started when there was a minimum of 5 participants with babies due in that month. Participants who commented at least once in the forum were included in this study. Data collected for this study include the period from antenatal signup to 26 weeks postpartum.

The Milk Man forum was moderated by the research team, and a set of management protocols was developed to govern the administration of the app. The protocols describe a hands-off approach to moderation, intervening only when certain criteria were reached. Among others, these criteria included if a contributor was using the forum to attack another user or if misinformation was being shared. In the event intervention was deemed necessary, a member of the research team who was a father of two young children assumed the role of *MacDaddy* to provide a peer response in consultation with another team member. The peer-dad responder was identifiable through his avatar (the Milk Man app logo) and username (MacDaddy), to ensure it was clear to participants that he was connected with the study, as opposed to another father participating in the trial.

Data Analysis

All comments posted by participants were included in this data analysis. The data were then imported into NVivo 11 (QSR International) [29] and analyzed using a thematic analysis that involved coding the data into themes to enable organization and understanding of data [30]. Line-by-line analysis was used to examine words and phrases to explore the frequency, intensity, and extensiveness of discussion. Nodes were initially generated and then collapsed to form key themes. Data were coded manually and then checked by a second researcher trained in qualitative analysis to ensure conformability [31]. A comment could be allocated to multiple individual nodes depending on the content. For example, the following comment was coded to four individual nodes (Concern: not being good father, reflective parenting, sharing intimate information, and getting ready to be a dad):

> *One thing I fear about fatherhood is not being the best parent and role model. I've got pretty big shoes to fill as my parents were pretty amazing in their approach!*

Results

Participant Demographics

A total of 586 participants signed up to the Milk Man app. Of those, 208 (35.5%, 208/586), hereafter known as contributors, posted at least once in the forum. Demographic information was available for 187 of these contributors (baseline questionnaire not completed by 21 individuals). Most contributors were in the age range of 30 to 34 years (47.1%, 88/187), had some university education (60.4%, 113/187), and approximately two-thirds were born in Australia (66.8%, 125/187). Table 1 describes the contributor characteristics. Contributors reflected Australian demographics in age (median age of men becoming fathers was 33.3 years in 2016) [32] and country of birth (67% of the population were born in Australia) [33]. However, they were more highly educated (28% of Australian men in the age range of 20-64 years have completed a Bachelor degree or higher) [34].

Qualitative Analysis of the Conversation Forum

A total of 1493 comments were posted in the forum from the 208 contributors. In addition, there were four comments posted by MacDaddy in response to fathers sharing misinformation. The comments posted by the research team mainly provided correct information and links for Milk Man users. These 1497 comments were assigned to a total 54 tree nodes, generating a total of 3799 individual nodes (comments could be assigned to multiple nodes). These 54 tree nodes were then collapsed to form four key themes.

The number of comments posted per contributor ranged from one to 71. The average number of comments posted per contributor was 7.2 (mode 1; median 36). The number of comments per discussion topic ranged from one to 86 (average 24, mode 4, median 26). Participation was concentrated in the antenatal period and up to 6 weeks post birth, with approximately 80% of commenting activity happening within this time. Four main themes emerged from the data, and these and the subthemes describing the way fathers used the forum are presented in Table 2.

Table 1. Contributor characteristics (N=187).

Characteristic	n (%)
Age in years	
<30	29 (15.5)
30-34	88 (47.1)
≥35	70 (37.4)
Education	
High school or trade	72 (38.5)
Some University education	113 (60.4)
Country of birth	
Australia or New Zealand	125 (66.8)
United Kingdom or Eire	22 (11.8)
Africa or Middle East	12 (6.4)
Asia	10 (5.3)
Other	16 (8.6)

Table 2. Themes and subthemes of how fathers used the conversation forum in the Milk Man app.

Theme and subtheme	Example quote[a]
Seek and offer support	
Support seeking	*My wife's friend who has had a baby said to be flexible with a plan as breastfeeding often does not go to plan has anyone else heard people say this?*
Support giving	[Responding to another user talking about the benefits of attending antenatal classes] *Yeh agreed! I gained allot more than anticipated tbh [to be honest]. Definitely recommend to up and coming future fathers :)*
Supporting mums	*I've found just sitting with her while she's breastfeeding is helping her. Doing small things like moving baby's hand out of the way rubbing her back getting her water or a snack etc.*
Health professional and other support	*I've learnt tonnes in all the antenatal classes looking forward to putting my knowledge to good use.*
Social connection	
Joining in	[In reply to "What's your best bloke outing?"] *Getting to footie.*
Conversational	*I play soccer. so I'll be keeping that up. great fitness and stress relief and catch up with friends after the match.*
Using humor	[when discussing skin-to-skin with baby] *My wife suggested I trim the rug [chest hair] down!! I've spent a lifetime on this.*
Informational support	*Up until now my main contribution to reducing the housework load was a simple lowering of standards (only half kidding). We recently sat down and spelled out / wrote down some specifics to go on my plate like kitchen benches cleared and wiped every night so not waking up to a depressing site.*
Sharing experiences	
Breastfeeding	*Just be supporting and encouraging will go a long way! I know If I give up my wife will give up on breastfeeding!*
Fatherhood	*I'm looking forward to be a loving supportive encouraging Dad with an aim to assist in moulding a wonderful self-sufficient human being in the long run. AND I want to be a great friend to my child.*
Sharing intimate information	*My son arrived last week and I can safely [say] words cannot describe how amazing it was and how proud I am of mum and Bub it really is an intense experience.*
Bonding	*Had some skin-to-skin contact directly after my wife about 30 minutes after our son was born. An amazing feeling that I'll cherish forever.*

[a]Quotes are reported verbatim as posted by the contributors.

Seek and Offer Support

Fathers used the forum in several different ways relating to social support. This included using it to seek support, to offer support, to discuss how they were supporting their partners, as well as discussing other forms of support, including from professionals and other apps.

Support-Seeking and Giving

Across a range of parenthood-related topics, fathers both sought and offered support within the forum. The giving of support, including offering tips and suggestions, was more common than fathers specifically seeking support. Support was offered directly in response to a request from another user, in response to a question posed within the app, or sometimes was unsolicited. The following comment is one example of a father offering unsolicited support to other fathers when discussing paternity leave (Fly In, Fly Out [FIFO] describes the shift work patterns of mining and oil or gas platform workers who work away from home):

> *[I am] Lucky with FIFO I will get 5 outa 6 weeks off so hopefully that works well before going back to the normal roster thinking the even time roster should work pretty well but you never know. Feel sorry for the boys who work the longer rosters away or fellas that can't have too much time off. Planning the flight home is the biggest gamble!!*

Support-seeking was characterized by direct questions posed to the group, or users posting about a difficult experience, as illustrated in the following post:

> *It is day 3 since our bundle of joy arrived. my wife is struggling to get the milk flowing and the baby is not sucking hard enough. We were told that it takes up to 72 hours before milk flows which I didn't know until the baby arrived. my worry is with bottle feed[ing] the baby seems to just easily get his feed. Will he choose to not work as hard when we try the breast and when should we say OK baby is hungry let's feed him bottle? I don't want my wife to feel as a failure if our desire to breastfeed fails. Any other fathers with similar dilemma?*

There were instances of fathers seeking more support and connection from the app than they were able to receive. This includes fathers expressing a desire for real-life meetups to be organized, posting questions or comments and not getting a response in return, or expressing disappointment in the lack of conversation, as illustrated in the following post:

> *I tell you who makes woman depressed it's the health nurses. She needs to put on weight or she has to be put on formula! She's only a few grams lighter she was born 2 weeks early and she eats like her Daddy and [I] can never [gain] weight, they go by a stupid table. She's nice and healthy. They tell you to eat healthy and then tell you [she's] eating too many greens. These health nurses are useless! We doing pretty well. Shame we don't have any family to help out here. No one wants to make friends on here? That's the whole point of the App?*

Supporting Mums and Other Support

Contributors used the app to talk about how they were supporting their partners. This included discussions about breastfeeding, work, practical support, and mental health. One father in discussing the way he was getting ready to support his partner with breastfeeding posted the following:

> *Got a rocking chair with leg rest set up next to the window looking out over the streetscape facing a TV and a tower speaker connected to an old iPad with her favorite music. I think we're ready!?*

Fathers also posted examples of specific topics in the app prompting real-life conversations with their partners about how they could better support them, as illustrated in the following posts:

> *This is a good idea. I might talk to my wife about a breastfeeding plan. I would be keen to know how she wants my help.*

> *I asked my wife what our plan was after reading this. Apparently if we get separated she would have already expressed milk and it won't be an issue. Plan ahead and hope for the best is our plan I suppose!*

Social Connection

Topics posted to the app by the research team varied in their intent. The content areas, while with a focus on breastfeeding, were broad and included other parent-related issues such as sleep, relationship changes, starting solids, and bonding among others. Throughout the schedule of topics was an ongoing focus on community building. Ensuring there were topics that provided opportunity for light conversation and connection was deemed important in keeping fathers engaged and interested in the forum content.

A major emergent theme was that fathers used the forum as a way of connecting with other fathers and seeking companionship by participation. This was evident in the posts which did not relate to a particular health or parenting issue and simply reflected fathers *joining in* or creating conversation, often by using humor. Many fathers used humor when posting conversationally. This included recounting experiences, anticipating experiences, and merely joining in. In responding to a post asking what tips fathers may have for new dads, one contributor wrote the following:

> *Learn how to make her Vegemite on toast just right. It sounds like an easy job but f**k me I never knew you could get it wrong! Tip for rookies ensure the butter is melted in before the vegemite is applied*
>
> *near death experience that one.*

Another father shared this post when answering a topic asking if he was talking to his baby antenatally. He stated the following:

> *We would often fall asleep listening to an audio book. Our bub might think Stephen Fry is her father…*

Posts coded as *joining in* included any time fathers came to the app to participate, rather than to specifically seek or share information. These were often shorter answers, yet these posts still reflect a commitment to participation and companionship.

The following is an example of answers given to the "Who is the best celebrity father?" question:

> *The Pitt has got it wrapped up in the current landscape!*
>
> *Has to be Phil Dunphy [Modern Family]. Everyone thinks I've modelled myself on him. Dad jokes just come natural for me though I'm still flattered.*
>
> *Homer Simpson.*
>
> *Hugh Hefner.*
>
> *Surely George Foreman. Has 10 children (5 boys all named George and 5 girls). He found new and innovative ways to feed them and in the process created an empire of cooking appliances.*

Informational Support

Informational support has been defined as the provision of advice, suggestions, or information that will be useful to someone else [35]. The provision of this type of support through the app also created opportunities for observational learning by modeling a behavior or an attitude and was one of the four key ways fathers used the forum. Sometimes these posts were in response to specific questions and sometimes were fathers simply sharing what had worked for them. These differed from the other subthemes in that they were not directed toward seeking or offering support to another person and involved a father providing a personal statement. They all displayed opportunities for other fathers to learn from and for normalization of specific behaviors or attitudes. One example is from a topic asking whether fathers were planning on having skin-to-skin contact with their babies in hospital. The topic linked to an article in the library section of the app containing information about one father's experience. The following posts provide an example of informational support:

> *I read an article on this app where the dad was the first skin to skin contact his baby received. Something to do with a complicated birth and having a caesarean. He went in prepared with a top he could un-button easily in fact. In the event of a tricky birth and if my Mrs wasn't in a position to make that first contact for sure I'd love to be the first person my son meets!!!*
>
> *Definitely keen to do skin to skin—or rather skin to chest rug—being more appropriate in my case.*
>
> *I did skin to skin it was cool and helped relieve some stress of the birth when mum was taken to theatre.*

This topic generated considerable discussion. The following examples are from fathers responding to the conversation and considering something they may not have thought of otherwise:

> *Hadn't thought about dad/baby skin to skin. It makes sense that it could benefit the bonding experience.*
>
> *Wow what a great read! Something for fathers right from baby's first hours alive.*

As research has demonstrated that some fathers report feeling uncomfortable about their partner breastfeeding in public, the app included content about this issue. The comments posted on this topic provide an example of how the forum provided opportunities for the normalization of public breastfeeding, which are as follows:

> *We have had no issues. Makes me think it really isn't an issue.*
>
> *My wife uses a shawl for a little discretion. She actually had a lady tell her that she shouldn't have to cover up!*
>
> *Pretty good, no issues or disagreeing public response.*

Sharing Experiences

Sharing experiences, both anticipatory and as reflections, emerged as a key way that fathers used the app forum. These experiences were broad, including a wide range of content areas, for example, breastfeeding, fatherhood, sleep, relationship changes, bonding, and mental health. One father stated the following:

> *We have just made it past week 2 but it has had some challenges especially the first week. Just need to persevere as it did get easier we got a lot of advice from the mid wives and you just need to figure out what is right for you and your new bub will pick it up. Just be supportive as the wife can get emotional during this.*

Some of the information and experiences shared was of an intimate nature. The following post is from one father who is discussing how they announced their pregnancy:

> *We lost [our first] one. The emotional struggles after that meant telling people the second time wasn't the same. All good now though. 34 weeks and the little one is fit as a malee bull!*

Other posts were confessional and honest, as illustrated in the following quote:

> *I must admit I like being at work a lot more than being left [with] the baby by myself for an extended period. Talk about stressful!*

Discussion

Principal Findings

The qualitative data reported in this paper demonstrate that fathers are prepared to use a breastfeeding-focused app-based forum. Contributors in this study used the forum in a variety of ways: to seek and offer support, to share experiences, to build connection, and to offer informational support. Some fathers used the app to share very personal information, including about miscarriage, resuming intimacy with their partner, and how fatherhood was making them feel. Others used it in a less intimate way, using it simply to join in, or to participate. This is an important finding, as even by contributors providing short comments, the commitment to seek companionship and to connect is evident by the completed action of writing and posting a comment.

An earlier study of an OHC found that discussion of topics other than the health issue were a key factor in retaining engagement [14]. The subtheme of users seeking connection by joining in suggest this may be a factor in this study as well. This is an interesting finding as although off-topic discussions may be viewed as irrelevant, including and encouraging this type of conversation and posting in an OHC may be a key component of sustained engagement. The relative anonymity of the online forum may have made fathers feel more comfortable participating in the conversation.

The Milk Man forum was a researcher-facilitated forum, in that fathers were encouraged to respond to questions posed by the research team. Naturally, this has guided the content covered by the posts. Approximately a third of users with access to the Milk Man app commented in the forum. This is a higher percentage than has been observed in other studies and is further validation of this approach with new and expecting fathers. For instance, in exploring interaction with OHCs, some researchers have described a 90-9-1 principle [36,37]. This principle observes that 90% of users are lurkers who observe but never post, 9% contribute a small amount of content, and 1% of users contribute most of the activity in the forum [37]. To investigate if this rule applied to digital health behavior change interventions, a study was carried out with four OHCs (based on alcohol, depression, panic, and smoking cessation) [36]. Across the four OHCs, there were 578,349 posts and 63,990 users. The authors found that overall, less than 25% of users posted at least once in a forum. Usage patterns were consistent with the 90-9-1 rule, with an average of 73.6% (59%-75%) of the content being generated by the top 1% of users, an average of 24.7% (17.3%-24.7%) by the next 9%, and the remaining 90% contributing an average of just 1.7% (1.1%-7.8%) [36]. Similar to these findings, a breastfeeding app for mothers with a sharing function found that 14% of their app users' commented at least once [38]. Other participants used the Milk Man app in different ways, and further evaluation is in progress of the benefit these noncontributors, or lurkers, received from the forum.

Most activity in the forum occurred between when fathers first signed up to the app (antenatally) and 6 weeks post the birth of their child. Content continued to be added to the conversation up to 26 weeks post birth. It is unclear if the drop-off in posting activity was because of reduced activity in the forum, or if that is the natural time that fathers would use the app for. There were examples of fathers wanting more support and connection from the app than they received. Due to the relatively small size of the conversation groups (average 32 participants, range: 16-47), participants may have been dissuaded to continue posting in the forum as momentum declined over time. More meaningful interaction between fathers, including more genuine conversation, may be achieved with a bigger cohort. It is important to note that participants in different groups will have had different experiences with participation in the forum as some groups were significantly more active than others, and users could only view the content in their own group. Further evaluation of the app and the wider project, including breastfeeding and other outcomes, is currently underway and will provide further insight into app engagement.

The research team took a very hands-off approach to the forum, intervening only when the management protocols required it. As there were examples of fathers wanting more support from the app than they received and that activity dropped off after 6 weeks postpartum, it would be valuable to examine the impact of an increased level of researcher interaction in the forum. This could include through the implementation of a peer-based coaching program embedded within the app. Peer mentors could help get discussions going, could lead conversations with fathers, and provide individualized support, and future research can investigate the impact this has on the way fathers use the app and their engagement with it. Other studies have found that participants can highly value professional moderation and feel that it can help create vibrant communities, provide information, and help with solutions [39].

The way this study has found how fathers used the forum will be useful in informing the development of strategies designed to engage participants in digital social support interventions. Researchers can create content designed to enhance opportunities for fathers to communicate in the way this study has described. For example, facilitating specific opportunities for fathers to broadly discuss different mechanisms of support and creating spaces for the sharing of intimate information. Additionally, including light, conversational-driven content may increase forum activity and the number of app users contributing in the conversation forum. Further research with a larger sample size and alterations to the forum to increase connectively will be of value in further determining the impact online forums can have on engaging fathers with breastfeeding information and support.

Strengths and Limitations

This study had some clear limitations. The forum discussion was researcher led and limited to topics posted by the research team. A decision was made to limit the conversation to content posed by the research team, and fathers were not able to post their own content for other fathers to comment on. The research team considered this function in the planning phase, however, determined there was a potential risk in topics being poorly informed or containing inaccurate or misleading information. Allowing this function may change the way fathers use the forum. Due to the way participants were grouped, the number of fathers in a conversation group were relatively small. Participants from across the study will have had different experiences of the forum as usage differed between groups, and users could only see content in their own group. This study consisted of a qualitative study looking at how fathers used the app. Further investigation, including consideration of the 90-9-1 principle and identifying key influencers, will be a focus of future research. Data from the app analytics framework are also currently being prepared for publication. The strength of this study is that this is the first paper we are aware of to report on the way fathers use a conversation forum about breastfeeding. Although there were limitations, the interaction reported in this study points to this being an area that requires further exploration as a way of supporting fathers.

Conclusions

Research has shown that fathers value peer support in the perinatal period, and this research adds to that evidence, including, importantly, that fathers are prepared to access that support online through a mobile app. Fathers have an important role to play in supporting their partners with breastfeeding; however, they are rarely a key target group for antenatal education and support services and are often a hard group to reach. To better support fathers in this important time in their life, as well as increase their support for their partners, it is that vital innovative ways to reach parents are explored. This paper demonstrates that an app-based online forum delivering parenting and breastfeeding information is an acceptable method and one in which fathers were prepared to use to share information and display supportive behaviors.

There remains more that can be done in terms of research with this hard to reach group. Future directions include conducting research on a population level with a larger sample, including more interactive features and investigating the impact peer coaching has on utilization of the app. This paper adds to the evidence on how to reach fathers in the perinatal period and discusses the different ways fathers use an app-based forum. This research will be of interest to anyone seeking to reach fathers in this critical period.

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Conflicts of Interest

None declared.

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Abbreviations

OHC: online health community
PIFI: Parent Infant Feeding Initiative

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Original Paper

A Newly Designed Mobile-Based Computerized Cognitive Addiction Therapy App for the Improvement of Cognition Impairments and Risk Decision Making in Methamphetamine Use Disorder: Randomized Controlled Trial

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Abstract

Background: Cognitive rehabilitation therapy has been found to improve cognitive deficits and impulse control problems in methamphetamine use disorder (MUD). However, there is limited research regarding this therapy's feasibility when using mobile-based health technologies in supporting recovery from MUD in China.

Objective: The main aim of this study was to test whether 4 weeks of a newly designed computerized cognitive addiction therapy (CCAT) app can improve cognitive impairments, eliminate drug-related attention bias, and attenuate risk decision-making behaviors in participants with MUD.

Methods: Forty MUD participants were assigned randomly to either the CCAT group (n=20), who received 4 weeks of CCAT plus regular detoxification treatment as usual, or the control group (n=20), who only received the regular detoxification treatment as usual, in drug rehabilitation centers in Shanghai. The CCAT was designed by combine methamphetamine use-related picture stimuli with cognitive training with the aim of improving cognitive function and eliminating drug-related attention bias. The CogState Battery, Delay Discounting Task (DDT), Iowa Gambling Task (IGT), and Balloon Analog Risk Task (BART) were administered face-to-face to all participants before and after CCAT interventions.

Results: Forty male patients were recruited. The mean age was 32.70 (SD 5.27) years in the CCAT group and mean 35.05 (SD 8.02) years in the control group. Compared to the control group, CCAT improved working memory in the CCAT group (P=.01). Group×time interactions were observed among DDT, IGT, and BART tasks, with rates of discounting delayed rewards, IGT, and BART scores (P<.001) being reduced among those who received CCAT, whereas no changes were found in the control group.

Conclusions: The newly designed CCAT can help to improve cognitive impairment and impulsive control in MUD. Further study is needed to understand the underlying brain mechanisms of the cognitive therapy.

Trial Registration: ClinicalTrials.gov NCT03318081; https://clinicaltrials.gov/ct2/show/NCT03318081 (Archived by WebCite at https://clinicaltrials.gov/ct2/show/NCT03318081)

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KEYWORDS

methamphetamine; methamphetamine use disorder; cognitive function; impulse control; risk decision making; attention bias

Introduction

Amphetamine-type stimulants are the second most widely abused illicit drugs worldwide, with methamphetamine being one of the most abused amphetamine-type stimulant drugs, especially in East and Southeast Asia and parts of North America and Europe [1]. Methamphetamine abuse has caused major public health consequences all over the world. Chronic methamphetamine use has been associated with abnormalities in brain function and metabolism [2,3], leading to many negative consequences, including cognitive impairments, high impulsivity, and poor psychological well-being [4].

Cognitive impairments and high impulsivity could lead to a paradox situation in which individuals often desperately continue to consume methamphetamine despite being fully aware of the negative consequences.

According to the dual-systems perspective of addiction, two unbalanced information processing mechanisms underlying methamphetamine use disorder (MUD) patients' behaviors might address this paradox situation: automatic and reflective processes. Automatic processes, which are overactivated in many substance use disorder (SUD) patients, are fast and automatic impulsive processes, often operating at early stages of response selection when facing high-risk situations [5]. A common feature of the sensitized automatic process is drug-related cognitive bias [6]. The reflective process, which is related to an individual's cognitive control function, is a considerably slower and relatively controlled process [7]. With continuous drug use, damaged cognitive functions, such as attention control, working memory, and response inhibition, might have a negative effect on this process. The sensitized automatic impulsive process and overslowed reflective process further deteriorates this paradox problem.

Studies have provided evidence that clinical neuropsychology-based rehabilitation techniques focused on cognitive function training and cognitive bias might ideally address this challenge. Computer-based cognitive rehabilitation therapies are one of these promising interventions and have shown beneficial effects for these cognitive deficits across several clinical groups, including schizophrenia [8], brain injury [9], and SUDs [10]. Cognitive bias modification is another computerized treatment technique that targets the sensitized automatic impulsive process. Previous evidence has shown that drug-related attention bias can be retrained, along with favorable short-term effects in reducing substance abuse [11].

Moreover, new technologies can notably enhance the efficacy of health care services. Currently, Web-based and mobile-based health (mHealth) services have been showing promising effects and flexibility in these field [12,13], including addiction treatments [14]. Importantly, these innovative technologies could also better enable service providers in collecting patient behavior data [15] and delivering appropriate interventions [16]. These technologies might help with reaching illicit drug users who were afraid of being stigmatized or monitored by detoxification service providers [17].

However, to the best of our knowledge, no interventions have addressed both cognitive deficits and cognitive bias among MUD patients. Considering both processes are impaired in MUD patients [18], interventions to address these two aspects may be more effective than single approaches [19]. Moreover, there are few published studies that have addressed the efficacy of mHealth technology in delivering cognitive addiction therapies. Therefore, we designed a mobile-based program called computerized cognition addiction therapy (CCAT) by combining cognitive training and cognitive bias modification. Furthermore, studies have shown that enhanced drug-related choice can be demonstrated even for pictorial stimuli [20], with simple passive pictures inducing strong cognitive biases while active pictures presenting drug use-related context induce a stronger urge for drugs [21]. Methamphetamine-related pictures were integrated into the programs, aiming to address both cognitive impairment and cognitive bias in MUD patients. We hypothesized that the CCAT would have beneficial effects in improving cognition impairment, attention bias, and risk decision-making behaviors in MUD patients.

Methods

Experimental Design

This study was a randomized, single-blind controlled clinical trial and it has been registered at ClinicalTrials.gov (ID: NCT03318081). All participants were instructed to be treated by computerized cognitive rehabilitation therapies or treatments as usual. All outcome measures were assessed by blinded researchers. The study protocol was approved by the institutional review board at the Shanghai Mental Health Center. All procedures followed were in accordance with the ethical standards of the Norwegian National Committee for Research Ethics in the Social Sciences and the Humanities and with the Helsinki Declaration of 1975, as revised in 2000.

Mobile-Based Computerized Cognitive Addiction Therapy App

The mobile-based CCAT app was designed to help MUD patients overcome their cognitive deficits, increased control of impulse problems, and enable them to better control methamphetamine-related attentional bias. The CCAT app contains four cognitive training tasks, including two working memory training tasks and two methamphetamine-related attention bias control training tasks. To date, this app is the first mobile app designed for people with MUD in China.

Methamphetamine Attention Bias Modification

Research has shown that attentional bias can be retrained along with good effects in reducing substance use [22]. This training task was based on tasks described by Cox et al [23] and Hester

et al [24]. In this newly developed task, methamphetamine-related pictures and words were added, patients were trained to judge whether the meaning of the word in the left box was consistent with the color of the word on the right, while ignoring the interference of methamphetamine pictures and words as quickly as possible (Figure 1).

Each training session began with 20 practice trials to help participants get familiar with the training, and methamphetamine cues were not presented during practice. During the real training, methamphetamine-related words and pictures were shown in the right rectangle. Methamphetamine-related words were the most frequently nominated words among Chinese MUD patients. Methamphetamine-related pictures were drawn from the Internet and adjusted using Adobe Photoshop CS6 (Adobe Systems Incorporated, San Jose, CA, USA) for picture size, exposure, brightness, and contrast. Every session lasted approximately 8 minutes. An incorrect response resulted in a red cross, whereas a correct response resulted in a green checkmark. The colors of the words were limited to red, yellow, blue, and green. Accuracy rates were shown at the end of the training session.

Methamphetamine Attention Control Training

This training task was derived from the alcohol attention control training project of Fadardi and Cox [25]. Previous studies have shown its efficacy in increasing control over substance-related distraction and reducing substance-related attention bias among SUD patients [26,27]. During the training, when there was only one methamphetamine-related picture, patients needed to determine the border color of the picture. However, if there were two pictures (one was methamphetamine-related and the other was a neutral picture), patients were to ignore the influence of the methamphetamine-related picture and push the button representative of the border color of the neutral picture. Each training task contained 240 trials. Accuracy rates were shown at the end of the training session (Figure 2).

Figure 1. Methamphetamine-related attention bias modification task. Patients were asked to decide whether the meaning of the word in the left box was consistent with the color of the word on the right. The Chinese word printed in green on the left means “red,” whereas the phrase presented on the right means “smoking methamphetamine.”.

Figure 2. Methamphetamine-related attention control training. In situation 1, the border of the methamphetamine-related image was red, and the patients needed to push the "red" button. In situation 2, the border of the neutral picture was yellow, and the patients needed to push the "yellow" button as quickly as possible.

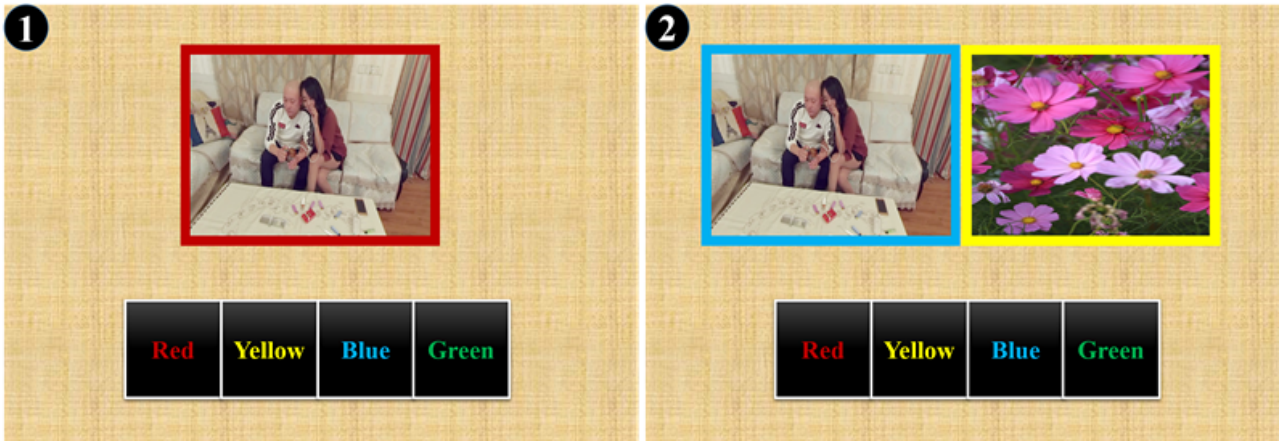
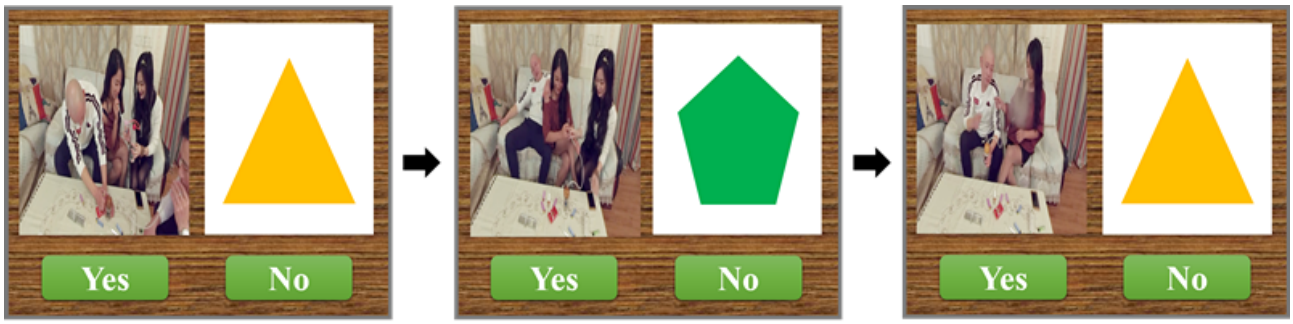


Figure 3. Methamphetamine-related working memory training task (N-back task). The previous Figure 2 is an example of 2-back task training. Patients in the CCAT group were asked to decide the whether the figure (both shape and color) on the right was consistent with the figure showing the previous two pictures while ignoring the methamphetamine-related picture on the left.



Working Memory Training (N-Back Task)

This task originated in the N-back task because N-back task-based working memory training has already shown good results in SUD [28] patients. During N-back tasks, participants were required to respond to a specified target, such as letters, figures, or numbers, which appeared on the screen consecutively and were the same as the previous N-back. This part of training was based on a modified version of the N-back task ranging from 1-back to 3-back, with methamphetamine-related pictures set as distractions. For the 1-back task, patients were required to decide whether the figure (eg, triangle, circle, or rectangle) was the same as the previous 1-back. For 2-back and 3-back, patients were required to decide when the current figure showed on screen was the same as the previous 2-back or 3-back earlier. During the training session, the figures shown on the right side of the screen were the target stimuli. Methamphetamine-related pictures on the left served as distractions (Figure 3). Patients identified targets by pressing the "yes" or "no" buttons. Training began with the 1-back task, and the training level was upgraded by achieving 90% accuracy twice in succession. The duration of each training session was set at 10 minutes; the accuracy rates were shown at the end of the training session.

Spatial Working Memory Training (Memory Matrix Task)

Spatial working memory training could also be improved through computerized visuospatial training [29]. Methamphetamine-related pictures were set as the background (at the bottom of Figure 4) or on the left as a distraction (at the top of Figure 4). During each trial, a rectangle (constituted by many squares) was shown for 1 second. After that, some of the squares turned blue and were shown for 3 seconds. Then they disappeared and returned to its original color. Patients were told to recall these blue squares by pressing the screen for 3 seconds. An incorrect response or failure to respond in 3 seconds resulted in a red cross, whereas a correct response resulted in a green checkmark. Three times were set as the response threshold. Training began with recalling three figures. If the patient successfully recalled or failed to remember the blue squares three times in succession, then the figures to be recalled were increased or decreased accordingly. Accuracy rates were shown at the end of the training session. The duration of each training session was set at 10 minutes.

Participants

A total of 40 male participants from one compulsory rehabilitation center in Shanghai who met the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) criteria for moderate or severe MUD were recruited to participate in the study. Inclusion criteria were (1) more than 9 years of education, (2) aged 18 to 49 years, (3) normal vision and audition, (4) receive no detoxification medications during treatment, (5) right handedness, and (6) no current use of methamphetamine or any other substances (except nicotine) for at least 7 days. Exclusion criteria included (1) current medical

diseases that required hospitalization or regular monitoring; (2) serious physical or neurological illness that required pharmacological treatment affecting cognitive function; (3) history of major psychiatric disorders such as bipolar disorder, schizophrenia, depression, and disorders of high comorbidity with SUD; (4) neurological diseases such as stroke, seizure, migraine, and head trauma; (5) intelligence quotient of less than 70; and (6) color blindness (see CONSORT flowchart in Figure 5). Written consent forms were obtained from all participants.

Figure 4. Memory matrix task. A few blue squares were shown for 3 seconds and then they disappeared and returned to the original color. Patients were told to indicate the squares that turned blue that were shown seconds before. An incorrect response resulted in a red cross, whereas a correct response resulted in a green checkmark.

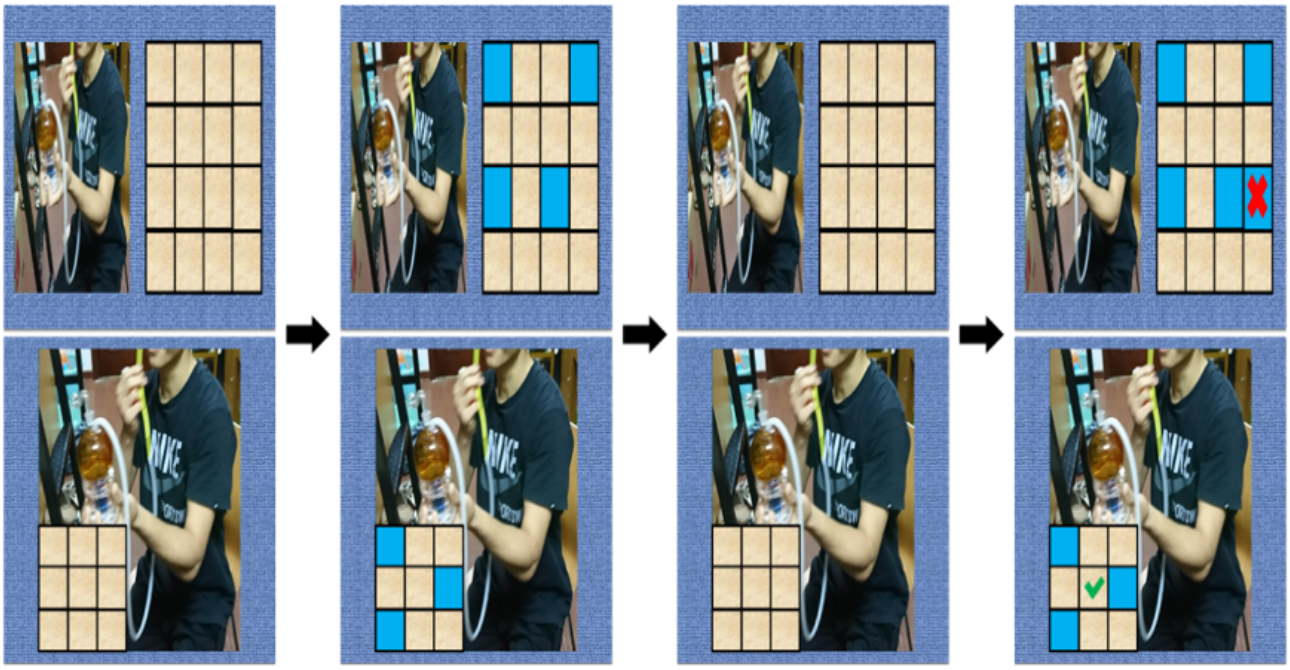
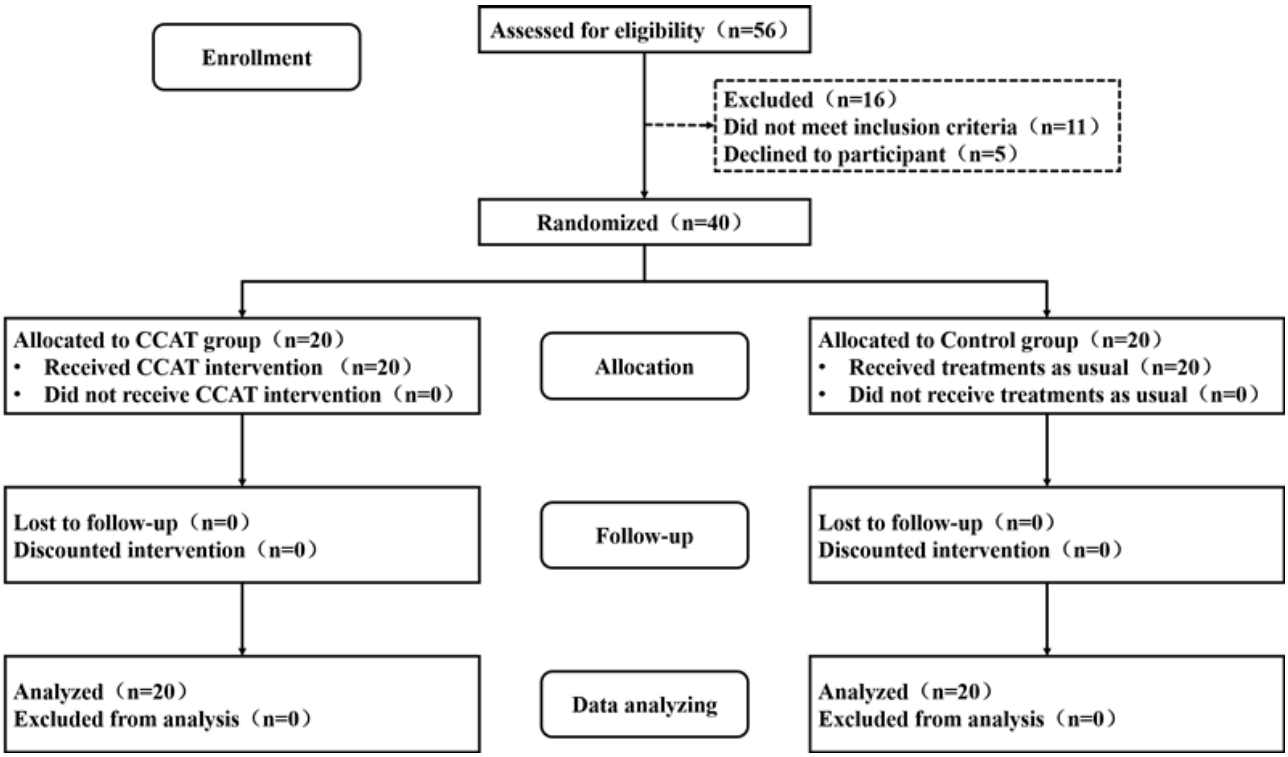


Figure 5. CONSORT flowchart of the study. CCAT: computerized cognitive addiction therapy.



Data Collection and Measurements

Demographic and Methamphetamine Use Information

Each participant was interviewed by one trained psychiatrist to collect the individual's sociodemographic characteristics and methamphetamine use histories.

Cognitive Function

Cognitive function was assessed using the Chinese version of the CogState Battery, which has good validity (Cronbach alpha=.8) [30]. The CogState Battery includes five cognitive tasks that assess verbal learning and memory, working memory, spatial working memory, problem solving/error monitoring, and social cognition. The total number of correct responses during the International Shopping List (ISL) task were used to reflect verbal learning and memory ability. Working memory was evaluated through the proportion of correct responses during the two-back task performance. Spatial working memory functions were reflected through the total number of errors in the continuous paired association learning (CPAL) task. The problem-solving/error-monitoring function was assessed by the Groton maze learning task, its assessment index was the same as CPAL during the Groton maze learning task. For social cognition function, the proportion of correct responses of the social emotional cognition task were applied.

Iowa Gambling Task

During the Iowa Gambling Task (IGT), participants were asked to choose among four decks of cards (A, B, C, and D) and accumulate as much money as possible by selecting one card at a time. Decks A and B were associated with high immediate wins, but larger future penalties that resulted in a net loss over time (ie, the disadvantageous decks). Decks C and D yielded lower immediate wins but smaller future penalties, such that participants gradually accumulated a profit by choosing these decks (ie, the advantageous decks). There were a total of 150 trials. The outcome was the net score (the number of cards from the disadvantageous decks subtracted from the advantageous decks). A positive score reflected the individual having a tendency to make a good decision [31]. Poor decision making was indicated by a lower IGT score.

Balloon Analog Risk Task

The Balloon Analog Risk Task (BART) was a measurement of the individual's risk-taking behavior [32]. On each single trial, an uninflated balloon appeared on the screen and pressing the button "1" inflated the balloon, and with each successful trial, the patient received 10 points and the balloon became considerably larger. Because the balloon had the possibility of explosion on each inflation, participants needed to press button "5" to stop inflating the balloon and obtain the benefit in time. In total, there were 100 trials. Before the test started, participants were told to obtain as high a score as possible, and total scores were presented on the lower-right corner of the monitor. BART scores (total number of balloon inflations/total number of unexploded balloons) were used to assess impulsive risk-decision making.

Delay Discounting Task

In the Delay Discounting Task (DDT), the delayed reward was set at 1000 Chinese yuan (approximately US $158); delay times were 2 days, 1 week, 1 month, 3 months, 6 months, and 1 year. The beginning immediate reward was 500 Chinese yuan (approximately US $15.80). Participants were told to choose the smaller immediate reward over the larger but delayed reward. The larger delayed reward stayed the same, whereas the immediate reward changed from trial to trial according to a decreasing-adjustment algorithm until an indi erence point was recorded (an indifference point means the participant changed choice between immediate and delayed rewards). The hyperbolic decay model was used to calculate the discounting rate (k) to reflect the individual's risky-decision making function [33]. A higher k meant the participant had much higher impulsiveness.

Methamphetamine Stroop Task

A Chinese version of the methamphetamine addiction Stroop task was applied to measure the methamphetamine-related attentional bias. The words used involved eight methamphetamine-related words and neutral words. Each of the 16 words was presented eight times in four different colors (red, green, yellow, and blue). Every word was shown on the screen for 3000 milliseconds. Participants were asked to ignore the meaning of the words by pressing the buttons corresponding to the color of the word presented as quickly as possible. Stimuli were presented in a pseudorandomized, nonstationary probabilistic sequence. Reaction time and errors rates were recorded. Attention bias was calculated by subtracting the time needed to name the color of the neutral words from the time taken to complete the methamphetamine-related words.

Cognitive tasks were programmed by E-prime 2.0 (Psychology Software Tools, Inc, Sharpsburg, PA, USA).

Procedures

Participants were randomly assigned to the CCAT group or control group by researchers who were not involved in other parts of this research. Pretraining and posttraining assessments were conducted by two other well-trained doctors. During the treatment, patients in the control group only received standard treatment in a compulsory rehabilitation center. Participants included in the CCAT group were also undergoing standard treatment; in addition, the participants received the CCAT training program that lasted for 4 weeks (20 sessions, five times a week, each session lasts approximately 60 minutes).

The CCAT training programs were displayed on an iPad. During each training session, participants in the CCAT group completed each of the four training programs twice. Standard treatment included health education (45 minutes per session, once a week), judicial education (45 minutes per session, once a week), sports activities (60 minutes per day), and vocational training (45 minutes per session, twice a week). Patients in the control group did not receive this type of CCAT training, and they only participated in the assessments at baseline and 4 weeks later.

Importantly, pictures involving drug-related stimuli and cues could still induce the individual's attention bias and craving for

drugs [20]. After every CCAT session, a 5-minute relaxation session was carried out to relieve possible psychological reactions and cravings induced by the methamphetamine-related cues. Relaxation included playing light music and watching pictures with relaxing effects.

Safety

Safety was assessed at every treatment session with a self-administered CCAT training form by recording spontaneous adverse events such as headaches and dizziness.

Statistical Analyses

Data were analyzed using SPSS 21.0. Group differences were compared using student's *t* test or analysis of variance (ANOVA) for continuous variables and a chi-square test for categorical variables. Generalized estimating equations were used to assess the main effects of groups (CCAT group vs control group), time (pretreatment vs posttreatment), and group×time interactions for all cognitive test variables. Statistical significance was set at alpha=.05. Bonferroni's test was used to resolve significant interactions for post hoc analysis.

Results

Demographic and Methamphetamine Use Information

Demographic characteristics and drug use histories are shown in Table 1. There were no differences between the CCAT group and control group in terms of mean age, education, marriage, onset age of first methamphetamine use, abstinence time, duration of methamphetamine use, dose, and frequency.

Effect of Computerized Cognitive Addiction Therapy on Cognitive Function

The CogState test, ISL, and CPAL scores increased significantly in the CCAT group, whereas the control group patients did not show significant changes. A significant time×group effect ($F_{1,1}$=31.78, P<.001), group effect ($F_{1,1}$=4.53, P=.03), and time effect ($F_{1,1}$=9.37, P<.001) were observed in ISL scores. Group effect ($F_{1,1}$=5.95, P=.02) and time effect ($F_{1,1}$=5.45, P=.02) in CPAL scores also reached a significant level. Although the group×time effect ($F_{1,1}$=6.68, P=.01) was significant for social emotional cognition scores, patients in the control group decreased significantly compared to the CCAT group. Groton maze learning and 2-back task scores did not show a significant change between the groups (Figures 6-8).

Effect of Computerized Cognitive Addiction Therapy on Impulsive Risk-Decision Making

A training effect was observed in the CCAT group for risk decision-making tasks. First, those undergoing CCAT training significantly decreased their discounting rate, whereas there was no significance in the control group. The group×time interaction effect was significant at each of the delayed times (Figure 9). A training effect was also observed with measures of IGT (Table 1 and Figure 10). The treatment×time effect, group effect ($F_{1,1}$=4.84, P=.03), and time effect ($F_{1,1}$=214.60, P<.001) were significant ($F_{1,1}$=49.07, P<.001). In the BART test, a significant group×time interaction ($F_{1,1}$=22.75, P<.001) and time effect ($F_{1,1}$=5.16, P=.02) had reached a significant level. Further comparison showed the CCAT group had better performance than the control group after CCAT invention.

Effect of Computerized Cognitive Addiction Therapy on Attention Bias

There were no significant differences between the two groups in attention bias. The treatment×time effect did not reach a significant level ($F_{1,1}$=0.92, P=.34). Only a time effect ($F_{1,1}$=6.23, P=.01) was observed (see Multimedia Appendix 1).

Safety

No patients reported any discomfort during the whole training session.

Table 1. Demographic and drug use characteristics of participants (N=40).

Characteristics	CCAT[a] group (n=20)	Control group (n=20)	$F_{1,38}$	χ^2_3	P
Age (years), mean (SD)	32.70 (5.27)	35.05 (8.02)	1.200		.28
Education (years), mean (SD)	10.00 (2.43)	9.55 (1.36)	0.525		.47
Age of onset (years), mean (SD)	24.45 (6.54)	25.15 (8.56)	0.084		.77
Abstinence (months), mean (SD)	4.30 (1.17)	4.10 (1.18)	0.224		.64
Duration of methamphetamine use (year), mean (SD)	6.02 (3.72)	7.00 (2.73)	0.891		.35
Dose of methamphetamine use (g/day), mean (SD)	0.60 (0.31)	0.66 (0.39)	0.294		.59
Frequency of methamphetamine use, n (%)				2.4	.56
Everyday	14 (70%)	10 (50%)			
3-5 times a week	4 (20%)	8 (40%)			
Once a week	1 (5%)	1 (5%)			
1-3 times a month	1 (5%)	1 (5%)			

[a]CCAT: computerized cognitive addiction therapy.

Figure 6. International Shopping List (ISL) scores before and after intervention. Verbal learning and memory function were evaluated by ISL; scores are total number of correct responses. Significant differences between the two groups (P<.001) are marked by the asterisk. CCAT: computerized cognitive addiction therapy.

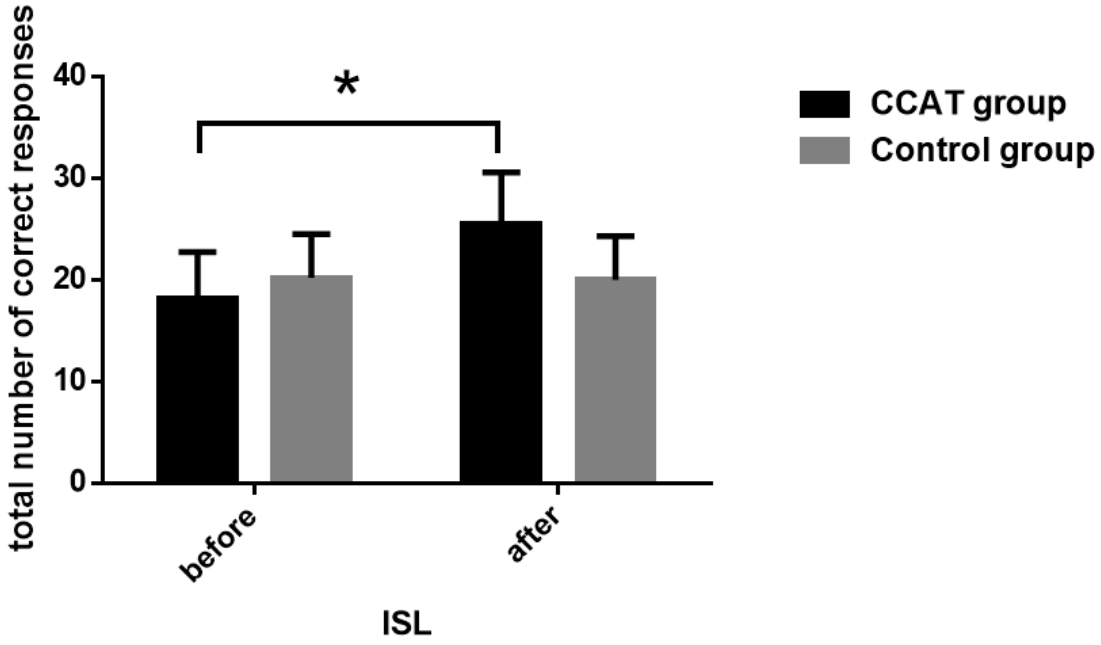


Figure 7. Continuous Paired Association Learning (CPAL) scores before and after intervention. Spatial working memory functions were reflected through the total number of errors in the CPAL. Significant differences between the two groups (P=.01) are marked by the asterisk. CCAT: computerized cognitive addiction therapy.

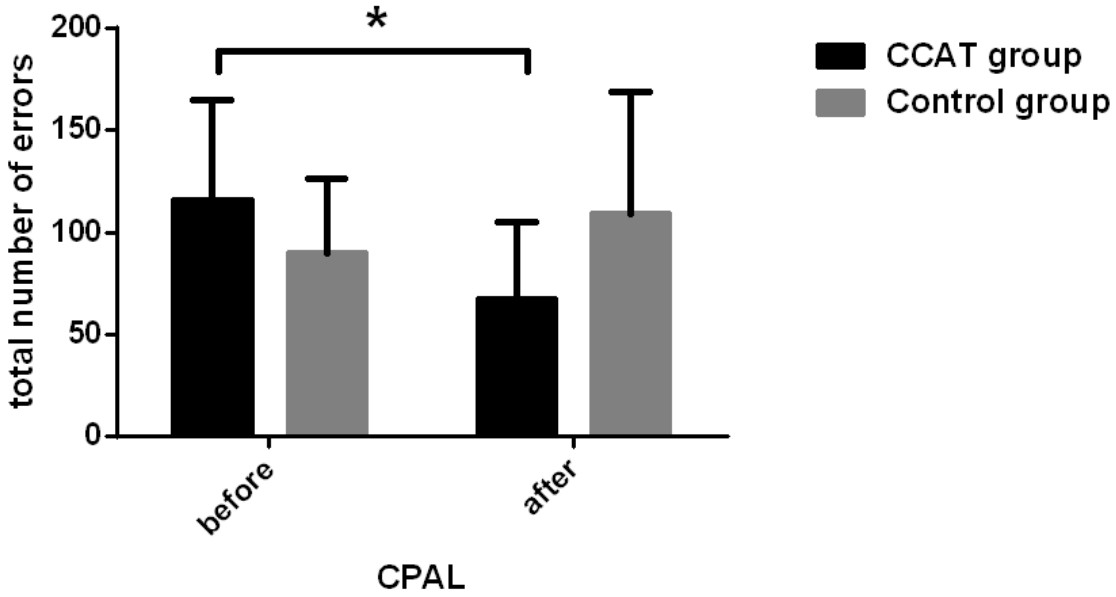


Figure 8. Social emotional cognition (SEC) task scores before and after intervention. Social cognition was evaluated by the SEC task; SEC scores were assessed by accuracy rate (the proportion of correct responses). Changes in SEC scores did not reach significant level in CCAT group (P=.56), whereas the accuracy rate decreased significantly in the control group (P=.02) as reflected by the asterisk. CCAT: computerized cognitive addiction therapy.

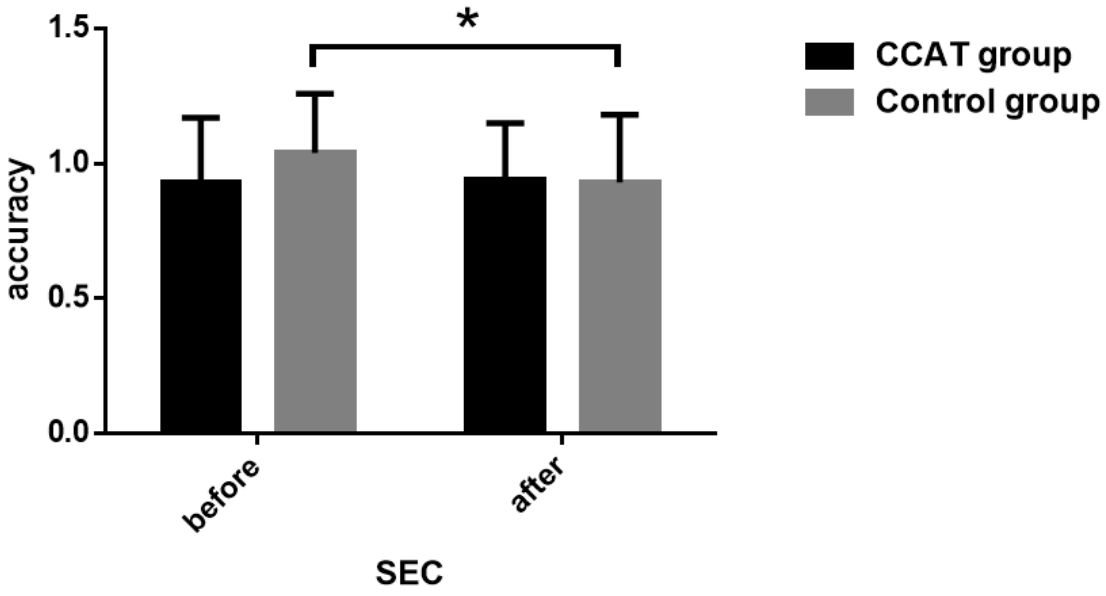


Figure 9. Discounting change ln(k) before and after computerized cognitive addiction therapy (CCAT) training. Change in discounting ln(k) for participants in CCAT and control groups, calculated as posttraining minus pretaining. Negative values indicate a decrease in discounting. The values 2, 7, 30, 90, 180, and 360 were delayed times in the delay discounting task.

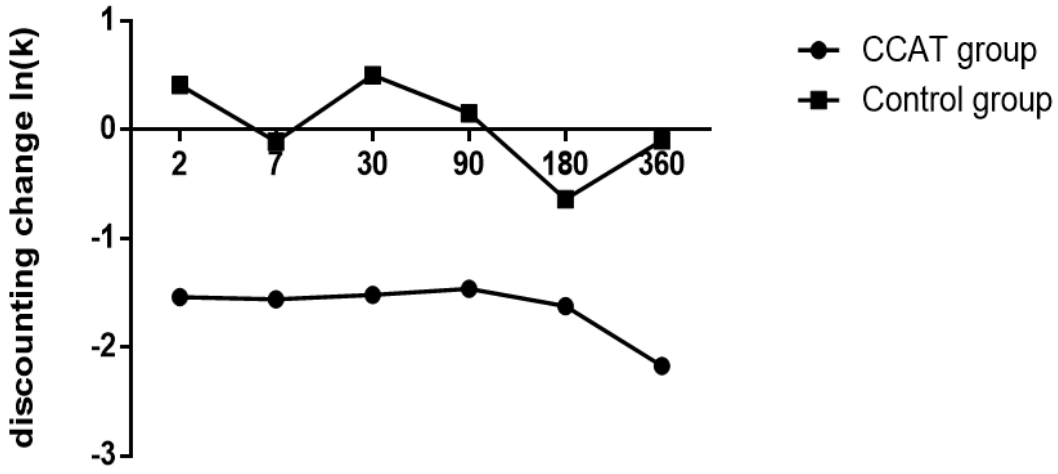
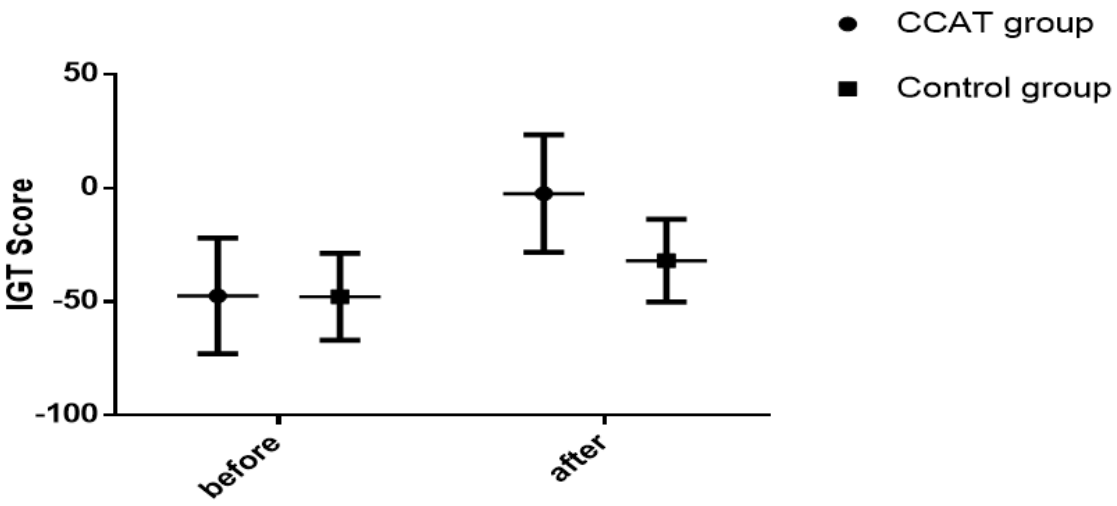


Figure 10. Iowa Gambling Task (IGT) scores after computerized cognitive addiction therapy (CCAT) or control training. The IGT score was calculated through the number of cards from the disadvantageous decks (C and D) subtracted from the advantageous decks (A and B). A positive score reflects the individual had a tendency to make better decisions. The lines are means and the error bars are the standard deviation.



Discussion

Principal Findings

To the best of our knowledge, this report describes the first pilot study that combined cognitive training and cognitive bias modifications adding methamphetamine-related stimulants in MUD treatment programs. As expected, compared to the control group, patients engaged in the CCAT group had better cognitive performance after 4 weeks of training, which coincided with changes in impulsive risk decision-making tasks measured by DDT, IGT, and BART. These results supported our hypotheses that 4-week CCAT training would have beneficial effects for improving cognition impairment and risk decision-making levels in MUD patients.

Previous studies have shown that computerized cognitive training showed promising treatment effects and even brain plasticity in SUD patients using such stimulants as cocaine, methamphetamine, alcohol, and nicotine [34]. However, these studies only used cognitive training, such as working memory training, or cognitive bias modification training. Although this research has provided primary evidence for combining general cognitive training, attentional bias retraining may further enhance the treatment prognosis.

One notable finding is that, along with cognitive function improvement, patients in the CCAT group also showed better performance of impulsive control tasks, which is in line with previous studies, indicating that good working memory functioning could allow for better decision making in SUD patients [35]. These studies have already indicated the underlying relationship between cognitive training and impulsive control enhancement, either by cognitive tasks or self-report measures [36,37]. In this study, our results not only revealed a similar trend but also for cognitive tasks, such as DDT and IGT. Importantly, previous study either included people with stimulant dependence, including cocaine and methamphetamine, or self-report measures. However, in our study, we only recruited patients with moderate to severe MUD, and these patients had better performance on cognitive tasks. Thus, although our findings are small and preliminary, our pilot study provided further evidence that cognitive training can affect impulsive control rehabilitation in MUD patients.

Unexpectedly, CCAT training did not show improvement in social cognition. However, preevaluation and postevaluations of social emotional cognition tasks revealed that patients in the control group showed a trend of deterioration. Our previous study found that social cognition also showed dysfunction in individuals with MUD [38]. Other studies have proved that enhancing working memory capacity could better help patients dealing with negative social emotional events [39]. Therefore, our research may indicate that 4 weeks of CCAT was not long enough to facilitate the recovery of social cognition and may serve as protective factors.

Although studies have indicated that substance-related attention bias can be retrained with favorable short-term effects and clinical effectiveness [40], in this research, attention bias did not show significant changes after CCAT training. Other studies also suggested home environments and mobile technology may promote robust reductions in bias and clinical effectiveness [41]. Our previous study on methamphetamine-related attention bias also showed that, although there was no significant difference in behavioral performance between MUD and healthy controls, increased P300 amplitudes by methamphetamine-related words were observed among MUD patients compared to healthy controls [42]. However, this report described a small pilot study, and well-powered clinical trials combined with event-related potentials are required to obtain a more conclusive answer on the potential clinical effectiveness of attention bias modification.

From a clinical standpoint, there is still no official approved medical treatment for MUD patients, making finding new

treatment approaches for MUD patients of great importance. Preserved cognitive function and decision making were key factors underlying patients' long-term prognoses [43]. These were consistent with evidence demonstrating that working memory and its interaction with impulsive risk-decision making could predict levels of substance use during treatment [44]. Therefore, strengthening these abilities during treatment might facilitate the individual's resilience and reduce relapse. Our research did show that 4-week CCAT training could enhance both patients' working memory ability and risk decision-making level. However, whether CCAT training can be implemented as conventional treatment in MUD patients and its mechanism remains a fertile area for further research.

Limitations

This study has several limitations. First, we employed a relatively small sample (n=20 in each group). We only recruited male patients in our study, which limited further highlighting of the difference in clinical efficacy of cognitive training. Given various constraints, we were unable to increase the number of participants to be recruited; however, considering our baseline data showed a normal distribution and homogeneity of variance, which could still increase the validity of our findings. The second limitation was that in order to make each task more engaging and relevant, we added methamphetamine-related pictures during training. However, we did not have enough sufficient trials to explore stimulus effects in these patients. To keep the training as effective as possible, we invited these patients to rate the pictures (valance, arousal, dominance, and craving) and only used pictures that exceeded five points. Third, given the increased risk of induced craving during CCAT training, we were careful about the side effects of CCAT. Relaxation was conducted at the end of each training session and no patients reported discomfort after the invention. Another limitation was the lack of data assessing the individual's motivation to participate in CCAT training. Because motivation level is an important moderator of the effectiveness of cognitive training and adherence [45], our future research would combine varieties of motivational approaches as a plug-in with a newly upgraded CCAT app to collect data on patients' motivational levels.

Conclusions

The results from our study support the fundamental dual process theory underlying cognitive based treatments for MUD individuals. Four weeks (20 sessions) of CCAT training could both better facilitate cognitive function rehabilitation and reduce impulsivity-related decision making in participants. Future studies will focus on functional magnetic resonance imaging and electroencephalograms to find the underlying mechanisms of CCAT.

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Authors' Contributions

All authors contributed to the design and execution of this study. MZ was in charge of the initial research design and the randomized controlled trial. NZ, HS, TC, HT, HJ, DX, HY, and Dawen Chen acquired the clinical data. XL was in charge of programming the cognitive tasks used during the study. YZ did the CCAT intervention and, together with help of JD, conducted the data analysis and drafted the manuscript. RL helped program the CCAT training projects. All authors provided critical revision of the manuscript for important intellectual content. All authors critically reviewed the content and approved the final version for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

IGT and BART score and attention bias scores before and after CCAT intervention.

[PDF File (Adobe PDF File), 19KB - mhealth_v6i6e10292_app1.pdf]

Multimedia Appendix 2

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 36MB - mhealth_v6i6e10292_app2.pdf]

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Abbreviations

BART: Balloon Analog Risk Task
CCAT: computerized cognitive addiction therapy
DDT: Delay Discounting Task
IGT: Iowa Gambling Task
ISL: International Shopping List
MUD: methamphetamine use disorder
SUD: substance use disorder

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Original Paper

Using the Habit App for Weight Loss Problem Solving: Development and Feasibility Study

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Abstract

Background: Reviews of weight loss mobile apps have revealed they include very few evidence-based features, relying mostly on self-monitoring. Unfortunately, adherence to self-monitoring is often low, especially among patients with motivational challenges. One behavioral strategy that is leveraged in virtually every visit of behavioral weight loss interventions and is specifically used to deal with adherence and motivational issues is problem solving. Problem solving has been successfully implemented in depression mobile apps, but not yet in weight loss apps.

Objective: This study describes the development and feasibility testing of the Habit app, which was designed to automate problem-solving therapy for weight loss.

Methods: Two iterative single-arm pilot studies were conducted to evaluate the feasibility and acceptability of the Habit app. In each pilot study, adults who were overweight or obese were enrolled in an 8-week intervention that included the Habit app plus support via a private Facebook group. Feasibility outcomes included retention, app usage, usability, and acceptability. Changes in problem-solving skills and weight over 8 weeks are described, as well as app usage and weight change at 16 weeks.

Results: Results from both pilots show acceptable use of the Habit app over 8 weeks with on average two to three uses per week, the recommended rate of use. Acceptability ratings were mixed such that 54% (13/24) and 73% (11/15) of participants found the diet solutions helpful and 71% (17/24) and 80% (12/15) found setting reminders for habits helpful in pilots 1 and 2, respectively. In both pilots, participants lost significant weight (P=.005 and P=.03, respectively). In neither pilot was an effect on problem-solving skills observed (P=.62 and P=.27, respectively).

Conclusions: Problem-solving therapy for weight loss is feasible to implement in a mobile app environment; however, automated delivery may not impact problem-solving skills as has been observed previously via human delivery.

Trial Registration: ClinicalTrials.gov NCT02192905; https://clinicaltrials.gov/ct2/show/NCT02192905 (Archived by WebCite at http://www.webcitation.org/6zPQmvOF2)

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KEYWORDS

mobile app; mHealth; weight loss; obesity; problem solving

Introduction

Reviews of weight loss mobile apps have revealed they include very few evidence-based features [1,2], rarely involve behavioral experts in the developmental process [1,3], and lack efficacy data [1]. The most common features in weight loss apps are self-monitoring and goal setting, which is a narrow list given that evidence-based behavioral weight loss programs deliver up to 20 different behavioral strategies [2]. Further, a behavior change taxonomy for diet and exercise includes 40 behavioral strategies [4]. Science that demonstrates how specific behavioral strategies can be effectively implemented via a mobile platform could improve the impact of weight loss apps.

Reliance on self-monitoring is a problem because adherence to self-monitoring is often low. In one study that prescribed a commercial weight loss mobile app to 212 primary care patients, more than half (56%) did not use it in the first month and by 6 months 84% were not using it [5]. With self-monitoring being the cornerstone feature, impact is limited to those willing to self-monitor regularly. A comprehensive set of behavioral strategies is needed in weight loss apps to increase relevance, utility, and impact in people at varying levels of adherence and motivation.

Some apps include a more comprehensive suite of behavioral strategies. For example, the Noom Coach app [6] connects users to a live coach who is trained to deliver the Diabetes Prevention Program, a behavioral weight loss program that includes 20 behavioral strategies [7]. The app itself does not deliver the strategies, but rather a trained coach, which costs US $45 to $90 per month. Higher levels of sophistication in behavioral strategies generally come with a cost relative to other weight loss apps, the majority of which are free. To the extent that an app can be programmed to deliver additional behavioral strategies automatically, less coach time and expense may be required which would facilitate wider reach and impact.

One behavioral strategy that is leveraged in virtually every visit of behavioral weight loss interventions and is specifically used to deal with adherence and motivational issues is problem solving. Problem solving is a counseling technique used to help an individual identify barriers to behavior change and generate solutions to be iteratively attempted until barriers are overcome [8]. In practice, the counselor works through five steps with the patient, including (1) identifying a significant barrier to behavior change, (2) brainstorming a list of solutions with the patient, (3) having the patient select a solution he/she would be willing to try over the next week, (4) scheduling a time to attempt the solution, and (5) evaluating the outcome and trying additional solutions until the problem is solved. At the end of each session of behavioral weight loss treatment, patients are asked to identify barriers that are likely to arise as they attempt the homework assignment and they are then assisted in making a plan to overcome those barriers [9]. Additionally, an entire session is devoted to problem-solving skills as well so that patients get more intensive training in how to make progress in the presence of barriers [7]. Given the systematic process of problem solving, it would seem conducive to being facilitated via a mobile app.

Another advantage of a problem-solving app is that studies have established problem solving is an "active ingredient" of behavioral weight loss interventions [10,11]. Problem solving has been shown to be effective as a standalone intervention for weight loss maintenance [12] and is a strong predictor of weight loss outcomes [13]. Finally, a problem-solving app can be designed to address a wide range of weight loss barriers.

Although problem solving has not been incorporated in a weight loss mobile app, it is a staple in multistrategy depression mobile apps [14-16] and three studies tested technology-based programs for depression exclusively focused on problem solving [17-19]. Two studies of Web-based problem-solving depression programs revealed statistically and clinically significant improvements in depression relative to waitlist controls [17,18], although one was only effective when paired with email coaching [18]. In a recent remote trial of a problem-solving therapy app for depression, participants were emailed links to a problem-solving app but they were provided no human contact during the study. Less than half of participants downloaded the app, which suggests that human contact may be necessary at treatment initiation [19]. Nonetheless, participants with elevated depression scores in the problem-solving app condition showed greater declines in depression relative to those in a control app condition. The lack of human contact may have undermined outcomes, given the far higher download rates in studies providing human contact [16]. Studies of weight loss mobile apps failed to establish their efficacy in the absence of other support [5]. As such, the problem-solving app proposed in this study will be paired with access to a social media-delivered weight loss intervention, which has been shown to have modest effects on weight [20-22].

This study describes the development and feasibility testing of the Habit app, which was designed to automate the problem-solving process for common weight loss barriers. Once developed, two iterative pilot studies were performed to evaluate the feasibility and acceptability of the Habit app. In each pilot study, adults who were overweight or obese were enrolled in an 8-week intervention that included the Habit app plus support via a private Facebook group. Feasibility outcomes include retention, app usage, usability, and acceptability. Changes in problem-solving skills and weight over 8 weeks are described, as well as app usage and weight loss at 16 weeks. After pilot 1, refinements were made to the program.

Methods

Habit App Development: Overview

To develop a database of weight loss problems, a steering committee of clinicians was queried and problem-solving sessions with patients were conducted. Solutions were derived in problem-solving sessions and by our investigative team, who have extensive experience in behavioral weight loss counseling. An algorithm was then designed to ensure solutions provided by the app were tailored to user characteristics.

Steering Committee of Clinicians

Eleven counselors (4 dietitians, 5 psychologists, 1 Master's-level counselor, and 1 health educator) with experience counseling

patients for weight management and practicing at UMass Memorial Medical Center composed our steering committee and were asked to name the most common problems patients experience when it comes to diet and exercise. A total of 77 problems were identified.

Problem-Solving Sessions

Adults with obesity (N=30; female: 27/30, 90%; age: mean 47, SD 13 years; body mass index [BMI]: mean 35.9, SD 4.2 kg/m^2; non-Hispanic white: 23/30, 77%) were recruited via ads to participate in a single session of problem solving with a weight loss counselor. Adults were eligible if they had BMI between 30 and 45 kg/m^2 and were currently trying to lose weight. Each participant attended a 1-hour session with a weight loss counselor in which the problem-solving session of the Diabetes Prevention Protocol Lifestyle Intervention was administered. These sessions followed the five-step problem-solving process described previously. Each participant was asked to discuss one diet and one exercise problem, and the counselor cycled through the process for each and came up with 10 solutions for each problem. These sessions generated 60 problems and 600 solutions, although many were duplicates.

Categorization of Problems

A total of 137 responses for problems (77 from steering committee, 60 from patients) were reviewed by the investigative team who removed duplicates and infrequent responses and classified the remaining into nine diet and six exercise problem categories (see Table 1).

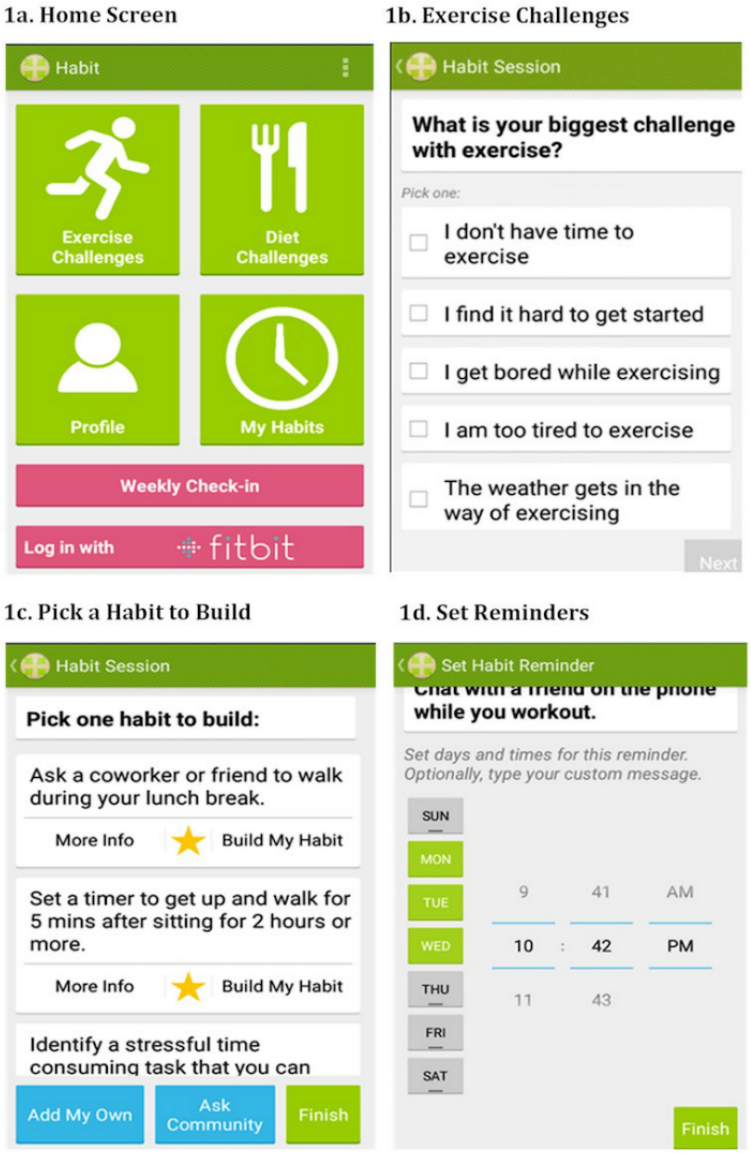
Algorithm Development

Many of the solutions generated were specific to user characteristics (eg, stay-at-home mom) and/or lifestyle factors (eg, currently exercises three times per week). For example, among patients who said they eat when they are bored, some engaged in this habit in the evening after work, whereas others while taking care of children at home during the day. Solutions would be different for these scenarios. To the extent the app provides many irrelevant solutions, the user would be unnecessarily burdened. As such, each problem was accompanied by a set of one to five questions regarding user and lifestyle characteristics that would eliminate as many irrelevant solutions for the user as possible. The user and lifestyle characteristics that had relevance to multiple problems were queried during the profile setup (see Figure 1). User characteristics included, but were not limited to, employment status, parental status, medical conditions, and climate. Lifestyle characteristics included, but were not limited to, sleep and work hours, current exercise regimen, and exercise preferences.

Table 1. Problem categories for diet and exercise.

Categories	Illustrative examples	Example solutions
Diet		
Stress	“I eat too much when I’m stressed”	“Make a list of stress foods and make sure not to bring them into the house”
Willpower	“I can’t resist junk food people bring to work”	“Bring healthy snacks to work to eat instead”
Hunger	“I feel hungry from 3 pm until bedtime”	“Have cut up fruit and veggies in the fridge ready to snack on”
Eat when bored	“I snack a lot when I’m home with the kids”	“Make a list of activities that involve going places that do not have food (eg, library)”
Restaurants	“It’s too hard to track what I eat when I eat out”	“Reduce the number of meals you eat out by 1 per week”
Weekends	“The lack of structure on weekends makes it harder to watch diet”	“Plan menus on the weekend like you would on a weekday”
Parties/holidays	“I want to try all the foods at a party”	“Take some food home to eat at your next meal time”
Sugary beverages	“I drink too much soda”	“Switch some sodas for noncalorie seltzers”
Alcohol	“I end up eating more when I drink”	“Have a glass of water between alcoholic beverages to slow you down and fill you up”
Exercise		
Time	“It’s hard to make time to exercise”	“Schedule in exercise like you would other appointments”
Hard to get started	“I’m so unmotivated to exercise”	“Start with a small goal like 10 minutes of exercise per day”
Boring	“I find exercise boring”	“Do something enjoyable while exercising like watching TV or listening to a book”
Too tired	“I’m too tired to exercise”	“Try these sleep hygiene techniques to improve your sleep”
Weather	“I miss workouts due to bad weather”	“Develop an indoor exercise plan to use as a backup”
Pain/injury	“Knee pain prevents me from exercising”	“Make appointment with a physical therapist to learn exercises that won’t cause pain”

Figure 1. Habit app screenshots.



Habit App

Home Screen

The home screen of the Habit app (see Figure 1) gives users the choice to update their profile, address a diet or exercise challenge ("problem solving"), view solutions they currently have scheduled, or complete a weekly check-in. In usability testing, participants did not prefer the terms "problems," "barriers," or "solutions," but rather suggested "challenges" and "habits." Therefore, language according to their preferences was adopted. Each feature is described subsequently.

Profile

The Habit app prompts users to set up a profile in which they enter their height, weight, goals, current exercise habits and preferences, employment status, parental status, and notification preferences. Users can indicate how often they prefer to be reminded to weigh in. In our pilot studies, users were instructed to weigh in weekly and work on one to two habits per week. Fitbit users can log in using their Fitbit credentials and transfer data logged by the Fitbit device or entered in the Fitbit app, which allowed Habit to remind the user to problem solve if they exceeded their calorie goal. The Habit profile page includes a weight graph and lists the participant's current list of habits.

Problem Solving

The first step of problem solving is "identify the problem." For this step, users can choose a diet or exercise challenge. Once selected, a list of challenges appears (see Figure 1). Once they choose a challenge, they are asked to further specify the challenge by answering one to five questions, depending on the challenge selected. Participants also have the option of adding habits to the app if the habit they would like to work on is not included in the app's database. The second step of problem solving is "brainstorm solutions." A screen appears with a list of solutions, referred to as "habits" in the app (see Figure 1). For each, the user can click "more info" to be linked to an online article that elaborates on the importance of the habit and how to implement it. The third step of problem solving is "pick a solution to try." For this, the user selects "build my habit" for

the habit they want to try. The fourth step of problem solving is "make a plan." A list of days of the week and hours of the day is presented and the app prompts the user to set reminders to implement the habit (see Figure 1). A reminder notification occurs on the selected time and days until the user deactivates the notification. All scheduled habits are viewable by clicking the My Habits button on the main page. Users can delete the reminders here and view all current habits and all habits in their history. The fifth step of problem solving is "follow-up." Each week, the user will be prompted to complete a weekly check-in, which asks the user to enter their current weight, to indicate all scheduled habits they successfully accomplished for the week, to indicate all the habits they would like to work on for the coming week, and to select new habits. Those indicating a desire to select new habits are brought back to the main page to enter a challenge.

Overview of Pilot Series

Two sequential single-arm pilot studies were conducted to examine the feasibility, acceptability, and use of the Habit app. Changes in problem-solving skills and weight over 8 weeks were described. The Habit app was paired with a private counselor-led Facebook group. Identical recruitment, screening, inclusion and exclusion criteria, and measures were used for pilots 1 and 2. Intervention refinements were made for pilot 2 based on pilot 1 results. All work was approved by the University of Massachusetts Medical School Institutional Review Board.

Recruitment and Screening

Participants were recruited for pilot 1 in December 2015 through January 2016, and for pilot 2 in July 2016 through September 2016. Online recruitment was used with ads posted in Facebook groups and Craigslist pages throughout the United States. A link to an initial online survey was included in the recruitment ad, which directed participants to a study description and initial screening questions. Eligible individuals were sent a consent form and booked for a telephone screening call. During the call, staff reviewed the consent document, asked remaining eligibility-related questions, and emailed a link to the baseline survey. The survey included questions about participant characteristics and problem-solving skills. Eligible participants were sent a unique link to download the app and join the Facebook intervention group and sent a Wi-Fi scale to measure their body weight during the study.

Inclusion and Exclusion Criteria

Participants were required to be age 18 years or older, have a BMI between 30 and 45 kg/m^2, currently use an Android smartphone daily, have a Gmail account or be willing to open one (the app was located on Google Play), have connectivity to the internet at home and work, and have written physician clearance. Participants were excluded if they were not regular users of Facebook, were not comfortable using a weight loss app, had severe mental illness or substance abuse, were pregnant or lactating, had bariatric surgery, were taking medication that affects weight, had type 1 or 2 diabetes, or had a medical condition that precludes lifestyle changes.

Habit App Orientation

Participants were emailed orientation materials and setup instructions for the app and Wi-Fi scale. The app and Facebook group were explained, including guidance on participation (eg, work on one to two challenges per week, check Facebook page daily).

Intervention

Participants were asked to use the Habit app to work on one to two weight loss challenges each week for 8 weeks while participating in a private counselor-led Facebook group. The counselor posted once per day in the Facebook group. On Monday mornings, the counselor's post prompted participants to use the Habit app to select one to two habits for the week, and on Sunday mornings they were asked to report how they did with the habits they chose for that week. Posts on Tuesday through Saturday covered basic behavioral weight loss strategies, including nutrition education, developing a physical activity regimen, stress management, negative thinking, and others as described elsewhere [23]. Content was consistent with that covered in the Diabetes Prevention Program Lifestyle intervention [7].

Follow-Up Assessments

Participants completed weigh-in and a follow-up survey at 8 weeks. At 16 weeks, their weight and use of the app over the previous 8 weeks was queried. Compensation of US $40 was provided at the end of the study.

Measures

Retention

Retention was defined as the percentage of participants who completed the follow-up weigh-in (via Wi-Fi scale) at 8 weeks.

App Usage

Participants received a weekly survey that asked how many times they used the Habit app over the past week, how many habits they tried, and how many reminder notifications they scheduled. At 16 weeks, they were asked to estimate how many times in the past 8 weeks (since the intervention ended) they used the app.

System Usability Scale

The System Usability Scale (SUS) includes 10 Likert scale items to estimate overall usability and participant satisfaction and is useful in comparing different versions of the same system [24]. A SUS score greater than 70 is considered adequate and a score greater than 80 is high [24,25].

Facebook Group Engagement

Engagement in the Facebook group was defined as the total number of likes, comments, and original posts. Engagement data was captured via the Facebook API using a computer program.

Acceptability

At the end of each pilot, participants were asked to rate on a five-point Likert scale how much they agreed with the following statements: "The diet-related habits in the Habit app were helpful

for me," "The exercise-related habits in the Habit app were helpful for me," "Being able to set reminders was helpful to me," "Coach posts on Facebook were helpful," "Participants posts on Facebook were helpful," and "I would recommend Habit app to my friends and family." Participants were also asked to list any challenges they experienced that were not addressed by Habit app.

Social Problem-Solving Inventory-Revised

The Social Problem-Solving Inventory-Revised (SPSI-R), which measures an individual's problem-solving ability, was administered at baseline and at 8 weeks. Scores are sensitive to change in interventions of problem-solving therapies [26,27] and have construct validity [28].

Weight

Weight was obtained using the Fitbit Aria scale at baseline, 8 weeks, 16 weeks, and whenever participants weighed themselves during the intervention period. Participants were mailed a scale once they were determined to be eligible and provided staff with log-in information for the scale so they could record weight during assessments. At the end of the study, participants were allowed to keep the scale.

Analytic Plan

In both pilots, retention, app usage, Facebook group engagement, and acceptability were summarized. Paired-samples *t* tests were used to evaluate change in problem solving and weight over 8 weeks. Baseline value carried forward was used to impute missing data at 8 weeks for problem solving and weight.

Sample Size Considerations

Leon et al [29] stated, "Power analyses should not be presented in a pilot study that does not propose inferential results." As they and others recommend [29,30], we based the sample size on necessities for examining feasibility. For each pilot, our recruitment target was a sample size of 20, which would allow us to identify usability issues under conditions of regular use. In pilot 1, we exceeded this target (N=27) so we recruited somewhat less in pilot 2 (N=16) for a total sample of 43. This sample size is consistent with recent pilot studies of similar technology-delivered weight loss interventions [23,31].

Results

Pilot 1

Participant Characteristics

Participants (N=27) had a mean age of 37.22 (SD 11.55) years and a mean baseline BMI of 31.14 (SD 4.63) kg/m^2; 67% (18/27) were female and 85% (23/27) were non-Hispanic white (see Table 2).

Feasibility

Three of 27 participants (11%) did not provide weight data at 8 weeks. Participants reported using the Habit app on average a total of 22.96 (SD 18.77) times over 8 weeks, with 18 of 27 participants (67%) using the app during week 8 (see Table 3). Participants reported trying a mean 2.46 (SD 1.61) habits per week and scheduled reminders for a mean 2.37 (SD 1.78) habits per week. Participants added a mean 3.59 (SD 6.56, range 0-29) habits of their own to the app. At 16 weeks, 15 participants (59%) had used the app at least once and the mean number of uses was 7.27 (SD 9.86). The mean SUS score was acceptable (mean 73.00, SD 15.82).

Participants engaged with the Facebook group a mean 70.96 (SD 77.21; range 0-265) times. Only one participant (4%) did not engage at all in the Facebook group. "Likes" were the most common form of engagement with a mean 41.44 (SD 58.42), followed by comments (mean 24.22, SD 26.81). Original posts were less frequent with a mean 5.30 (SD 6.24) total per participant. Participants made a mean 8.87 (SD 9.65) engagements per week.

In terms of acceptability, of the 24 (89%) who completed the 8-week follow-up survey, 54% (13/24) agreed/strongly agreed the diet habits in the app were helpful, and 14 of 24 (58%) agreed/strongly agreed the exercise habits in the app were helpful. Most (17/24, 71%) agreed/strongly agreed that being able to set reminders was helpful and most agreed/strongly agreed that the coach posts in the Facebook group were helpful (20/24, 83%), but somewhat fewer agreed/strongly agreed (15/24, 63%) that participants' posts in the Facebook group were helpful. Thirteen (54%) agreed or strongly agreed that they would recommend the Habit app to friends. Three participants mentioned a total of three problems that were not addressed in the app.

Problem Solving and Weight Loss

No significant changes were observed in total problem-solving score (t_{26}=–0.50, P=.62) from baseline to 8 weeks.

Participants' weight changed by a mean –3.53 (SD 5.91, range –20.10 to 6.80) pounds (t_{26}=3.10, P=.005), which is –1.61% of baseline weight (SD 2.52, range –7 to 3), or 0.20% (SD 0.03%) per week (see Table 4). At 16 weeks, participants' weight changed by a mean –3.33 (SD 10.12, range –28.90 to 12.60) pounds from baseline (t_{26}=1.71, P=.09), which is –1.26% of baseline weight (SD 4.55, range –12% to 9%).

Table 2. Participant characteristics in pilots 1 and 2.

Demographics	Pilot 1 (N=27)	Pilot 2 (N=16)
Gender (female), n (%)	18 (67)	12 (75)
Age (years), mean (SD)	37.22 (11.55)	37.35 (10.85)
Race/ethnicity (white), n (%)	23 (85)	12 (75)
Baseline body mass index (kg/m^2), mean (SD)	31.15 (4.63)	32.96 (5.99)

Table 3. App usage and system usability for pilots 1 and 2.

Use and usability	Pilot 1 (N=27)	Pilot 2 (N=16)
App usage during 8 weeks of intervention, mean (SD)	22.9 (18.7)	24.9 (19.8)
App usage during 8 weeks following intervention, mean (SD)	7.27 (9.86)	3.73 (6.43)
Participants using app during 8 weeks following intervention, n (%)	16 (59)	8 (50)
System Usability Scale score, mean (SD)	73.00 (15.82)	64.00 (11.83)

Table 4. Weight change and problem-solving skills in pilots 1 and 2.

Weight change and problem solving skills	Pilot 1 (N=27)	Pilot 2 (N=16)
Percent weight loss at 8 weeks (%), mean (SD)	–1.61 (2.62)[a]	–2.25 (3.92)[a]
Participants losing ≥3% at 8 weeks, n (%)	10 (37)	8 (50)
Percent weight loss at 16 weeks (%), mean (SD)	–1.26 (4.55)	–1.03 (5.31)
Participants losing ≥3% at 16 weeks, n (%)	7 (26)	9 (56)
SPSI-R[b] total standard score change, mean (SD)	0.67 (6.83)	–2.68 (9.32)

[a]$P<.05$.

[b]SPSI-R: Social Problem-Solving Inventory-Revised.

Modifications

Following pilot 1, findings were reviewed by the investigative team to determine changes needed to the Habit app and/or the intervention model. Participants running older versions of Android on their phones had a disproportionate amount of bugs, thus the Android version was restricted to version 4.0 (released October 2011) or later for pilot 2. Further, given that no improvement was observed in problem-solving skills, the team decided to add a webinar that demonstrated the problem-solving process to participants before using the app. Simply using the app might not result in learning the problem-solving process, but this added tutorial might give participants a clear understanding of the problem-solving process facilitated by the app and how they might generate habits to add to the app or solve problems even without the app. Before receiving the intervention, participants attended the problem-solving webinar led by the principal investigator. In the webinar, participants learned that the Habit app was designed to deliver a five-step problem-solving process known to be effective in helping people change behavior. They received a rationale for problem solving and the process was modeled with a volunteer from the group who shared a problem. The investigator engaged the group in brainstorming and the volunteer was asked to select a solution and make a plan to try it. Participants were encouraged to share problems in the Facebook group to tap the group for brainstorming, particularly if problems arose that were not addressed in the Habit app.

Pilot 2

Participant Characteristics

Participants (N=16) had a mean age of 37.35 (SD 10.85) years and a mean baseline BMI of 32.96 (SD 5.99) kg/m^2; 71% (11/16) were female and 71% (11/16) were non-Hispanic white (see Table 2).

Feasibility

All participants (16/16; 100% retention) provided weight data at 8 weeks. Participants reported using the Habit app a mean 24.93 (SD 19.86) times over 8 weeks, with 9 of 16 participants (56%) using the app on week 8 (see Table 3). They reported trying a mean 1.67 (SD 0.98) habits per week and scheduled reminders for a mean 2.11 (SD 1.60) habits per week. Participants added a mean 2.93 (SD 3.66, range 0-12) habits of their own to the app. At 16 weeks, 50% (8/16) of participants had used the app at least once and mean number of uses was 3.73 (SD 6.43). Mean SUS scores were below the acceptable cut-off of 70 (mean 64.00, SD 11.83).

Mean total engagement was 40.25 (SD 12.94; range 1-97). “Likes” were the most common form of engagement with a mean total of 18.50 (SD 20.32), followed by comments (mean 21.00, SD 12.94). Original posts were less frequent with only a mean 0.75 (SD 1.24) per participant. Participants made a mean 5.03 (SD 3.72) engagements per week.

All but one participant completed the 8-week follow-up survey on acceptability (see Table 5). Of the 15 who did, nearly three-quarters (11/15, 73%) agreed/strongly agreed that the diet habits in the app were helpful, and 10 of 15 (67%) agreed/strongly agreed the exercise habits were helpful. Most participants agreed/strongly agreed that being able to set up reminders and the coach posts were helpful (12/15, 80% and 13/15, 87%, respectively). Most (12/15, 80%) also agreed/strongly agreed that participants’ posts were helpful. Five participants (33%) said they would recommend the Habit app to a friend. Four participants mentioned a total of four problems that were not addressed in the app.

Table 5. Acceptability of the Habit app in pilots 1 and 2.

Acceptability	Pilot 1 (N=24)[a], n (%)	Pilot 2 (N=15)[a], n (%)
Diet solutions were helpful (% agree or strongly agree)	13 (54)	11 (73)
Exercise solutions were helpful (% agree or strongly agree)	14 (58)	10 (67)
Being able to set reminders was helpful (% agree or strongly agree)	17 (70)	12 (80)
Facebook: coach posts were helpful (% agree or strongly agree)	20 (83)	13 (87)
Facebook: participants posts were helpful (% agree or strongly agree)	15 (63)	12 (80)
Would recommend Habit app to friends/family (% agree or strongly agree)	13 (54)	5 (33)

[a]Three participants did not complete the survey in pilot 1; one did not complete the survey in pilot 2.

Problem Solving and Weight Loss

No significant changes were observed in total problem-solving score (t_{15}=1.15, *P*=.27). Participants weight changed by a mean –5.01 pounds (SD 8.04, range –24.10 to 8.10), which was 2.25% of baseline weight (SD 3.92, range –8 to 6; t_{15}=2.49, *P*=.03) or 0.28% (SD 0.05) per week of baseline weight. At 16 weeks, participants weight changed by a mean –2.37 pounds (SD 10.68, range –22.90 to 16.20; t_{15}=0.89, *P*=.39), which is on average –1.03% of baseline weight (SD 5.31, range –12 to 8).

Discussion

Results from pilots 1 and 2 show acceptable use of the Habit app over 8 weeks with, on average, two to three uses per week, which was the rate of use recommended in the program. Acceptability ratings were mixed such that 54% (pilot 1) to 73% (pilot 2) of participants found the diet and/or exercise solutions helpful and the majority (pilot 1: 70%; pilot 2: 80%) found setting reminders for habits helpful, but only 54% (pilot 1) to 33% (pilot 2) said they would recommend the app to a friend. The usability scores measured by SUS (pilot 1: 73%; pilot 2: 64%) also followed this trend in which pilot 2 SUS scores were less than acceptable. In spite of this, 59% (pilot 1) to 50% (pilot 2) continued to use the app in the 8 weeks to some degree following the intervention. These data suggest the app may have been very useful for some, but not useful for others. Most participants (pilot 1: 83%; pilot 2: 86%) found the Facebook group helpful suggesting it added value to the intervention. A larger trial will be needed to compare how the app is used by individuals and how different use patterns/choices affect (1) user experience, (2) how much an individual finds the app helpful, and (3) how likely they are to recommend the app to others.

Participants lost weight during the 8-week intervention, which when converted to mean weekly weight loss (pilot 1: –0.20%; pilot 2: –0.30%), is fairly consistent with the weekly rate of weight loss over 6 months in the Diabetes Prevention Program (0.28%) [32]. However, further research is needed to determine whether weight loss from a program of this nature would continue through 6 months. In the 8 weeks after the intervention program ended, some weight regain was observed. Weight change in this intervention was highly variable with 37% (pilot 1) to 50% (pilot 2) losing 3% or more of their baseline weight in 8 weeks, but 38% to 41% not losing any weight. The Diabetes Prevention Program weight loss goal for 6 months was 7%, thus those achieving 3% or more over 2 months (8 weeks) were on track toward that goal. The lack of benefit for some participants suggests that remotely delivered weight loss programs may not be suitable for everyone. The sample was too small to explore predictors of intervention efficacy, but this will be an important question for larger trials.

Contrary to our hypotheses, no changes were observed in problem-solving skills. This may have been due to lack of power or it may be that having technology facilitate problem solving does not translate into improved problem-solving skills in the same way that human-delivered problem-solving therapy does. Only one of the three existing studies testing technology-delivered problem solving for depression examined problem-solving skills as an outcome and it did not find an effect [17]. In human-delivered problem-solving therapy, the therapist provides input into the selection of both problems and solutions. Efficacy of an app then would depend on the extent to which participants chose to work on problems that were significantly obstructing their weight loss progress versus problems that even if solved would not have much impact on weight loss. Patients might not always be aware of which problems if solved would deliver the best return on investment in terms of their weight. For example, one participant said she would have liked the app to help her increase her water consumption, a problem she felt was obstructing her weight loss. Because this problem was not in the app, she hand entered drinking more water as a solution so she could set reminders to do it. Unfortunately, the evidence for increasing water consumption on weight loss is weak [33], so using the app to build this habit would not likely result in much if any weight loss, especially to the extent that her energy was focused on this habit to the exclusion of others that would more directly impact energy balance. On the one hand, allowing participants to add their own solutions engages them in the brainstorming process; on the other hand, it may lead them to enter solutions that are ineffective. Although the counselor in the Facebook group can provide feedback to participants on the habits they choose, not all participants discussed the habits they chose in the group. Given the volume of misconceptions around weight management in public and professional discourse [34], some effort may be needed to debunk myths and keep patients focused on behavioral strategies that are supported by evidence.

Problem-solving skills may not have improved because the degree of automation of the process of problem solving compromised participant's ability to learn the skills. The Habit

app could be improved by including a way for the counselor to provide input into the problems and solutions selected by participants. The next iteration of the app will give the user feedback on whether the habits selected are resulting in weight loss and prompt them to switch habits when weight is not declining.

Automating the problem-solving process provides a unique opportunity to access data on specific habits and associated weight loss, which could lend insights into which specific habits work best for whom. In future work using mobile app-delivered problem solving, the specific problem and solution sets associated with the greatest weight loss should be identified so that users can be pointed to the habits that are likely to produce the greatest results. For example, habits could have an efficacy rating to let users know which have worked best for users like them. This would help streamline the number of solutions offered and perhaps curb people from adding solutions that have intuitive appeal but are not useful. Such data would also push our knowledge of which specific behavior changes are most impactful when it comes to weight loss. Behavioral weight loss interventions include a collection of strategies focused on myriad behaviors (eg, meal planning, shopping habits, exercise) that can be overwhelming for patients to implement all at once. Granular behavioral data collected from mobile apps provide an enormous opportunity to increase our understanding of behavior.

This study has a number of limitations. The sample sizes in both pilots were not powered to test efficacy on weight loss. Instead, the first step in this line of research was to examine the use and acceptability of the app to test "proof of concept" and inform refinements without the investment of a fully powered trial. Resources to retrieve clickstream data from the app were lacking and thus self-report was relied on to measure use, which may have been biased toward overreporting. Clickstream data would have provided data on the specific problems and solutions selected, although with such small samples conclusions drawn from these data would be very limited. Going forward, these data will be critical to answer questions about how participants use the app and how certain patterns of use are related to weight loss. Another limitation is the lack of diversity in the sample, a problem that has plagued weight loss intervention studies for decades [35]. Research investigating what men and non-white adults want from a weight loss mobile app is needed. We developed the app for the Android platform because Android was one of the two mobile platforms with the largest market share in the United States and availability of low-cost Android devices made this platform more accessible to diverse user groups compared to the iOS platform. Future research will include development of the app for iOS platform to increase eventual reach. Finally, the impact of the Facebook group and the Habit app cannot be disentangled; however, research shows that apps with no accompanying support are insufficient to produce weight loss.

The next step in this research is further developmental work and feasibility testing to (1) improve the impact of the app on problem-solving skills, (2) assist users in selecting problem and solution sets that have a high likelihood of impacting weight, and (3) better integrate the app (and problem-solving process) with the online social network. Mobile delivery of complex behavioral strategies may require extensive developmental work to achieve treatment fidelity and affect treatment mechanisms. For this reason, treatment fidelity and mechanisms should always be measured in pilot and feasibility studies of mobile apps that deliver behavioral strategies. Problem solving is among a collection of behavioral counseling strategies that if effectively and inexpensively implemented in the mobile environment could increase the reach and impact of behavioral interventions.

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Conflicts of Interest

SP serves as a paid consultant for Fitbit, Inc. All other authors have no conflicts.

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Abbreviations

BMI: body mass index
SPSI-R: Social Problem-Solving Inventory-Revised
SUS: System Usability Scale

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Original Paper

Applying Natural Language Processing to Understand Motivational Profiles for Maintaining Physical Activity After a Mobile App and Accelerometer-Based Intervention: The mPED Randomized Controlled Trial

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Abstract

Background: Regular physical activity is associated with reduced risk of chronic illnesses. Despite various types of successful physical activity interventions, maintenance of activity over the long term is extremely challenging.

Objective: The aims of this original paper are to 1) describe physical activity engagement post intervention, 2) identify motivational profiles using natural language processing (NLP) and clustering techniques in a sample of women who completed the physical activity intervention, and 3) compare sociodemographic and clinical data among these identified cluster groups.

Methods: In this cross-sectional analysis of 203 women completing a 12-month study exit (telephone) interview in the mobile phone-based physical activity education study were examined. The mobile phone-based physical activity education study was a randomized, controlled trial to test the efficacy of the app and accelerometer intervention and its sustainability over a 9-month period. All subjects returned the accelerometer and stopped accessing the app at the last 9-month research office visit. Physical engagement and motivational profiles were assessed by both closed and open-ended questions, such as “Since your 9-month study visit, has your physical activity been more, less, or about the same (compared to the first 9 months of the study)?” and, “What motivates you the most to be physically active?” NLP and cluster analysis were used to classify motivational profiles. Descriptive statistics were used to compare participants’ baseline characteristics among identified groups.

Results: Approximately half of the 2 intervention groups (Regular and Plus) reported that they were still wearing an accelerometer and engaging in brisk walking as they were directed during the intervention phases. These numbers in the 2 intervention groups were much higher than the control group (overall P=.01 and P=.003, respectively). Three clusters were identified through NLP and named as the Weight Loss group (n=19), the Illness Prevention group (n=138), and the Health Promotion group (n=46). The Weight Loss group was significantly younger than the Illness Prevention and Health Promotion groups (overall P<.001). The Illness Prevention group had a larger number of Caucasians as compared to the Weight Loss group (P=.001), which was composed mostly of those who identified as African American, Hispanic, or mixed race. Additionally, the Health Promotion group tended to have lower BMI scores compared to the Illness Prevention group (overall P=.02). However, no difference was noted in the baseline moderate-to-vigorous intensity activity level among the 3 groups (overall P>.05).

Conclusions: The findings could be relevant to tailoring a physical activity maintenance intervention. Furthermore, the findings from NLP and cluster analysis are useful methods to analyze short free text to differentiate motivational profiles. As more sophisticated NL tools are developed in the future, the potential of NLP application in behavioral research will broaden.

Trial Registration: ClinicalTrials.gov NCT01280812; https://clinicaltrials.gov/ct2/show/NCT01280812 (Archived by WebCite at http://www.webcitation.org/70IkGagAJ)

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KEYWORDS

mobile apps; physical activity; fitness trackers; women; maintenance; accelerometer; randomized controlled trial; motivation; barriers; behavioral change

Introduction

Regular physical activity is associated with reduced risk of chronic illnesses, such as hypertension, type 2 diabetes, and several types of cancers [1-6]. Despite various types of successful physical activity interventions, maintenance of activity over the long term is extremely challenging [7]. In fact, approximately half of individuals who start a physical activity program will relapse or return to their previous inactive lifestyle within the first 6 months [8]. Given the high prevalence of relapse, understanding factors associated with increasing and maintaining physical activity is critical for women and racial or ethnic minority groups who have a higher prevalence of physical inactivity [9,10]. In a recent systematic review and meta-analysis, motivation and goals followed by belief about consequences and self-report of good or excellent health status are the strongest predictors of physical activity maintenance [8]. A motivational profile determines the reason(s) for one's actions, desires, and needs, and can be multi-dimensional and complex. Furthermore, this profile can be dynamic and fluctuate over time [11] based on one’s experiences, like going through a physical activity program. However, data related to long-term maintenance after cessation of an intervention is still limited.

As smartphone ownership has significantly increased in the past 10 years, (77% in 2018 in the US) [12], the use of digital technologies (ie, smartphone apps and activity trackers) to promote physical activity has gained popularity. These technologies allow investigators to incorporate critical components of physical activity maintenance like self-motivation, goal setting, and self-efficacy, to one’s daily life [7,13]. A recent systematic review has shown that smartphone apps and accelerometer-based interventions appear to improve physical activity and sedentary behaviors for at least a short period of time [14]. However, few clinical trials involving digital technologies to increase physical activity have examined sustainability of these interventions over time.

To fill this knowledge gap, we recently completed the mobile phone—based physical activity education (mPED) study, a randomized controlled trial (RCT) designed to examine the efficacy of a 3-month mobile app and accelerometer-based physical activity intervention and a 6-month maintenance intervention for physically inactive women. In this paper, semi-structured interview data collected at a 12-month telephone interview (study exit) were analyzed by natural language processing (NLP), a field of computer science which incorporates artificial intelligence and computational linguistics [15] to formulate algorithms used to extract information from textual inputs. Use of NLP in clinical and medical research began to appear in the 1980s, primarily by applying it to electronic health records (EHRs) [16-19], while NLP was brought into broader use more recently [20]. However, its application to behavioral research is still in its infancy. Therefore, to the best of our knowledge, this is the first study to use NLP to explore interview data to identify key motivational elements.

The aims of this paper are to 1) describe physical activity engagement post-intervention, 2) identify motivational profiles using NLP, and clustering techniques in a sample of women who completed the physical activity intervention, and 3) compare sociodemographic and clinical data among these identified cluster groups [15,17,18].

Methods

Study Design and Participants

The mPED trial is a randomized controlled trial (RCT) with 3 groups. In this paper, we analyzed the 12-month telephone interview (study exit) data of the mPED trial. Supplement 1 describes an overall study design. The primary outcome in this mPED trial was accelerometer recorded physical activity (average daily steps) over the 9-month period. Overall, the 3-month intervention resulted in a significant increase in physical activity (Regular and Plus groups versus Control group), but physical activity during the 6-month maintenance period did not significantly differ between the Regular and Plus groups.

The study protocol was approved by the University of California, San Francisco Committee on Human Research (CHR) and the mPED Data and Safety Monitoring Board. Detailed description of the study design and inclusion or exclusion of the study participants has previously been published [21-23]. In short, community dwelling physically inactive women age 25 to 65 with a body mass index (BMI) of 18.5–43.0 kg/m^2 who do not have medical conditions or physical problems that require special attention in an exercise program were recruited from the San Francisco Bay Area between May 2011 and April 2014.

Summary of a 3-Month Physical Activity and 6-month Maintenance Intervention

A total of 210 women were randomized into 1 of the 3 groups after completion of the run-in period. The control group received

an accelerometer for 9 months but did not receive any physical activity intervention. The Regular and Plus groups received an accelerometer, an identical physical activity trial app developed by the investigator, and brief in-person sessions for the first 3 months after randomization. While the study trial app was removed from the Regular group at the 3-month visit, the Plus group kept the trial app and was encouraged to continue using the physical activity diary in the app for the remaining 6-month maintenance period. Both groups also kept an accelerometer for 9 months. At the 9-month visit, participants in all groups returned the accelerometer (and study mobile phone with app for the Plus group) to the research staff. If the study app was installed on a participants' phone, it was removed by the research staff. Participants were encouraged to obtain and wear a pedometer/activity tracker/accelerometer to maintain their physical activity after the 9-month visit. Since the accelerometer used in the study was not commercially available, a research staff provided a list of pedometer/activity tracker/accelerometers and prices to participants who did not own one of these devices.

Procedures of 12-month Telephone Interview and Data Collection

Research staff scheduled a 12-month follow-up telephone intervention at the end of the 9-month visit. Participants then received a text, email or telephone call to confirm their 12-month appointment, and a list of interview questions was mailed or emailed to participants prior to their interviews. After completion of the 12-month telephone interview, participants received a check in the amount of US $40. The 12-month interview consisted of two parts: 1) a survey and 2) a semi-structured, telephone interview consisting of open-ended questions. This paper focuses on the survey data.

12-month Telephone Interview Survey

The survey consists of 2 types of questions: 1) close-ended questions and 2) open-ended questions to assess the use of digital technologies and maintenance of physical activity, such as "What type of phone do you have?"; "Do you currently have a health-related mobile app?"; "Do you have your own pedometer?"; "Do you currently wear a pedometer?" Self-reported physical activity level and types of physical activity were assessed by the question: "Since your 9-month visit, what types of exercise have you engaged in to be physically active?" A list of exercise types was provided to participants. Additionally, participants were asked the following question, "Since your 9-month study visit, has your physical activity been more, less, or about the same as compared to the first 9 months of the study?" To assess participants' motivation to maintain physical activity after the intervention, the research staff asked the following open-ended question: " What motivates you the most to be physically active?" They were encouraged to list at least two motivational reasons. Responses were transcribed by research members during or immediately after the interview. Later, all transcriptions were reviewed, and all typos and errors were corrected before analysis.

Analytic plans

Natural Language Processing, K-Means Clustering, and Principal Component Analysis

Motivational profiles for each of the participants were generated using machine learning. First, participants' responses to the open-ended question "What motivates you the most to be physically active?" were converted into numerical vectors that quantify responses. The numerical vectors were constructed by averaging 1000-dimensional word-vectors generated by a word2vec model trained on the Wikipedia corpus using a bag-of-words method by first converting each word in a participants' response into an equivalent word-vector and then averaging the resulting vectors. Word-vectors were generated using a skip-gram word2vec model [24,25] trained on the data of a Wikipedia data dump from 2015 [26], common words like "and" and "the" were removed by using the stop-word set in the Natural Language Toolkit (NLTK) software package [27], and the word-vector model itself was implemented using the Genism Python package [28]. Unlike traditional statistical approaches, selection of corpus (a large collection of texts) is extremely critical in an NLP analysis. To our knowledge, a Wikipedia data dump is one of the largest open source available corpora. Second, K-means clustering [29] was performed on the numerical vectors (which are a quantitative representation of participants' responses) using sci-kit learn [30]. The number of clusters used in the K-means clustering was derived using the elbow criterion [29]. Then, Principal Component Analysis (PCA) was used to reduce the dimensionality of the data to visualize the resulting clusters in two dimensions [29]. PCA preserves linear relationships and large distances between data points. For example, if two data points are widely separated, then they will also be widely separated in the PCA projection. The analysis was conducted on a Windows 7 laptop with a 2.4Ghz processor and 16GB of RAM, using Python 3.5.2 and Anaconda.

Other Analyses

Chi-square test or Analysis of Variance (ANOVA) was used to compare the sample baseline characteristics among identified cluster groups and responses to survey questions among the Control, Regular, and Plus groups. To ensure that the sample of 203 participants was sufficiently large to conduct these analyses, we performed post hoc power analysis for the ANOVA and chi-squared comparisons across the 3 motivational groups. This analysis showed that the minimum observed power obtained by our comparisons is 0.71 for this sample size and group distribution, which would indicate that the sample size is sufficient to generalize these conclusions for the study population. All survey data were entered into the software program using a double-data entry system. *P* values less than a Bonferroni-corrected .017 were considered statistically significant.

Results

Baseline Sociodemographics

Of those randomized 210 participants, 203 (97%) completed a 12-month survey. Mean participant age was 52.6 (SD 11.0)

years, 56.7% self-identified as non-Hispanic White, and 74.4% had a full or part time job. Age, race or ethnicity, education, annual household income, marital status, and employment status did not differ between 3 treatment groups (Control, Regular, and Plus; overall *P*>.05).

Use of Digital Technologies and Self-Reported Sustainability of Physical Activity at 12 months

At 12 months, 41.4% (84/203) of participants reported that they currently had at least 1 health-related app on their mobile phones, but this prevalence did not differ among the 3 treatment groups (*P*>.05; Table 1). While 61.6% (125/203) of the study participants reported that they owned a pedometer, physical activity tracker, or accelerometer, only 41.4% (84/203) reported they currently wore it. Use of pedometer or physical activity tracker/accelerometer in the Regular and Plus groups was significantly higher than in the Control group (52.2% and 46.2% versus 26.1%; overall *P*=.005). Among 38.1% (78/203) participants who did not have a pedometer or physical activity tracker/ accelerometer at the 12-month interview, 13.8% (28/203) reported that they were still looking for or planning to purchase one soon, and 8.4% (17/203) reported that they were too expensive to purchase or that they were going through financial difficulties.

In response to the question “Has your physical activity been more, less, or about the same compared to the first 9 months of the study?” a significantly higher proportion of participants in the Control group, compared to the Regular and Plus groups, reported engaging in more physical activity from 9 to 12 months (overall *P*=.006). However, a greater proportion of participants in the Regular and Plus groups engaged in more brisk walking compared to the Control group (overall *P*=.003). Among the 36% (73/203) of women who reported “less active,” “lack of time” (work or school cited as the main time constraint), “study ended,” and “did not have a pedometer” were the most frequently reported reasons. The proportion of women who reported lack of time and study ended in the Regular and Plus groups were statistically greater than the Control group (*P*=.02 and *P*=.04 respectively).

Profiles of Motivation to Be Active Using Natural Language Processing and K-Mean Clustering Techniques.

Overall, the top 3 most commonly used words (which are not stop words, like "the" or "and") are: "health" (n=67), "weight" (n=66), and "better" (n=65). Numerical vectors that quantify participants’ response to the question “What motivates you the most to be physically active?” were constructed by averaging 1000-dimensional word-vectors generated by the Wikipedia trained word2vec model (excluding common words like “and” and “the”). The elbow criterion was used to determine the number of clusters to set in the K-means clustering, and the resulting elbow curve is shown in Figure 1. Using this method, we determined that 3 clusters are most suitable to partition the motivational profiles effectively. Figure 2 shows the result of the Principal Components Analysis (PCA), “a statistical procedure that uses an orthogonal transformation to convert a set of observations of possibly correlated variables into a set of values of linearly uncorrelated variables called principal components” [33].

As seen in Figure 2, the 3 clusters are very distinct groups. Using these 3 clusters, we performed post-hoc qualitative analysis to define cluster names based on the motivations given by each of the patients. From this analysis, we determined that there was one cluster where individuals were mainly motivated to maintain physical activity for weight loss (Weight Loss group), one cluster which primarily focused on illness prevention such as diabetes and hypertension (Illness Prevention group), and one cluster that was mainly motivated by improving overall health (Health Promotion group). Overall, 19, 138, and 46 participants were classified to the Weight Loss group, the Illness Prevention and the Health Promotion groups. Table 2 shows the results comparing baseline sociodemographic characteristics and cardiovascular risks among these 3 groups. The Weight Loss group was significantly younger than the Illness Prevention and Health Promotion groups (overall *P*<.001). The racial and ethnic distribution also significantly differed among the 3 groups (*P*=.002). The Illness Prevention group has a larger number of Caucasians compared to the Weight Loss group (*P*=.001), while the Weight Loss group tended to be composed mostly of those who identified as African American, Hispanic, or mixed race compared to the Illness Prevention and Health Promotion groups (*P*=.008, *P*=.006, respectively). Additionally, the Health Promotion group tended to have lower BMI scores compared to the Illness Prevention group (overall *P*=.02). No other significant differences at the 95% confidence level were found across the remaining sociodemographic and cardiovascular risk factors (overall *P*>.05; see Table 2). The baseline moderate-to-vigorous intensity activity level did not differ among the 3 groups (overall *P*>.05).

Table 1. Use of digital technology and physical activity at 12 months after the intervention. The presence of two footnotes indicate a pairwise comparison.

Digital technology and activity	Overall (N=203), n (%)	Control (n=69), n (%)	Regular (n=69), n (%)	Plus (n=65), n (%)	Overall *P* value
Do you currently have a health-related mobile app? (Yes)	84 (41.4)	29 (42.6)	30 (44.1)	25 (39.1)	.94
Do you currently wear a pedometer? (Yes)	84 (41.4)	18 (26.1)[a,b]	36 (52.2)[a]	30 (46.2)[b]	.01
Do you have your own pedometer? (Yes)	125 (61.9)	35 (51.1)	47 (68.1)	43 (66.2)	.09
Types					.50
Fitbit	50 (24.6)	11 (5.4)	23 (11.2)	16 (7.9)	
Omron	26 (12.8)	7 (3.5)	8 (3.9)	11 (11.2)	
Other	23 (11.2)	11 (5.4)	8 (3.9)	7 (3.5)	
Do not know	26 (12.8)	6 (3.0)	8 (3.9)	9 (4.4)	
Do you have your own pedometer? (No)	78 (38.1)	34 (48.9)	22 (31.9)	22 (33.8)	
Reasons for not purchasing					.17
Still planning to purchase/keep looking	28 (13.8)	13 (6.4)	9 (4.4)	6 (3.0)	
Too expensive/financial difficulty	17 (8.4)	2 (1.0)	9 (4.4)	6 (3.0)	
Use app/phone/be able to estimate steps	9 (4.4)	4 (2.0)	1 (0.5)	4 (2.0)	
Do not help/do not like	7 (3.5)	5 (2.5)	0 (0)	2 (1.0)	
Technology challenging/not accurate	6 (3.0)	4 (2.0)	1 (0.5)	1 (0.5)	
Has one somewhere/hasn't set up	3 (1.5)	2 (1.0)	0 (0)	1 (0.5)	
Other	5 (2.5)	2 (1.0)	1 (0.5)	2 (1.0)	
Since your 9-month visit, what types of exercise have you engaged in to be physically active? (multiple choice question)					
Walking	126 (62.1)	49 (71.0)	44 (63.8)	33 (50.8)	.05
Brisk walking	94 (46.3)	21 (30.4)[a,a]	35 (50.7)[a]	38 (58.5)[a]	.003
Yoga	20 (9.9)	3 (4.3)	7 (10.1)	10 (15.4)	.10
Hiking	15 (7.4)	5 (7.2)	4 (5.8)	6 (9.2)	.75
Gardening/Yard work	16 (7.9)	7 (10.1)	3 (4.3)	6 (9.2)	.40
Cycling	19 (9.4)	7 (10.1)	5 (7.2)	7 (10.8)	.75
Other	110 (54.2)	39 (56.5)	35 (50.7)	36 (55.4)	.77
Since your 9-month study visit, has your physical activity been more, less, or about the same (compared to the first 9 months of the study)?					.006
More	64 (31.5)	29 (42.0)[c]	16 (23.2)[c]	19 (29.2)	
Less	73 (36.0)	13 (18.8)[a,d]	33 (47.8)[a]	27 (41.6)[d]	
About the same	66 (32.5)	27 (39.2)	20 (29.0)	19 (29.2)	
Top 3 reasons for being less active after the 9-month visit (multiple choice question)	**n=73**	**n=13**	**n=33**	**n=37**	
Study ended	20 (27.4)	0 (0)	12 (16.4)	8 (11.0)	.04
Lack of time	20 (27.4)	4 (5.8)	9 (13.0)	7 (10.8)	.02
Did not have a pedometer	12 (16.4)	2 (2.7)	3 (4.1)	7 (9.6)	.21

[a]*P*<.001.

[b]*P*=.008.

[c]*P*=.009.

[d]*P*=.002.

Figure 1. Elbow curve used to determine the number of clusters to be used in K-means clustering. On the x-axis are the number of clusters which the algorithm was set to fit and on the y-axis is the mean squared error of the clustering. The red dot is located at the mark which corresponds to 3 clusters and corresponds to the closest number of clusters to the "bend" of the elbow curve.

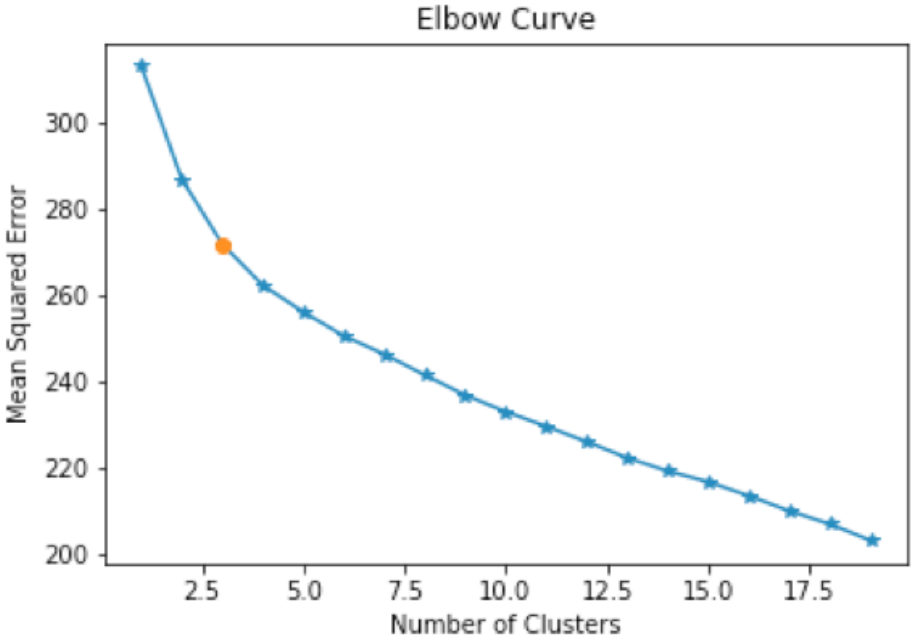

Figure 2. Principal Components Analysis (PCA) Visualization of motivational profiles. The plot axes represent the first two principal components of the bag-of-words vector representations of the motivations given by patients. The purple cluster corresponds to the responses of patients who listed weight loss as their sole motivation for physical activity, the teal cluster corresponds to patients who were primarily motivated by illness prevention, and the yellow cluster corresponds to those patients primarily motivated to do physical activity due to health promotion.

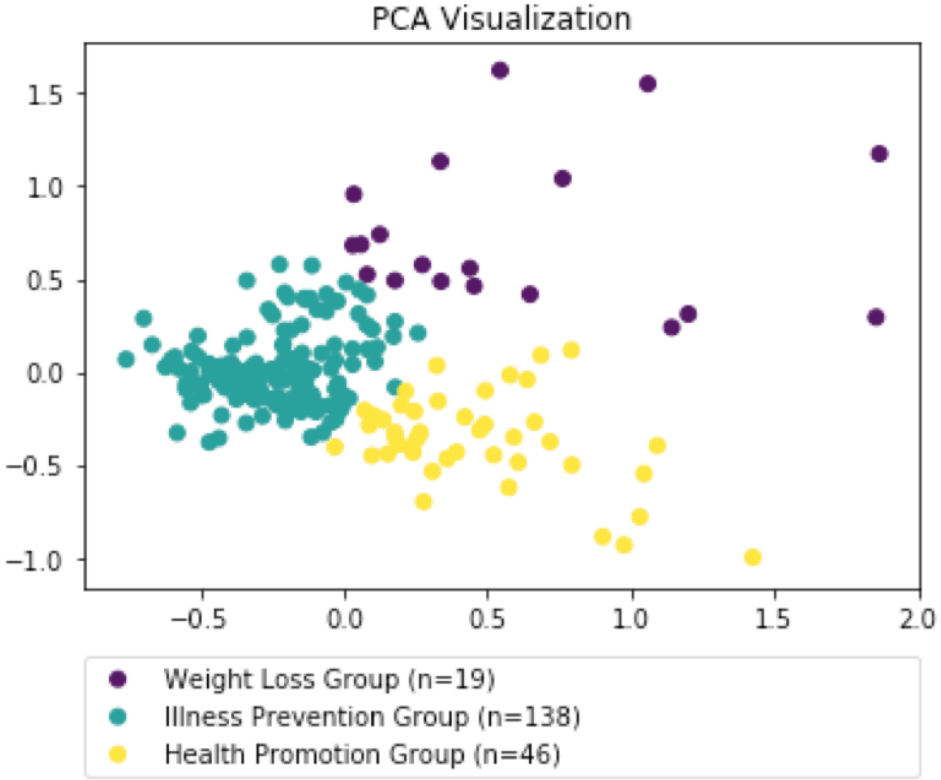

Table 2. Baseline characteristics of participants by 3 cluster groups. The presence of two footnotes indicate a pairwise comparison.

Demographic[a]	Weight Loss group (n=19)	Illness Prevention group (n=138)	Health Promotion group (n=46)	Overall *P* value
Age (years), mean (SD)	41.5 (12.0)[b,b]	53.9 (10.4)[b]	53.2 (9.7)[b]	<.001
Race/Ethnicity, n (%)				
White	4 (21.1)[c]	87 (63.0)[c]	24 (52.2)	.002
Asian	5 (26.3)	22 (15.9)	14 (30.4)	
African American, Hispanic, mixed	10 (52.6)[d,e]	29 (21.0)[d]	8 (17.4)[e]	
Education, n (%)				
Completed high school and some college	6 (31.6)	34 (24.6)	11 (23.9)	.43
Completed college	6 (31.6)	62 (44.9)	15 (32.6)	
Completed graduate school	7 (36.8)	42 (30.4)	20 (43.5)	
Marital Status, n (%)				
Currently married/cohabitating	8 (42.1)	75 (54.3)	23 (50.0)	.57
Employment, n (%)				
Employed for pay (full or part time)	14 (73.7)	100 (72.5)	37 (80.4)	.56
Cardiovascular risk factors				
Body mass index (kg/m^2), mean (SD)	31.2 (6.9)	30.4 (6.0)[f]	27.7 (5.8)[f]	.02
Smoking Status, n (%)				
Current smoker	1 (5.3)	2 (1.4)	1 (2.2)	.53
Menopause, n (%)	6 (31.6)[g]	88 (63.8)[g]	27 (58.7)	.03
High blood pressure, n (%)	3 (15.8)	50 (36.2)	15 (36.2)	.21
High total cholesterol, n (%)	4 (21.1)	51 (37.0)	14 (30.4)	.33
High glucose Diabetes, n (%)	3 (15.8)	10 (7.2)	3 (6.5)	.40
CESD score>16 points or taking antidepressant, n (%)	5 (26.3)	48 (34.8)	14 (30.4)	.70

[a]For the continuous variables, the mean and standard deviation, minimum, and maximum are shown; P value is based on ANOVA test. For categorical variables, frequency and percent are shown, where percentages are computed based on the number of non-missing observations in each treatment group and overall; P value is based on Chi-square test or Fisher exact test. Pairwise between-group differences with $P<.05$ and Bonferroni adjustment were used to control for multiple comparisons

[b]$P<.001$

[c]$P=.001$

[d]$P=.007$

[e]$P=.01$

[f]$P=.03$

[g]$P=.027$

Discussion

Principal Results

The present study aims to describe utilization of digital technologies and physical activity engagement post intervention, and to identify motivational profiles using NLP and clustering techniques in women who completed the mPED trial. We demonstrated the value of the use of NLP for participants' responses to an open-ended question. NLP and cluster analysis resulted in 3 distinguished clustering groups that were labeled as 1) the Weight Loss group, 2) the Illness Prevention group, and 3) the Health Promotion group. [16-20] In a recent study of applying NLP to EHR to automatically assess delivery of weight management counseling in two regions of Kaiser Permanente, it was demonstrated that NLP had similar capabilities as trained medical record abstractors [16]. Additionally, use of a Wikipedia data dump in our NLP analysis in this paper was supported by the study finding by Ramesh and colleagues in 2013 that Wikipedia, compared to MedlinePlus and the Unified Medical Language System, significantly improved EHR note readability [19]. Thus, NLP appears to offer an effective way to classify short free texting interview data.

Several studies examined physical activity motivational profiles using cluster analysis techniques [32-41], but the clear majority of these studies targeted children and college students and used

the Self-Determination Theory. In addition, none of these studies applied NLP in their studies. Therefore, it is difficult to make head-to-head comparisons with those studies in terms of characteristics of the cluster groups. While our study applied NLP to female participants' responses to an open-ended question, the previous studies used a questionnaire in a sample of both men and boys and women and girls [32-34,36-40]. For example, in the cluster analysis study of profiling physical activity motivation based on the Exercise Self-Regulation Questionnaire in a large adult sample participating in a physical activity study, 3 cluster groups (the low motivation, controlled motivation, and autonomous motivation groups) were identified. The autonomous motivation group, representing 53% of the sample, had a higher level of education and a lower BMI than the other 2 groups [32]. Race and ethnicity for the groups was not reported in the study.

It is important to note that in this study, 3 cluster groups were identified, but overall the characteristics of the Weight Loss group differed considerably from the other 2 groups, and the Weight Loss group represent only a small proportion of the sample (19/203). A much higher number of younger women and African American, Latino, or mixed-race women were in the Weight Loss group. These study findings are like our previous focus group study findings that physical appearance was not a big motivator for healthy eating in most participants, especially the older ones [42]. The most frequently reported motivation was to imagine unwanted outcomes from bad eating habits, such as a heart attack and diabetes [42]. We believe that understanding an individual's motivation is important because it helps clinicians and researchers tailor a physical activity maintenance intervention for women. Additionally, previous systematic reviews suggest one's motivation plays a critical role in sustaining physical activity after the intervention, and tailoring the intervention significantly improves adherence [43,44].

Lastly, it is encouraging that even after all subjects returned the study accelerometer and stopped accessing the study app (if any) at 9 months, approximately half of the 2 intervention groups (Regular and Plus) reported still wearing an accelerometer and engaging in brisk walking as they were directed during the intervention phases. These numbers in the 2 intervention groups were much higher than the Control group. In contrast, a much higher proportion of the sample in the 2 intervention groups reported that they became less active than the Control group since the last research office visit. This finding is probably due to the small increase of physical activity in the Control group during the 9-month study period, while a substantial increase in physical activity was observed in the intervention groups [21-23]. We could assume that the intervention groups were less active in the 3 months post-study than they were during the first 9 months of the study period itself, but their level of physical activity engagement was probably still greater than the Control group. However, as we demonstrated in our previous report [23], without objectively measured physical activity data, this assumption could not be confirmed.

Strengths and Limitations

Although to the best of our knowledge, this was the first study to examine physical activity maintenance motivational profiles using NLP and cluster analysis, several limitations need to be acknowledged. First, the sample represents only physically inactive female adults. The findings may not be generalizable to men or children, and physical activity engagement post intervention might be overestimated due to self-reported measures. Second, because this study was an exploratory investigation limited to the 12-month cross-sectional data, any causal relationship cannot be established. Third, the bag-of-words model that was used in this study for NLP tasks does not take into consideration the order in which words appear in a sentence, nor does it take into consideration part of speech labels. The strength of the bag-of-words model is that it can generate insights based on frequently occurring combinations of words. In addition, we note that word-vectors produced by the word2vec model cannot be easily interpreted, and that the effectiveness of these vectors for classification and clustering is dependent on hyper-parameters such as the word-vector dimension. However, the word2vec model has the advantage that it preserves semantic and synthetic relationships from the original text [45]. Similarly, the K-means cluster analysis used in this study is an unsupervised method which identifies patterns using criteria only based on data and not ground truth labels, and it is sensitive to the total number of clusters used. We used the elbow criterion [29] to mitigate the sensitivity in our analysis to the number of clusters.

Conclusion

The motivation profiles for being physically active post-intervention was classified into three cluster groups: The Weight Loss group; the Illness Prevention group; and the Health Promotion group. The Weight Loss Group differed considerably from the other two groups. This information could be relevant to tailoring a physical activity maintenance intervention. Furthermore, the findings from NLP and cluster analysis are useful methods to analyze short free text to differentiate motivational profiles. As more sophisticated NLP tools are developed in the future, the potential of NLP applications in behavioral research will broaden.

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Conflicts of Interest

None declared.

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Abbreviations

RCT: randomized controlled trial
BMI: body mass index
NLP: natural language processing
PCA: principal component analysis
mPED: mobile phone—based physical activity education

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Original Paper

Tobacco-Smoking, Alcohol-Drinking, and Betel-Quid-Chewing Behaviors: Development and Use of a Web-Based Survey System

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Abstract

Background: Smoking tobacco, drinking alcohol, and chewing betel quid are health-risk behaviors for several diseases, such as cancer, cardiovascular disease, and diabetes, with severe impacts on health. However, health care providers often have limited time to assess clients' behaviors regarding smoking tobacco, drinking alcohol, and chewing betel quid and intervene, if needed.

Objective: The objective of this study was to develop a Web-based survey system; determine the rates of tobacco-smoking, alcohol-drinking, and betel-quid-chewing behaviors; and estimate the efficiency of the system (time to complete the survey).

Methods: Patients and their family members or friends were recruited from gastrointestinal medical–surgical, otolaryngology, orthopedics, and rehabilitation clinics or wards at a medical center in northern Taiwan. Data for this descriptive, cross-sectional study were extracted from a large series of research studies. A Web-based survey system was developed using a Linux, Apache, MySQL, PHP stack solution. The Web survey was set up to include four questionnaires: the Chinese-version Fagerstrom Tolerance Questionnaire, the Chinese-version Alcohol Use Disorders Identification Test, the Betel Nut Dependency Scale, and a sociodemographic form with several chronic diseases. After the participants completed the survey, the system automatically calculated their score, categorized their risk level for each behavior, and immediately presented and explained their results. The system also recorded the time each participant took to complete the survey.

Results: Of 782 patient participants, 29.6% were addicted to nicotine, 13.3% were hazardous, harmful, or dependent alcohol drinkers, and 1.5% were dependent on chewing betel quid. Of 425 family or friend participants, 19.8% were addicted to nicotine, 5.6% were hazardous, harmful, or dependent alcohol drinkers, and 0.9% were dependent on chewing betel quid. Regarding the mean time to complete the survey, patients took 7.9 minutes (SD 3.0; range 3-20) and family members or friends took 7.7 minutes (SD 2.8; range 3-18). Most of the participants completed the survey within 5-10 minutes.

Conclusions: The Web-based survey was easy to self-administer. Health care providers can use this Web-based survey system to save time in assessing these risk behaviors in clinical settings. All smokers had mild-to-severe nicotine addiction, and 5.6%-12.3%

of patients and their family members or friends were at risk of alcohol dependence. Considering that these three behaviors, particularly in combination, dramatically increase the risk of esophageal cancer, appropriate and convenient interventions are necessary for preserving public health in Taiwan.

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KEYWORDS

tobacco smoking; alcohol drinking; betel-quid chewing; Web-based survey system

Introduction

Tobacco smoking has devastating global health, social, environmental, and economic consequences [1]. Each year, >7 million people worldwide die from tobacco use [2], with over 80% of deaths occurring in low- or middle-income countries [3]. On average, tobacco users lose 15 years of life [4]. Up to 50% of all tobacco users die of tobacco-related causes, including heart disease, cancer, diabetes, and lung disease [5]. Illnesses caused by tobacco use also contribute to poverty by increasing health care spending for individuals and families [1]. In addition, tobacco waste contains over 7000 toxic chemicals, including human carcinogens. Tobacco smoke emissions also contribute thousands of tons of human carcinogens, toxicants, and greenhouse gases to the environment [1]. Moreover, tobacco use imposes a substantial economic burden globally. Smoking-attributable costs, both direct (eg, the cost incurred by the utilization of health care services) and indirect (eg, any additional cost incurred as a result of the utilization of health care services), are estimated to be US $ 1400 billion or 1.8% of the global gross domestic product [6].

Excessive alcohol use has been associated with a large variety of health, social, and legal problems [7]. In 2012, approximately 3.3 million deaths, or 5.9% of all deaths worldwide, were attributable to alcohol consumption [8]. Alcohol consumption is associated with an increased risk of over 200 diseases and injuries [8]; it has also been associated with mental and behavioral disorders, including alcohol dependence, liver cirrhosis, some cancers, and cardiovascular diseases, as well as injuries from violence and traffic accidents [8].

Betel-quid chewing is a popular habit in south and Southeast Asia [9]; it has a carcinogenic effect and is associated with obesity, hypertriglyceridemia, hyperglycemia, metabolic syndrome, cardiovascular disease, hepatic dysfunction, liver cirrhosis, and liver cancer [10-12].

In countries such as Taiwan, where people commonly smoke, drink alcohol, and chew betel quid, esophageal cancer is prevalent [13]. Indeed, the concurrent use of alcohol and tobacco leads to a higher risk of esophageal cancer (odds ratio [OR] 8), and the addition of betel-quid chewing can increase the odds ratio to 195.6 (95% CI 64.0-894.2) [14,15].

In Taiwan, the smoking rate of adults dropped from 32.5% in 1990 to 15.3% in 2016, but there were still 3.13 million tobacco smokers (individuals who smoked >100 cigarettes to date and had smoked in the last 30 days) [16]. Alcohol, which is legally accessible in Taiwan, plays an important role in Chinese culture as it is viewed as an acceptable drink to relieve stress and enhance social interaction [17]. Consequently, drinking problems are easily ignored. In Taiwan's general hospitals, the prevalence of patients' alcohol-drinking problems (Alcohol Use Disorders Identification Test, AUDIT, score ≥8) ranges from 5.7% to 19.2% due to different settings (wards versus clinics) selected [18,19]. In addition, chewing betel quid is a part of traditional Chinese culture, and it is often offered during many social occasions in Taiwan [20]. A national survey conducted in the last 6 months of 2013 found that the rates of adult smoking (individuals smoking >100 cigarettes) and alcohol drinking (individuals drinking alcohol liquor not included in cooking) were 22.6% and 39.2%, respectively; in both the previous year and previous 6 months, the rate of chewing betel quid was 6.4% [21]. These statistics indicate that smoking, drinking alcohol, and chewing betel quid are troubling health-risk behavior indicators in Taiwan.

Considering that individuals who smoke tobacco, drink alcohol, and chew betel quid are likely to suffer adverse effects on their health (eg, cancer, cardiovascular disease, and diabetes), they will need to seek health care. Thus, health care providers are in a unique position to both identify and treat patients with these unhealthy behaviors. However, limited time often presents providers with a barrier to implement both appropriate assessment and intervention strategies [22,23]. This barrier may be overcome by using a Web-based system. Indeed, Web-based systems have been found to arouse participants' interests about their own health, maintain privacy, increase reasonable response rates, and save costs [24]. Unfortunately, most Web-based systems are available only for alcohol screening and interventions [25], and no Web-based system combines tobacco smoking, alcohol drinking, and betel-quid chewing. To address this knowledge gap, we undertook this study to develop a Web-based survey system and determine the rates of tobacco-smoking, alcohol-drinking, and betel-quid-chewing behaviors in patients and their family members or friends recruited from a medical center in Taiwan. We also estimated the efficiency of this system by calculating the time to complete the survey.

Methods

Design

This descriptive cross-sectional study was a part of an extensive research series to promote healthy lifestyle behaviors for the general population. Data were collected using a Web-based survey from 2015 to 2016.

Sample and Setting

The sample was recruited by a trained research assistant (RA) from the waiting areas of gastrointestinal medical–surgical, otolaryngology, orthopedics, and rehabilitation clinics/wards

at a medical center in northern Taiwan. These clinics and wards were chosen because most patients with alcohol or smoking problems in Taiwan are seen here [26]. Patients were included if they met the following criteria: (1) ≥20 years old, (2) outpatients or inpatients in the above clinics or wards, (3) had mobile phones or email access, and (4) able to read Chinese. Similar inclusion criteria were used for patients' family members, partners, and friends.

Patients were approached by the RA who told them that our research team was interested in developing a Web-based substance-use intervention system and would like their participation for at least 20 minutes to help develop the new system. After obtaining written consent from patients, family members, and friends to participate, the RA screened each one for both inclusion and exclusion criteria. Of the 1400 patients approached, only 1210 agreed to participate. Those who refused to participate gave lack of time as the main reason for refusing. Of the patients who agreed to participate, 3 did not meet the inclusion criteria; thus, 1207 completed the survey. No participants dropped out of this study.

The Web-Based Survey System

The system was built using a Linux, Apache, MySQL, PHP stack solution. The Linux operation system was hosted on a lightweight Dell server (with two Intel 3.0-GHz CPU processors and 8G RAM) to provide the survey via the internet. The Apache web server system runs on the Dell server. To address the gap of no appropriate software packages available to set up a Web-based survey system, we developed our system from scratch using *PHP: hypertext preprocessor* (PHP) language, a well-known, reliable server-site technology. Within the survey system, we set up four questionnaires or scales: the Chinese-version Fagerstrom Tolerance Questionnaire (C-FTQ) [27], the Chinese-version AUDIT (C-AUDIT) [26], the Betel Nut Dependency Scale (BNDS) [28], and a sociodemographic form. The C-FTQ was chosen because it has been used as a screening tool for tobacco control by Taiwan's Health Promotion Administration, Ministry of Health and Welfare [27]. The C-AUDIT was translated and validated by our research team [26] from the World Health Organization (WHO)-developed AUDIT, a commonly used and widely translated tool for screening alcohol problems [29]. The BNDS, which is the only available screening tool for betel-nut dependence in the general population of Taiwan, has undergone comprehensive psychometric testing [28]. After participants completed the survey, their scores were automatically calculated, their risk behaviors were categorized (from no risk to high risk, depending on each questionnaire's definitions; see next section), and their results were immediately presented with explanations. The system also recorded the time required for each participant to complete the survey.

Before using the Web-based survey system in clinical settings, we tested its stability and accuracy. Testing involved the following: setting up an account and password to access the survey; answering questions; and checking scores, categories, and explanations. A technician and RAs in our lab tested the system more than 10,000 times over 3 months. In addition, we retrieved all data, entered it into statistical software, and regularly calculated the total score for each tool to ensure the accuracy of the process. No mistakes were detected.

Study Variables

These scales were used to collect data on participants' physical dependence on nicotine, alcohol drinking-related behaviors, betel-quid dependency, and sociodemographic characteristics plus several chronic diseases.

Physical dependence on nicotine in the previous year was measured using the 7-item C-FTQ. The first item asks, "Did you smoke in the past year?" If the participant answers "no," he or she skips the remaining 6 items and the score is 0. If the participant answers "yes" to the first item, he/she answers the remaining items. The total C-FTQ score represents the sum of items 2-7; possible score range 0-10. A score of 0 indicates no smoking behavior. Summed scores ≤3 indicate mild nicotine addiction, 4-6 indicates moderate addiction, and 7-10 indicates high addiction [27]. The validity and reliability of the FTQ [30,31] and C-FTQ [32] were acceptable. The internal consistency of the C-FTQ in this study was 0.76.

Alcohol drinking-related behaviors in the previous year were measured using the 10-item C-AUDIT. Each item was scored on a 4-point Likert scale from 0 to 1, with total scores ranging from 0 to 40. Scores 0-7 indicate low-risk drinking, 8-15 indicate hazardous drinking, 16-19 indicate harmful drinking, and ≥20 indicate dependence in drinking [29]. The validity and reliability of the AUDIT [29] and C-AUDIT [26] were acceptable. The internal consistency of the C-AUDIT in this study was 0.83.

Betel-quid dependency in the previous year was measured using the 11-item BNDS. Items were scored on a 4-point Likert scale (1=*totally agree*, 2=*agree*, 3=*disagree*, 4=*totally disagree*). Item scores were summed for a total score, with a possible range of 11-44; scores ≥24 indicate a tendency toward betel-quid dependency [28]. The validity and reliability of the BNDS were acceptable [28]. The internal consistency of the BNDS in this study was 0.96.

Sociodemographic characteristics (age, gender, education level, marital status, number of children) were measured using a sociodemographic form. Chronic illnesses (arthritis, cancer, cardiovascular disease, cataract, diabetes, digestive system disease, epilepsy, gout, hyperlipidemia, hypertension, kidney disease, liver disease, stroke, urinary tract disease) were measured using a chronic illness checklist.

Data Collection

After screening participants for study criteria, the RA provided each one a sealed envelope containing a login account and password. The RA also provided written instructions for accessing the web system. The participants read these instructions by themselves. The RA then helped the participants find a seat in the waiting area, gave them a laptop computer, and let them complete the survey alone. The participants connected to the internet via the participating hospital's free Wi-Fi. If the free Wi-Fi was not accessible in the waiting area, the participants connected to a 4G wireless network paid by researchers. After the participants finished the online survey, it automatically provided their score on each questionnaire with

explanations of the scores. The system also reminded the participants to discuss any health concerns with their health care providers. After the participants finished the survey, they caught the RA's attention to return the laptop computer. The RA stayed in the waiting area in case the participants needed any help. In addition, the RA provided information to the participants about tobacco smoking, alcohol drinking, and betel-quid chewing, if they needed it, after completing the survey.

Ethical Considerations

After the institutional review board of Chang Gung Memorial Hospital approved the study, the RA approached patients, their family members, or friends in the wards or clinic waiting areas. The RA described the study purpose and procedure, the required time commitment, confidentiality, and participants' rights not to participate or to withdraw from the study at any time and obtained their written consent to participate. The participants received a small gift (approximately US $ 3) for their participation.

Data Analysis

Sociodemographic and questionnaire data were analyzed by descriptive statistics (mean, standard deviation, and frequency [percentage]) using SPSS, version 22.

Results

The average age of the 782 patients who participated in this study was 35.9 years (SD 11.9; range 20-83). Most of the patients were male (533/782, 68.2%), had graduated from a college or university (435/782, 55.6%), were single (408/782, 52.2%), and sought treatment in orthopedics clinics or wards (492/782, 62.9%). For details, see Table 1. Patients' top three chronic diseases were liver diseases (77/782, 9.8%), hypertension (71/782, 9.1%), and diabetes (31/782, 4.0%) (see Table 2 for details).

The 425 patients' family members and friends in our sample were on average 35.3 years old (SD 10.8; range 20-79). Most of them were male (216/425, 50.8%) and had graduated from a college or university (250/425, 58.8%). Approximately half of them were single (207/425, 48.7%) or married (206/425, 48.5%). For details, see Table 1. For these family members and friends, the top three common chronic diseases were liver diseases (19/425, 4.5%), hypertension (19/425, 4.5%), and diabetes (9/425, 2.1%) (see Table 2 for details).

Table 1. Participants' demographic characteristics.

Variable	Patients	Family members and friends
Gender, n (%)		
Male	533 (68.2)	216 (50.8)
Female	249 (31.7)	209 (49.2)
Age (years), mean (SD)	35.9 (11.9)	35.3 (10.8)
Visit clinic or ward, n (%)		
Orthopedics	492 (62.7)	232 (54.5)
Otolaryngology	188 (23.9)	114 (26.8)
Gastroenterology	99 (12.6)	75 (17.6)
Rehabilitation medicine	3 (0.4)	4 (0.9)
Education level, n (%)		
Illiterate	4 (0.5)	4 (0.9)
Primary school	20 (2.6)	2 (0.5)
Junior high school	46 (5.9)	18 (4.2)
Senior high school	165 (21.1)	113 (26.6)
College or university	435 (55.6)	250 (58.8)
Master's degree or above	112 (14.3)	38 (8.9)
Marital status, n (%)		
Single	408 (52.2)	207 (48.7)
Married	354 (45.3)	206 (48.5)
Divorced	17 (2.2)	11 (2.6)
Widowed	3 (0.4)	1 (0.2)
Number of children, mean (SD)	0.9 (1.2)	0.9 (1.2)

Table 2. Participants' chronic illnesses.

Illness	Patients, n (%)	Family members and friends, n (%)
Liver disease	77 (9.8)	19 (4.5)
Hypertension	71 (9.1)	19 (4.5)
Diabetes	31 (4.0)	9 (2.1)
Arthritis	29 (3.7)	2 (0.5)
Cancer	23 (2.9)	1 (0.2)
Digestive system disease	15 (1.9)	8 (1.9)
Cardiovascular disease	15 (1.9)	7 (1.6)
Hyperlipidemia	8 (1.0)	5 (1.2)
Gout	8 (1.0)	4 (0.9)
Urinary tract disease	7 (0.9)	2 (0.5)
Kidney disease	6 (0.8)	2 (0.5)
Cataract	2 (0.3)	0 (0.0)
Epilepsy	1 (0.1)	1 (0.2)
Stroke	1 (0.1)	0 (0.0)

Table 3. Participants' smoking, drinking, and betel-quid-chewing scores.

Variable	Patients	Family members and friends
C-FTQ[a] score, mean (SD)	1.1 (2.2)	0.7 (1.9)
C-FTQ addiction level, n (%)		
No addiction	550 (70.3)	341 (80.2)
Mild addiction	111 (14.2)	44 (10.4)
Moderate addiction	84 (10.7)	25 (5.9)
High addiction	37 (4.7)	15 (3.5)
C-AUDIT[b] score, mean (SD)	2.8 (4.5)	1.7 (3.2)
C-AUDIT level, n (%)		
Low-risk drinker	678 (86.7)	401 (94.4)
Hazardous drinker	78 (10.0)	18 (4.2)
Harmful drinker	18 (2.3)	6 (1.4)
Dependent drinker	8 (1.0)	0 (0.0)
BNDS[c], mean (SD)	11.6 (2.9)	11.4 (2.6)
BNDS level, n (%)		
No potential addiction	770 (98.5)	421 (99.1)
Potential addiction	12 (1.5)	4 (0.9)

[a]C-FTQ: Chinese-version Fagerstrom Tolerance Questionnaire.

[b]C-AUDIT: Chinese-version Alcohol Use Disorders Identification Test.

[c]BNDS: Betel Nut Dependency Scale.

Patients' mean C-FTQ, C-AUDIT, and BNDS scores were 1.1 (SD 2.2), 2.8 (SD 4.5), and 11.6 (SD 2.9), respectively. Among patients, 29.7% (232/782) were mildly to highly addicted to nicotine; 13.3% (104/782) were hazardous, harmful, or dependent drinkers; and 1.5% (12/782) were betel-quid dependent. Family members' and friends' mean C-FTQ, C-AUDIT, and BNDS scores were 0.7 (SD 1.9), 1.7 (SD 3.2), and 11.4 (SD 2.6), respectively. Among family members and friends, 19.8% (84/425) were addicted to nicotine, 5.6% (24/425) were hazardous or harmful drinkers, and 0.9% (4/425) were betel-quid dependent. For details, see Table 3.

Table 4. Participants' smoking, drinking, and betel-quid-chewing behaviors.

Risk behavior	Patients, n (%)	Family members and friends, n (%)
None	256 (32.7)	179 (42.1)
Smoking only	35 (4.5)	20 (4.7)
Drinking only	287 (36.7)	161 (37.9)
Betel-quid chewing only	0 (0.0)	0 (0.0)
Smoking and drinking	131 (16.8)	44 (10.4)
Smoking and betel-quid chewing	9 (1.2)	4 (0.09)
Drinking and betel-quid chewing	7 (0.09)	1 (0.02)
Smoking and drinking and betel-quid chewing	57 (7.3)	16 (3.8)

Only 32.7% (256/782) of patients did not smoke, drink alcohol, and chew betel quid in the previous year. Over 60% (482/782, 61.6%) of patients drank alcohol in the past year (including drinking only, smoking and drinking, drinking and betel-quid chewing, and smoking and drinking and betel-quid chewing). Similarly, only 42.1% (179/425) of family members and friends did not smoke, drink alcohol, and chew betel quid in the previous year. Over 52% (222/425, 52.2%) of family members and friends drank alcohol in the past year. For details, see Table 4.

Regarding the mean time to complete the survey, patients needed 7.9 minutes (SD 3.0; range 3-20) and family members or friends needed 7.7 minutes (SD 2.8; range 3-18). Most patients completed the survey within 5-10 minutes (656/782, 83.9%), and most family members or friends completed it within 5-10 minutes (363/425, 81.7%).

Discussion

Web-Based Survey System

Our Web-based survey system to assess behaviors regarding drinking alcohol, smoking tobacco, and chewing betel quid contributes to the literature on health-risk behaviors by providing a survey that patients can complete easily, quickly, and entirely. Most participants completed it within 5-10 minutes and perceived it as being easy to self-administer. The survey was designed to ensure that the participants could not skip any item, thus avoiding missing data, by requiring that each item be filled in before moving to the next page. Furthermore, our data on the internal consistency of the Web-versions of the C-FTQ, C-AUDIT, and BNDS were all acceptable. Unlike other assessment tools, such as the Kihon checklist [33], which must be administered by health care providers, using this survey can save time for providers to assess these risk behaviors in clinical settings. Moreover, the survey results provide client data for health-promotion strategies on smoking tobacco, drinking alcohol, and chewing betel quid.

Regarding internet access for the online survey, we initially used the participating hospital's new, free Wi-Fi for visitors, but this system was unstable. We did not want to ask the participants to use their own smart phone, if the free Wi-Fi did not work, because they might have worried about increasing their internet service fee and refused to participate in our study. Therefore, we provided a laptop for the participants and allowed them to use either free Wi-Fi or a researcher-paid 4G network to complete the survey. Currently, the hospital's free Wi-Fi system for visitors is stable. Once our research on the Web-based survey and its efficacy is published, we plan to add a quick response (QR) code system to the survey. Patients and family members can use their own smart phone to scan the QR code and fill out the survey. This change will increase the accessibility of the online survey system in clinical settings. After the present Web-based survey system matures, its use may be expanded to include the public setting for assessing health behaviors in the general population.

Smoking, Drinking, and Betel-Quid-Chewing Behaviors

Approximately 30% of patients and 20% of family members and friends smoked in the past year, but all of them were categorized as having mild-to-severe nicotine addiction. These prevalence rates for tobacco smoking are in line with the 2010 WHO global prevalence of 22.1% [34] but exceed Taiwan's national rate of 15.3% established by the Adult Smoking Behavior Surveillance System in 2016 [13]. Given that tobacco smoking has a negative impact on health, it is essential to decrease smoking behaviors. To assist governments worldwide in reducing both tobacco demand and use**,** in 2008, the WHO introduced a package of six evidence-based strategies [34]. These strategies, known as the MPOWER package, include Monitoring tobacco use and prevention policies; Protecting people from tobacco smoke; Offering help to quit tobacco use; Warning about the dangers of tobacco; Enforcing bans on tobacco advertising, promotion, and sponsorship; and Raising taxes on tobacco [34]. Among these strategies, those that could be implemented in clinical settings include establishing smoke-free buildings and grounds, offering smoking-cessation programs, providing warning labels on tobacco packages, and enforcing bans on tobacco promotion.

Among our participants, over 60% of patients and over 52% of family members or friends drank alcohol in the past year, and 13.3% of patients and 5.6% of family members or friends were categorized as hazardous, harmful, or dependent drinkers. The prevalence for our patient sample is at the low end of the range reported for alcohol-drinking problems in general hospitals in western countries, that is, 12% to 26%, due to different assessment methods and units selected [35,36]. However, no information is available on studies conducted in western

countries for the prevalence of alcohol-drinking problems among family members of these patients. Our patient sample's prevalence of hazardous, harmful, or dependent drinkers is consistent with that of patients' alcohol-drinking problems in Taiwan's general hospitals, that is, 5.7% to 19.2%, depending on the unit selected [18,19]. However, our finding on the prevalence of patients' family members'/friends' hazardous/harmful/dependent drinking (5.6%) is much lower than that of hazardous alcohol-drinking problems among family members of patients with alcohol-drinking problems in Taiwan (13.3%) [37]. The difference between the findings of these studies may be because our sample of family members or friends included approximately 25% friends (105/425). Indeed, individuals with a family history of alcoholism have been linked to a greater risk of developing alcoholism than those without such a history [38].

To manage the drinking behavior of individuals with hazardous and harmful drinking, a brief intervention [18] has proven to be effective in a Taiwanese hospital patient population [18,22]. This brief intervention is offered to problem drinkers at four levels, based on their AUDIT score [22]. The first level, for low-risk drinkers, is to provide alcohol education. The second level, for hazardous drinkers, is to give simple advice (including giving feedback, providing information, establishing goals to change drinking behavior, giving advice on drinking limits, reviewing the amount of alcohol in standard drinks, and concluding with encouragement). The third intervention level, for harmful drinkers, is to provide simple advice plus brief counseling and continued monitoring. The fourth level, for dependent drinkers, is to refer them to a specialist for diagnostic evaluation and treatment [22]. This brief intervention should be considered as a strategy to decrease our participants' alcohol drinking behaviors.

The prevalence of betel-quid dependency was low in both patients and family members or friends. Currently, no effective interventions for betel-quid chewing are available. Our findings show that no participants chewed betel quid alone; they only used it in combination with smoking or drinking alcohol. This finding implies that interventions against betel-quid chewing should be combined with antismoking or alcohol-drinking interventions.

Strengths and Limitations

Our study fills a knowledge gap by both developing and applying a convenient Web-based survey system to assess behaviors regarding smoking tobacco, drinking alcohol, and chewing betel quid. Our results demonstrate that the system is easy to use for both patients and their family members or friends. However, this study had four limitations. First, the study population was a convenient sample recruited from one hospital in northern Taiwan. Second, participants were included only if they had mobile phones or email access. In other words, they had some experience using Web-based systems. Third, participants may have been hindered in expressing whether the survey was difficult when asked in person by the RA. Fourth, we did not follow-up with participants to determine if they had discussed their survey results with their health care providers because this follow-up was beyond the scope of our study. For the same reason, we did not survey physicians regarding both their knowledge of the widely used tobacco-smoking, alcohol-drinking, and betel-quid-chewing scales used in our survey and their readiness to assess their clients for these health-risk behaviors. Further studies may consider using a random sampling strategy; expanding the study criteria to include people naïve to computers, communication, and consumer products; following up with both patients and their health care providers on the application of survey results; and including an item at the end of the survey to ask anonymously about the difficulty in completing the survey.

Conclusions

Smoking, drinking alcohol, and chewing betel quid are risk behaviors with severe impacts on health. However, health care providers often have little or limited time to evaluate their clients for these risk behaviors. Using our newly developed Web-based survey system can save clinicians' time for assessing patients and offering participants data about their health behaviors. We also found that all smokers had a mild-to-severe nicotine addiction, and both patients and their family members or friends had a high prevalence of drinking alcohol in the past year. Furthermore, 5.6%-12.3% of patients and their family members or friends were at risk of alcohol dependence. Since these three behaviors, particularly in combination, dramatically increase the risk of esophageal cancer, appropriate and convenient interventions are necessary for maintaining public health in Taiwan.

Acknowledgments

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Authors' Contributions

KYH assisted with designing the study, collecting and analyzing the data, and writing the manuscript. YFT designed the study, supervised the data collection, analyzed the data, and wrote the manuscript. CCH designed the Web-based survey system, assisted with collecting and analyzing the data, as well as writing the manuscript. WLY, KPC, CCL, CYC, and HLL assisted with collecting and analyzing the data, as well as writing the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
BNDS: Betel Nut Dependency Scale
C-AUDIT: Chinese-version Alcohol Use Disorders Identification Test
C-FTQ: Chinese-version Fagerstrom Tolerance Questionnaire
FTQ: Fagerstrom Tolerance Questionnaire
RA: research assistant
WHO: World Health Organization

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Original Paper

Effectiveness of a Text Messaging–Based Intervention Targeting Alcohol Consumption Among University Students: Randomized Controlled Trial

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Abstract

Background: Excessive drinking among university students is a global challenge, leading to significant health risks. However, heavy drinking among students is widely accepted and socially normalized. Mobile phone interventions have attempted to reach students who engage in excessive drinking. A growing number of studies suggest that text message–based interventions could potentially reach many students and, if effective, such an intervention might help reduce heavy drinking in the student community.

Objective: The objective of this study was to test the effectiveness of a behavior change theory–based 6-week text message intervention among university students.

Methods: This study was a two-arm, randomized controlled trial with an intervention group receiving a 6-week text message intervention and a control group that was referred to treatment as usual at the local student health care center. Outcome measures were collected at baseline and at 3 months after the initial invitation to participate in the intervention. The primary outcome was total weekly alcohol consumption. Secondary outcomes were frequency of heavy episodic drinking, highest estimated blood alcohol concentration, and number of negative consequences attributable to excessive drinking.

Results: A total of 896 students were randomized to either the intervention or control group. The primary outcome analysis included 92.0% of the participants in the intervention group and 90.1% of the control group. At follow-up, total weekly alcohol consumption decreased in both groups, but no significant between-group difference was seen. Data on the secondary outcomes included 49.1% of the participants in the intervention group and 41.3% of the control group. No significant between-group difference was seen for any of the secondary outcomes.

Conclusions: The present study was under-powered, which could partly explain the lack of significance. However, the intervention, although theory-based, needs to be re-assessed and refined to better support the target group. Apart from establishing which content forms an effective intervention, the optimal length of an alcohol intervention targeting students also needs to be addressed in future studies.

Trial Registration: International Standard Randomised Controlled Trial Number ISRCTN95054707; http://www.isrctn.com/ISRCTN95054707 (Archived by WebCite at http://www.webcitation.org/70Ax4vXhd)

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KEYWORDS

alcohol consumption intervention; text message-based intervention; university students; brief intervention

Introduction

Excessive drinking among college and university students remains a challenge despite numerous efforts to reduce students' drinking habits [1,2]. Only a minority of students seek advice and support from student health care (SHC) services, and it is therefore urgent to find new means of reaching students who drink excessively [3].

Previous studies suggest that text messaging can be a cost-effective mode of delivery of interventions targeting health behavior change [4-6]. Text messaging–based, or text-based, interventions are effective in supporting behavior change in various areas such as weight loss, smoking cessation, and diabetes management [7]. A recent review of 36 studies on the use of text messages in mental health concluded that text messaging is a promising tool for managing excessive drinking and other mental health conditions [8].

Furthermore, text-based interventions have several advantages compared with other digital interventions (eg, web portals requiring users to log in multiple times) because they allow for high accessibility, that is messages are likely to be read within minutes of being received, receiving and reading messages requires limited time and effort by the user [9-11], and they can enable continuous, real-time, brief support in a real-world setting [12]. A common challenge in technology-based interventions is participant retention; however, in a review by Head et al [4], the retention in text-based interventions was approximately 70%. However, retention per se does not reflect engagement and adherence to an intervention and can only be seen as a proxy for both [13].

Despite the omnipresence of mobile phones with text messaging capacity, few studies have explored the potential of text messaging for changing risky drinking behaviors [4-6]. In a recent 2013 review, none of the 19 randomized controlled trials (RCTs), from 13 countries, addressed alcohol consumption [4]. Some years later, in a review of text-based interventions for young adults, 3 out of 14 studies included alcohol consumption. All 3 studies were feasibility trials with few participants [5]. A year later, a systematic review on mobile technology-based interventions for adult users of alcohol identified 8 studies, 5 of which featured interventions that were primarily delivered through text messaging [6]. However, the interventions considerably varied with regards to the length and dosage, with the longest being a 6-week intervention. Dosage varied from weekly text messages to text messages 4-6 times daily. However, most studies reported significant behavior outcomes, although outcome measures greatly varied among interventions [6]. Moreover, the few studies of text-based interventions that targeted alcohol consumption mostly lacked theory-guided content and typically included a small number of participants [4-6].

Despite the promising potential of text-based alcohol interventions, it is unclear how their effectiveness can be optimized; for example, message content and structure [14-15] or how users' interest and adherence can be maximized [16]. User compatibility is seldom evaluated and, at best, is performed after delivery of the intervention [16]. The intervention in the present study was built upon behavior change theory using a formative development design involving users in the target group as well as experts in alcohol overuse prevention [17-18].

The aim of the present RCT was to explore the effectiveness of a theory-based intervention, using text messages, targeting college and university students.

Methods

Study Design

This study was a two-arm RCT. Participants were randomized to either an intervention group or a treatment as usual group (control). Outcome measures were collected at baseline and at follow-up.

Study Setting and Inclusion Criteria

All students at 14 universities and colleges in Sweden were simultaneously invited to take part in the study. Inclusion criteria were as follows: drinking at least 4 standard drinks (females) or 5 standard drinks (males) on at least 2 occasions per month; willingness to attempt to reduce alcohol consumption; owning a mobile phone; and willingness to disclose their mobile phone number. A standard drink of alcohol in Sweden is defined as 12 g of pure alcohol. A protocol article describes the study in more detail [17].

Follow-Up

Follow-up was carried out simultaneously for all participants 3 months after the initial invitation to the study. All participants received an email including a link to a follow-up questionnaire that investigated the primary and secondary outcomes. Two reminders via email, 1-week apart, were sent to non-responders. In addition, participants who continued to not respond received a text message every second day for 6 days (ie, 3 additional reminders). These text messages only included a single question investigating the primary outcome (total weekly consumption). Finally, non-responders were contacted via telephone (maximum of 10 calls). Again, only the primary outcome was investigated.

Intervention

The intervention was a 6-week automated text message–based program with a total of 62 messages, as described in more detail in previous papers [17,18]. The intervention was developed using formative methods including focus groups with students, an expert panel with students and professionals, and a behavior change technique analysis [18]. Twenty-three behavior change techniques were identified in the final version of the intervention, using the taxonomy developed by Michie et al [19]. Some techniques were used in more than 1 message or across 2 messages. The techniques aimed to motivate students to reduce their alcohol consumption, address self-regulation, increase self-efficacy, and increase students' awareness of social and professional support.

The first 4 weeks of the program had a higher frequency of messages, 9 in each week, followed by 7 messages in weeks 2-5, and 5 messages in week 6. Two messages were repeated at the start of each week; students were asked to report via a text message the number of drinks they had consumed the

previous week. Subsequently, they received a second text message including feedback on their performance in relation to their goal set at the start of the intervention. These paired messages were repeated every Sunday [17].

Control

The control group was offered treatment as usual. At present, the typical practice at the SHCs, besides motivating advice delivered face-to-face, is to recommend a website to the students where they can estimate their alcohol consumption, receive feedback on their drinking levels and more information on health consequences of drinking. Participants allocated to the control group were informed of this and told that they would gain access to the intervention once the main trial had ended. No additional prompts or reminders about the websites were given [17].

Outcome Measures

A baseline questionnaire included 9 items investigating (1) age (continuous), (2) gender (female/male), (3) relationship status (single/in a relationship). Four items investigated outcome measures (4) total weekly alcohol consumption during a typical week computed as the sum of alcohol consumption (in standard units) for each day in a typical week, (5) number of days with heavy episodic drinking (HED) during the most recent month, (6) estimated blood alcohol concentration (eBAC) during the heaviest drinking occasion the most recent month, and (7) number of negative consequences caused by drinking alcohol during the most recent month. In addition, students were asked to (8) state a goal for reducing their weekly alcohol consumption. Finally, students were asked to (9) specify the mobile phone number to which they wished to receive the intervention [17].

We estimated eBAC based on reported greatest alcohol intake during a single-drinking occasion the past month. The time spent consuming the alcohol, weight, and gender were also evaluated. A variation of the Widmark formula developed for road safety research was used to compute eBAC [20].

The follow-up questionnaire included 4 questions investigating the primary and secondary outcomes: (1) total weekly alcohol consumption during a typical week, (2) HED during the last month, (3) eBAC during the last month, and (4) number of negative consequences caused by drinking alcohol during the last month [17]. Participants responding to the email follow-up were asked to estimate their weekly consumption every day, and researchers summed these estimates to create the primary outcome variable. Participants responding via text or telephone were asked to estimate their consumption over a week. No recall methods were used at baseline or follow-up.

Recruitment Process

Students were invited to participate through an email from their local SHC including 2 reminders issued at one and 2 weeks after the initial invitation. Students were allowed to respond up to 7 days after the final reminder. No other advertisement strategy was used. The invitation email aimed to attract and reach students who thought they drank too much and were willing to reduce their consumption. Students could choose between 2 links in the email: (1) “Yes, I would like to know more about the study” or (2) “No, I do not wish to take part in the study or receive any reminders.” Students who clicked on the first link were transferred to an eligibility criteria screen.

Students who did not meet the inclusion criteria were automatically referred to a screen including tips from a website where they could find support if needed. Students who met the inclusion criteria were automatically referred to an informed consent screen that also included detailed information on the study and participation. Interested students gave their informed consent to participate by clicking on a link that automatically transferred them to the baseline questionnaire.

After completion of the baseline questionnaire, students were asked to provide their mobile phone number. Students then immediately received a text message asking them to confirm their mobile phone number by responding “start.” All students who confirmed their mobile phone number were randomized to either the intervention or control group. A text message was sent to each participant with information about which group they were allocated to. Figure 1 depicts a flowchart of the recruitment procedure of the study.

Randomization and Blinding

Each participant was allocated either number 1 or 2 with equal probability using Java’s built-in random number generator (java.util.Random). Randomization was thus fully computerized, did not use any strata or blocks, and was not possible to subvert, because this and all subsequent study processes were fully automated.

Power Calculation

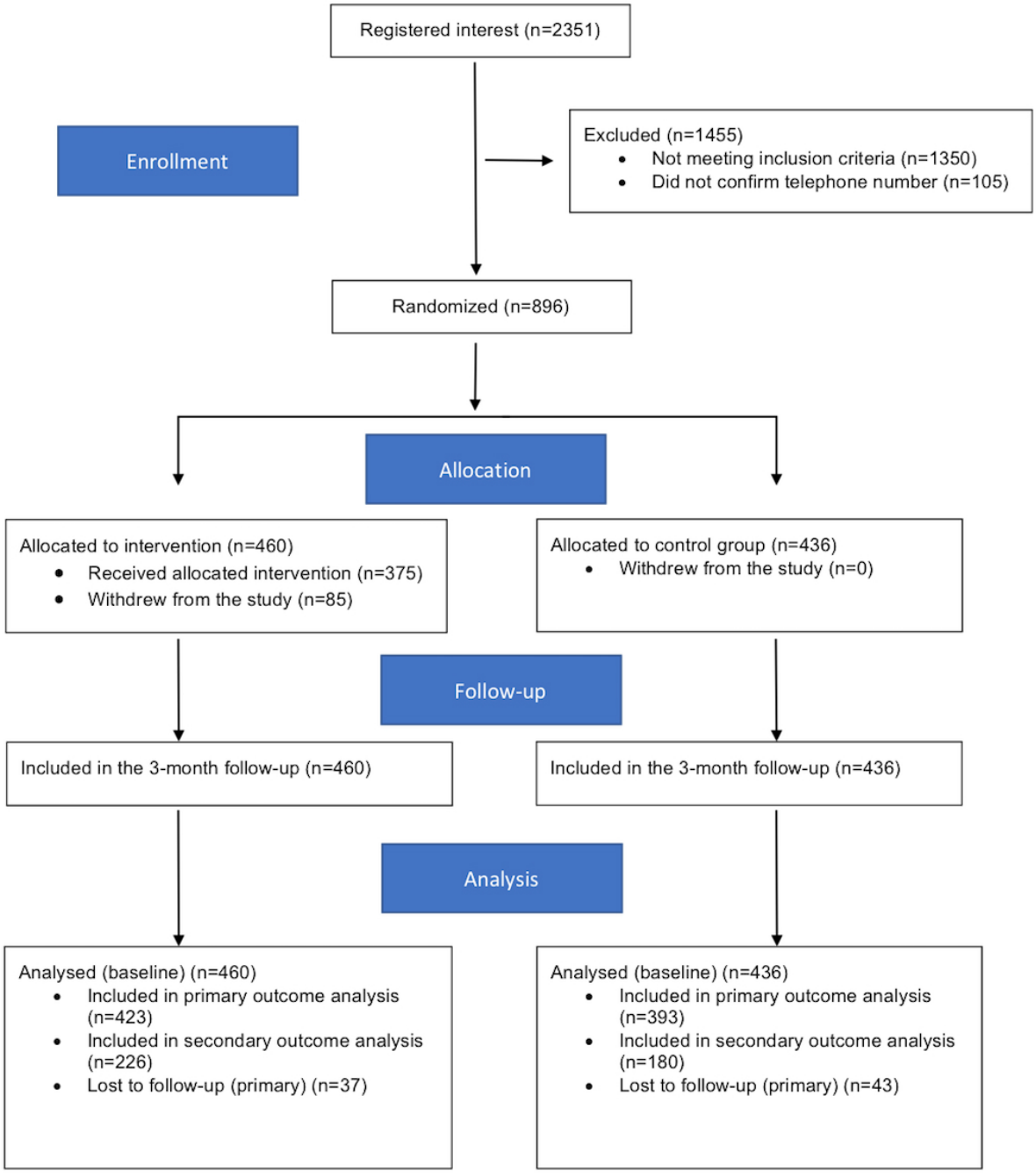
To detect a standardized effect size of 0.15 between the 2 groups at 3-months’ follow-up with a 5% significance level and 80% power, we calculated that we would require 699 individuals analyzed per group, ie, a total of 1398 individuals. Assuming a 3-month follow-up rate of 80%, we needed 874 per group (ie, a total of 1748 individuals).

Statistical Analysis

All statistical analyses were performed as described in the protocol article [17]. The data was examined graphically for outliers but no such outliers were found.

Baseline characteristics of responders were compared between randomized groups using the chi-squared test or Fisher’s exact test for comparison of proportion, and Student’s t test for comparison of means.

Figure 1. The Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram.



All outcome analyses were compared between the 2 randomized groups (both with the same follow-up time) under the intention-to-treat principle (that is, all randomized individuals were included in their originally randomized groups). Total weekly consumption, eBAC, and the number of negative consequences were skewed as seenby visual inspection of histograms or Q-Q plots. Due to the fact that they these outcomes were skewed, eBAC was log-transformed and analyzed with linear regression, and weekly alcohol consumption and negative consequences were analyzed with negative binomial regression. Group specific means were reported for log-transformed variables asgeometric means with back-transformed standard deviations, and for variables analyzed by negative binomial regression as back-transformed means and standard deviations. Frequency of HED occasions was analyzed by ordered logistic regression. All regression analyses were first performed unadjusted, and then adjusted for weekly alcohol consumption at baseline, age (analyzed as continuous variable), university

Missing outcome data were initially handled by a complete-cases analysis, which assumes that the data are missing at random (MAR). In a sensitivity analysis, we explored the plausibility of the MAR assumption by regressing the primary outcome (weekly alcohol consumption) on the number of follow-up attempts needed before an individual responded. Any significant association could be evidence against the MAR assumption.

Attrition was investigated for statistically significant differences between the study groups regarding completion of the follow-up questionnaire. This was done by comparing baseline characteristics among participants who did and did not respond at follow-up. Any significant associations could provide possible evidence against the MAR assumption.

None of the primary analyses were completed with imputed values. In a sensitivity analysis we carried over baseline values and used follow-up group means for the primary outcomes. No sensitivity analysis or imputation was done for secondary outcomes. Effect modification tests for total weekly consumption as baseline, age, university, and gender were undertaken for the primary outcome only. All analyses were performed as two-sided tests with a 5% level of significance.

Results

Overview

A total of 896 participants were randomized: 460 (51.3%) to the intervention group and 436 (48.7%) to the control group. The number of female participants was slightly more in both groups. A summary of all baseline characteristics is given in Table 1. University code represents an id for the university the participant attends, and eBAC is reported *per mille*. There were no significant differences in any of the sociodemographic characteristics or drinking variables.

Primary Outcome Analysis

The primary outcome analysis was done on a total of 423 (92.0%) randomized participants in the intervention group and 393 (90.1%) in the control group (P=.34 by chi-squared test). Weekly alcohol consumption decreased in both groups with no statistically significant difference between groups (Table 2). There was no evidence of a statistically significant effect modifier between baseline variables (weekly alcohol consumption at baseline, age, university, and gender) and treatment group at the 5% level of significance.

Secondary Outcome Analysis

Secondary outcome data were available only for participants completing the follow-up by email and included 226 (49.1%) of the participants in the intervention group and 180 (41.3%) in the control group (P=.02 by chi-squared test). Both groups exhibited decreased frequency of HED with no statistically significant differences between the groups (Table 2). The eBAC declined between baseline and follow for both groups, from around 1.4 to 0.9, with no statistically significant difference between groups. The number of negative consequences associated with excessive drinking declined from just above 3 to just above 2, with no statistically significant differences between groups.

Sensitivity Analysis

Based on negative binomial regression, there was a statistically significant decrease in weekly alcohol consumption at follow-up as a function of number of attempts before answering the follow-up (incidence rate ratio [IRR] 0.94 (0.92,0.96), P<.001). This trend can be seen when plotting the mean total weekly consumption reported at the respective attempts, which is depicted in Figure 2. No changes to the primary analyses, with respect to statistical significance, were found when the analyses were redone under the assumption that missing data were equal to baseline values (carry over) nor when setting missing values to respective group follow-up means.

Attrition was investigated for statistically significant differences between the study groups regarding completion of the follow-up questionnaire. Baseline characteristics were compared between participants who did and did not respond at follow-up. No statistically significant differences were found among those for which primary outcome data was collected. However, there were statistically significant differences for secondary outcomes: non-responders were younger (P<.001), more often single (P=.03), and had a higher eBAC (P=.02) than responders

Post-Hoc Analysis

Because there was a statistical association between number of attempts to record follow-up data and the mean weekly consumption at these follow-up attempts we re-conducted the primary analysis using data collected only via the email (ie, attempts 1, 2, and 3), leaving aside follow-up data collected through text messages and telephone. In this analysis, a much lower P-value was recorded (IRR 0.90 (0.80, 1.02), P=.11), although not below the predefined 0.05 threshold. No such reductions of P-values were found when only considering text message follow-ups or telephone calls.

Table 1. Comparison of groups at baseline.

Variable	Intervention (n=460)	Control (n=436)	*P* value
Gender (females), n (%)	265 (57.6)	244 (56.0)	.62
Age (years), mean (SD)[a]	25.3 (6.7)	25.6 (6.8)	.43
Age (years), categorical, n (%)			.36
<21	119 (26.0)	110 (25.4)	
21-25	207 (45.2)	175 (40.4)	
26-30	76 (16.6)	85 (19.6)	
>31	56 (12.2)	63 (14.5)	
Marital status (single), n (%)	288 (62.9)	256 (59.1)	.25
University code, n (%)			.89
1	55 (12.0)	45 (10.3)	
2	13 (2.8)	9 (2.1)	
3	30 (6.5)	36 (8.3)	
4	47 (10.2)	47 (10.8)	
5	27 (5.9)	30 (6.9)	
6	41 (8.9)	42 (9.6)	
7	10 (2.2)	12 (2.8)	
8	12 (2.6)	12 (2.8)	
9	18 (3.9)	12 (2.8)	
10	32 (7.0)	31 (7.1)	
11	5 (1.1)	10 (2.3)	
12	157 (34.1)	141 (32.3)	
13	13 (2.8)	9 (2.1)	
Alcohol parameters			
Weekly alcohol consumption, mean (SD)	13.90 (8.43)	13.66 (8.30)	.67
Frequency of HED[b], n (%)			
2-3 times a month	131 (28.5)	130 (29.8)	.77
Approximately 1 time a week	241 (52.4)	218 (50.0)	
More than 1 time a week	88 (19.1)	88 (20.2)	
Highest eBAC[c], mean (SD)	1.32 (0.86)	1.38 (0.94)	.32
Number of negative consequences of excessive drinking[d], mean (SD)	3.19 (1.96)	3.17 (1.95)	.88

[a]Intervention (n=458); control (n=433).

[b]HED: heavy episodic drinking (how often, during the past 3 months, have you consumed 4 (for females) / 5 (for males) standard drinks on one occasion?).

[c]eBAC: estimated blood alcohol concentration.

[d]Includes negative consequences on studies, academic results, finances, social relationships, gender, regrettable situations, mental health, injuries, conflict, violence, and sleep.

Table 2. Drinking outcomes at follow-up and analysis of treatment effect intervention versus control.

Outcome	Intervention (n=423)	Control (n=393)	Unadjusted ratio (95% CI)	*P* value	Adjusted[a] ratio (95% CI)	*P* value
Primary outcomes, mean (SD)						
Weekly alcohol consumption	8.75 (7.28)	8.55 (7.13)	1.02 (0.91, 1.15)[c]	.70	0.99 (0.90, 1.09)[c]	.83
Secondary outcomes[d], mean (SD)						
Number of negative consequences of excessive drinking	2.17 (1.56)	2.33 (1.63)	0.93 (0.81, 1.07)[c]	.33	0.92 (0.81, 1.06)[c]	.24
Frequency of HED[e], n (%)	—	—	0.92 (0.64, 1.31)[f]	.65	0.85 (0.58, 1.22)[f]	.37
Never	11 (4.9)	7 (3.9)	—	—	—	—
Less than once a month	9 (4.0)	8 (4.4)	—	—	—	—
Approximately once a month	41 (18.1)	30 (16.7)	—	—	—	—
2-3 times per month	57 (25.2)	46 (25.6)	—	—	—	—
Approximately once a week	91 (40.3)	74 (41.1)	—	—	—	—
More than once a week	17 (7.5)	15 (8.3)	—	—	—	—
Highest eBAC[g], mean (SD)	0.96 (0.80)	0.93 (0.80)	1.02 (0.94, 1.10)[h]	.66	0.99 (0.92, 1.07)[h]	.85

[a]Adjusted for weekly alcohol consumption at baseline, age, university, and gender. Includes negative consequences on studies, academic results, finances, social relationships, gender, regrettable situations, mental health, injuries, conflict, violence, sleep.

[b]Values refer to intervention compared with control.

[c]Ratio of means, by negative binomial regression.

[d]Intervention (n=226); control (n=180).

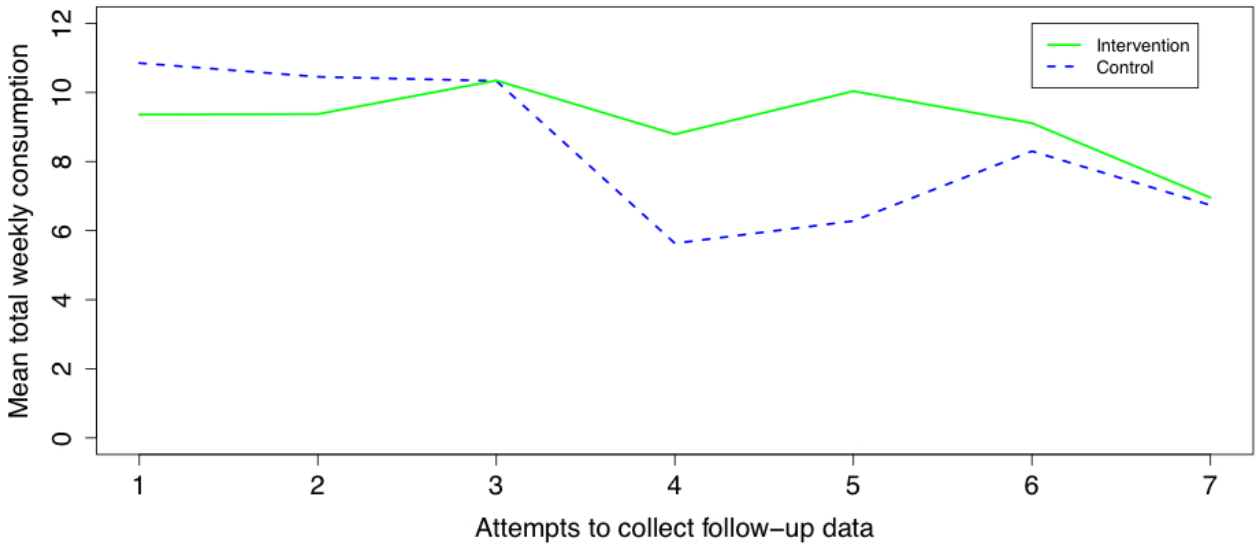
[e]HED: heavy episodic drinking.

[f]Odds ratio, by ordered logistic regression.

[g]eBAC: estimated blood alcohol concentration.

[h]Ratio of geometric means, by linear regression after log transformation.

Figure 2. Mean total weekly consumption reported at the different attempts to collect follow-up data.



Discussion

We could not demonstrate any statistically significant between-group differences relative to the novel intervention or treatment as usual. This is one of the largest studies on the subject of alcohol consumption reduction performed so far [6]; however, we did not reach a sufficient number of participants according to initial power calculations. This could partially explain the lack of statistical difference between the groups. Regulations at the participating universities and colleges required us to limit email reminders; therefore, it was not possible for us to continue to email and recruit more students. Apart from this, the intervention itself needs to be re-assessed

and refined to better support the target group for reducing alcohol consumption.

The primary analyses were performed under the assumption of MAR. The attempts model and differences between responders and non-responders, with respect to the secondary outcomes, question this MAR assumption. Although no changes in the primary analyses were found under different assumptions about the missing data (carry over and group means), these trends are still interesting to discuss. There could potentially be a bias that late responders drink less, ie, participants were not willing to engage because they did not think that their alcohol consumption was a problem. There could also be a time component where general alcohol consumption in the study population decreased (the follow-ups conducted over telephone happened several weeks after the first follow-up email). The high response rate alleviates the problem of these 2 cases to some degree because if the trend continues beyond 7 attempts, only a few cases would report even lower consumption rates. Given that the trend was present in both groups, this bias was alleviated in group comparisons. However, one might question if the aim of measuring the 3-month effect of the intervention is still relevant in light of this trend. The post-hoc analysis using only data collected via email (the first 3 attempts) lowers the *P*-value for a positive effect of the intervention, suggestive of a 3-month positive effect. However, one must be aware that the *P*-value was not less than the predefined level, and attrition analysis showed that there were significant differences between responders and non-responders when only considering follow-up data collected via email.

There are 2 more potential reasons why the attempt model showed a statistically significant trend. First, we asked email responders to estimate every day how many standard drinks they consumed, and then we summed these estimates to get the total weekly consumption. However, for practical reasons, we asked text and phone responders to directly estimate their total weekly consumption, and such differences in reporting may introduce bias to estimates given by responders. Second, the mode by which the data was collected may also bias the responses, especially when calling respondents because they may feel social pressure to report more positive answers than the truth. If either of these are the reasons for the trend, then the results in Table 2 are highly suspicious.

In the invitation to the study, we emphasized that participants should be willing to try to reduce their alcohol consumption. This was stated as information about the study, and in the informed consent text. There was not an explicit question about willingness in the baseline questionnaire. However, participants were asked to state a presumptive reduction goal in the baseline questionnaire. After this, the randomization took place. This means that all participants in the control group stated to what extent they wished to reduce their consumption. This may have influenced the outcome in the control group; however, the study aimed to investigate whether support via text messages helped reduced alcohol consumption, compared with routine practice.

The study has several limitations. This study was under-powered, and the MAR assumption was questionable. Among early responders (all using the same mode of response, estimating weekly consumption every day), the *P*-value for a positive effect of the intervention decreased but not enough to be statistically significant. The MAR assumption should still be questioned in this subset of the data. Another limitation is the proportion of participants exposed to the whole intervention because approximately 18% dropped out before the intervention finished. This might also have influenced the negative findings in the study.

A major strength of the study was the formative development design that entailed revision of all messages based on both user and expert feedback. Another strength of the study was the use of BCT analysis that elucidated the theory base of the messages, giving readers a better understanding of what the intervention entailed and enabling comparison with other interventions [21]. However, despite using 23 behavior change techniques that have been identified as effective for mobile interventions targeting alcohol interventions [20], we observed no treatment effect.

The inclusion of a weekly normative feedback was also hypothesized to be effective based upon a Cochrane review that showed receiving normative feedback had a small effect on reducing alcohol consumption in student populations [22]. Furthermore, self-monitoring is associated with improved effectiveness of brief interventions [19]. An earlier study also found that reporting alcohol use on a daily basis reduced drinking among heavy drinkers by 20% [23]. We could however not show any effect despite including the above elements in the intervention.

In most previous studies, the intervention had a longer duration (ie, around 12 weeks). This is twice as long as the 6 weeks used in the current study [6]. We still do not know whether a 6-week intervention is too short for supporting behavior change.

The present study did not demonstrate any differences in effects on alcohol consumption between a 6-week theory-based intervention and treatment as usual, among college and university students. Future studies should consider the length of the intervention and also whether techniques used in face-to-face interventions could be applied in text-based interventions [21].

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Authors' Contributions

All authors participated in the planning of the study. MB did the programing. MB and NK did the analysis. KT and PB wrote the first draft of the manuscript. All authors gave comments to the draft and contributed to the final manuscript.

Conflicts of Interest

MB and PB own a private company that develops and distributes evidence-based lifestyle interventions to be used in health care settings. No other disclosures were reported.

Multimedia Appendix 1

CONSORT - EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 320KB - mhealth_v6i6e146_app1.pdf]

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Abbreviations

eBAC: estimated blood alcohol concentration
HED: heavy episodic drinking
IRR: incidence rate ratio
MAR: missing at random
RCT: randomized controlled trial
SHC: student health care

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Original Paper

The Rise and Need for Mobile Apps for Maternal and Child Health Care in China: Survey Based on App Markets

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Abstract

Background: Mobile health services are thriving in the field of maternal and child health in China due to expansions in the field of electronic health and the introduction of the two-child policy. There are numerous maternal and child health apps in computer stores, but the exact number of apps, number of downloads, and features of these apps is not known.

Objective: This study aimed to explore the use of maternal and child health apps in Android and iOS app stores and to describe the key functional features of the most popular apps, with the purpose of providing insight into further research and development of maternal and child health mobile health products.

Methods: The researchers conducted a search in the 3 most popular Android app stores (Tencent MyApp, Baidu Mobile Assistant, and 360 Mobile Assistant) and the iTunes App Store in China. All apps regarding family planning (contraception and preparing for pregnancy), pregnancy and perinatal care, neonatal care and health, and development for children under 6 years were included in the initial analysis. Maternal and child health mobile apps with predominant features of product marketing, children's songs, animation, or games were excluded from the study. The 50 most frequently used apps in each of the Android stores as well as the iTunes store (a total of 78 deduplicated apps) were selected and downloaded for an in-depth analysis.

Results: A total of 5276 Android apps and 877 iOS apps developed for maternal and child health care were identified. Of the 78 most frequently used apps, 43 (55%) apps focused on one stage of MCH care, mainly targeting child care (25 apps) and before pregnancy care (11 apps), whereas 35 (45%) of the apps covered 2 or more stages, most of which (32 apps) included both pregnancy and child care services. The app features that were commonly adopted by the popular apps were health education, communication, health status self-monitoring, a diary, reminders, and counseling. Within the app feature of "health status self-monitoring," the researchers found 47 specific tools supporting activities such as pregnancy preparation, fetal heart monitoring, blood glucose and blood pressure monitoring, and doctor visits. A few apps were equipped with external devices (n=3) or sensors. No app with intelligent decision-support features to support disease management for conditions such as gestational diabetes and pregnancy-induced hypertension was found. A small number of apps (n=5) had a Web connection with hospital information systems to support appointment making, payments, hospital service guidance, or checking of laboratory results.

Conclusions: There are thousands of maternal and child health apps in the Chinese market. Child care, pregnancy, and before pregnancy were the mostly covered maternal and child health stages, in that order. Various app features and tools were adopted by maternal and child health apps, but the use of internal or external sensors, intelligent decision support, and tethering with existing hospital information systems was rare and these features need more research and development.

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KEYWORDS

mHealth; health services, maternal-child; mobile apps; market research

Introduction

In the 21st century, mobile health (mHealth), defined as the use of mobile phones and other wireless technology in health care, is a burgeoning field within public health [1]. On July 1 2015, the State Council of the people's republic of China issued "the Guiding Opinions of the State Council on Actively Promoting the Internet + Action," outlining the idea of promoting a new model of Web-based health care [2], with mHealth playing an increasing role in the delivery of health care. Improving the health and well-being of women and children has remained a common goal throughout the world [3-6].

With the rapid development of mHealth, thousands of maternal and child health (MCH) apps have appeared in China in Android app markets and Apple's app market. The popularity of mobile internet use (through devices such as mobile phones) and the universal two-child policy [7] will most likely result in an expansion of the current app market on MCH care. The market research agency "iResearch" reported that the use of Chinese maternal and child mobile apps (excluding mobile business apps) increased at a rate of 40% and 60% in 2015 and 2016, respectively [8]. However, almost no research seems to focus on the development and functional features of the Chinese mHealth products on MCH care. Hence, we conducted a study intending to find the most frequently used apps on MCH care in Android and iOS app stores, describe the utility and features, and to provide recommendations for app developers and researchers.

Methods

Selection of App Markets

According to "The most popular apps for Androids" released by the *Internet Weekly* in 2016, *Tencent MyApp*, *Baidu Mobile Assistant*, and *360 Mobile Assistant* were the top 3 Android app markets in China [9]. Hence, we selected the 3 mainstream Chinese Android app markets and iOS application market iTunes App store to retrieve MCH-related apps.

Selection of Maternal and Child Health Apps

We selected the apps developed for family planning (contraception and preparation for pregnancy), pregnancy and perinatal care, neonatal care and health, and development of children under 6 years. We did a preliminary search in the 4 app markets using the following keywords in the Chinese language: *pregnant*, *pregnancy*, *postpartum*, *child care*, *maternity*, *maternal and child*, *child*, *infant*, and *mother*. On the basis of the preliminary search results, a few other phrases frequently used in MCH app descriptions were added to the keyword searches, which were *menstruation*, *women*, *pregnancy stage*, *baby*, *fashion mother*, *fetus*, *mother and child*, *children's songs*, and *early education*.

For each of the 4 app markets, the official website or App store was visited, and we searched for the MCH apps using the identified keywords. For each search, we logged in as a guest so that the search results could not be tailored to an existing account [10]. The app name and the number of downloads (Android apps) or the number of reviews (iOS apps) for all apps generated from a search of each keyword in each app market were recorded. Two blinded investigators screened the name and the description of the searched apps. The apps that were not relevant to MCH care and product marketing apps were excluded. App deduplication was conducted for Android and iOS apps separately. The number of downloads for the same Android app in different markets were summed to obtain the total downloads for the app. The search of the app stores was conducted between February 15 2017 and to March 1 2017.

Selection of Frequently Used Apps for In-Depth Analysis

All found apps were ordered by number of downloads (Android) or reviews (iOS). The top 50 apps from Android and iOS markets respectively were deemed as the most frequently used apps and were selected for in-depth analysis in this study. A large number of apps were found which focused on early child education by predominantly using children's songs, animation, and intelligence games. These apps had limited features or research significance, but the rankings were comparatively high. For our research purposes, we excluded these apps when identifying the top 50 apps in both markets.

For the apps that employed both Android and iOS systems, only the iOS system was used for in-depth analysis, as small differences could be identified between the different versions. Finally, the lists of the top 50 searches for Android and iOS were integrated into a combined list, which contained 78 unique apps.

Additionally, apps developed by, or mainly used by MCH institutions, were ordered by number of downloads (Android) and reviews (iOS), and the 10 most frequently used "top 10 institution apps" were selected for further analysis.

In-Depth Analysis of Maternal and Child Health Apps

The 78 frequently used apps and the top 10 institution apps were all downloaded and installed on an iPhone 6s (iOS 10.3.1) or a Huawei MATE8 (NXT-AL10 Android 6.0) for in-depth analysis. For each app, 2 independent investigators registered and logged in to check all app modules and information. For the app or interventions that could only be activated at specific situations or stages, we activated them by simulating the required situations such as setting the expected date of confinement or fetal birth, registering multiple accounts, and adjusting the system time of the mobile phone.

To conduct the in-depth analysis, a semistructured database to collect and record the app characteristics was used. This database included the app's name, the number of downloads or reviews, MCH stages, mHealth app features, specific interventions or services, and the mobile phone functions. Specifically, the MCH stages were classified as before pregnancy, pregnancy, birth, postpartum (mother), and child care (covering postnatal newborn, infancy, and childhood). The

mHealth app features we intend to analyze comprise of 3 key components, namely (1) a list of 12 common app features mainly targeting health care providers, (2) a list of 5 app features serving client users, and (3) a list of 4 app features observed in the identified apps during the in-depth analysis. The first list of app features was based on a 12-category framework evaluating health systems performance for mHealth innovations in MCH field [11]. They are client education and behavior change communication (subdivided into health education and counseling in this study), sensors and point-of-care diagnostics, registries and vital events tracking, data collection and reporting, electronic health records, electronic decision support, provider-to-provider communication, provider work planning and scheduling, provider training and education, human resource management, supply chain management, and financial transaction and incentive [11]. The second list of app features came from a study which added amendments to the 12-category framework and included health status self-monitoring (expanded from the name of physical or bio data monitoring to cover social and psychological status evaluation, could be facilitated by specific sensors or standardized assessment scales), reminders, appointment making, client-to-client communication, and laboratory result checks [12]. The third list of app features, which were observed during the in-depth analysis, included client diary, shopping, games, and hospital service promotion (including introduction of hospitals, departments, doctors, and hospital events as well as hospital navigation or intelligent guidance).

Results

Characteristics of Identified Apps

A total of 5276 Android system MCH apps and 877 iOS system MCH apps were identified. The flowchart of MCH app selection is shown in Figure 1. Table 1 shows the distribution of the identified MCH apps with different numbers of downloads or reviews.

After excluding apps whose predominant feature was early child education through songs, animation, and games (n=2774), the top 50 apps from Android and iOS app markets separately were selected, and 78 deduplicated apps were regarded as the most frequently used ones and downloaded for analysis.

All of the 78 frequently used apps used in this study were developed by private companies and were available for free download and use. Each app had over 2,570,000 downloads or more than 1235 reviews. For *Meet You*, an MCH app developed by Xiamen Mei Pomelo Information Technology Co, Ltd, the cumulative number of downloads exceeded 100 million since it was put into use in 2013. As shown in Figure 2, more than half of the frequently used apps (43/78, 55%) focused on only 1 stage, and nearly half (35/78, 45%) covered 2 or more stages of MCH care. For the apps that had covered only 1 stage, child care was most targeted, followed by before pregnancy (family planning); for those targeting 2 or more stages, the entire range of MCH care (ie, from family planning to child care), or nearly the entire range (ie, from pregnancy to child care), were covered.

Features of the Frequently Used Apps

The app features adopted by the 78 frequently used apps are illustrated in Figure 3. Health education (71/78, 91%), client-to-client communication (52/78, 67%), health status self-monitoring (44/78, 56%), shopping (44/78, 56%), diary (36/78, 46%), reminders (34/78, 44%), and counseling (30/78, 39%) were among the most commonly developed app features. A handful of apps (n=5) had links to existing hospital information systems to support appointment making, payment, hospital service promotion, and to check laboratory results.

The top 10 MCH institute apps developed for maternal and child health organizations were also screened for and analyzed. They had, at most, 18,000 downloads and no more than 39 reviews. The main app features were hospital service promotion, appointment making, health education, financial transaction and incentive (only payment for service), checking laboratory results, and counseling. Figure 4 shows the detailed features of these apps.

Specific Tools Supporting Health Status Self-Monitoring

Within the “health status self-monitoring” app feature, 47 specific tools were found to provide users with individualized feedback as a response to regular or occasional health data collection (Table 2). The tools were designed to provide certain support on pregnancy preparation, fetal heart monitoring, blood glucose and blood pressure monitoring, and some action reminders. Three apps were equipped with external sensors or devices to monitor basal body temperature, body weight, physical exercise, fetal movement, and contractions. One app adopted intelligent technology to monitor heart rate through “fingertip scanning” using a phone camera. No intelligence support tools or app features in the studied apps to support electronic and smart management of diseases such as gestational diabetes and pregnancy-induced hypertension were found.

Figure 1. Flowchart of app selection for maternal and child health. MCH: maternal and child health.

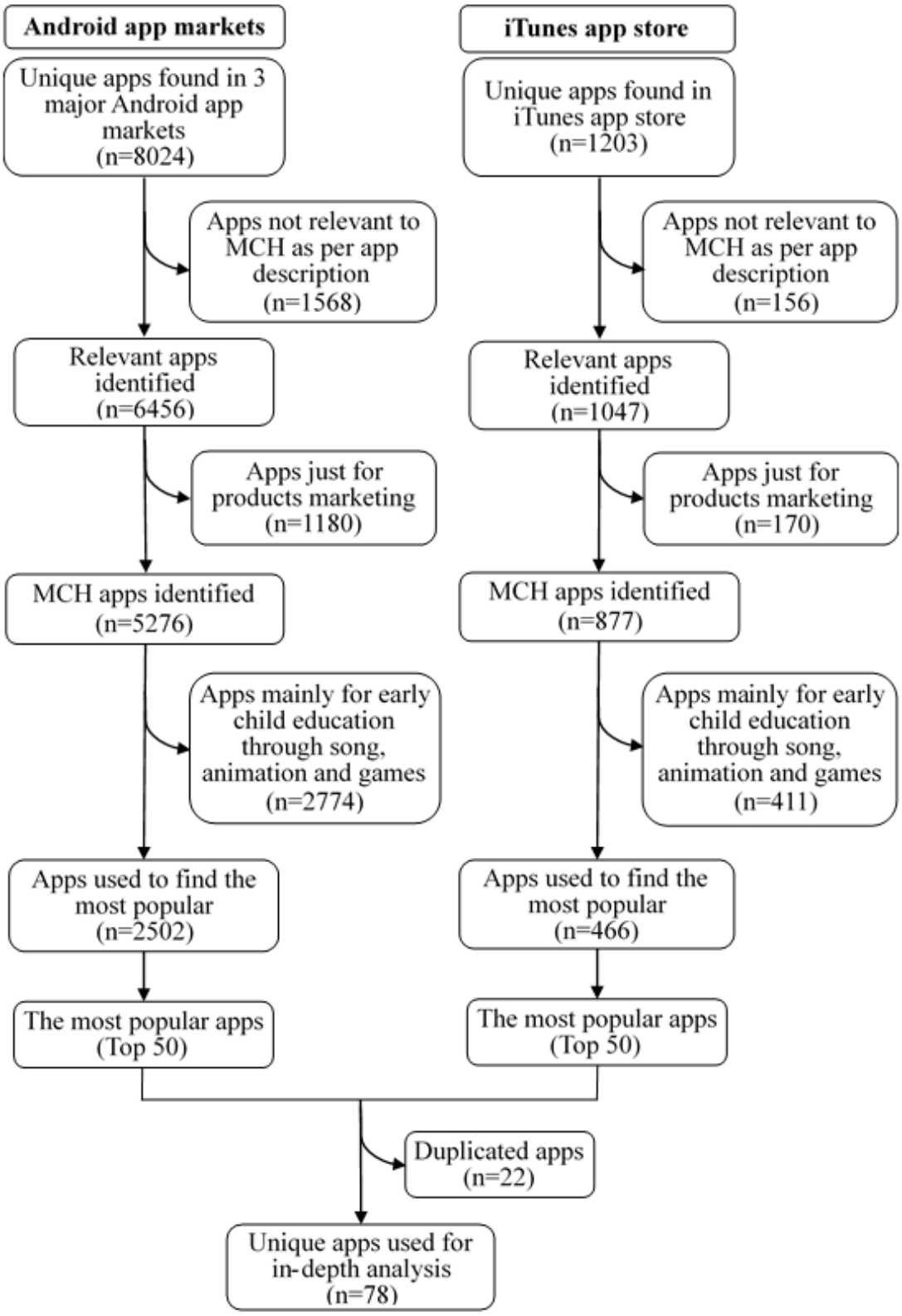

Table 1. Distribution of maternal and child health care apps with different number of downloads or reviews.

Frequently used apps	n (%)
Android apps, number of downloads	**5276 (100)**
≥50,000,000	8 (0.15)
≥10,000,000	40 (0.76)
≥5,000,000	40 (0.76)
≥1,000,000	219 (4.15)
≥500,000	148 (2.81)
≥100,000	488 (9.25)
≥50,000	303 (5.74)
≥10,000	781 (14.80)
≥5000	411 (7.79)
≥1000	1074 (20.36)
<1000	1764 (33.43)
iOS apps, number of reviews	**877 (100)**
≥100,000	3 (0.3)
≥50,000	3 (0.3)
≥10,000	24 (2.7)
≥5000	25 (2.9)
≥1000	96 (10.9)
≥500	64 (7.3)
≥100	197 (22.5)
≥100	465 (53.0)

Figure 2. Stages of maternal and child health care covered by the 78 most popular apps.

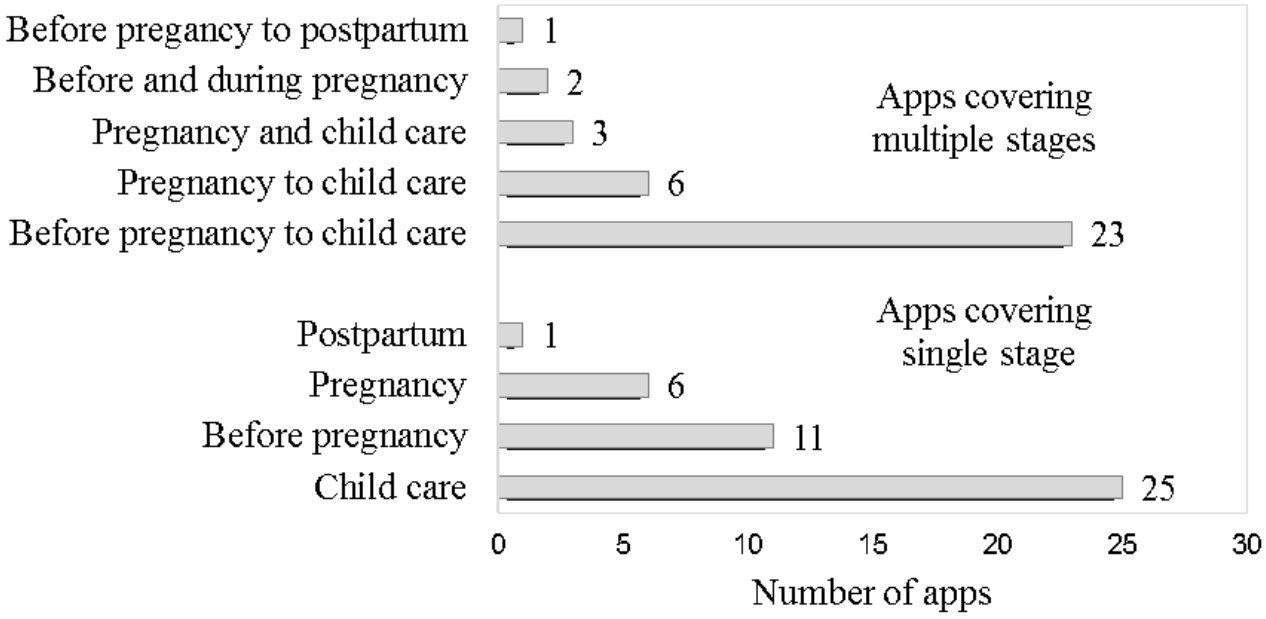

Figure 3. App features adopted in the 78 most popular apps on maternal and child health care.

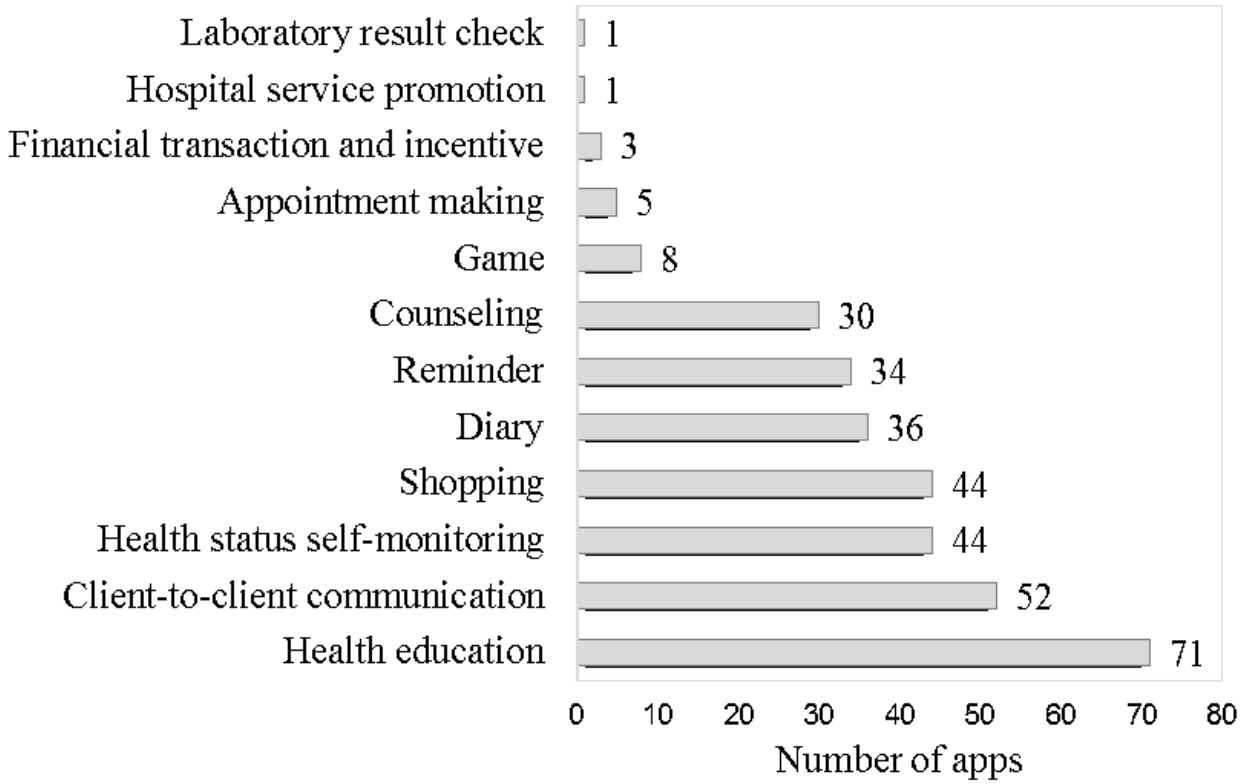

Figure 4. App features covered in apps developed by maternal and child health institutions.

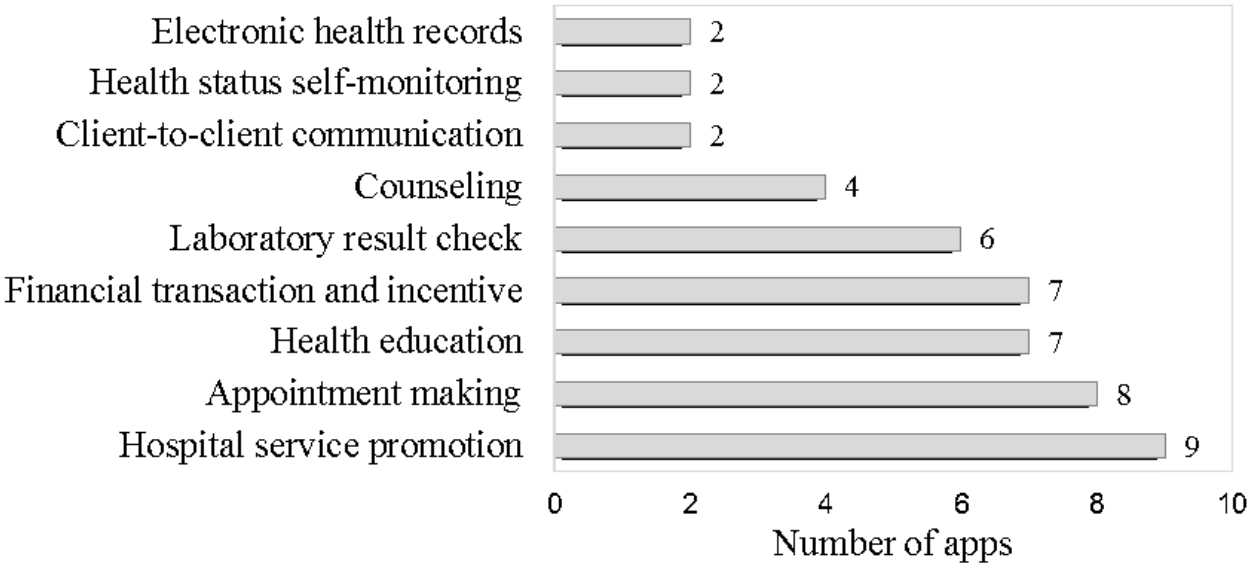

Table 2. Specific tools within the "health status self-monitoring" feature found in the 78 popular apps on maternal and child health.

Tools	Apps, n (%)
Planning for pregnancy	
Menstruation	21 (27)
Sex life	16 (21)
Ovulation	13 (17)
Body symptoms	13 (17)
Basic body temperature	13 (17)
Leucorrhea	7 (9)
Defecation	4 (5)
Folic acid	3 (4)
Type-B ultrasonic to test ovulation	2 (3)
Sleep	2 (3)
Medication	2 (3)
Pregnancy stage	
Fetal movement	13 (17)
Antenatal examination	10 (13)
Expected date of confinement	10 (13)
Abdominal girth perimeter	10 (13)
Biparietal diameter	9 (12)
Femur length	9 (12)
Uterine contraction	8 (10)
Antenatal examination report	2 (3)
Blood pressure	2 (3)
Fetal heart	2 (3)
Parents blood type	2 (3)
Progesterone value	1 (1)
Human chorionic gonadotropin value	1 (1)
Blood glucose	1 (1)
Fundal height	1 (1)
Postpartum stage	
Postpartum depression	1 (1)
Parenting stage	
Children's height	18 (23)
Children's weight	18 (23)
Vaccination	11 (14)
Children's head circumference	9 (12)
Nurse	5 (6)
Children's sleep	5 (6)
Children's defecation	4 (5)
Supplementary food	3 (4)
Children taking drugs	2 (3)
Children's body temperature	1 (1)
Before and during pregnancy	

Tools	Apps, n (%)
Exercise	9 (12)
Diet	7 (9)
All stages	
Body weight	23 (29)
Body height	11 (14)
Body mass index	3 (4)
Medical advice	2 (3)
Medical records	2 (3)
Heart rate	1 (1)
Users' blood type	1 (1)
Laboratory test report result	1 (1)

Discussion

Principal Findings

This study revealed that there is a large demand for MCH mobile apps in the Chinese market. The cumulative downloads for all MCH apps amounted to hundreds of millions. When considering the stage of MCH which the developed apps targeted, child care was the most covered stage if the app was developed to target only 1 stage or the whole stage from (before) pregnancy to child care were the most covered stages when the apps were developed. Health education, communication, health status self-monitoring, shopping, diary, reminders, and counseling were the most developed app features. With respect to the specific app feature, "health status self-monitoring," there were 47 tools helping women through family planning to child care. However, very few apps had effective communication between market MCH apps and existing hospital information systems, and very few apps were equipped with external or internal sensors or devices to support prompt data collection and point-of-care diagnostics.

Applications Adopted

Given that the target population of the most frequently used apps was the general public , the application features facilitating professional staff providing health service management and reporting were rarely adopted. These features included registries and vital events tracking, data collection and reporting, electronic health records, electronic decision support, provider-to-provider communication, provider work planning and scheduling, provider training and education, human resource management, supply chain management, and financial transaction and incentive. Instead, health education, personalized reminders, health status self-monitoring, counseling and client-to-client communication were the most adopted app features.

mHealth has large potential in health education activities due to its effectiveness in delivering verbal and visual messages [13]. More than 90% (71/78) of the frequently used apps had adopted health education app features. According to social cognitive theory, individuals would gain better understanding and learn quickly from observing and are likely to remember and repeat the behaviors provided by a model [14,15]. App developers could strengthen health education activities by improving user interface design to include more pictures, scene animation, and video information which is more easily understood by a wider range of people.

Personalized reminders can reinforce behavioral changes in app users [16,17]. In the studied apps, the reminders were customized to the specific health status of users and included the events such as antenatal examinations, vaccinations, drinking water, taking drugs, etc. However, the reminders were of varying quality; in many cases, further improvement and standardization are needed.

Health status self-monitoring tools are often a means to track changes in physical, biological, social, and psychological indicators, which in turn can guide corresponding behavior change [18]. In this study, dozens of tools were found (Table 2). Some tools were used quite frequently in certain MCH stages; however, further studies are needed to explore the validity and effectiveness of these tools.

Counseling is also a widely adopted app feature among the studied MCH apps. It can be a convenient way to connect users and experts, including either real-time consultations or nonreal-time queries through text, voice, and picture messages. This feature could facilitate, if adopted properly, education, medication instruction, and appointment scheduling. However, it must be noted that all the counseling behaviors should comply with the local regulations and laws.

Client-to-client communication could meet the desire of users to seek peer support by communicating with people who had similar health issues. Many apps would assign some pregnant women who are experienced in receiving health service with the support of app to answer questions in order to enhance the interaction. In fact, communication has been determined as an important measure to ensure the success of an app [19].

Other supportive features such as diaries, shopping, and games, which were not key components of MCH care but were highly welcomed by users, had a large impact on users' adherence to apps. A diary can help people to record their mood and psychological status and experience being a new mother;

shopping features can help people finding food, clothes, and other daily necessities good for health; and games might attract continuing use of an app. More and more apps now have features that promote what to eat and where to shop; however, this would have a negative impact if the app gives improper advice regarding food, nutritional products, and other daily necessities. The shopping app feature is the main profit model of current MCH apps in the Chinese app markets and needs further improvement.

Some apps were trying to connect with the MCH units in hospitals through features on clinical support services, namely appointments, payments, test results, etc; however, the relative downloads of apps with these features were much lower. Currently, most hospital information systems are closed networks. It is challenging to achieve free data transmission between apps and existing hospital electronic systems, given the concern over safety issues. Another attempt to connect with medical system was to develop MCH hospitals' own apps. Such apps focused on hospital service promotion, appointment making, and checking of laboratory results. Due to the lack of commercial running, most of the apps were not well developed or maintained.

Limitations

The study retrieved 5276 and 877 MCH apps, respectively, in the Android market and iTunes App store by using the most comprehensive keywords. However, not all apps were recruited, given that an increasing number of apps were developed on WeChat (a communication app of Tencent), and we did not include them in the study due to its unique interface and app structure. In addition, we are not able to backtrack the dates of release for all the studied apps. The difference on survival time will have an influence on the number of downloads and reviews. As a result, this may cause bias when identifying the most frequently used apps based on the number of downloads or reviews of the apps.

Conclusions

MCH apps have been rising in China's market. Most of the apps were equipped with various features and tools. This study may provide an insight on the selection of appropriate features, functions, and tools and may facilitate a better understanding for mobile app developers of the gaps existing in mHealth products.

Acknowledgments

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Authors' Contributions

PZ and JL designed the study. LD and YC were responsible for app search, analysis, and data collection. LD, PZ, and HC drafted the manuscript. All authors contributed to the review and editing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

MCH: maternal and child health
mHealth: mobile health

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Original Paper

Analysis of the Features Important for the Effectiveness of Physical Activity–Related Apps for Recreational Sports: Expert Panel Approach

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Abstract

Background: A large number of people participate in individual or unorganized sports on a recreational level. Furthermore, many participants drop out because of injury or lowered motivation. Potentially, physical activity–related apps could motivate people during sport participation and help them to follow and maintain a healthy active lifestyle. It remains unclear what the quality of running, cycling, and walking apps is and how it can be assessed. Quality of these apps was defined as having a positive influence on participation in recreational sports. This information will show which features need to be assessed when rating physical activity–related app quality.

Objective: The aim of this study was to identify expert perception on which features are important for the effectiveness of physical activity–related apps for participation in individual, recreational sports.

Methods: Data were gathered via an expert panel approach using the nominal group technique. Two expert panels were organized to identify and rank app features relevant for sport participation. Experts were researchers or professionals in the field of industrial design and information technology (technology expert panel) and in the field of behavior change, health, and human movement sciences who had affinity with physical activity–related apps (health science expert panel). Of the 24 experts who were approached, 11 (46%) agreed to participate. Each panel session consisted of three consultation rounds. The 10 most important features per expert were collected. We calculated the frequency of the top 10 features and the mean importance score per feature (0-100). The sessions were taped and transcribed verbatim; a thematic analysis was conducted on the qualitative data.

Results: In the technology expert panel, applied feedback and feedforward (91.3) and fun (91.3) were found most important (scale 0-100). Together with flexibility and look and feel, these features were mentioned most often (all n=4 [number of experts]; importance scores=41.3 and 43.8, respectively). The experts in the health science expert panels a and b found instructional feedback (95.0), motivating or challenging (95.0), peer rating and use (92.0), motivating feedback (91.3), and monitoring or statistics (91.0) most important. Most often ranked features were monitoring or statistics, motivating feedback, works good technically, tailoring starting point, fun, usability anticipating or context awareness, and privacy (all n=3-4 [number of experts]; importance scores=16.7-95.0). The qualitative analysis resulted in four overarching themes: (1) combination behavior change, technical, and design features needed; (2) extended feedback and tailoring is advised; (3) theoretical or evidence base as standard; and (4) entry requirements related to app use.

Conclusions: The results show that a variety of features, including design, technical, and behavior change, are considered important for the effectiveness of physical activity–related apps by experts from different fields of expertise. These insights may assist in the development of an improved app rating scale.

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KEYWORDS

mobile applications; exercise; healthy lifestyle; mHealth; measures; health behavior; features

Introduction

Recreational Sport Participation

Starting with and maintaining physical activity (PA) is a challenge for many citizens. We see that in the United States and Europe, physical inactivity and sedentary behavior are increasing, causing health-related problems such as decreased quality of life and increase in health care costs [1]. Potentially, participation in sports can contribute to a more healthy lifestyle [2-6]. However, participation rates are also quite low, with 59% of European citizens exercising or playing a sport less than once a week [7]. In the Netherlands, the situation is slightly more positive, with 44% of Dutch citizens participating in sports less than once a week or never [8]. Of the citizens that participate in recreational sports in the United States and Europe, a large number of people participate in individual or unorganized sports (eg, running and cycling) [9-13]. In the Netherlands, the participation in recreational individual sports such as running, cycling, walking, and fitness is increasing as well [8]. A large part of these participants are beginners or less experienced. These individual sports are often practiced in lighter nonclub-organized settings (leisure time sport participation that allows for a flexible experience) or individually [14]. In the latter, there exist no or limited support and guidance of a trainer or coach. Therefore, these individual athletes are at risk of injuries or loss of motivation and hence dropping out and therefore decreasing PA [15]. Substantial guidance is necessary to prevent injuries and to stay motivated to participate in sports, especially among beginner and less experienced participants [16,17].

Potential of Physical Activity–Related Apps

Potentially PA–related apps could motivate these people during sport participation and help them to follow and maintain a healthy and active lifestyle. Mobile health (mHealth)–related apps are popular; in 2016, the app stores displayed 105,000 (Google Play) and 126,000 (Apple Play Store) mHealth-related apps in health and fitness and medical categories [18]. In recent years, a large number of PA–related apps have been developed for people in individual sports, and every day, new apps are being launched in the app stores [19,20]. Previous research shows that approximately 50% to 75% of (event) runners use a running app [15,21]. Cycling and walking apps are gaining in popularity as well. For instance, Strava (an app for running and cycling) has millions of users and the number of users increases each month. [22-24]. In contrast to the published data available on the use of running and cycling apps, little is known about the use of walking apps.

These running, cycling, or walking apps provide possibilities to support people in participation in exercise and sports (such as monitoring activities, setting goals, and comparing your results to others) [25,26]. However, the question is whether the quality of currently available apps is sufficient to support recreational sport participants. An analysis of the quality of apps and knowledge about which app features matter the most is necessary to determine whether apps have added value.

Assessment of Physical Activity–Related Apps

The quality of PA–related apps has been evaluated in various manners in previous research. Some studies have examined if and how many behavior change techniques (BCT's) are applied in current health– or PA–related apps by using an app taxonomy of Abraham and Michie [26-30]. Results showed that only a small amount of BCT's (mean number of 3.7-8 BCT's) are applied in PA or healthy nutrition apps [26,28,30]. Content analyses of apps also showed that the evidence base of currently available health and fitness apps is limited [31-33]. A recent study evaluated if and how gamification was used in health and fitness apps [34]. They showed that gamification features were often used in popular apps; however, low adherence to professional guidelines or industry standard for gaming was found [34]. Other app rating scales have been developed as well, such as the Mobile App Rating Scale (MARS) and an app rating scale for exercise apps [35,36]. The MARS was developed for classifying and assessing the quality of mHealth apps [35]. In general, moderate quality scores were found for mental health and wellbeing apps and weight management apps [35,37]. The app rating scale for exercise apps developed by Guo et al (2017) was based on exercise prescriptions developed by the American College of Sports Medicine (ACSM) for aerobic exercise, strength and resistance, and flexibility [36]. On the basis of this scale, low scores (maximum 35 out of 70 points) were found for the tested exercise apps [36]. Another method to evaluate the quality of PA–related apps is by assessing technical features or design. The mHealth taxonomy of Olla and Shimskey examines features such as data management, user interface, and device type [38]. The MARS evaluated technical features as well, such as having an app community and containing data protection using a password [35]. However, these technical features were not included in the quality score of the app.

In summary, a variety of app features have been examined in current app rating scales, including design, technical, and behavior change features. In some of these rating scales (eg, MARS and taxonomy of Abraham and Michie) [29,35], all app features are considered evenly important, whereas the rating scale developed by Guo et al applied a weighting to the items [36]. The time allocated to different components (aerobic exercise, strength and resistance, and flexibility) of a standard

exercise program for health and fitness (ACSM guidelines) was used to weigh the items [36].

Problem Statement

This study is innovative in two ways: the incorporation of experts' opinions (instead of based on literature or theories on behavior change) and the assessment of the importance of features (instead of only the presence of features). It remains unclear how the quality of running, cycling, and walking apps, defined as having a positive influence on participation in recreational sports, can be assessed. We do not know if some app features may be more important than others for participation in recreational sports and if a weighing should be applied. In addition, there is currently no PA–related app rating scale that scores design, technical, and behavior features. Currently available app rating scales are based on literature or theories on behavior change but do not take into account the opinion of experts regarding the importance of app features. In this study, experts were defined as researchers or professionals in the field of behavior change, psychology, health, and human movement sciences, as well as industrial designers and information technologists. Their knowledge of and experience with design and evaluation of PA–related apps is deemed to be very valuable. The obtained additional information regarding the rating of features can be used in the development of an improved PA–related app check list.

Objective

Therefore, the aim was to identify expert perception on which features are important for the effectiveness of PA–related apps for participation in individual, recreational sports.

Methods

Design

The data were gathered via an expert panel approach in which the nominal group technique (NGT) was used [39]. Two expert panels were organized to identify and rank app features relevant for effectiveness of PA–related apps for participation in individual, recreational sports. This NGT was chosen for this study as it provides the possibility to identify problems and gain more insight in a topic by quantifying opinions of participants in a democratic way [39,40]. In addition, the NGT includes a structured group process and can be used to generate and rank ideas for group discussion, to reach consensus, and to engage group members to solve a problem [41]. The NGT was proven evenly effective as other methods in terms of accuracy, idea selection, and satisfaction with the process, such as face-to-face meetings, Delphi method, and interactive groups [42,43]. Moreover, a previous study showed that it was an effective and efficient tool to generate ideas and to develop consensus in a group of experts [44]. Small and rather homogeneous groups are preferred in using NGT [45].

Participants

A total of 12 experts for each panel (24 experts in total) were recruited and approached, taking into account dropout, among others, because of time constraints. Convenience sampling was used to recruit the experts. These experts were selected based on their experience, expertise, and perception concerning PA–related apps [39]. All experts needed to have a Master's degree. Two types of experts were selected for these two panels. Inclusion criteria for the first group (technology expert panel) included scientific background in information and communication technology (ICT), service design, industrial design, or research through design (or other comparable fields). Inclusion criteria for the second group (health science expert panel) included (1) Scientific background in behavioral, psychological, health, or human movement sciences (or other comparable fields) *or* professional experience in these domains and (2) Research *or* professional experience (at least 3 years) with PA–related apps. This way, knowledge and expertise from different disciplines was collected. This study was part of a larger research project called "An app for everyone?!" The aim of this project was to determine which (popular) sport app fits which type of user or professional based on their goals and wishes. If the selected experts were already involved as partner in this research project, they were excluded. All experts signed an informed consent before participating in the expert panels.

Of the 24 approached experts, 11 (46%) were able to attend the expert panel sessions. Four experts were included in the first session and seven in the second group session. Due to time restrictions, the other 13 experts were not available on the scheduled sessions. Still, we were able to include all relevant expertise in the panels.

Table 1 presents the characteristics of the experts who participated in the panels. For the NGT, the health science expert panel was divided into two subgroups (a group of three [health science expert panel A] and a group of four experts [health science expert panel B]), to make sure that all experts had enough time to express their thoughts and that there was enough time for discussion [45].

Procedure

First, the selected experts were contacted via email to participate in the NGT. All experts who agreed to participate received an email with additional information about the purpose and procedure of the study. The first expert panel (technology expert panel) was organized on October 18, 2016 and was facilitated and observed by two of the authors (RW and JD). Subsequently, the second expert panel (health science expert panel) interview was organized on October 31, 2016 and was facilitated by two of the authors (JD and JvdW). The sessions were organized at a location that was most convenient for the experts (Eindhoven and Amsterdam, The Netherlands). To increase the reliability and validity of the results, the moderators followed the same protocol, and one moderator attended both sessions.

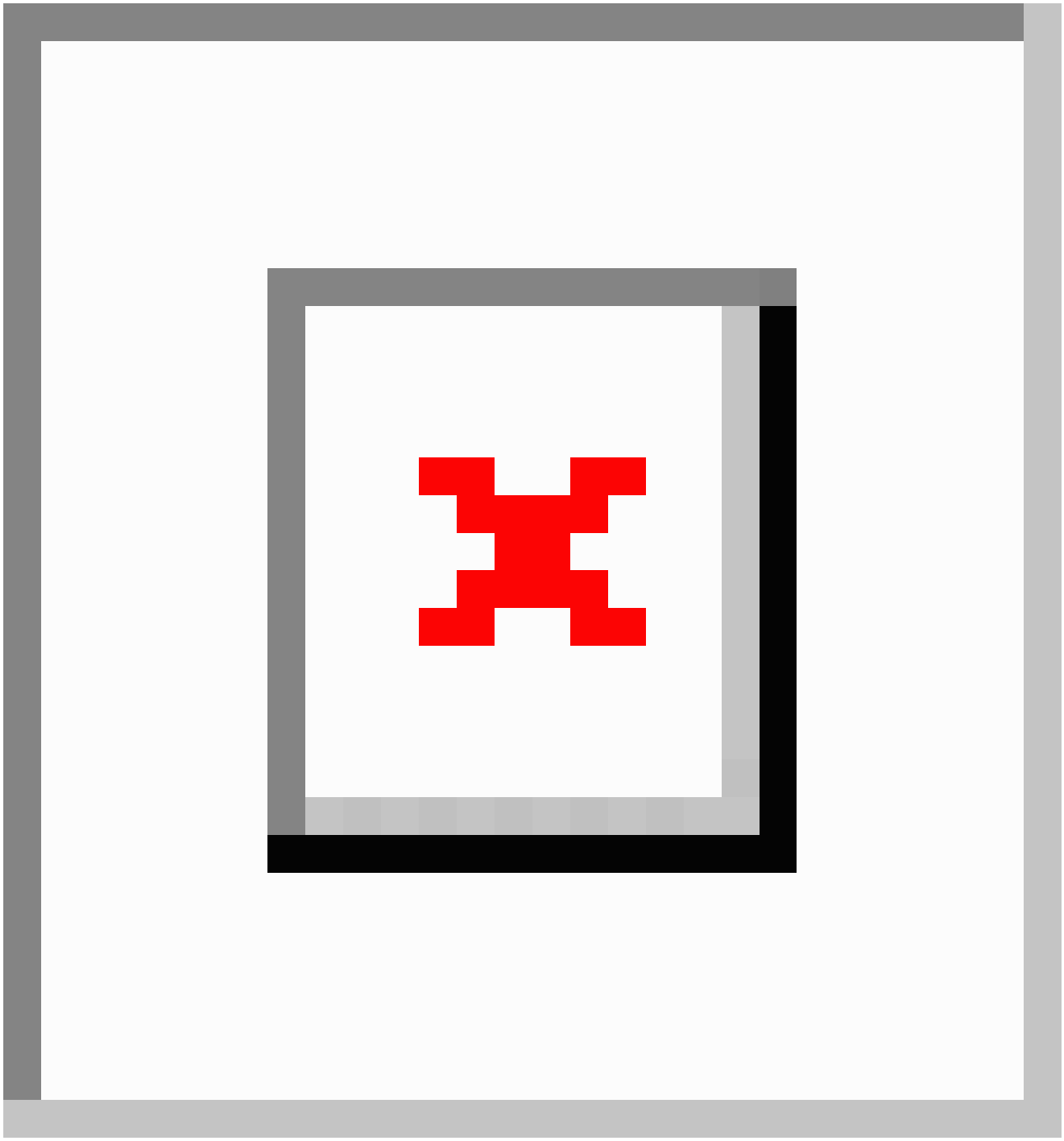
In alignment with the NGT, each session consisted of three consultation rounds [46]. In these three rounds, the goal was to rank and prioritize PA–related app features (Figure 1). To facilitate interaction, name tags were placed in front of the experts, and the experts were positioned in a half-circle. The moderator facilitated the discussion, provided instructions about the assignments, and ensured that all experts had an equal say. If necessary, the moderator asked for clarification of the answers provided by the experts.

Table 1. Expert characteristics.

Characteristics	Technology expert panel (n)	Health science expert panel A (n)	Health science expert panel B (n)
Sex			
Male	4	2	0
Female	0	1	4
Expertise			
Behavior change	0	1	2
Human movement sciences (injury prevention or monitoring)	0	1	1
Health sciences	0	1	0
Persuasive technology	0	0	1
ICT[a] service design	2	0	0
Industrial design	2	0	0
Degree			
MSc	2	3	2
PhD	2	0	2

[a]ICT: information and communication technology.

Figure 1. Three rounds of the nominal group technique.



In a short introduction, the moderator explained the framework of the session. The moderator asked the experts to focus on running, cycling, and walking apps for recreational athletes, with a goal to start and maintain sports participation. After this introduction, all participants introduced themselves and explained their experience with PA–related apps. Subsequently, the moderator informed the experts about the purpose of the research project and the protocol. To set a framework for the assignments in the sessions, we asked the experts to define the concept "effectiveness of apps." The experts discussed in their own sessions their shared idea about what effectiveness meant to them (social construction).

In the first round, the experts were asked to individually list all app features that they found necessary for effectiveness of PA–related apps for sport participation (Multimedia Appendix 1). After that, these features were collected, explained, and listed on a white board. In the second round, the experts were asked to individually rank the 10 features they found most important (Multimedia Appendix 2). Subsequently, these rankings were collected, presented on a screen, and discussed groupwise. In the last round, the experts individually made a final list of their 10 most important features (Multimedia Appendix 3). In addition, they were also asked to appoint a score to each feature (0-100), to indicate importance. The duration of both expert panel sessions was 2 hours.

Data Analysis

Nominal Group Ranking

On the basis of the third round, the 10 most important features per expert were collected. The features generated by the expert panel sessions were combined into one list per panel. We calculated the frequency of the features in the top 10, as well as the mean importance score per feature. Differences between groups were not calculated because of small sample size.

Qualitative Analysis

The sessions were audiotaped and videotaped and transcribed verbatim. On the basis of these transcripts, a list of features generated by each group and their definitions was created. The transcripts were read and reread by one of the authors (JD). After that, a thematic analysis was conducted on the qualitative data from the expert panels. This thematic analysis focused on the answers that illustrated and supported the experts' ranking choices. The coding was performed manually based on a coding framework that was developed inductively. This coding frame was discussed and checked by a coinvestigator (JvdW) who was a moderator as well (investigator triangulation) [47].

Results

Structure of Results

The results from this study are presented in three sections. The first section shows how the experts defined the concept effectiveness of PA–related apps as a starting point of the discussion. The second section presents the various features that were ranked and their importance. The third section provides some of the overarching themes that were extracted from the panel sessions. These themes can be considered important areas to address in the development of a new app rating scale.

Definition of Effectiveness

At the start of the panel sessions, the experts defined the concept effectiveness of PA–related apps to delineate the topic.

In the first expert panel, the experts agreed that an app was effective if a (safe, sustainable and healthy) change of behavior was established. Experts from the second panel (health science expert panel A and health science expert panel B) agreed on that and added that an app was effective if it could change behavior determinants such as knowledge, attitude, risk perception, and awareness to influence behavior on the long term.

Nominal Group Ranking

In total, 51 features were collected in round one. After selecting, prioritizing, and discussing these features in round two and three, 25 features remained and were ranked by the experts in both expert panels. Table 2 shows for each panel frequency of the features in the top 10, as well as the mean importance score per feature (on a scale of 0-100). The total frequency of individually ranked features ranged from 1 to 9.

The features that were perceived as most important by the technology expert panel (with industrial designers and information technologists) were applied feedback and feedforward (anticipating on future behavior or goals; 91.3) and fun (91.3). Besides those two features, look and feel and flexibility were also mentioned most often (all n=4 [n denotes the number of experts]). The importance scores of these two features were considerably lower (43.8 and 41.3, respectively). The experts in the health science expert panel A (behavior change and human movement sciences) found instructional feedback (95.0), motivating feedback (91.3), and monitoring or statistics (90.0) most important. The features that were ranked most often (number of experts=4) were monitoring or statistics, motivating feedback, technically properly working, tailoring starting point, fun or pleasure, and usability. The importance scores of these features were high as well (82.0-95.8).

Experts in the health science expert panel B found motivating or challenging (95.0), monitoring or statistics (95.0), and peer rating and use (92.0) most important. Usability, anticipating or context awareness, and privacy were ranked by all experts in this subpanel, with importance scores ranging from 16.7 to 85.0.

Qualitative Analysis

During the panel sessions, the experts elaborated on the features they ranked and explained why they found them important. This section outlines the overarching themes that were found.

Each theme is discussed below and illustrated with quotes of the experts. In Multimedia Appendix 4, a detailed version of the qualitative analysis is presented, and in Multimedia Appendix 5, the corresponding coding scheme is provided.

Combination Behavior Change, Technical, and Design Features Needed

In line with the expertise of the expert panels, features for behavior change as well as technical and design features were considered as important for effectiveness of PA–related apps. For instance, in the technology expert panel next to technical and design features, applied feedback, fun, rewards, and context awareness were ranked in the top 10. In addition, in health science expert panel A and health science expert panel B, next to behavior change features, reliability, usability, works good technically, and visibility were ranked in the top 10. Experts in technology expert panel indicated that, for these features, in general, domain specific knowledge is required, as illustrated in the following quote:

> *Basically applied feedback includes knowledge of sports, motivational support and quality of coaching, and depends on the intended application.* [Technology expert panel, expert in industrial design]

Table 2. Features ranked by experts in round 3 (based on top 10 ranking).

Feature	Technology expert panel		Health science expert panel A		Health science expert panel B		All experts	
	Mean importance score[a]	Frequency	Mean importance score[a]	Frequency	Mean importance score[a]	Frequency	Mean importance score[a]	Frequency
Instructional feedback	—[b]	—	95.0	2	—	—	95.0	2
Motivating or challenging	—	—	—	—	95.0	1	95.0	1
Peer rating and use	—	—	—	—	92.0	1	92.0	1
Applied feedback and forward	91.3	4	—	—	—	—	91.3	4
Motivating feedback	—	—	91.3	4	—	—	91.3	4
Monitor or statistics	—	—	90.0	4	95.0	1	91.0	5
Stability	90.0	1	—	—	—	—	90.0	1
Engagement	—	—	—	—	87.5	2	87.5	2
Technically properly working	—	—	87.5	4	—	—	87.5	4
Tailoring starting point	—	—	85.0	4	—	—	85.0	4
Continues tailoring	—	—	85.0	3	—	—	85.0	3
Usability	60.0	1	87.5	4	85.0	3	83.1	8
Fun or pleasure	91.3	4	73.8	4	85.0	1	82.8	9
Rewards	65.0	2	—	—	95.0	1	75.0	3
Reliability	—	—	80.0	1	70.0	1	75.0	2
Theoretical (scientific) base or evidence + BCT's[c]	—	—	—	—	75.0	2	75.0	2
Check on health	—	—	73.3	3	—	—	73.3	3
Visibility or exposure or reputation	—	—	—	—	72.5	2	72.5	2
Social	80.0	2	55.0	2	90.0	1	72.0	5
Coaching styles	—	—	—	—	70.0	1	70.0	1
Tailoring content that cannot be changed	—	—	70.0	1	—	—	70.0	1
Connectivity	70.0	2	—	—	—	—	70.0	2
Costs	—	—	70.0	1	—	—	70.0	1
Fit to user or everyday life or tailoring	71.7	3	—	—	60.0	1	68.8	4
Sustainable training plan	—	—	60.0	1	—	—	60.0	1
Anticipating or context awareness	35.0	2	73.0	2	48.3	3	51.9	7
General information healthy behavior	—	—	50.0	1	—	—	50.0	1
Increase awareness	50.0	2	—	—	—	—	50.0	2
Flexibility or adjustable or adaptive	41.3	4	—	—	60.0	1	45.0	5
Look and feel	43.8	4	—	—	—	—	43.8	4
Portability	40.0	1	—	—	—	—	40.0	1
Privacy	—	—	—	—	16.7	3	16.7	3

[a]On a scale from 0 to 100.

[b]Experts from respective panel did not rank feature.

[c]BCT: behavior change technique.

Extended Feedback and Tailoring Is Advised

Experts emphasized that a feedback option, as well as extended tailoring, needs to be integrated in a PA–related app. Several feedback options were suggested, such as motivational feedback (positive framing) and instructional feedback (health science expert panel A), as illustrated in the following quote:

> *You should be approached in a positive way, even if you haven't done anything that day.* [Health science expert panel B, expert in persuasive technology]

Coaching styles in a PA–related app matter as well and should be tailored to the individual athlete (health science expert panel B). Tailoring in general can be applied in several ways: at the moment a person starts using the app or continued tailoring during the whole process of using an app. This tailoring should be aligned with the current level of health, knowledge, functioning, personal goals, competitiveness, PA, and personal characteristics. One expert stated the following:

> *To me, it is important that the tailoring should fluctuate with one's life.* [Health science expert panel B, expert in behavior change]

Another element of tailoring is the flexibility of the app, in other words being able to adjust the app and adaptivity of the app. One expert stated the following:

> *For instance, if your running performance improves, the app should develop as well.* [Technology expert panel, expert in industrial design]

One step further would be that the app should anticipate on the user. For instance, by accounting for schedules and location. This feature was described as context awareness and was discussed in all panel sessions. One expert stated the following:

> *That you reckon with someone's context. That it can account for the fact that not all things go as planned.* [Health science expert panel B, expert in persuasive technology]

As an example, a recommender system was described. A recommender system is a machine learning, information-retrieval software tool that predicts what a user may or may not like or need [48]. It can provide suggestions based on these predictions.

Theoretical or Evidence Base Is the Standard

Two experts from health science expert panel A and health science expert panel B indicated that in general, a theoretical or evidence base was important for the effectiveness of PA–related apps. Some examples of BCT's were briefly mentioned, including self-regulation, goal setting, overview of results, tailoring, monitoring, context awareness, nudging, and self-learning. Other BCT's were discussed more in detail in the panels, such as fun, social component, monitoring, rewarding, feedback or coaching, tailoring, and information about healthy and safe sport participation. Besides BCT's, other potential theories were mentioned, such as technological- and medical-based theories or engagement theories for the development of apps, as illustrated in the following quote:

> *There are many other theories for building apps and you could take these into account as well. It is not only about behavior change. The app could be built based on a technical or medical view or engagement theories as well.* [Health science expert panel A, expert in health sciences]

One expert in behavior change highlighted that an evidence and a theoretical base are two different things. An app can be based on a theoretical model but can lack an evidence base. The transtheoretical model was used as an example. One expert stated the following:

> *For instance, the Transtheoretical model, which is a typical theoretical foundation. If you look at the empirical evidence, it is not that good.* [Health science expert panel A, expert in behavior change]

The same expert indicated that an expert rating of the PA–related app could also be interpreted as an evidence base.

Entry Requirements Related to App Use

These are minimum conditions that support the use of the app. Examples are looks and usability, image of the app, and other requirements such as privacy and costs of the app.

At first, form, language, design, tone, and interaction were described as important entry requirements for an effective app. Second, usability was found important. It was defined in several ways and was related to functioning and simplicity of the app. One expert stated the following:

> *Does the app do what you expect from it and do specific functions work properly. It shouldn't be too complex and searching for functions should not take too much time.* [Health science expert panel B, expert in injury prevention and monitoring]

Furthermore, according to an expert, usability of an app could be related to motivation to be active; the technical application and design of push notifications directed at motivating the app-user matter. He stated the following:

> *Usability, or ease of use, does it motivate you? Think about a push notification if you haven't done a task. This is a more functional application to motivate you. Not so much the knowledge and content is important, but also the technical application of a push message.* [Technology expert panel, expert in ICT service design]

Stability, reliability, and robustness of the app were related to usability as well, as illustrated in the following quote:

> *So actually it is about how much you trust the app.* [Technology expert panel, expert in ICT service design]

A third requirement was that the app should function properly, without bugs. Moreover, being able to connect the app to other tools (such as an online platform, activity tracker, or smartwatch) or being able to exchange data between platforms (ie, portability) contributes to the usability of the app.

Experts from the health science expert panel B noticed that the image of the app may contribute to the effectiveness of a

PA–related app. The image of the app depended on the reliability (credibility and properly functioning measurements and feedback), visibility, exposure, and popularity of the app. Exposure was described as brand awareness. One expert stated the following:

> *If there are a thousand apps in the app stores, you should be able to look at a screen shot and know "this is what I was looking for"...This has to do with exposure and marketing.* [Health science expert panel A, expert in behavior change]

Two other entry requirements were discussed: costs of the app and privacy. Some experts thought that people would be more willing to download an app if it is free. However, according to some of the experts, you could see it as an investment as well. When you invest money in an app, then you may be more motivated to continue using it and potentially stay active as well. Two experts thought the price-quality ratio was more important for the effectiveness of an app, than the price only, as illustrated in the following quote:

> *The price does not determine the quality! That is not how I experience it.* [Technology expert panel, expert in ICT service design]

Privacy was described as an upcoming topic. In other words, what do you have to say about your data, but additionally, what do app owners do with the collected data of users. The experts indicated that knowing how the privacy of your data is secured is an important entry requirement.

Discussion

Principal Findings

In this study, we conducted expert panels using the NGT to determine the perception of experts on which features are important for effectiveness of PA–related apps for participation in individual, recreational sports. A total of 25 features were ranked. Applied feedback and feedforward and fun were the most important features for experts in the field of industrial designers and information technologists. Instructional feedback, motivating feedback, motivating or challenging and monitor or statistics, and peer rating and use were the most important features for experts on behavioral, health, and human movement sciences. The features monitoring or statistics, motivating feedback, technically properly working, tailoring starting point, fun or pleasure, usability, flexibility, look and feel, anticipating or context awareness, and privacy were frequently ranked in the top 10 as well. In line with the expertise of the two expert panels, features for behavior change as well as technical and design features were collected.

A qualitative analysis of the reasons behind the expert's choices showed four overarching themes: (1) combination behavior change, technical, and design features needed, (2) extended feedback and tailoring is advised, (3) theoretical or evidence base is the standard, and (4) entry requirements related to app use.

Comparison With Prior Work

The experts found a theoretical framework important; they ranked several features that were previously defined as BCT's in the taxonomy of Abraham and Michie [29]. Some of the ranked features were included in the MARS as well, such as engagement, usability, customization, and aesthetics [35]. However, based on the results of this study, more advanced features seem necessary to support sport participation. For instance, tailoring was an important feature with several subdomains, such as tailoring on start level, continued tailoring, adaptivity, and flexibility of the app. In contrast, the MARS only includes one question about customization [35]. A recent review suggested that a tailored approach in PA–related apps may increase their efficacy [49], which is in line with the present results. Furthermore, Op den Akker et al (2014) proposed a framework for tailoring of real-time PA coach systems [50]. The key concepts of this framework were feedback, interhuman interaction, adaptation, user targeting, goal setting, context awareness, and self-learning, which corresponds partly to our findings. Most of these concepts, such as feedback, adaptation, goal setting, context awareness, and self-learning were mentioned by the experts. In summary, the features the experts in this study described as important were in line with previous studies; however, subcategories of these features were ranked that were not perceived as evenly important. Potentially, a more detailed analysis of app subfeatures is necessary to determine the quality of PA–related apps for individual, recreational sport participants.

One expert highlighted that it is important to pay attention to the health aspects and safe sport participation. This was supported by the other experts (although not ranked in top 10). This matches with one of the BCT's (provide information about behavior-health link) as defined by Abraham and Michie [29]. The MARS offers an option to rate the potential impact of the app on the user's knowledge, attitudes, and intentions related to the healthy behavior [35]. However, according to the experts, these features seem essential and therefore, need to be included in the assessment of the quality of apps.

The experts rated and prioritized several types of features, including design, technical, and behavior change features. Interestingly, they also emphasized that domain specific knowledge should be integrated into PA–related apps. Technical features such as stability, portability, and connectivity were not included in the MARS [35]. In the MARS, some technical elements can be scored as yes or no in a checkbox. This does not indicate the degree in which this feature is integrated or designed. In line with our results, a previous study proposed that technical modalities in apps need to be considered in a taxonomy for mHealth apps [38]. Examples are the device type (which device is needed), interface (user-friendly interface), operating system type (eg, Android or iPhone operating system, iOS, Apple Inc), and features (audio, video, email). In summary, current app ranking tools often focus mostly on one domain [29,36]. For instance, the MARS focuses mostly on behavior change [35], whereas the taxonomy of Olla and Shimskey focuses mostly on technical features [38]. We suggest that a multidisciplinary approach is suitable when examining the quality of PA–related apps. Behavior change, design, and

technical features need to be assessed in a PA–related app rating scale.

The results of this study indicate that experts find some features from the top 10 more important than others. For instance, instructional feedback was ranked most important and privacy as least important in the health science expert panel. This may suggest that an app rating scale should apply a weighing of the items. Additionally, the qualitative analysis also showed that there are some entry requirements for the effectiveness of a PA–related app. Without these features, the app probably will not be used. Therefore, we suggest that an app rating scale should contain a specific subsection in which entry requirements should be scored.

Interestingly, the experts indicated that more advanced features are needed to support sport participation. However, we need to keep in mind that the PA–related apps available in the app stores often lack a theoretical or evidence base and do not include advanced features. For instance, to the best knowledge of the authors, current PA–related apps do not take into account more advanced forms of tailoring, such as context awareness or tailoring on starting level and continued tailoring as suggested in this study. This highlights a gap between desired features in an optimal PA–related app and the features that are included in PA–related apps at this moment.

Strengths and Limitations

A strength of our study was that we included experts from different expertise in the panels. Our study is subject to some limitations as well. First, several potential experts (2x12) were selected and invited for the sessions; however, many of them were not able to attend the session because of practical matters. Therefore, the number of experts was low. This may have decreased the generalizability of the results. Next, a convenience sample of experts were selected, as the experts needed to be able to travel to one of the two locations. This selection method could have resulted in selection bias, which could imply that we may have missed some important perspectives. Still, we were able to select experts with relevant experience and knowledge of development and evaluation of PA–related apps. Therefore, we think that these 11 participants provide a quite good representation.

We selected experts based on their scientific and professional expertise and therefore, think the experts had knowledge about current literature on PA–related apps. However, it is still possible that the experts believe that certain features are important for effectiveness of PA–related apps that in fact objective evidence may show are not effective. In the development of an improved PA–related rating scale, it is therefore recommended to combine the results of this study on expert opinions about important features with a literature review.

Conclusions

Taken together, the results show that experts from different fields of expertise think that a variety of features, including design, technical, and behavior change, are considered as important for the effectiveness of PA–related apps for sport participation. These results may assist in the development of an improved app rating scale for these apps that can indicate the quality. In other words, which PA–related apps could motivate (beginning) individual recreational sport practitioners during sport participation and support or help them with a healthy active lifestyle. On the basis of the results of this study, we recommend for the development of an improved PA–related app rating scale:

- To rate as well behavior change features as design and technical features
- Include assessment of theoretical or evidence base of the app
- A more detailed analysis of app subfeatures, for instance tailoring on start level, continued tailoring, adaptivity, and flexibility of the app
- Rate if the app informs about healthy and safe sports participation
- Rate entry requirements such as usability, bugs in the app, and image

The results of this paper are relevant for PA–related app designers as well. On the basis of this study, our advice is to work together with experts from different domains in the development of PA–related apps, take into account factors related to app use and app engagement (entry requirements), and make sure the app has a theoretical or evidence base. Furthermore, this paper indicates which features may be important to include in a PA–related app.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Expert panel form A.
[PDF File (Adobe PDF File), 46 KB - mhealth_v6i6e143_app1.pdf]

Multimedia Appendix 2

Expert panel form B.
[PDF File (Adobe PDF File), 53 KB - mhealth_v6i6e143_app2.pdf]

Multimedia Appendix 3
Expert panel form C.
[PDF File (Adobe PDF File), 53 KB - mhealth_v6i6e143_app3.pdf]

Multimedia Appendix 4
Extended version of the qualitative analysis.
[PDF File (Adobe PDF File), 49 KB - mhealth_v6i6e143_app4.pdf]

Multimedia Appendix 5
Coding scheme.
[PDF File (Adobe PDF File), 31 KB - mhealth_v6i6e143_app5.pdf]

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Abbreviations

ACSM: American College of Sports Medicine
BCT: behavior change technique
ICT: information and communication technology
MARS: Mobile App Rating Scale
mHealth: mobile health
NGT: nominal group technique
PA: physical activity

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Original Paper

Characterizing Geosocial-Networking App Use Among Young Black Men Who Have Sex With Men: A Multi-City Cross-Sectional Survey in the Southern United States

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Abstract

Background: Understanding where and how young black men who have sex with men (YBMSM) in the southern United States meet their sexual partners is germane to understanding the underlying factors contributing to the ongoing HIV transmission in this community. Men who have sex with men (MSM) commonly use geosocial networking apps to meet sexual partners. However, there is a lack of literature exploring geosocial networking app use in this particular population.

Objective: Our aim was to examine the characteristics, preferences, and behaviors of a geographically diverse sample of geosocial networking app-using YBMSM in the southern United States.

Methods: Data were collected from a sample of 75 YBMSM across three cities (Gulfport, Mississippi; Jackson, Mississippi; and New Orleans, Louisiana). Multiple aspects of geosocial networking app use were assessed, including overall app use, age of participant at first app use, specific apps used, reasons for app use, photos presented on apps, logon times and duration, number of messages sent and received, and characteristics of and behaviors with partners met on apps. Survey measures of app-met partner and sexual behavior characteristics assessed at midpoint (Day 7) and completion visits (Day 14) were compared using McNemar's test or Wilcoxon signed-rank test. In addition, we assessed activity spaces derived from GPS devices that participants wore for 2 weeks.

Results: Of the 70 participants who responded to the overall app-use item, almost three-quarters (53/70, 76%) had ever used geosocial networking apps. Jack'd was the most commonly used geosocial networking app (37/53, 70%), followed by Adam4Adam (22/53, 42%), and Grindr (19/53, 36%). The mean and median number of apps used were 4.3 (SD 2.7) and 4.0 (range 0-13), respectively. Most app-using participants displayed their face on the profile picture (35/52, 67%), whereas fewer displayed their bare legs (2/52, 4%) or bare buttocks (or ass; 2/52, 4%). The mean age at the initiation of app use was 20.1 years (SD 2.78) ranging from 13-26 years. Two-thirds (35/53, 66%) of the sample reported using the apps to "kill time" when bored. A minority (9/53, 17%) reported using the apps to meet people to have sex/hook up with. The vast majority of participants reported meeting black partners for sex. Over two-thirds (36/53, 68%) reported that the HIV status of their app-met partners was negative, and 26% (14/53) reported that they did not know their partner's HIV status. There was a significant difference in GPS activity spaces between app using YBMSM compared to nonapp using YBMSM (2719.54 km^2 vs 1855.68 km^2, P=.011).

Conclusions: Use of geosocial networking apps to meet sexual partners among our sample of YBMSM in the southern United States was common, with a diverse range of app use behaviors being reported. Further research should characterize the association between geosocial networking app use and engagement in sexual behaviors that increase risk for HIV acquisition and transmission. In addition, geosocial networking apps present a promising platform for HIV prevention interventions targeting YBMSM who use these apps.

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KEYWORDS

HIV prevention; black MSM; dating apps; homosexuality; male; men who have sex with men; mobile apps; mobile phones

Introduction

While overall HIV incidence in the United States has declined over the past several years [1], this progress has not been shared equally among all demographic subgroups or geographic regions. Black men who have sex with men (BMSM) continue to account for the greatest proportion of new HIV diagnoses of any demographic group, despite reporting higher engagement in prevention behaviors such as condom use and fewer sexual partners compared to other groups of men who have sex with men (MSM) [2,3]. Estimated lifetime risk for HIV infection for BMSM is 50% [4], and despite a potentially large benefit from pre-exposure prophylaxis (PrEP) use [5], the awareness, access, and use of PrEP are low among BMSM [6-8]. Young BMSM (YBMSM) in the "Deep South," the geographic region in the southern United States comprising Georgia, Alabama, Arkansas, South Carolina, Mississippi, and Louisiana, are an especially high-priority community for HIV prevention efforts. Of all new HIV diagnoses among BMSM in 2016, 75% occurred among those aged 13-29 years [3], and more than half occurred in the Deep South [3].

Millions of MSM worldwide use geosocial networking (GSN) apps to meet romantic and sexual partners [9-11], and approximately 33% of MSM have used GSN apps in their lifetime [11]. Up to 85% of app-using MSM engage with apps daily [12]. Given the increasing integration of mobile phone use into daily living activities, current trends in GSN app use by MSM will likely continue, if not increase, in coming years. The importance of mobile phones in daily life warrants further investigation of GSN app use, beliefs, and behaviors in priority populations such as YBMSM in the Deep South, the epicenter of the HIV epidemic in the United States.

The available evidence affirms that app-using BMSM constitute a high-priority population for HIV prevention. Therefore, understanding where and how YBMSM in the Deep South meet their sexual partners is germane to understanding the underlying factors contributing to their HIV risk. The role of GSN apps in the life of YBMSM in the Deep South is especially important to study because unlike in urban areas, there are few (if any) venues available for socializing or developing relationships, so GSN apps could play a more significant role in these processes. The Deep South is also different from regions where research has typically been conducted because of its long-standing history and continued instances of oppression, racism, and homophobia (eg, legislation that will allow for businesses to not serve or provide services to lesbian, gay, and bisexual individuals based on their religious beliefs).

The literature shows mixed evidence for the association between GSN app use and sexual risk among MSM. Some studies have found that app-using MSM commonly engage in sexual behaviors associated with an elevated risk of HIV infection [13-15] compared to MSM who did not use apps. Such behaviors include having multiple sexual partners, engaging in condomless anal intercourse (CAI), engaging in group sex, and using alcohol and drugs during sex [11,14-22]. App-using MSM have also been shown to have a higher prevalence of sexually transmitted infection diagnosis, which is associated with an elevated risk of HIV seroconversion [11,14,23]. However, other studies show similar rates of sexual risk behaviors between MSM who use GSN apps and those who do not [17,24]. Interestingly, a study of BMSM in 6 cities found that HIV-uninfected participants were more likely to engage in serodiscordant / serostatus-unknown CAI with partners met offline at sex-focused venues than with partners met online [25]. A recent meta-analysis of app-using MSM found that 46% of MSM had CAI with all partners within the previous 3 months, yet as many as 70% of those engaging in CAI had a low self-perceived risk of HIV [11]. Despite these mixed findings, GSN apps constitute a potential platform for dissemination of HIV prevention-related information or interventions [26], such as reminders for HIV testing or delivery of home HIV test kits [27,28], identifying locations for HIV testing and treatment centers [12,18,29], and recruitment for inclusion in studies of novel HIV prevention and treatment methods [16,30].

Maximizing the potential efficacy of interventions will necessitate a rich understanding of the personal characteristics, preferences, and behaviors of app-using MSM subgroups, such that interventions will be socioculturally informed and acceptable to the populations they are designed to benefit. There is a lack of literature available on app-using YBMSM in most app-based studies. Even in studies based in the Deep South, study populations are multiracial or have samples of predominantly white MSM, thereby limiting their generalizability to BMSM. A study by Goedel and Duncan of GSN app use among 92 MSM in Atlanta, Georgia, for instance, included only 19% black participants [9]. A study of 110 MSM in Washington, DC, by Lehmiller et al included only 14% nonwhite participants [14]. Given the lack of literature specifically exploring GSN app use in this population, we conducted a survey of the characteristics, preferences, and behaviors of a geographically diverse sample of GSN app-using black MSM in the Deep South. We evaluated a range of GSN apps, including Grindr, Jack'd, and Hornet. Because YBMSM may also use more mainstream social medial platforms such as

Instagram to find sex partners, we included these platforms in our analysis as well.

Methods

Study Design

This study was primarily designed to understand the feasibility of collecting global positioning system (GPS) data over 2 weeks from BMSM in four cities in the Deep South: Gulfport, Mississippi; Hattiesburg, Mississippi; Jackson, Mississippi; and New Orleans, Louisiana. These locations were selected because they are locations where we had community partners. Of note, Jackson leads the nation with the number of MSM living with HIV (4 in 10) [31], and surveillance data suggest that 3 in 4 of these men are black [32]. Both Jackson and New Orleans are in the top 5 cities in the nation for the number/rate of new infections [3]. Although reported anecdotally, there are major thoroughfares that connect all four of these cities (eg, Interstate 10 and US Highway 29), and unpublished data from the Louisiana and Mississippi state health departments document that MSM seek HIV testing/care services in neighboring jurisdictions.

Data were collected from March 2016 to August 2016. One study site (Hattiesburg) was removed from analyses due to protocol violations. Potential participants were considered eligible if they self-reported (1) African American or black race, (2) assigned male sex at birth, (3) being 18 years or older, (4) residence in one of the four study cities, and (5) oral or anal sex with another man within the 6 months prior to study enrollment. Participant recruitment was conducted via community-based sampling methods (eg, word-of-mouth, posted flyers). Enrollment was coordinated and facilitated by community-based organizations and AIDS-service organizations, specifically My Brother's Keeper (Mississippi) and CrescentCare/The Movement Office and Priority Health Care (Louisiana).

Participants' study involvement included an enrollment (baseline) visit and two follow-up visits (midpoint and completion) at the offices of the partnering community-based and AIDS-service organizations. The midpoint visit occurred approximately 7 days after the enrollment visit (usually on Day 7), and the completion visit occurred approximately 7 days after the midstudy survey visit (usually on Day 14). At the enrollment visit, participants were given a US $25 VISA gift card, a US $50 Shell gas card, and a bag of condoms and water-based lubricants as remuneration for their participation. At the midpoint visit, participants were given a US $75 VISA gift card and a bag of condoms and water-based lubricants. At the end of the completion visit, participants received a US $100 VISA gift card and a bag of condoms and water-based lubricants. While GPS tracking was conducted throughout the 2-week GPS protocol, a few participants came in for their visit after 14 days for various logistical reasons. All participants provided written informed consent prior to enrollment, and all protocols were approved by the Sterling Institutional Review Board. The secondary analyses reported here were determined to be exempt by the New York University School of Medicine Institutional Review Board.

Global Positioning System Data Processing

Prior to distribution, we programmed the GPS device to log in in 30-second intervals. Consistent with our past GPS protocols [33], during the study orientation and baseline assessment, participants were instructed to place the small QStarz's BT-Q1000XT GPS device on their belt (using the manufacturer-provided case), in their pocket, or to connect the GPS device in the provided case to an item on their person (such as to a key chain or backpack strap), and to complete a travel diary. Participants were asked to wear the GPS units at all times, except for sleeping, swimming, or showering. The travel diary asked the participant questions related to GPS protocol compliance: "Did you charge the GPS monitor today?" and "Did you carry the GPS monitor with you today?" This was meant to help the participant remember to charge the unit and carry it with him. The GPS device was given to participants in a large plastic zipper storage bag, which also contained a mini-USB charging cord for the GPS device, a USB wall adapter for charging, a manufacturer-provided GPS belt holder (if requested), a pamphlet containing background information on GPS, and the travel diary. GPS participant data were downloaded using the Qstarz proprietary software and stored as .gpx files. The GPS data were then cleaned using several scripts written in the Python programming language and ArcGIS models to eliminate duplicate data, GPS points likely caused by multipath reflectance, GPS data likely caused by timing errors, and isolated GPS data (Python Software Foundation, Python Language Reference, version 2.7) and ArcGIS version 10.2 (ESRI).

Study Variables

Geosocial Networking App Use

Overall App Use

At the enrollment visit, we asked participants, "Have you EVER used a sexual networking mobile application or 'app' such as Grindr or Jack'd?" At the midpoint and completion visits, we asked, "In the past 7 days, have you used a mobile application or 'app' such as Grindr or Jack'd?" Response options were "Yes" and "No."

Age of First App Use

At the enrollment visit, we asked participants, "How old were you when you started using sexual networking 'apps' such as Grindr, or Jack'd?" An open-ended response format was provided to the participant.

Specific Apps Used

At the enrollment visit, we asked, "Which of the following 'apps' do you have an account or profile?" We provided a list of apps, including Adam4Adam, BGC Live, Grindr, Hornet, Jack'd, and Scruff.

Reasons for App Use

At all three visits, we asked, "Which of the following describes your reason(s) for using these apps?" Response options included "I want to make new friends," "I want to meet people to have sex/hook up with," "I want to find someone to date," "Bored;

I want to kill time," "I want to connect to the gay community," and "I want to find people to drink/use drugs with."

Self-Presentation on App Profiles

At the enrollment visit, we asked, "Which of the following describes the photo(s) on your profile?" Response options included "My profile picture shows my face," "My profile picture shows my bare chest or abs," "My profile picture shows my bare arms or biceps," "My profile picture shows my bare back or shoulders," "My profile picture shows my bare legs," "My profile picture shows my bare buttocks (or ass)," "My profile picture shows my bare penis," and "My profile picture does not show any part of my body." Participants could select all that applied.

Logon Times and Duration

At the enrollment visit, we asked, "In the past 30 days, on average, how many times each day did you open or login to mobile 'apps' such as Grindr or Jack'd?" At the midpoint and completion visits, we asked, "In the past 7 days, on average, how many times each day did you open or login to a mobile 'app' such as Grindr or Jack'd?" An open-ended response format was provided for this item. At the enrollment visit, we also asked, "In the past 30 days, on average, how many hours and/or minutes did you spend each day on mobile 'apps' such as Grindr or Jack'd chatting or viewing photos or profiles?" At the midpoint and completion visits, we asked, "In the past 7 days, on average, how many hours and/or minutes did you spend each day on mobile 'apps' such as Grindr or Jack'd chatting or viewing photos or profiles?" An open-ended response format was provided for this item. Duration of app use reported in minutes was converted into hours for the analysis.

Messaging Behaviors

At the enrollment visit, we asked, "In the past 30 days, on average, how many messages did you *send* each day on mobile 'apps' such as Grindr or Jack'd?" At the midpoint and completion visits, we asked, "In the past 7 days, on average, how many messages did you *send* each day on these 'apps' such as Grindr or Jack'd?" An open-ended response format was provided to the participant. In addition, at the enrollment visit, we also asked, "In the past 30 days, on average, how many messages containing nude or suggestive photos did you *receive* each day on these 'apps' such as Grindr or Jack'd?" At the midpoint and completion visits, we asked, "In the past 7 days, on average, how many messages containing nude or suggestive photos did you *receive* each day on these 'apps' such as Grindr or Jack'd?" An open-ended response format was provided to the participant.

Sex Behaviors With App-Met Partners

At the enrollment visit, we asked, "In the past 30 days, how many men did you begin talking to on these mobile 'apps,' meet in person, and engage in anal sex as a TOP (where you put your penis in his anus/rectum)?" At the midpoint and completion visits, we asked, "In the past 7 days, how many men did you begin talking to on these apps, meet in person, and engage in anal sex as a TOP (where you put your penis in his anus/rectum)?" An open-ended response format was provided to the participant. Those who responded more than 0 to these questions, were asked, "Was a condom used each time from start to finish (ejaculation)?" at the enrollment, midpoint, and completion visits. Response options were "Yes" and "No."

Additionally, at the enrollment visit, we asked, "In the past 30 days, how many men did you begin talking to on these mobile 'apps,' meet in person, and engage in anal sex as a BOTTOM (where he put his penis in your anus/rectum)?" At the midpoint and completion visits, we asked, "In the past 7 days, how many men did you begin talking to on these mobile 'apps,' meet in person, and engage in anal sex as a BOTTOM (where he put his penis in your anus/rectum)?" An open-ended response format was provided to the participant. Those who responded more than 0 to these questions were asked, "Was a condom used each time from start to finish (ejaculation)?" at the enrollment, midpoint, and completion visits. Response options were "Yes" and "No."

Characteristics of Partners on Apps

We assessed multiple characteristics of the sexual partners met on these apps, including partner age and partner race/ethnicity. To examine partner age, at the enrollment visit, we asked, "In general, are the majority of your sexual partners met on these apps?" At midpoint and completion visits, we asked, "In general, in the past 7 days, were the majority of the men met on these apps?" Response options included "A lot older (>5 years)," "Slightly older (2-4 years)," "Approximately the same age," and "Younger (≤3 years)," and "Unsure/Don't know." "Did not have anal sex with any men met on 'apps' such as Grindr or Jack'd" was a response option at the midpoint and completion visits.

To assess race/ethnicity, at the enrollment midpoint and completion visits, we asked, "Are the majority of your sexual partners met on these apps Latino or Hispanic?" Response options included "Yes," "No," and "Unsure/Don't Know." In addition, at the enrollment, midpoint, and completion visits, we asked, "Are the majority of your sexual partners met on these apps?" Response options included "White," "Black or African American," "Asian Indian or Alaska Native," "Asian"; "Native Hawaiian or Pacific Islander," and "Unsure/Don't Know." To assess partner HIV status, at the enrollment, midpoint, and completion visits, participants were asked, "Are the majority of your sexual partners met on these apps?" Response options included "HIV Positive," "HIV Negative," and "I did not ask."

Global Positioning System Activity Space Size Calculation

Using data from the 2-week period, GPS activity space buffers were created using ArcGIS version 10.3 (ESRI). There are various ways to define and conceptualize an activity space as well as various distance thresholds for these measurements [34]. In this study, we used a daily path area (a buffering zone drawn around the GPS tracks), which is a common method in behavioral geography research to understand where participants spend the majority of their time and exposure to environments [34]. We buffered all the processed and cleaned GPS points at four distances (400 m, 800 m, 1600 m, and 8000 m) and dissolved these buffers into a single feature to create an activity

space for each participant at the various buffer distances. The activity space size was expressed in square kilometers.

Sociodemographic Variables

Sociodemographic data collected at the enrollment visit were analyzed. Age was categorized as 19-22, 23-25, and 26-29 years. Ethnicity included Latino/Hispanic or non-Latino/Hispanic. Sexual orientation included gay/homosexual, bisexual, straight/heterosexual, questioning, or "I do not identify with any of these." Sexual attraction included attracted to males only, most attracted to males, equally attracted to males and females, attracted to females only, mostly attracted to females, or not sure. Sexual partners in past 6 months included men, women, transgender women, or transgender men. Education levels included less than a 12th grade education, high school diploma or general educational development (GED), community college, trade school or vocational school, bachelor's degree, or graduate degree or professional degree. Current student status was categorized as full-time or part-time. Employment status groups were defined as "working full-time," "working part-time or occasionally," "unemployed," and "unable to work (disabled)." Annual household income was coded as <US $12,000; $12,000-$19,999; and $20,000+ categories. Current living situation included alone/by myself, roommate(s) or friend(s), parent(s) or other family member(s), partner or significant other (with or without children), and "I do not have a stable living situation/other." Relationship status was coded as yes or no. Number of places lived in past 2 years was categorized 1, 2, and 3 or more. Vehicle ownership was coded as yes, no, or unknown. Study site included Jackson (Mississippi), Gulfport (Mississippi), or New Orleans (Louisiana). Participants reported their HIV status as negative, positive, or unknown.

Results

Statistical Analysis

Of the 75 participants who enrolled in the study (25 per site), 3 did not complete the study. One participant was arrested during the 2-week GPS protocol and spent time in jail; one participant was in a car accident and although the accident was not fatal, the participant withdrew from the study; and one participant withdrew from the study because of his demanding work schedule. At the midpoint visit, 3 participants (4%) did not complete the survey, yielding 72 who completed the survey. At the completion visit, 4 participants (5%) did not complete the survey, yielding 71 who completed the survey. For Table 1, data from 70 participants, which included both app users (n=53) and nonusers (n=17), was included in the analysis. We excluded 3 participants who did not respond to the question regarding the use of GSN apps. First, chi-square or Fisher's exact test was used to compare the sociodemographic characteristics of individuals who reported using such apps with those of individuals who did not. Using GPS data, we calculated means and standard errors (SE) of the activity spaces (ie, 400 m, 800 m, 1600 m, and 8000 m buffer sizes). For the largest buffer size (8000 m) of the total activity spaces, we categorized data into quartiles based on the distribution of values. Student's *t* tests were used to estimate for differences in mean activity spaces by GSN app user status. Table 2 reports the frequency with which each type of GSN app was used, the number of apps used, and the types of profile pictures among those who reported ever using GSN apps at the enrollment visit (53/70, 75.7%). In Table 3, we show the characteristics of app use (ie, age at first use of apps, reasons for using apps, and login times and durations), app-met sexual partners (ie, relative partner's age, race/ethnicity, and HIV status), and app-related sexual behaviors (ie, engagement in anal sex and condom use) based on data obtained at baseline, the midpoint, and study completion. Those who reported ever using GSN apps at the enrollment visit (53/70, 75.7%) and those who reported using GSN apps in the past 7 days at midpoint visit (27/70, 38.5%) and completion visit (19/70, 27.1%) were included for the analyses. Descriptive statistics are presented as mean (standard deviation [SD]), range, and interquartile range (IQR) for continuous variables and sample size (n) with percentage for categorical variables. To compare between data obtained at midpoint and on completion, we combined these data. Five participants who reported *not* using GSN apps in the past 7 days at the midpoint visit reported using apps at the completion visit. Thus, a total of 32 participants were included in the analyses. McNemar's test or the Wilcoxon signed-rank test was used as appropriate. Statistical significance was determined by $P<.05$. All statistical analyses were conducted with Stata version 14.0 (Stata Corp).

Sample Sociodemographic Characteristics

The sociodemographic characteristics of the sample of YBMSM are presented in Table 1. Of the 70 participants, 76% (53/70) of the sample reported ever having used GSN apps and the mean age of this group was 24.7 years (SD 2.6). All participants self-identified their race as black, and approximately 8% of YBMSM using GSN apps reported Latino/Hispanic ethnicity. Approximately two-thirds of participants identified as homosexual: 68% (36/53) of app users and 65% (11/17) of nonusers. The majority of app users reported attraction to males: 91% (48/53) of app users versus 71% (12/17) of nonusers, $P=.043$. Among app users, 30% (16/53) reported being attracted to men only while 60% (32/53) reported being mostly attracted to men. Overall, there were no significant sociodemographic differences between app users and nonusers, except for sexual attraction. Additionally, 100% of the 53 app users reported that their sexual partners in the past 6 months were men. Approximately 6% (3/53) of app users had a high school education or less, and 45% (24/53) were enrolled in school. For 71% (37/53) of app users, the annual individual-level income was less than US $20,000. Just over 80% (43/53) of app users reported owning a vehicle, 38% (20/53) reported being in a committed relationship, and 28% (15/53) were HIV-positive.

Spatial Mobility Among Sample

The activity space size of app users was usually larger than nonusers. Among app users, the overall average activity space (8000 m buffer) was 4057.19 km (SE 772.82). Among nonusers, the overall average activity space was 2281.02 km (SE 1149.61). For Quartile 3 (for the 8000 m buffer), there was a significant difference in GPS activity spaces between app using YBMSM compared to nonapp using YBMSM (2719.54 km^2 vs 1855.68 km^2, $P=.011$).

Table 1. Sample sociodemographics (N=70).

Demographic and socioeconomic variables	App users (n=53)	Nonusers (n=17)	*P* value[a]
Age, years, n (%)			
19-22	14 (26.4)	8 (47.1)	.182
23-25	18 (34.0)	6 (35.3)	
26-29	21 (39.6)	3 (17.7)	
Latino/Hispanic ethnicity, n (%)	4 (7.6)	0 (0.0)	.566
Sexual orientation, n (%)			
Gay or homosexual	36 (67.9)	11 (64.7)	.117
Bisexual	12 (22.6)	2 (11.8)	
Straight or heterosexual	0 (0.0)	2 (11.8)	
Questioning	1 (1.9)	1 (5.9)	
Do not identify with any of these	4 (7.6)	1 (5.9)	
Sexual attraction, n (%)			
Attracted to males only	16 (30.2)	4 (23.5)	.043[b]
Mostly attracted to males	32 (60.4)	8 (47.1)	
Equally attracted to males and females	4 (7.6)	2 (11.8)	
Attracted to females only	0 (0.0)	3 (17.7)	
Not sure	1 (1.9)	0 (0.0)	
Sexual partners in past 6 months (missing=1), n (%)			
Men	53 (100.0)	13 (81.3)	N/A[c]
Women	3 (5.7)	4 (25.0)	
Transgender women	0 (0.0)	0 (0.0)	
Transgender men	1 (1.9)	0 (0.0)	
Education, n (%)			
High school diploma or less	3 (5.7)	1 (5.9)	.851
High school diploma or GED[d]	20 (37.7)	7 (41.2)	
Community college/trade school/ vocational school	19 (35.9)	7 (41.2)	
Bachelor’s degree	9 (17.0)	1 (5.9)	
Graduate degree	2 (3.8)	1 (5.9)	
Currently enrolled in school, n (%)			
Yes	24 (45.3)	5 (29.4)	.248
No	29 (54.7)	12 (70.6)	
Full-time student status (n=29), n (%)			
Full-time	16 (66.7)	2 (40.0)	.339
Part-time	8 (33.3)	3 (60.0)	
Annual household income (missing=1), US$, n (%)			
<$12,000	18 (34.6)	11 (64.7)	.128
$12,000-$19,999	19 (36.5)	3 (17.7)	
$20,000+	15 (28.9)	3 (17.7)	
Current employment status, n (%)			
Full-time	24 (45.3)	9 (52.9)	.115
Part-time or working occasionally	19 (35.9)	2 (11.8)	

Demographic and socioeconomic variables	App users (n=53)	Nonusers (n=17)	*P* value[a]
Unemployed	10 (18.9)	6 (35.3)	
Current living situation, n (%)			
Alone/by myself	12 (22.6)	7 (41.2)	.066
Roommate(s)/friend(s)	20 (37.7)	3 (17.7)	
Parent(s)/other family members	17 (32.1)	3 (17.7)	
Partner/significant other	3 (5.7)	4 (23.5)	
Other/unknown	1 (1.9)	0 (0.0)	
Committed relationship, n (%)			
Yes	20 (37.7)	9 (52.9)	.268
No	33 (62.3)	8 (47.1)	
Number of places lived in past 2 years, n (%)			
1	21 (39.6)	6 (35.3)	.761
2	24 (45.3)	7 (41.2)	
≥3	8 (15.1)	4 (23.5)	
Vehicle ownership, n (%)			
Yes	43 (81.1)	13 (76.5)	.732
No	10 (18.9)	4 (23.5)	
Study site, n (%)			
Jackson, MS	16 (30.2)	9 (52.9)	.235
Gulfport, MS	18 (34.0)	4 (23.5)	
New Orleans, LA	19 (35.9)	4 (23.5)	
HIV status (missing=1), n (%)			
HIV-infected	15 (28.9)	3 (17.7)	.638
HIV-uninfected	35 (67.3)	14 (82.4)	
Unknown/Do not know	2 (3.9)	0 (0.0)	
GPS activity space (missing=5), mean (SE)			
400 m	233.34 (35.23)	143.19 (53.01)	.195
800 m	462.59 (78.19)	271.67 (116.97)	.215
1600 m	893.67 (160.77)	509.19 (240.07)	.224
8000 m	4057.19 (772.82)	2281.02 (1149.61)	.243
Quartile of GPS activity space (8000 m), mean (SE)			
Quartile 1	606.77 (57.13)	650.86 (58.81)	.657
Quartile 2	1016.69 (40.81)	1065.62 (72.93)	.554
Quartile 3	2719.54 (157.83)	1855.68 (109.70)	.011[b]
Quartile 4	9252.10 (1742.20)	19426.56 (—)	—

[a]Chi-square test, Fisher's exact test or two-sample *t* test was conducted as appropriate.

[b]Statistically significant.

[c]N/A: not applicable. Multiple response (categories are not mutually exclusive).

[d]GED: General Education Diploma.

Table 2. Geosocial networking app use[a] among MSM (N=53[b]).

Geosocial app use[c]	n (%)
Adam4Adam	22 (41.5)
BCG Live	15 (28.3)
Bender	0 (0.0)
Boy Ahoy	3 (5.7)
Distinc.tt	0 (0.0)
DowneLink	2 (3.8)
Grindr	19 (35.9)
GROWLr	3 (5.7)
Guy Spy	0 (0.0)
Hornet	3 (5.7)
Hunters BBS	0 (0.0)
Jack'd	37 (69.8)
Maleforce	0 (0.0)
Planet Romeo	3 (5.7)
Scruff	2 (3.8)
Skout	2 (3.8)
Tinder	3 (5.7)
U2nite	0 (0.0)
U4Bear	1 (1.9)
VGL	0 (0.0)
Other	7 (13.2)
Instagram	39 (73.6)
Kik	27 (50.9)
SnapChat	39 (73.6)

[a]Assessed in the enrollment visit.

[b]Those who reported ever using GSN apps at the enrollment visit.

[c]Multiple response (categories are not mutually exclusive).

Geosocial Networking App Use

Table 2 shows GSN app use among respondents who reported having ever used GSN apps at the enrollment visit. Jack'd was a popular GSN app (37/53, 69.8%), followed by Adam4Adam (22/53, 41.5%), and Grindr (19/53, 35.9%). Nearly three-quarters of the sample reported using Instagram and Snapchat apps. The number of GSN apps used varied among the sample, with values ranging from 0-13. The mean and median number of apps used were 4.3 (SD 2.66) and 4.0 (range 0-13), respectively. Most of the sample (47/53, 88.7%) reported using 2 or more apps. In terms of the body content appearing on the profile pictures, most participants displayed their face (35/52, 67.3%) followed by their bare chest or abs (10/52, 19.2%), and bare penis (4/52, 7.7%), whereas fewer displayed their bare legs (2/52, 3.9%) or bare buttocks (or ass; 2/52, 3.9%).

Table 3 shows app use across the three study time points. The mean age at initiation of app(s) use was 20.1 years (SD 2.8), with values ranging from 13-26 years. Among 53 participants at baseline, an average of 8.2 (SD 16.8) apps were logged onto or opened each day during the past 30 days, and an average of 2.1 (SD 3.1) hours was spent each day in the past 30 days chatting or viewing photos/profiles on the apps. Two-thirds of the sample reported using the apps to "kill time," just over half reported using the apps to make new friends, and approximately a third reported using the apps to connect to the gay community or to find someone to date. Only 9 participants reported using the apps to meet people to have sex/hook up with.

Table 3. Messaging behaviors across three time periods among app-using men who have sex with men.

Messaging behaviors	Baseline (n=53)	Midpoint (n=27)	Completion (n=19)	*P* value[a]
Age when started using app, mean (SD), range, interquartile range (IQR)	20.06 (2.78), 13-26, 18-22	N/A	N/A	—
Reason for using these apps[b], n (%)				
I want to make new friends	29 (54.7)	18 (66.7)	12 (63.2)	—[c]
I want to meet people to have sex/hook up with	9 (17.0)	4 (14.8)	4 (21.1)	.564
I want to find someone to date	16 (30.2)	7 (25.9)	5 (26.3)	.564
Bored; I want to kill time	35 (66.0)	25 (92.6)	12 (63.2)	.317
I want to connect to the gay community	17 (32.1)	9 (33.3)	8 (42.1)	.999
I want to find people to drink/use drugs with	0 (0.0)	0 (0.0)	0 (0.0)	—[c]
Number of times (on average) opened or logged on to apps each day in past 30 days, mean (SD), range, IQR	8.21 (16.79), 0-100, 0-9	N/A	N/A	—
Number of times (on average) you opened or logged on to apps in past 7 days, mean (SD), range, IQR	N/A	9.26 (18.73), 1-100, 3-9	6.16 (7.03), 0-30, 2-10	.184
Hours (on average) spent each day on apps chatting or viewing photos or profiles in past 30 days, mean (SD), range, IQR	2.06 (3.07), 0-12.50, 0.08-2.50	N/A	N/A	—
Hours (on average) spent each day on apps chatting or viewing photos or profiles in past 7 days, mean (SD), range, IQR	N/A	2.68 (3.57), 0.08-15.00, 0.33-3.75	3.35 (5.73), 0-23, 0.5-3.0	.875
Number of messages (on average) *sent* each day on apps in past 30 days (missing=1), mean (SD), range, IQR	10.06 (27.84), 0-200, >0-10	N/A	N/A	—
Number of messages (on average) *sent* each day on apps in past 7 days, mean (SD), range, IQR	N/A	8.44 (10.17), 0-50, 3-10	5.74 (7.19), 0-30, 3-5	.055
Number of messages (on average) *received* each day on apps in past 30 days, mean (SD), range, IQR	27.02 (55.64), 0-300, 2-25	N/A	N/A	—
Number of messages (on average) *received* each day on apps in past 7 days, mean (SD), range, IQR	N/A	14.33 (14.59), 3-70, 5-20	9.89 (9.51), 0-30, 3-10	.079

[a]McNemar's test or Wilcoxon sign-rank test was conducted as appropriate to compare characteristics between midpoint and completion survey.

[b]Multiple response (categories are not mutually exclusive).

[c]Could not estimate because of sparse cells.

Table 4. Sex behaviors with app-met partners across three time periods among app-using men who have sex with men.

Sex behaviors with app-met partners	Baseline (n=53)	Midpoint (n=27)	Completion (n=19)	*P* value[a]
Number of explicit or x-rated messages (on average) *received* on mobile apps, mean (SD), range, interquartile range (IQR)	18.43 (35.65), 0-200, 0-15	N/A[b]	N/A	—
Number of messages (on average) containing nude or suggestive photos you *sent* each day on apps in the past 30 days, mean (SD), range, IQR	3.13 (6.21), 0-30, 0-3	N/A	N/A	—
Number of messages (on average) containing nude or suggestive photos you *sent* each day on apps in the past 7 days, mean (SD), range, IQR	N/A	1.81 (3.29), 0-15, 0-3	1.00 (1.56), 0-5, 0-2	.276
Number of messages (on average) containing nude or suggestive photos you *received* each day on apps in the past 30 days, mean (SD), range, IQR	33.15 (139.25), 0-1000, 0-15	N/A	N/A	—
Number of messages (on average) containing nude or suggestive photos you *received* each day on apps in the past 7 days, mean (SD), range, IQR	N/A	4.81 (6.88), 0-25, 0-5	3.58 (4.73), 0-20, 0-5	.046[c]
Number of men you began talking on the these apps, met in person, and engaged in anal sex as a TOP in the past 30 days, mean (SD), range, IQR	1.19 (3.57), 0-25, 0-1	N/A	N/A	—
Condom used each time from start to finish (ejaculation), n (%)	12/17 (70.6)	N/A	N/A	—
Number of men you began talking on the these apps, met in person, and engaged in anal sex as a TOP in the past 7 days, mean (SD), range, IQR	N/A	0.30 (0.72), 0-3, 0-0	0.26 (0.56), 0-2, 0-0	.103
Condom used each time from start to finish (ejaculation), n (%)	N/A	4/5 (80.0)	3/4 (75.0)	.317
Number of men you began talking on these apps, met in person, and engaged in anal sex as a BOTTOM in the past 30 days, mean (SD), range, IQR	0.58 (1.31), 0-7, 0-1	N/A	N/A	—
Condom used each time from start to finish (ejaculation), n (%)	13/15 (86.7)	N/A	N/A	—
Number of men you began talking on these apps, met in person, and engaged in anal sex as a BOTTOM in the past 7 days, mean (SD), range, IQR	N/A	0.04 (0.19), 0-1, 0-0	0.05 (0.23), 0-1, 0-0	__[d]
Condom used each time from start to finish (ejaculation), n (%)	N/A	0/1 (0)	1/1 (100.0)	__[d]

[a]McNemar's test or Wilcoxon sign-rank test was conducted as appropriate to compare characteristics between midpoint and completion survey.

[b]N/A: not applicable.

[c]Statistically significant.

[d]Could not estimate because of sparse cells.

Sexual Behaviors With and Characteristics of App-Met Partners

Table 4 shows the sexual behaviors that participants engaged in with app-met partners. At baseline, participants had 1.2 app-met male partners (SD 3.6) during the past 30 days who they engaged in anal sex with as a "Top"; 70.6% (12/17) of them used condoms throughout the sexual encounter. According to the data collected at the midpoint, the range of male partners from who they engaged in anal sex as the Top were 0-3; participants reported from 0-2 at the completion visit. At baseline, respondents had 0.6 app-met male partners engaged in anal sex as the "Bottom" in the past 30 days, and more than three-quarters (13/15, 86.7%) of them used condoms throughout the sexual encounter. The average numbers of outgoing and incoming app-delivered messages containing nude/suggestive photos in the past 30 days were 3.1 and 33.2, respectively.

Table 5 shows the characteristics of app-met partners. The majority of the baseline sample reported meeting partners approximately the same age or slightly older (43/51, 84.3%) than themselves during the past 30 days. In the midpoint and final surveys, approximately 35% (10/27 and 7/19) reported that they met partners approximately the same age. The vast majority of participants reported meeting black partners across all three time points. At baseline, over two-thirds (36/53, 67.9%) reported that the HIV status of their app-met partners was negative, and 26.4% (14/53) reported that they did not know their partner's HIV status. Most participants also reported their app-met partners' HIV status as negative or unknown at the midpoint and completion visits.

Table 5. App-met partner characteristics across three time periods among app-using men who have sex with men.

App-met partner characteristics	Baseline (n=53), n (%)	Midpoint (n=27), n (%)	Completion (n=19), n (%)	*P* value[a]
The majority of your sexual partners met on these apps in the past 30 days (missing=2)				
A lot older (>5 years)	4 (7.8)	N/A[b]	N/A	–
Slightly older (2-4 years)	21 (41.2)	N/A	N/A	–
Approximately the same age	22 (43.1)	N/A	N/A	–
Younger (≤3 years)	4 (7.8)	N/A	N/A	–
Don't know/not sure	0 (0.0)	N/A	N/A	–
The majority of the men met on these apps in the past 7 days				
A lot older (>5 years)	N/A	1 (3.7)	1 (5.3)	_[c]
Slightly older (2-4 years)	N/A	7 (25.9)	3 (15.8)	.564
Approximately the same age	N/A	10 (37.0)	7 (36.8)	.999
Younger (≤3 years)	N/A	1 (3.7)	1 (5.3)	_[c]
Did not have anal sex with any men met	N/A	8 (29.6)	7 (36.8)	.564
The majority of your sexual partners met on these apps: Latino or Hispanic				
Yes	3 (5.7)	1 (3.7)	0 (0.0)	_[c]
No	49 (92.5)	18 (66.7)	12 (63.2)	–
Missing	1 (1.9)	8 (29.6)	7 (36.8)	–
The majority of your sexual partners met on these apps				
White	1 (1.9)	1 (3.7)	0 (0.0)	_[c]
Black or African American	51 (96.2)	18 (66.7)	12 (63.2)	–
Asian Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)	–
Asian	0 (0.0)	0 (0.0)	0 (0.0)	–
Native Hawaiian or Pacific Islander	0 (0.0)	0 (0.0)	0 (0.0)	–
Missing	1 (1.9)	8 (29.6)	7(36.8)	–
The majority of your sexual partners met on these apps				
HIV positive	2 (3.8)	0 (0.0)	0 (0.0)	.317
HIV negative	36 (67.9)	9 (33.3)	7 (36.8)	–
I did not ask	14 (26.4)	10 (37.0)	5 (26.3)	–
Missing	1 (1.9)	8 (29.6)	7 (36.8)	–

[a]McNemar's test or Wilcoxon sign-rank test was conducted as appropriate to compare characteristics between midpoint and completion survey.

[b]N/A: not applicable.

[c]Could not estimate because of sparse cells.

Discussion

Principal Findings

To our knowledge, this is the first study to examine GSN app use patterns among YBMSM in the southern United States, specifically the Deep South. The majority (76%) of the sample reported using GSN apps and reported using multiple apps. Jack'd was the most commonly used GSN app. Interestingly, few participants (17%) in our sample reported using Grindr, which is in contrast to previous research with racially diverse MSM samples [9]. To date, YBMSM have been underrepresented in MSM studies recruited from GSN apps, perhaps because many of these samples have been recruited from Grindr [18,19,21]. Therefore, our study is an important contribution to the literature.

The mean age at initiation of app use was 20.1 years with the youngest reported age being 13 years old, which reinforces the idea that GSN apps are a relevant virtual venue to reach YBMSM for HIV prevention and treatment messaging. Despite research showing that MSM commonly meet sexual partners on GSN apps, over 60% (35/53) of the sample reported that their primary reason for using these apps was to "kill time." These findings suggest GSN apps could be useful for sending HIV prevention-related messages through advertisements [35]

or through direct messaging [36]. Similar to other studies demonstrating high levels of assortative mixing based on race/ethnicity in the networks of BMSM [25,37], the vast majority of participants reported meeting black sexual partners on these apps.

Interestingly, less than half of app users reported being in a committed relationship. The majority of the baseline sample reported meeting partners approximately the same age or slightly older than themselves. This is significant because age discordance, particularly meeting older partners, is associated with increased HIV risk [25,38-40]. Over two-thirds of participants at the enrollment visit reported that the HIV status of their app-met partners was negative. Almost one-third of participants did not know the status of their partner. If BMSM are meeting and having CAI with people they think are HIV negative (because they self-reported their HIV status as negative or unknown) on an app, this could lead to increased HIV acquisition. This finding of not knowing one's partners' HIV status points to the need for further communication in sexual dyads about HIV risk reduction practices [41]. Moreover, these findings illustrate the need for encouraging the disclosure of HIV status and decreasing stigma for HIV-positive users on GSN apps. Interestingly, in terms of the body content appearing on the profile pictures, most participants (over two-thirds) displayed their face. Compared to nonusers, a majority of app users reported attraction to males.

Additionally, because we found inconsistent condom use with app-met partners, on GSN apps there should be increased efforts promoting condom use, HIV testing, treatment as prevention for those living with HIV, and PrEP for those who are HIV-negative. This is especially important in the context of the low number of reported sexual partners, which is consistent with the BMSM paradox and previous research showing few sexual partners among BMSM [25]. The intersection of inconsistent condom use and a higher HIV prevalence among older BMSM (many of whom have unknown HIV statuses) presents a critical need for interventions among young BMSM in the Deep South.

Compared to previous research among app-using MSM in the Deep South, our study reported similar reasons for and patterns of GSN app use. A prior study (where MSM from a single city in the Deep South were recruited from a single popular app) found that over one-third used mobile apps to meet new sexual partners and about one-fifth used them to "kill time" when bored [9]. In that study, MSM participants had current accounts on 3.1 mobile apps per day, with Grindr being the most common (100%), followed by Scruff (52.5%), and Jack'd (45.7%). Each day, men reported opening these mobile apps 8.4 times and spending 1.3 hours on these mobile apps. However, two notable differences between the current study and the aforementioned study are the respondents' race/ethnicity and the apps most commonly used. Our study was composed of 100% BMSM while the other was 19% BMSM; Jack'd was the most popular GSN app in the current study, while Grindr was the most common app in the other study.

Future Research

Further research can contribute to a better understanding of the role of GSN apps in the sexual lives of YBMSM and the way that app use behaviors may contribute to the increased risk of HIV infection among this population. Future research among YBMSM in the Deep South should be conducted through population-based samples and larger samples to further understand the prevalence and common patterns of GSN app use. Given that YBMSM who use GSN apps represent a diverse population in terms of their motivations and patterns of use as well as their sexual behaviors with app-met partners, future research should apply novel techniques, such as latent class analysis [42,43] to further understand the associations of various GSN app use profiles with risk for HIV infection. Latent class analysis is a useful tool to explore conditional probabilities of co-occurring behaviors within distinct classes and has been used to identify sexual risk profiles among black MSM [44]. Additionally, future investigations should include longitudinal designs to understand potential changes in GSN app use and associated changes in sexual risks, since GSN app use could be contextual and change as individual life circumstances change (eg, changes in partner type). Other research has found that sexual risks among BMSM vary with differing life phases and contexts of sexual relationships [45]. Future research should assess the HIV status that participants include in their app profile(s) and should also examine homophily in partner selection, such as HIV status homophily, as this may drive partner selections. Future research could also ask participants about their app-met partners' PrEP use (if HIV-negative) or antiretroviral therapy use (if HIV-positive), as these factors may have an influence on app use or meeting partners. Additionally, given that GSN apps use GPS technology to connect nearby users, future research employing GPS tracking may be of use in understanding how GSN app use links MSM across geographies. GPS tracking could also illuminate how geography plays a role in transitioning user interactions from virtual app-based conversations to physical meetings for sexual encounters. It would also be helpful to know what influences certain patterns of app use and whether these influences differ from those in other geographic regions. This is especially important in the Deep South given its high rates of HIV infection; perhaps in this region there are specific geographical features that increase risk of HIV acquisition. Furthermore, as previously mentioned, it would be helpful to know what app use behaviors leads to certain health behaviors (including sexual health behaviors) as well as how app-based interventions could modify these behaviors. Future research studying GSN app use among YBMSM or using advertising capabilities on GSN apps could recruit YBMSM into HIV prevention and treatment programs. For example, research could examine app-specific promotions of PrEP use among YBMSM.

Strengths and Limitations

Our study's small sample was recruited through community-based methods via local organizations, including AIDS-service organizations. Subsequently, the sample may be subject to selection bias and therefore may not be representative of the wider population of BMSM in the Deep South. However, our study presents a strength over previous app-based research

with MSM, which has traditionally been limited to white participants in a single geographic region, often recruited from apps. Our sample represents a smaller yet broader cross-section of BMSM who use GSN apps across three cities in the Deep South. More importantly, our study prompts future research into GSN app use among this subpopulation and highlights the need for more focused prevention efforts. Additionally, given the small sample size, we might not be adequately powered to compare participants who use GSN apps to those who do not. All data were collected via self-report, introducing potential for social desirability bias (ie, underreporting instances of CAI) and recall bias. In addition, we assessed behaviors using different time periods across the three waves of data collection, making comparison across waves difficult. While behaviors may differ depending on the app and many participants reported using multiple apps, we did not analyze behaviors by individual apps. Nonetheless, our findings represent a novel characterization of GSN app use among YBMSM in the Deep South—a topic and population warranting further study given the high rates of HIV diagnoses

Conclusions

Among our sample of YBMSM in the Deep South, GSN app use for the purpose of meeting sexual partners was common, with a diverse range of app use behaviors being reported. Further research should characterize the association between GSN app use and engagement in sexual behaviors that increase risk for HIV acquisition and transmission. In addition, HIV prevention interventions for YBMSM who use GSN apps should be developed and evaluated. It should be noted that GSN apps themselves present important platforms for such interventions.

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Conflicts of Interest

None declared.

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Abbreviations

BMSM: black men who have sex with men
CAI: condomless anal intercourse
GSN: geosocial networking
GPS: global positioning system
HIV: human immunodeficiency virus
IQR: interquartile range
MSM: men who have sex with men
PrEP: pre-exposure prophylaxis
YBMSM: young black men who have sex with men

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Review

mHealth Technology Use and Implications in Historically Underserved and Minority Populations in the United States: Systematic Literature Review

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Abstract

Background: The proportion of people in the United States who are members of at least two ethnic groups is projected to increase to 10% by the year 2050. This makes addressing health disparities and health inequities in minority populations increasingly more difficult. Minority populations, including those who classify themselves as African American and Hispanic, are using mobile phones to access health information via the internet more frequently than those who classify themselves as white, providing unique opportunities for those in public health and health education to reach these traditionally underserved populations using mobile health (mHealth) interventions.

Objective: The objective of this review was to assess studies conducted in the United States that have used mHealth tools and strategies to develop and implement interventions in underserved populations. This review also examines the ways in which mHealth strategies are being employed in public health interventions to these priority population groups, as mobile phone capabilities include text messaging, mobile apps, internet access, emails, video streaming, social media, instant messaging, and more.

Methods: A systematic literature review was conducted using key search phrases, the matrix method, and Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart diagram to identify key studies conducted between the years of 2009-2016 in the United States. These studies were reviewed for their use of mHealth interventions in historically underserved and minority populations.

Results: A total of 16,270 articles were initially identified using key search phrases in three databases. Titles were reviewed and articles not meeting criteria were excluded, leaving 156 articles for further review. After additional review for relevance and inclusion criteria, 16 articles were qualified and analyzed.

Conclusions: mHealth is a promising area of development for public health and health education. While successful research has been done using text messaging (short message service, SMS) and other mHealth strategies, there is a need for more research using mobile phones and tablet applications. This literature review demonstrates mHealth technology has the ability to increase prevention and health education in health disparate communities and concludes that more specified research is needed.

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KEYWORDS

mHealth; mobile health; digital health; smartphone; text messaging; minority; ethnic group; health disparity; underserved population

Introduction

mHealth in the United States

Mobile phone use has become a part of daily life for most people in United States with wireless users sending and receiving an average of 6 billion text messages per day or 69,635 text messages every second [1,2]. Mobile cellular subscriptions have reached 90% of the world's population and have reached nearly 80% of the global population living in rural areas [3]. Serving as a 2-way interactive communication tool, mobile health (mHealth) can present opportunities for researchers and program developers to capitalize on the existing cultural behaviors of their target populations, given their rates of access to and use of mobile technology [4]. As van Velthoven et al explain, "the widespread use of mobile devices and almost universal coverage of the world's population by a network signal has given mHealth a great opportunity to improve global health" [5]. As a result, mHealth interventions have become increasingly common in low-income and third world countries. In areas where financial resources and health care workforces are lacking, and high rates of disease occur, short message service (SMS) text messaging could potentially make the ability to obtain to health care more accessible and more affordable [6].

With almost 100% of the total US population owning a mobile phone of some kind, health communication technologies could be incredibly beneficial for those with limited English proficiency, individuals with disabilities, and persons living in rural and other isolated geographic areas [7]. The ability to tailor mHealth interventions in a culturally competent manner and implement program curriculum at the literacy levels of the target population makes mHealth not only adaptable but also optimal. The mobility of the technological platform allows population groups experiencing the greatest health disparities to have improved access to health care and health resources.

Mobile phones are a more cost-effective way to access health information for those of a lower socioeconomic status (SES). In addition, mobile technologies have potential to ameliorate the management of chronic diseases and smoking cessation while simultaneously improving communication between patient and provider [8]. A recent report by the Institute of Medicine notes, "[health information technology] provides an opportunity for engaging populations not historically well served by the traditional health community…The impact of facilitating patient and population contribution to, and control of, their health information has the potential to provide further insights into, and opportunities to address, disparities in underserved populations" [9,10].

As the US population diversifies, health disparity incidence and prevalence rates are not expected to decline; health disparities are predicted to be even more difficult to diagnose. According to Yancey et al, the proportion of people in the United States who are members of at least 2 ethnic groups will increase 10% by the year 2050, complicating assessments of health disparities [11]. However, recent technology trends in the United States indicate mobile phone usage and smartphone adoption rates by those experiencing the highest rates of health disparities are increasing, providing a means for those who work in public health and health education to reach these populations through mHealth interventions. As of January 2017, technology trends indicate that 95% of American adults own a mobile phone, 77% own a smartphone, 22% own an e-reader, 51% own a tablet computer, and 78% own a desktop or laptop computer [7]. The objective of this review was to assess studies conducted in the United States that have used mHealth tools and strategies to develop and implement interventions in underserved populations. This review also examines the ways in which mHealth strategies are being employed in public health interventions to these priority population groups, as mobile phone capabilities include text messaging, mobile apps, internet access, emails, video streaming, social media, instant messaging, and more.

mHealth: Text Messaging

The use of SMS text messaging and mobile apps for improving health and providing health information [12] are gaining momentum for incorporation into interventions and programmatic efforts in the United States. Statistics regarding SMS text message trends in the United States indicate 80% of all US mobile phone owners text, 92% of US smartphone owners text, and US SMS users text, on an average, 35 texts per day [13]. SMS text messaging interventions in health education and behavior show promise in underserved and minority populations due to increasing usage trends. To date, research shows, African American and Hispanic mobile phone users are more intense and frequent users as compared to white mobile phone users. As of 2011, non-white mobile phone users (African American users in particular) were found to text more often than white mobile phone users, and those with lower levels of income and education were found to text more often than those with higher levels of income and education. Smartphone owners (mean 52.0; median 20) also send and receive a significantly larger number of texts per day than owners of more basic phones (mean 29.7; median 10) [14]. Because more than 70% of all African American and English-speaking Latino mobile phone users use text messaging, versus just over half of white mobile phone users, and 92% of black adults are mobile phone owners, and 56% own a smartphone of some kind [13], the usage of mHealth strategies as a tool to eliminate health disparities shows opportunities of promise.

mHealth: Phone Internet Use Trends

The utilization of mobile phones for internet access allows for a higher likelihood of mHealth interventions and programs being used among underserved populations. Referencing internet usage, approximately 88% of Americans (9 out of 10 individuals) use the internet on a consistent basis and 73% use high speed broadband service in their home. Among all Americans, those who classify themselves as Hispanic (58%) and African American (65%) have the lowest rates of high-speed internet access at home compared those who classify themselves as white [7]. This has significantly increased from projections made by Pew Research Center in 2000 and 2010, indicating a doubling of internet use from 11% to 21% [13]. These findings are of particular interest to those interested in trends related to young people, and those who classify themselves as Latino or

African American, as these groups are significantly more likely than other groups to have mobile internet access [13].

Not only has there been an increase in minority internet use overall, but the use of mobile phones to access the internet has also increased bridging the digital divide between upper and lower classes [15]. A 2013 report indicated that those who classify themselves as Latino or African American are more likely to use a mobile phone to search for health information via the internet [16]. This is reiterated by 2016 data which shows that those who classify themselves as Hispanic (23%) or black (15%) tend to be more smartphone dependent and are smart-phone only internet users, meaning that they only utilize their smartphone to access Web-based information [7]. In fact, some innovative uses of mHealth technologies have been successfully implemented among low-income pregnant women, Spanish-speaking migrant workers, and homeless and at-risk youth [17,18]. This, then, validates the importance of examining these trends.

Methods

Overview

Keywords were searched using the institution's e-library database to access peer-reviewed journal articles from a variety of electronic databases and Web-based academic journals including PubMed, Health Reference Center, SAGE Journals, and Info Trac. mHealth is a newer concept in the field of public health and technology; therefore, only research literature published in English from 1 February, 2009 to 2 February 2016 was considered and included. The year 2009 was selected because in the United States, mobile phones started to evolve from the basic mobile phone to more of a smartphone [19]. Articles also had to be scholarly publications with full text available on the Web for review. The key search terms consisted of 2-3 components, a word that described historically underserved or minority populations, a word that described mHealth technology and related technology, and a word or phrase that described health, public health, or health access. Keywords related to historically underserved and minority populations, health, and mHealth technology were used to create a total of 18 preselected search phrases. The complete list is available in Textbox 1.

Selection Criteria

Before conducting the review, the inclusion and exclusion criteria were established. To be included, articles had to (1) focus on a specific priority population group or subgroup; (2) discuss technology use, specifically mHealth among priority population; and (3) relate to public health, health education programs, and health behavior interventions in the priority populations. To ensure that the third criterion was met, search terms were filtered by subject terms which included (1) medicine and public health; (2) health care; (3) public, environmental, and occupational health; (4) health; (5) health aspects; and (6) public health.

Studies were excluded from initial review if they were (1) not related to health, (2) addressed research conducted outside the United States, (3) discussed the historically underserved population as current or future employees of the health system instead of as patients, (4) surveyed members of the underserved population on their ownership and usage of mobile phones but did not include an intervention, or (5) surveyed members on their openness to an intervention utilizing mHealth strategies but did not implement an intervention aimed at improving health outcomes. In addition, articles were excluded if manuscripts were not written in English or examined cost as the main variable.

Data Extraction and Coding

Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Flow Diagram as a guide, the systematic literature review results were organized and reported based on identification, screening, eligibility, and inclusion criteria. The matrix method was also utilized for papers that met the inclusion criteria following review of the abstract and full papers. To ensure a systematic method for reviewing and extracting data from the paper, a coding matrix was created with rows and columns summarizing key sections in each article. These included the author, title, journal, year, purpose, study design, theoretical constructs, demographic characteristics of the study participants (to include gender, race and/or ethnicity, and urban and/or rural setting), and how technology was used focusing on which health issue was addressed.

Textbox 1. Search strategy terms and phrases for the systematic literature review.

Search term and phrase:

1. Short message service (SMS) health, minority groups
2. mHealth, health disparities
3. Mobile health, ethnic groups
4. Internet, racial health
5. Text message, health, underserved populations
6. SMS, cultural diversity, health
7. Health technology, health education, underserved populations
8. Digital health, diversity, health education
9. Mobile phone, ethnic groups, public health
10. Smartphone, health, ethnic groups
11. Tablet, health equity, underserved populations
12. Health information technology, cultural competence, ethnic groups
13. mHealth, underserved populations
14. Mobile apps, cultural competence, minority health
15. Health communication, health equity, ethnic groups
16. Diversity, health technology, minority group
17. Health literacy, health disparities, mobile health
18. Health equity, educational technology, health disparities

Results

Principal Results

The 18 search phrases returned 16,210 articles; however, 16,053 articles were excluded either because they were duplicates or because they did not meet initial inclusion criteria based on their titles. Abstracts and full papers were pulled and reviewed (N=157), and an additional 141 articles were excluded based on the inclusion criteria stated above. A total of 16 papers met the inclusion criteria specifications and were included for review, as shown in Figure 1.

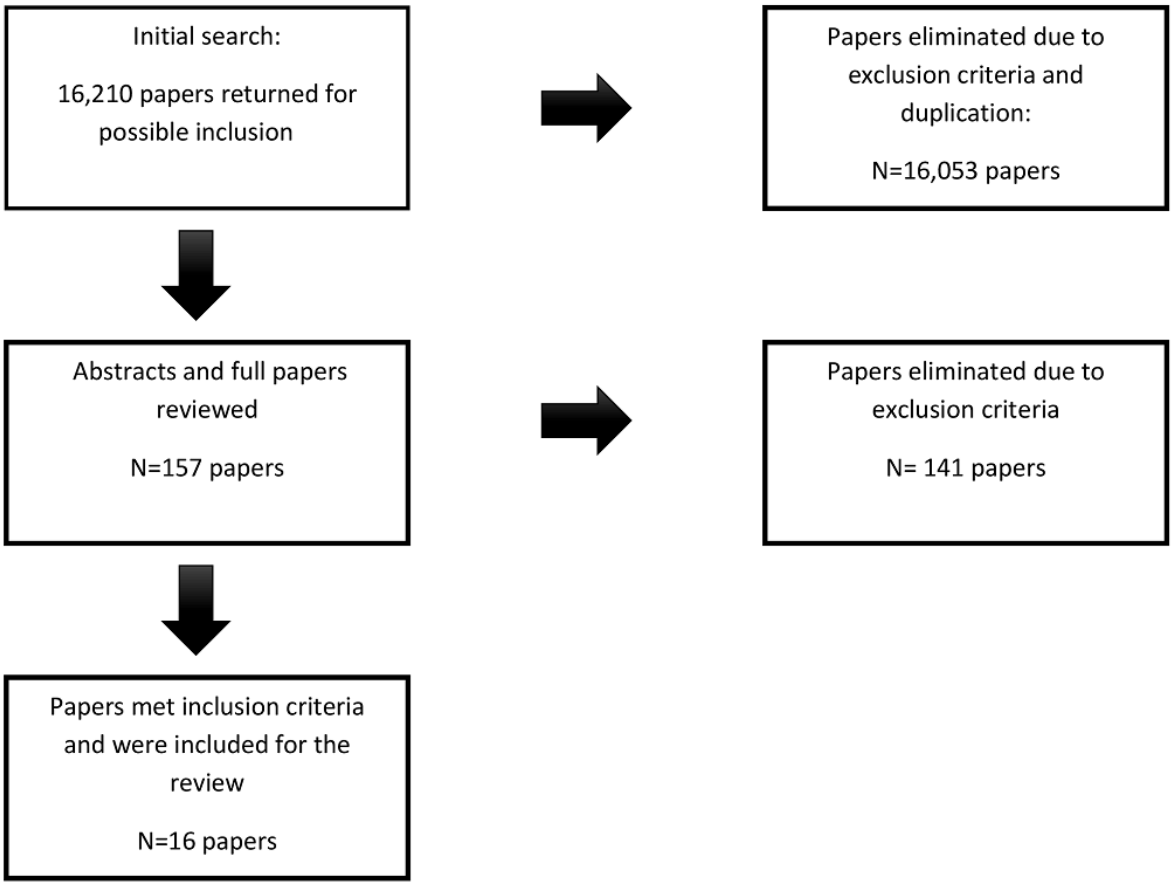
Of the 16 articles reviewed, all were published during the years 2010-2016. The most prevalent demographic variables included being a female (woman), urban and/or metropolitan setting, and having participants aged between 15 and 30 years. One study addressed health behaviors in men, and another's target population consisted of children and adolescents in which parents acted as mediators for change due to technology access [20,21]. Moreover, 9 of the 16 studies focused on populations who classify themselves as African American or a mix of populations who classify themselves as African American and Latino and/or Hispanic, and 7 studies targeted predominately Hispanic and Latino populations. Finally, 1 study addressed Korean American women.

The 2 most commonly included issues were diabetes and sexual, reproductive, and maternal and child health. Other key issues also included influenza vaccinations and health and HIV and AIDS prevention for high-risk population groups [21]. Each study identified additional characteristics that determined participant eligibility. These are presented in Multimedia Appendix 1.

The review also assessed differences relating to the methodology in research design for the mHealth interventions. Only 7 of the 16 studies had a theoretical grounding or based their research design and evaluation on theoretical constructs. Most of the studies were quantitative rather than qualitative; however, 1 did not employ either methodology. Moreover, 5 of the studies were randomized controlled trials and reported 2 statistically significant outcomes, 5 were pilot studies, and 1 was a prospective cohort study. The 5 remaining studies had mixed designs.

Although all studies utilized mHealth technology in the implementation of their intervention, the method varied from study to study. In 3 of the studies, mobile phones were provided by researchers or the program coordinator. In the remaining studies, program participants had to have a working mobile phone to be enrolled in the intervention. In 1 intervention designed to provide counseling services to parenting teen mothers, phones were contracted and limited to a certain minute limit per month, with no texting or internet features [18]. In another study, smartphones provided by researchers were used as an education platform by streaming video episodes to prevent HIV sex risk behaviors [22]. Only 8 of the 16 studies used SMS text messaging as a communication strategy.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) literature search results.



Article Content Overview

HIV Prevention: The 411 Safe Text Project

The 411 for Safe Text project is an mHealth intervention that utilized SMS text messages to deliver HIV prevention program among 60 young black men in Philadelphia aged between 16 and 20 years, who met eligibility criteria and had a mobile phone. Moreover, 30 were assigned to the control group and 30 to the intervention group. The men in the study received SMS text messages 3 times a week for 12 weeks about nutrition (control group) and sexual health (intervention group), with follow-up assessments performed after 12 weeks and afterward. This study aimed to test the feasibility of enrollment, participation, and retention of young black men in a SMS text message program for HIV prevention. A total of 67% of control group members completed the assessment and program; 63% of intervention group members completed the assessment and program.

Efficacy of a Mobile Phone–Based Counseling Intervention Among Pregnant Teen Mothers

The mHealth intervention conducted by Katz et al recruited pregnant teens aged 15 to 19 years in Washington, DC, to test the efficacy of mobile phone intervention in postponing subsequent teen pregnancies [18]. Comparison was made between the intervention and standard of care to see what effect the intervention might have on the amount of time before the participants experienced a subsequent pregnancy. Intervention group teens received mobile phones for 18 months of counseling sessions, in addition to quarterly group sessions in which minutes, texting, and internet features were limited. Moreover, 249 African American and Latina primiparous pregnant teens aged 15 to 19 years who had not graduated from high school participated in the research study. Within the 2-year follow-up period, 31% of the intervention group and 36% of the usual care group became pregnant again. Although the use of mobile phones allowed for more opportunities to communicate with the participants, inconsistency with counseling sessions over an 18-month period occurred (52% completed). The study presented unforeseen challenges in relation to motivations for participation (free phone was a selling point) and communication.

Pilot Evaluation of the Text4baby Mobile Health Program

In the study conducted by Evans et al, a pilot evaluation of the *text4baby* mobile health program was randomized and delivered to an intervention group (received usual health care and *text4baby* SMS text messages) and control group (received usual health care) [23]. Specific aims of the text4baby program were to (1) assess exposure, awareness, and reactions to the messages and (2) identify direct effects of the messages on maternal prenatal care and related health attitudes, beliefs, and behavioral outcomes. This program sent text messages that offered immediate just-in-time tips geared at improving prenatal and postpartum health care outcomes in incredibly disparate women. Conclusively, participants sought prenatal care information on the Web (5%), alcoholic consumption decreased after

confirmation of their pregnancy (3% to 1%), consumption of 3 or more servings of fruit a day increased (3%), and tobacco use decreased in the last 30 days (6% to 1%). Increased exposure to text4baby messages resulted in program participants being 3 times (odds ratio 2.73) more likely to believe that they were more prepared to be a new mother.

Influenza Vaccination in Low-Income Pediatric and Adolescent Populations

In an effort to increase influenza vaccination rates among low-income urban children and adolescents, researchers designed a randomized control trial where parents of the target population would receive SMS text messages promoting influenza vaccines [21]. Conducted in 4 community-based pediatric clinics that primarily serve Latino and publicly insured populations, children and adolescents were eligible for free vaccination through the Vaccines for Children Program. Parents received a series of automated SMS text messages over 5 weeks featuring educational information specific to the child's age, which provided notification of upcoming vaccine clinics. The messages were personalized based on language preference of the parents and later discontinued once the children or adolescents were vaccinated. As a result of the intervention, a higher proportion of the children and adolescents in the intervention group (44%) received the influenza vaccine compared with the control group (40%).

Text4baby Program: An Opportunity to Reach Underserved Pregnant and Postpartum Women

This study was a prospective cohort study conducted in 2 Women, Infants, and Children centers in Atlanta, GA. A total of 468 randomly selected pregnant and postpartum women were asked about their mobile phone use and given information about the text4baby program for enrollment. Pregnant women and new mothers received tailored and targeted SMS text messages on prenatal and postpartum services and behaviors. Conclusively, 9 out of the 10 participants of the text4baby program read the messages and planned on continuing with the program despite disruption of the mobile service. Additionally, underserved pregnant women and new mothers widely accepted the program. Over two-thirds of the women had no month to month mobile phone plan, which affected the response rate and message reception ultimately presenting barriers [17].

Streaming Weekly Soap Opera Video Episodes on Smartphones to Reduce HIV Risk Among Black Women

Love, Sex, and Choices is an mHealth intervention that utilized data only on smartphones to stream 12 episodes of a soap opera video series designed to reduce HIV sex risk practices among low SES African American women aged 18 to 29 years. Researchers conducted a randomized control trial assigning 238 participants to both comparison (text) and intervention (video) groups. Researchers were able to track the participant's trends in actually accessing, watching, and completing the video modules. If participants failed to watch the video by a particular benchmark in the week, reminders were made to account for possible attrition and track intervention fidelity. Individuals in the intervention group were responded to questions about each episode by entering the responses on the phones, whereas the comparison group received only written messages communicating HIV risk reduction on the phones. Regarding the intervention group, 97% of the participants reported that they enjoyed watching the video on the mobile phone, 99% thought it was easily accessible, and 97% thought that using the mobile phone was easy. Also, 95% enjoyed the video and enjoyed being able to watch the videos on their phone wherever they went and 93% believed phone training was very helpful. Advantages to the program included mobility, privacy, and increasing the participant's self-efficacy smartphone usage. Disadvantages included damaged mobile phones (almost half of 161; n=55), stolen mobile phones (56), misplacing login information, inability to recall passwords, and server issues. An alternative identified to accessing the videos via their emails included the creation of a mobile app. This app provided a new channel to address health disparities in traditionally underserved populations [22].

Print Versus Culturally Relevant Facebook and Text Message Intervention to Promote Physical Activity Among African American Women

Joseph et al conducted a research study among African American women looking at the difference between electronic intervention (Facebook and text message) and print intervention (brochures delivered via postal mail) to promote physical activity. Participants (N=29) were randomly assigned to one of the 2 physical activity interventions for 8 consecutive weeks. Moreover, 1 group used Facebook and text message to promote physical activity (F1), and the other group delivered the intervention by mailing brochures to participants' homes (P1). Participants of the study also self-reported their physical activity levels, psychosocial variables, and satisfaction of the program. Participants in the F1 group showed a decrease in sedentary time and an increase in intensity compared with participants in the P1 group while also demonstrating greater enhancements in self-regulation for physical activity and increased moral support. Satisfaction in this group was high (100%), and ultimately, the F1 group showed more positive outcomes compared with the P1 group [24].

Efficacy of a Telephone-Delivered Sexually Transmitted Infection and HIV Prevention Intervention for Adolescents

DiClemente et al performed a randomized clinical trial looking at the efficacy of a telephone-delivered phone intervention for prevention and maintenance program in sexually transmitted diseases and HIV. This particular study used phone counseling to prevent behaviors and sexually transmitted infection (STI) incidence in a 36-month follow-up. Participants were recruited from 3 clinics in Atlanta, GA, including African American adolescent girls aged 14 to 20 years. All participants received primary treatment and were split into 2 groups to receive supplemental treatment to help the effects of the primary treatment. The experimental group (n=343) was provided an STI intervention plan and was contacted by telephone every 8 weeks for 36 months. The purpose of the calls was to reinforce and complement prevention. The condition group (n=359) also received their STI intervention plan, HORIZONS, but they received information that focused on general health. This study

looked at 3 behaviors: the proportion of condom-protected sexual acts in 6 months and 90 days before assessments, number of sexual episodes while participants were under the influence of drugs or alcohol, and number of vaginal partners before assessments. Conclusively, fewer participants had chlamydia infections in the experimental group than in the condition group, 20% reduction rate, and also fewer gonococcal infections (48 to 54). Participants in the experimental group had a lower risk for chlamydial infections and reported higher condom use and fewer sexual acts while under the influence of drugs, alchohol or both. STI maintenance interventions in adolescents are critical because the population is at such high risk [25].

How Do Mobile Phone Diabetes Programs Drive Behavior Change?

Nundy et al conducted a study to determine how mobile phone programs for diabetes can drive behavior change using a mixed observational cohort study. Participants classified themselves as African American and lived in a working class, urban community. The authors studied the behavioral effects of CareSmart, a theory-driven intervention that includes SMS text messages and remote nurse support. Participants of the study received educational messages and reminders on nutrition, glucose monitoring, medications, foot care, and exercising. On the basis of the participants' responses to SMS text messages, nurses would contact patients periodically. Of the 372 members that were eligible for the study, 67 participants completed the 6-month program with follow up. One-third of participants reported well-controlled diabetes, one-third reported moderately controlled diabetes, and one-third reported poorly controlled diabetes. At 3 months into the program, researchers conducted a survey that showed improvement in the number of days on which participants were performing self-foot care and exercise compared with the initial start of the program. At 6 months of the program, along with exercising and foot care, healthy eating and glucose monitoring also improved [26].

An Automated Telephone Nutrition System for Spanish Speaking Patients With Diabetes

Khanna et al conducted a mobile technology and diabetes study focusing on Spanish-speaking patients. Over the course of a 12-week period, calls were made to participants at least 2 times a week asking participants about food portion consumption and tabling the glycemic index of foods while tailoring messages to each participant based on responses. This study included 75 participants with 1 group receiving an average of 26 calls, 2.2 times per week. An average of 10 phone calls per week were completed. Challenges of the study included difficulty reaching participants and phone numbers becoming disconnected [27].

Enhancing a Teen Pregnancy Prevention Program With Text Messaging

Devine et al conducted a pilot study (with a purpose of preventing teen pregnancy via SMS text messaging) that included a total of 96 teens enrolled in a month-long program receiving SMS text messages from Teen Outreach Program Text Plus. The study gathered information on teens' values, social support, self-efficacy, trouble with the law, and sexual activity. Moreover, 30 males and 29 females, aged 14 to 18 years, were recruited. One-third of the participants were African American and two-thirds were Latino. Before the intervention of the study, focus groups were held with participants to determine how to best implement the SMS text messaging component of the program and concluded that 15% of the participants did not own a mobile phone. The participants that did own a mobile phone stated they were heavy texters. Participants suggested that the 15% of teens without phones should pair up with the ones who did, and also to make it fun by adding games, contests, and fun facts among the Teen Outreach Program group texts. At the start of the program, multiple risky behaviors, such as having sex at an early age, were recorded, with a total of 63% reported having sex at the age of 13 years or younger. Teens that reported an intention to have sex stated that they had no intention of using contraception (fewer than 44%). Conclusively, a total of 23.7% of the teens reported to having more than one partner within the past 3 months and 37% of teen, ages 14-15, reported to having concurrent sexual partners [28].

Adherence to Self-Monitoring via Interactive Voice Response Targeting Weight Gain Prevention Among Black Women

A study was conducted by Steinberg et al to look at the adherence to self-monitoring via interactive voice response (IVR) technology in an eHealth intervention targeting Weight Gain Prevention among Black Women. The purpose of the study was to examine the correlation between IVR self-monitoring and weight change among black women of a lower SES enrolled in the Shape Program, which was an 18-month randomized controlled study comparing an eHealth weight gain prevention intervention with usual care among overweight and class 1 obese black female primary care patients. Intervention participants were asked to self-monitor their behavior and change goals via weekly IVR phone calls, which lasted 2 to 4 min on average. Other area of focus consisted of incorporating behavior change goals to promote weight change, tailored skills training, monthly training calls with a registered dietitian, and a 12-month gym membership. There were a total of 91 participants with a total IVR completion of 72% over the 12 months. The rate of IVR completion had a positive correlation with weight loss; participants with an IVR completion of 80% showed higher weight loss numbers than participants with less than 80% completion rate [29].

Mobile Phone Text Messaging Intervention for Cervical Cancer Screening

Because Korean American women have the highest mortality rates in regards to cervical cancer, Lee et al aimed to study how mobile phone text messaging can be used to promote cervical screenings and assess changes in knowledge and behavior. A focus group with 13 women from the target population was developed according to the community-based participatory research approach. The focus group determined the target populations' actions, motivators, and barriers. This information was used to create a text campaign for 30 study participants that was tailored specifically to each participant's time and educational needs. Participants received their personalized texts about cervical health and screenings at their specified times for

7 consecutive days. Comparing baseline data and post intervention data, there were statistically significant increases in knowledge of general cervical health, cancer, risk factors, and pap tests as well as change in beliefs about pap tests. Moreover, 23% of participants received pap tests, 83% of participants were satisfied with the program, and 97% stated that they would recommend the program to others [30].

Text Messaging to Motivate Exercise Among Latino Adults at Risk for Vascular Disease

This study developed a 2-part study with a questionnaire and 6-week trial first, distributing a 15-item survey to determine how often Latino adults use their phone. The second part of the study focused on exercise. Potential participants were to be 50 years or older with one or more atherosclerotic risk factors. The trial consisted of a questionnaire to measure physical activity and time active. Participants then received 30 text messages using software that allowed confirmation receipts of text messages. Authors found that mobile phone use and texting is common in the Latino population and is a viable option to motivate physical activity among this target group [31].

Automated Pain Intervention for Underserved Minority Women With Breast Cancer

This study focuses on high-risk underserved minorities suffering from cancer. The study examined IVR in assessing patients' pain level and barriers to controlling pain, which accessed (1) patient pain levels and symptoms, (2) determination of pain and symptoms that exceed a threshold of severity, and (3) feedback about symptoms for physicians. When barriers were reported, staff would contact the patient to provide them with educational material. The study consisted of 60 low-income African American and Latina women who had breast cancer and cancer-related pain. Participants in the intervention group received phone calls twice a week, whereas the control group received usual care of pain and symptom management given by the clinic. Results showed that patients enrolled in the intervention group had a significant decrease in the proportion of women reporting moderate to severe pain. There was a decrease in the control group as well, but it was not statistically significant. The IVR intervention improved other cancer-related symptoms such as sleep disturbance and drowsiness [32].

Mobile Surveillance for Acute Respiratory Infections and Influenza-Like Illness in the Community

Stockwell et al used mobile surveillance for reported acute respiratory infections and influenza-like illness in the community. Data were collected for 44 weeks from 789 people, making up 161 households, in a community that primarily classified themselves as Latino. They received SMS text messages twice a week, urging them to report if anyone in the household was sick. The designated reporter of the household received the following SMS text message: Reply with 1 or 2. Does anyone in the household have runny nose, congestion, sore throat, cough, body aches, or fever, or feels [sick] hot? 1: yes; 2: no. If participants reported they were ill, a home visit was then conducted to obtain a nasal swab. Overall, 11,282 SMS text messages were sent, with a 73% response rate in the first month. From the time a patient showed symptoms, it took a median of 2 days for them to receive a nasal swab. Results of the samples obtained showed 236 samples (65%) were positive for a respiratory pathogen and 44 (19%) were positive for influenza. The nasal swabs also detected 12 other pathogens including coronavirus and respiratory syncytial virus. The use of SMS text messaging for interventions allows participants to report symptoms in a timely manner and also allows for a large number of participants to be simultaneously monitored [33].

Discussion

Principal Findings

Mobile technologies used to access and distribute health information have great potential to ameliorate outcomes within health care in the United States. This is imperative as it relates to underserved populations, as they suffer from the poorest of health outcomes, comprise the population served most via government assistance programs such as Medicaid and Medicare, and contribute to the astronomical health care cost and expenditures to our health care system. As Kumar et al explains, these technologies can support continuous health monitoring at both the individual and population level, encourage healthy behaviors to prevent or reduce health problems, support chronic disease self-management, enhance provider knowledge, reduce the number of health care visits, and provide personalized, localized, and on-demand interventions in ways previously unimaginable [34]. This is important when we compare the potential of mHealth in underserved, low SES population groups where traditional mass media health campaigns have been unsuccessful. Messages need to be designed to meet the "literacy, language, cultural and motivational needs of the population [35]. mHealth technologies can meet these needs by effectively tailoring health information using a tool that most patients already use or have access too. Due to this, mHealth has proven to be a potential route in reducing the incidence and prevalence of health disparities among our disadvantaged and underserved populations.

Although this systematic literature review revealed a number of mHealth interventions targeting underserved and minority populations here in the United States from a public health perspective, there are still several health problems that would make logical targets for SMS and mHealth interventions. Most of the current apps are developed from the perspective of the health care system for the general population versus public health interventions to underserved communities. As a result, research regarding the use of mHealth interventions for the populations that need it the most remains sparse. All chronic health conditions experienced by underserved populations could benefit from mHealth interventions due to the vast range of apps they can cover. As Nundy et al argues, wider mobile phones usage among minority groups has expanded access to address health disparities [36]. However, though the numbers of mHealth pilot studies are increasing, many of these pilot studies are focused solely on the assessment of mobile phone usage and ownership and fail to follow through with an implementation component to the study design.

One of the most notable mHealth interventions in the United States was the text4baby program dedicated to improving

maternal and child health outcomes among low-income, minority, and underserved women [17]. The program utilizes culturally tailored health messages and uses in depth strategies to survey and identify the optimal methods for delivery of service and care among the target population. It also includes regular evaluation to ensure that the frequency, length, and content of the messages sent to participants are appropriate. Additionally, the literacy levels of the population that the text4baby program serves is always taken into consideration in the development phase [17].

Evaluation Strategies and Theoretical Models

Despite the promise, some key challenges remain. As mHealth is still a relatively new field, different methods used and standards for measuring success varied from study to study based on the strategy used. This can affect the ability to compare results and implications across studies. Additionally, 7 of the studies in this review were randomized control trials and 3 were pilot studies that provided little to no information concerning the long-term effectiveness of mHealth strategies relating to that topic area.

Again, only 7 of the studies reviewed in this systematic literature review had theoretical constructs or grounding that guided the methods employed, and only 4 of those studies incorporated theories from health education and behavior, identified as Social Cognitive Theory (SCT), Transtheoretical Model, and the Health Belief Model [23]. This highlights the need for newer health behavior models applicable to mHealth interventions. As Evans et al argues, recent studies have noted both the relevance of existing behavioral theory, such as Social Cognitive Theory (SCT) and Theory of Planned Behavior (TPB), need to be examined and new models considered for their applicability to mHealth [23].

Limitations

The review is limited by the nature of the literature search, which only assessed actual mHealth interventions among minority and underserved populations. An overview of the field indicates mHealth is becoming more common in health care and public health, and this collection of 16 articles does not represent the full range of projects being implemented using mobile phones in the United States. Interventions included in our review had to outline in the title, abstract, or in the study's participants sections that the target participants were members of minority or underserved population subgroups, thus severely limiting studies that could be examined. Names of specific race and ethnic groups (African American or black, Latino or Hispanic, Native American, Asian, etc) were not used during the search results, although doing so might have yielded more studies. We wanted to search on a broader more general level instead of focusing on a specific race and ethnicity. It may be beneficial to conduct searches for specific races and ethnicities. Additionally, because the term mobile health has been previously associated with mobile health units, which are also used to increase access to care in low-income and disparate populations, it was decided to limit articles to those published between 2009 and 2016, which could have eliminated mHealth studies published earlier. Finally, when completing the literature search using key search phrases in the institution's e-library database, 3 of the search phrases returned more than 2000+ articles; however, articles past the first 1000 articles could not be accessed. Therefore, for those 3 key phrases, search filters had to be applied individually rather than all at once, which could have affected the overall number of articles obtained

Conclusions

mHealth has potential for influencing behaviors within public health and health education, particularly with regard to underserved and minority populations due to increased access to smartphones. Although projects using SMS text messaging interventions in low-income populations globally have begun to develop a strong evidence base for success, more research studies need to be conducted in the United States using SMS text messaging and additional mHealth strategies such as mobile apps gamification, and mobile Web (mWeb). In addition, more dissemination and implementation studies need to be conducted. Several pilot studies have been conducted, but it is important to understand and explore this research in the real world with different populations.

Although many of the studies reviewed in this systematic literature review primarily applied to populations in urban and metropolitan areas, those in rural populations can also benefit from mHealth technology. According to the Information and Communication Technology Policy Division of the World Bank, with every 3 out of 4 people living in developing countries or from low socioeconomic populations, the value and benefits of mobile phone services are considerably higher in rural areas [37]. According to PEW Research Center, Mobile technology use among rural adults has also risen rapidly, with the share of those owning smartphones and tablets increasing sharply. Ownership of desktop or laptop computers, in contrast, has only slightly risen since 2008.

In the United States, statistics indicate that during 2011 and 2012, there was a 13% increase in smartphone ownership among rural populations. As of 2014, we see that among young adults, 52% of rural populations compared with urban (68%) and suburban (66%) own smartphones, indicating a decreased gap [38]. Increased technology use among rural populations increased the opportunity for easier, faster, and more efficient access to health information for this population subgroup. As Bhavnani et al explains, mobile services are being used to disseminate locally-generated and locally-relevant educational and health information, in order to target rural communities whose populations typically have low levels of education and income and would not otherwise benefit from such information. There is evidence to suggest that this type of benefit could save lives in rural communities [38]. This highlights the need for similar mHealth interventions to benefit this population subgroup.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Research study background.

[PDF File (Adobe PDF File), 103KB - mhealth_v6i6e128_app1.pdf]

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Abbreviations

IVR: interactive voice response
mHealth: mobile health
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SCT: social cognitive theory
SES: socioeconomic status
SMS: short message service
STI: sexually transmitted infection

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Original Paper

Implementing Systematically Collected User Feedback to Increase User Retention in a Mobile App for Self-Management of Low Back Pain: Retrospective Cohort Study

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Abstract

Background: Promising first results for Kaia, a mobile app digitalizing multidisciplinary rehabilitation for low back pain, were recently published. It remains unclear whether the implementation of user feedback in an updated version of this app leads to desired effects in terms of increased app usage and clinical outcomes.

Objective: The aim is to elucidate the effect on user retention and clinical outcomes of an updated version of the Kaia app where user feedback was included during development.

Methods: User feedback of the initial app versions (0.x) was collected in a quality management system and systematically analyzed to define requirements of a new version. For this study, the anonymized data of Kaia users was analyzed retrospectively and users were grouped depending on the available version at the time of the sign-up (0.x vs 1.x). The effect on the duration of activity of users in the app, the number of completed exercises of each type, and user-reported pain levels were compared.

Results: Overall, data of 1251 users fulfilled the inclusion criteria, of which 196 users signed up using version 0.x and 1055 users signed up with version 1.x. There were significant differences in the demographic parameters for both groups. A log-rank test showed no significant differences for the duration of activity in the app between groups (P=.31). Users signing up during availability of the 1.x version completed significantly more exercises of each type in the app (physical exercises: 0.x mean 1.99, SD 1.61 units/week vs 1.x mean 3.15, SD1.72 units/week; P<.001; mindfulness exercises: 0.x mean 1.36, SD 1.43 units/week vs 1.x mean 2.42, SD 1.82 units/week; P<.001; educational content: 0.x mean 1.51, SD 1.42 units/week vs 1.x mean 2.71, SD 1.89 units/week; P<.001). This translated into a stronger decrease in user-reported pain levels in versions 1.x (F1,1233=7.084, P=.008).

Conclusions: Despite the limitations of retrospective cohort studies, this study indicates that the implementation of systematically collected user feedback during development of updated versions can contribute to improvements in terms of frequency of use and potentially even clinical endpoints such as pain level. The clinical efficiency of the Kaia app needs to be validated in prospective controlled trials to exclude bias.

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KEYWORDS

low back pain; app; mHealth; retrospective cohort study; self-management; user feedback; quality management; usability

Introduction

Chronic health disorders of the musculoskeletal system such as low back pain are among the conditions with the highest impact on global disability and account for a significant share of direct and indirect costs in health care systems worldwide [1,2]. As many as four out of five people experience low back pain in their lifetime. Furthermore, it is the leading cause of disability worldwide [1] and one of the most frequent reasons for doctor visits [3]. Costs of back pain in most countries are significant economic factors, as the estimate of more than US $90 billion annually spent on low back pain in the United States suggests [4].

The ideal care of low back pain is the subject of ongoing discussion, but therapeutic efforts that emphasize an active role of patients play a key role in the recommendations of international guidelines. Favored strategies for self-management range from exercise therapy and relaxation exercises to constant behavior change via cognitive behavioral therapy [5,6].

However, long-term adherence to any of these strategies is a crucial requirement to achieve enduring clinical benefits for patients. Traditionally, there is a lack of established means to achieve such a goal because long-term behavioral change has received little attention as a means to address chronic diseases such as pain conditions until recently [7]. Recent advances in technological adoption of mobile devices and technological advances in the field have created a promising new strategy aimed at achieving these goals. Mobile health, or mHealth, supports health care methods with the use of apps on mobile phones or tablets. The evidence for its effect is growing in numerous diseases in the form of digital therapeutics [8].

Self-management in the form of digitally supported rehabilitation is a striking candidate for digital interventions supporting patients with musculoskeletal pain [9]. Proof-of-concept studies have consistently shown promising results in terms of clinical endpoints such as pain reduction for patients engaging in the app. At the same time, these studies have shown that long-term engagement is still a challenge [10,11]. A previous retrospective analysis evaluated the effect of the Kaia app, which digitalizes multidisciplinary rehabilitation for self-management of low back pain. It showed that users benefitted from engaging in the app, while the number of users decreased to 32.2% and 17.8% of the original number of users after 8 and 12 weeks, respectively [10].

The involvement of potential users, for example in focus groups, has often been described as a potentially helpful way for early collection of user feedback during app development [12,13]. However, the life cycle of medical apps poses the opportunity to identify and address user feedback in the form of a dynamic and ongoing process even after development and release of first versions [14].

Quality management systems for medical device manufacturers according to standards, such as the European ISO 13485 or US standard 21 CFR part 820, pose a potential framework to systematically collect ongoing user feedback after product release and to document its integration into the development process. The ISO 13485 even requires manufacturers to systematically evaluate feedback with the aim of continuous product improvement [15].

Based on this background, we hypothesized that the implementation of systematically collected user feedback of early versions of the Kaia app for development of updated versions may serve as a potential tool to promote desired outcomes, such as long-term engagement in apps.

In this retrospective study of the Kaia user database, we analyze the effect of the integration of systematically collected user feedback into the development of a new software version on clinical endpoints such as the dropout rate and user-reported pain levels.

Methods

Study Design and Users

The study was designed as a retrospective analysis of the user database of Kaia. All users agreed to the collection of data presented in this publication by signing the terms and conditions for use of Kaia. All data used for the study were anonymized for statistical analysis.

The study cohort was recruited via online channels (Facebook, Google Ads, company home page) in Germany, Austria, Switzerland, the United Kingdom, and the United States. The criteria for participation were age older than 18 years, declaration of medical treatment of back pain, no history of indicators for specific causes of back pain (“red flags”), and sufficient level of physical fitness as indicated in the self-test.

The study sample consisted of all users in the user database of the company fulfilling the inclusion criteria listed subsequently.

Users included in the study had to be users of the Pro version of the app because non-Pro users are limited to 1 week of usage only. Users were divided into two groups to reflect whether they signed up to one of the first versions (version 0.x) or version 1.x (starting with 1.4) depending on whether they signed up before or after the release date of version 1.4 (users signing up before April 30, 2017 versus May 1, 2017 or later).

The study was reported to the Institutional Research Board of the Bavarian Regional Medical Council (Bayerische Landesärztekammer) and was waived because of its nonexperimental retrospective and anonymized design.

Data Collection

Data Collection of App Use

All data analyzed in this study were entered by app users as part of their self-test or in-app diaries and stored on company servers in Frankfurt, Germany. Only anonymized data were extracted from the user database via reporting criteria and no personal data were submitted for scientific evaluation.

Data Collection of Feedback

All messages from the respective channels that were collected in the quality management system (QMS) were counted and divided into patterns by two different researchers into one metafile on Microsoft Excel.

Collection of User Feedback in the Quality Management System

Kaia Health Software implemented a QMS for medical device manufacturers that complied with the ISO 13485:2012 standard in September 2016 [15]. In December 2016, the QMS was certified to fulfill the regulatory standards of the ISO 13485 by a notified body (TÜV Süd, Munich, Germany). In line with requirements from the standards of the ISO 13485, a defined analysis for evaluation of user feedback in the form of a standard operating procedure was implemented after initializing the QMS. The channels for user feedback were defined to include in-app coach chat messages, emails to the customer support, comments on app stores, and user surveys.

According to a standard operating procedure, all persons receiving user-related messages continuously monitor all messages to these channels for potential feedback and enter this into the QMS. The original messages containing the feedback are then extracted to metafiles and reviewed during a mandatory feedback meeting held at least twice a year, which systematically collects feedback and transforms it into requirements for the development of further versions of the app. The generation of requirements and evaluation of feedback comments for future versions is continuously monitored by a panel of one managing director of the company, one member of the development team and one member of the quality management team. Metadata of feedback was collected using Microsoft Excel version 12.3.6.

Description of the Intervention

Overall Description of the Intervention

Kaia (Kaia Health Software GmbH, Munich, Germany) is a multiplatform app for iOS, Android, and native Web solutions. Kaia has been on the market since September 2016 and the Kaia app is classified as a medical product class I. It is available via the App Store (iOS), the Google Play Store, or as a native website. Download of the app is free, but to remain active in the app for longer than 7 days, and to unlock the full functionality, users need to upgrade to the Pro version via an in-app purchase.

After downloading the app, there is an explicit sign-up process that consists of questions concerning the user's previous medical history, pain intensity, and fitness level. Four screens with several items deal with the detection of red-flag conditions that preclude users from exercise in the app as well as medical conditions that pose a contraindication against exercise therapy (see Assessment of Red Flags).

Conditions that require potential urgent medical attention, such as spinal infection or disk herniation associated with neurological deficits, are asked for by the condition names explicitly as well as typical findings in the patient history during the self-test. Patients that show any signs of red-flag conditions in the self-test are only permitted to use the app after they explicitly claim that they have undergone a check-up with a physician and that no contraindication exists that does not permit exercise.

Furthermore, an additional screen asks for the user's general fitness level to allocate the right exercise difficulty of physiotherapeutic exercises and once more checks for contraindications in terms of insufficient cardiac status. Depending on the results of this initial test, the exercise regimen and content are tailored to the individual user from a pool of exercises based on an algorithm.

Users record their levels of pain on a numeric rating scale (NRS; 0-10 with 10 being the worst imaginable pain) and sleep quality (0-10 with 10 being the best imaginable sleep) at the beginning of each day of therapy in a pain diary as a separate function of the app. Users progress within the app from day to day of practice and the development of user-reported pain and sleep are constantly visible on a screen. There is also a chat function in the app that connects users to a coach (physiotherapist or sport scientist) for motivational and exercise-related questions. A more detailed description of the Kaia app was previously provided [10].

Description of the Different Features of Versions

At the end of April 2017, a new version of the Kaia app (version 1.4 and later updates, 1.x) was launched. Requirements for the development of the updated version were generated using user feedback for the previous versions starting the release of Kaia as described previously. Key features of version 1.4 compared to the previous versions (0.x) are listed subsequently.

The updated content features an increased pool of each of the different exercise types (physiotherapy, mindfulness, and education). Furthermore, exercises in each of the categories are customized more clearly to the user's feedback. Physiotherapeutic exercises are subdivided into 19 different difficulty levels in version 1.4 instead of three different difficulty levels in previous versions. The physiotherapeutic exercises in the Kaia program are exercises based on the concept of lumbar motor control exercise, which has been the subject of many controlled studies [16]. The exact sequence of exercises used in the app, however, has not been scientifically validated before and is based on a consensus of several physiotherapists and sports scientists with experience in pain management programs.

Educational exercises can be chosen from a preselected pool instead of a linear flow. Mindfulness exercises offer a choice of breathing techniques and progressive muscle relaxation after completion of a predefined core set of exercises.

Updates in general app design include customizable reminders, an illustrated sign-up process, a new design, new reminder notifications, and an explanatory introductory day.

Statistical Analysis

All statistics given for feedback analysis were simple descriptive statistics (absolute numbers or relative numbers) as a fraction of the total of received feedback messages.

A Kaplan-Meier curve with a log-rank test was calculated to estimate the users still active in the app over time. Users still active within 28 days before generation of the dataset were counted as active users and censored.

To analyze the development of pain levels and body, mind, and educational exercises between the two app versions over the weeks, linear mixed effect models were computed.

We opted to use an advanced statistical model, such as the mixed model, in the unbalanced panel dataset because it allows individual-specific inference and is advantageous when dealing with missing values as is the case in this large dataset. Further details on the mixed-model approach have been previously described [17].

Differences in selective time points were also analyzed using *t* tests. For the comparisons of individual values at baseline versus follow-up, we used paired *t* tests. For comparison between groups, nonpaired *t* tests were used. Bonferroni-correction was used adjust for potential multiple test problems. All variables were represented using means and standard deviations. All statistical analyses were done using R version 3.4.3 (November 30, 2017).

Results

Analysis of User Feedback and Improvements from Versions 0.x

Overall, 110 unique points of feedback from 41 different users were logged in the QMS during the availability of versions 0.x, 55 (50.0%) of which were submitted using coach chats, 23 (20.9%) using emails, and 32 (29.1%) during user phone calls.

The most frequent parts of the app that were subject of customer feedback were physiotherapeutic exercises with 38 feedback points (34.5%), general app features with 15 feedback points (13.6%), and technical problems during app use with 15 feedback points as well (13.6%).

Of 110 feedback points, 84 (76.4%) were addressed by improvements in versions 1.x in the following release. 23.4% of improvement suggestions from users were not addressed in the development of version 1.4, either due to low priority or because the required effort was deemed too high. Of 16 individual improvements in version 1.4, the improvements addressing most feedback were: better individualization of physiotherapeutic exercises (24 points, 21.8%), new flow of push notifications (10 points, 9.1%), and new educational content and flow of educational section (9 points, 8.2%). Details are shown in Tables 1 and 2.

Sample Characteristics of Users

Overall, data of 1251 users of the Pro version were available for the study, of which 196 signed up to versions 0.x and 1055 signed up to versions 1.x. The ratio of male to female users differed significantly between the two groups (version 0.x: 58.2%, 114/196 female users; version 1.x: 49.3%, 634/1055 female users, P=.03). There was also a significant difference in the mean age of users between the two groups (version 0.x: mean 34.8, SD 11.0 years; version 1.x: mean 45.6, SD 11.6 years, P<.001). At baseline, there was no significant difference in pain levels between the two groups (version 0.x: mean 4.41, SD 1.57 NRS; version 1.x: mean 4.19, SD 1.55 NRS, P=.08).

Dropout of Users Over Time

We assessed whether users were still active in the app by signing on and finishing at least one exercise type each week following sign-up. The results for both groups are shown in a Kaplan-Meier-plot (Figure 1; Table 3). A log-rank test revealed no significant difference in dropout for users of the two groups (P=.31), indicating a comparable rate of dropouts over time for both groups, whereas many users in the version 1.x cohort had to be censored because they were still counted as active users by definition.

Completion of Exercises by Type

To assess whether there was a difference in the rates of exercise completion, we analyzed the rate of weekly units per user and week for each of the different types of content (physical and mindfulness exercises, educational units).

Table 1. Domains of app affected by feedback.

Domain	Messages, n (%)
Physiotherapeutic exercises	38 (34.5)
Mindfulness exercises	12 (10.9)
Educational content	9 (8.2)
Notifications	10 (9.1)
Pain diary and self-test	4 (3.6)
Chat	1 (0.9)
Design features	2 (1.8)
General app features	15 (13.6)
Technical problems	15 (13.6)

Table 2. Improvements in version 1.x with number of feedback issues fixed by individual improvements.

Improvement	Feedback messages fixed by improvement, n (%)
Not implemented	26 (23.6)
New educational content	9 (8.2)
New in-app flow to access content	4 (3.6)
Audio files stored locally on client	2 (1.8)
New content for physiotherapy	3 (2.7)
New flow for push notifications	10 (9.1)
Better adaptation of physiotherapeutic exercises to individual user	24 (21.8)
New concept for daily renewal of content	4 (3.6)
Increase stability on Android devices with testing on several devices	1 (0.9)
New audio content for physio exercises	5 (4.5)
Show more clearly how app adapts to user feedback	2 (1.8)
Redesign self-test questions	1 (0.9)
Real-time synchronization of data	6 (5.5)
Record new and extended content for mindfulness exercises	6 (5.5)
Fix password reset option	1 (0.9)
Exchange library for video playback	5 (4.5)

Figure 1. Kaplan-Meier plot of dropout of users in percentage over time in weeks.

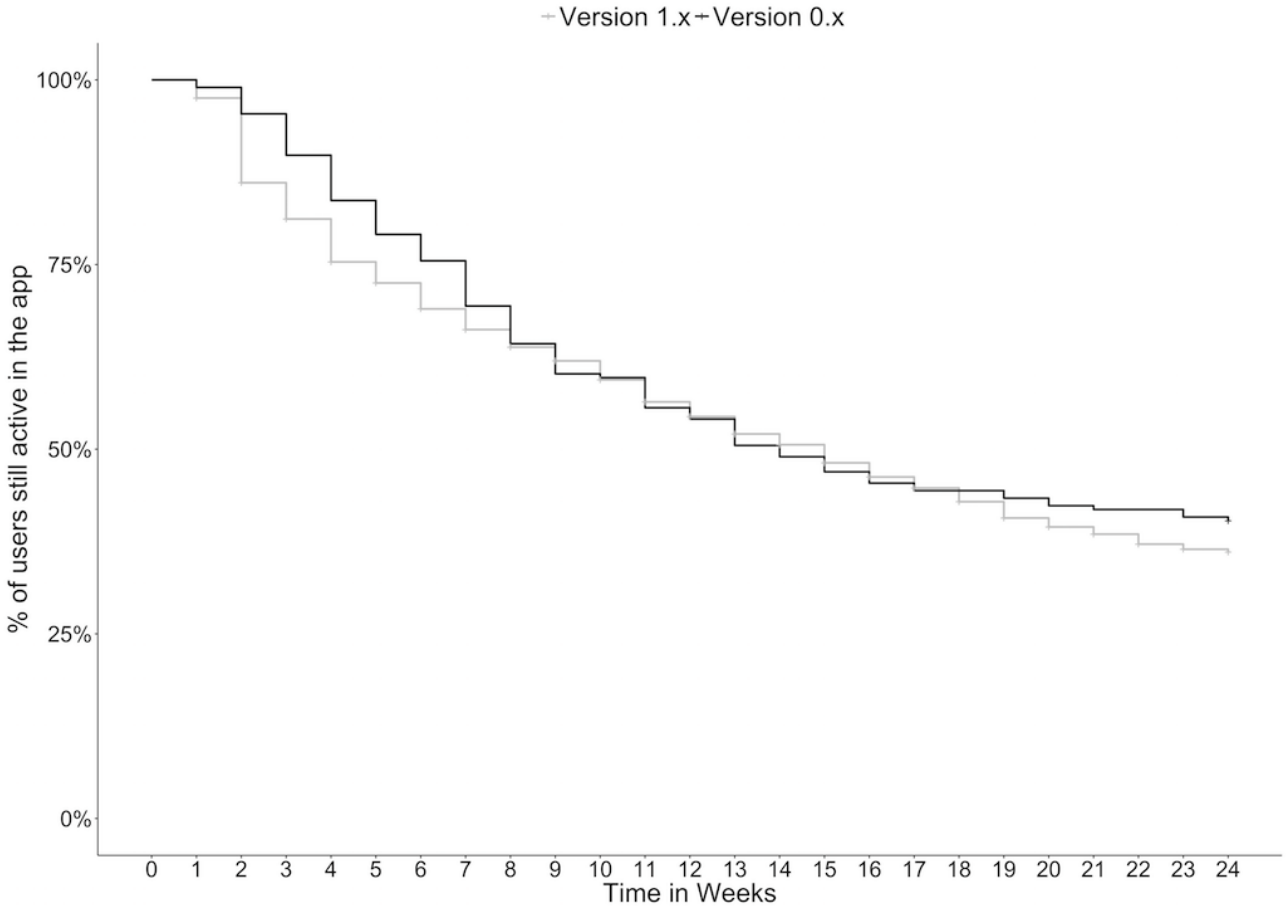

Table 3. Weekly active users, dropouts, and censored users for both groups.

Week	Versions 0.x			Versions 1.x				
	Active users, n	Dropouts, n	Users still active, %	Active users, n	Dropouts, n	Censored, n	Cumulative censored, n	Users still active, %
1	196	2	99.0%	1055	26	8	8	97.5%
2	194	7	95.4%	1021	120	58	66	86.1%
3	187	11	89.8%	843	48	42	108	81.2%
4	176	12	83.7%	753	54	37	145	75.4%
5	164	9	79.1%	662	25	38	183	72.5%
6	155	7	75.5%	599	29	29	212	69.0%
7	148	12	69.4%	541	22	17	229	66.2%
8	136	10	64.3%	502	18	38	267	63.8%
9	126	8	60.2%	446	13	23	290	62.0%
10	118	1	59.7%	410	17	35	325	59.4%
11	117	8	55.6%	358	18	28	353	56.4%
12	109	3	54.1%	312	11	23	376	54.4%
13	106	7	50.5%	278	12	16	392	52.1%
14	99	3	49.0%	250	7	16	408	50.6%
15	96	4	46.9%	227	11	15	423	48.2%
16	92	3	45.4%	201	8	7	430	46.2%
17	89	2	44.4%	186	6	11	441	44.7%
18	89	0	44.4%	169	7	7	448	42.9%
19	87	2	43.4%	155	8	12	460	40.7%
20	85	2	42.3%	135	4	10	470	39.5%
21	83	1	41.8%	121	3	4	474	38.5%
22	83	0	41.8%	114	4	3	477	37.1%
23	82	2	40.8%	107	2	8	485	36.4%
24	80	1	40.3%	97	1	96	581	36.1%

A mixed-model analysis revealed a significant difference between groups for all types of content (physical exercises: $F_{1,1249}$=52.303, P<.001; mindfulness exercises: $F_{1,1249}$=28.62, P<.001; educational units: $F_{1,1249}$=42.891, P<.001), indicating that users in the 1.x group completed more of each unit in each category. The amount of completed units for each type of content for each week is shown in Figures 2-4.

This finding was also confirmed when comparing mean values of each of the types of content averaged over the 24 weeks with a paired t test (physical exercises: version 0.x mean 1.99, SD 1.61 units/week vs version 1.x mean 3.15, SD 1.72 units/week, P<.001; mindfulness exercises: version 0.x mean 1.36, SD 1.43 units/week vs version 1.x mean 2.42, SD 1.82 units/week, P<.001; educational content: version 0.x mean 1.51, SD 1.42 units/week vs version 1.x mean 2.71, SD 1.89 units/week, P<.001).

In-App Reported Pain Levels

To see, whether the increase in completed units translated into a significant benefit in terms of the clinical endpoint of pain as reported on the NRS, we assessed pain levels over time for both groups. A mixed-model analysis showed a significant difference between groups that was indicative of an increased reduction in terms of user-reported pain levels in the 1.x group ($F_{1,1233}$=7.084, P=.008). There was a decrease in pain levels from baseline to 24 weeks in both groups (mean 4.4, SD 1.5 at baseline vs mean 3.48, SD 2.1 at week 24 for version 0.x; mean 4.2, SD 1.6 at baseline vs mean 3.0, SD 2.1 at week 24 for version 1.x; P=.29). The course of user-reported pain levels over time is depicted in Figure 5 and Table 4.

Figure 2. Mean physiotherapeutic exercises per week for each content type over time for both groups.

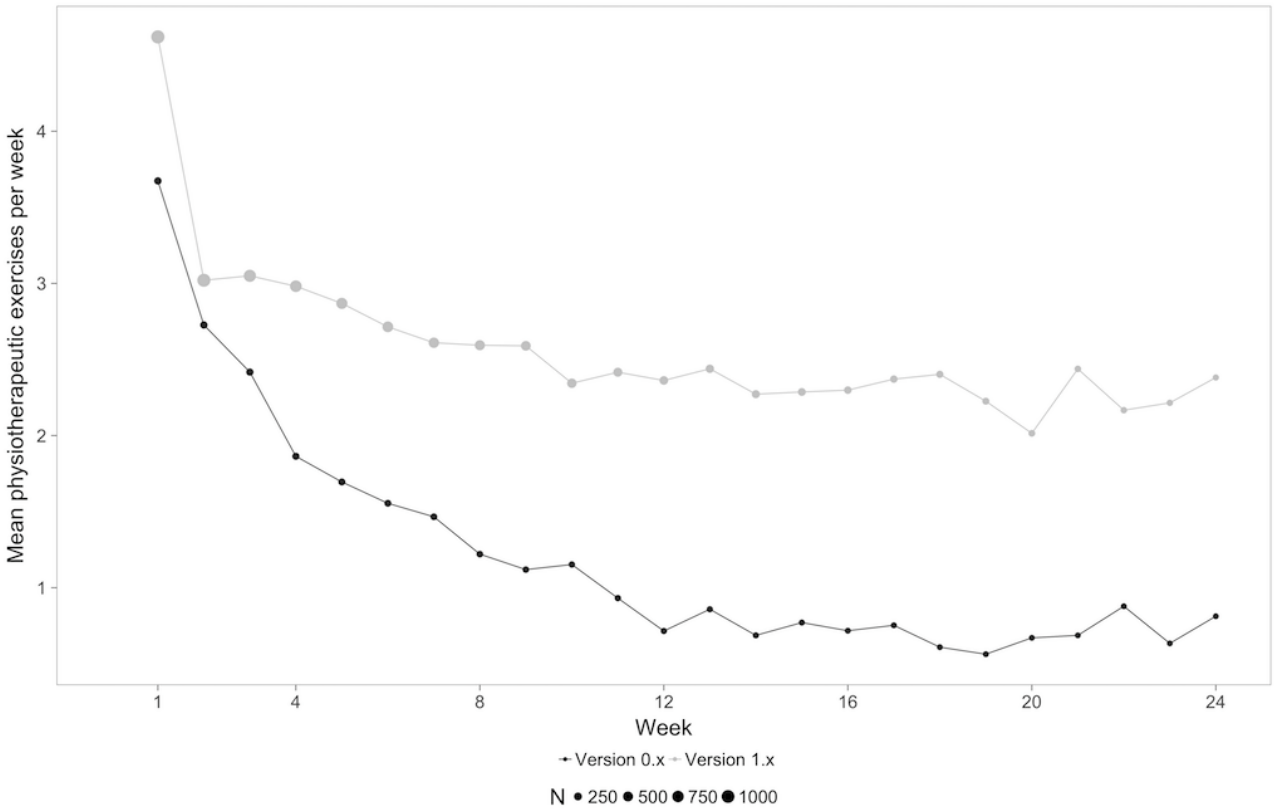

Figure 3. Mean mindfulness exercises per week for each content type over time for both groups.

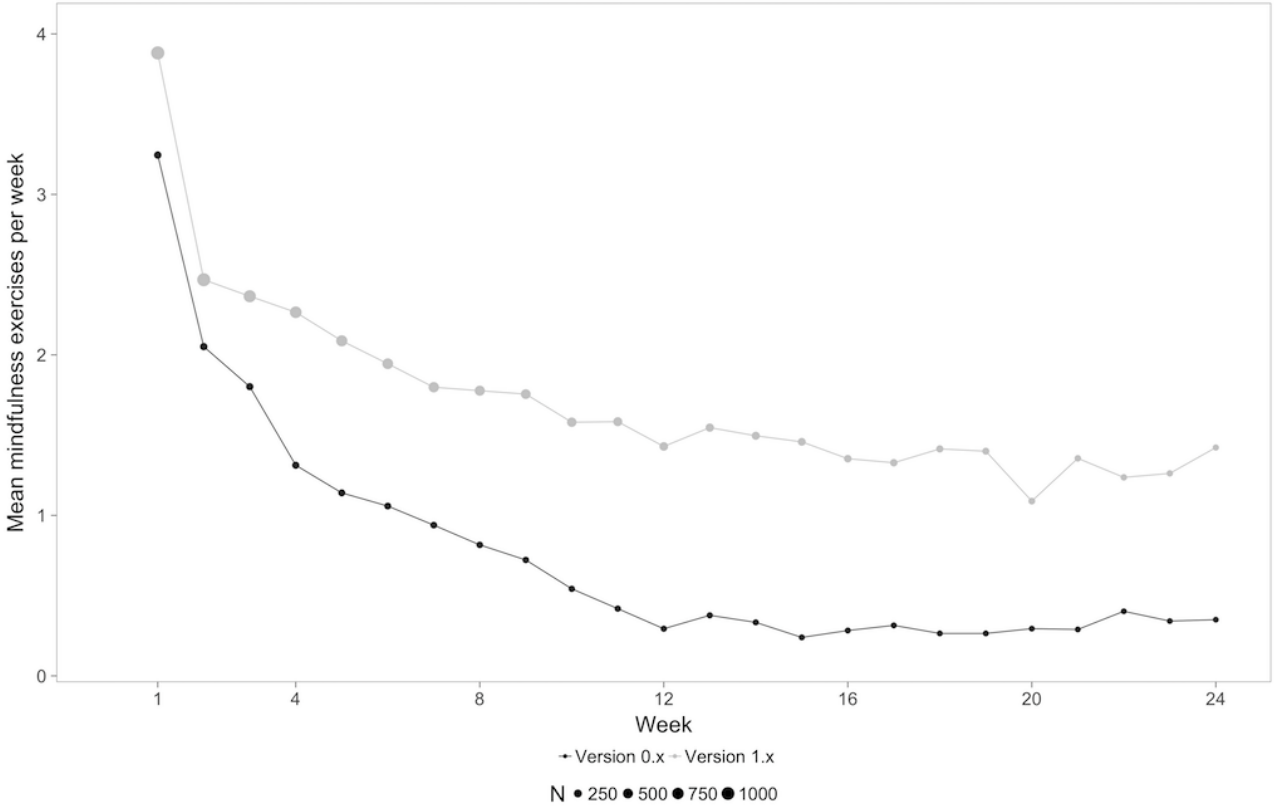

Figure 4. Mean educational exercises per week for each content type over time for both groups.

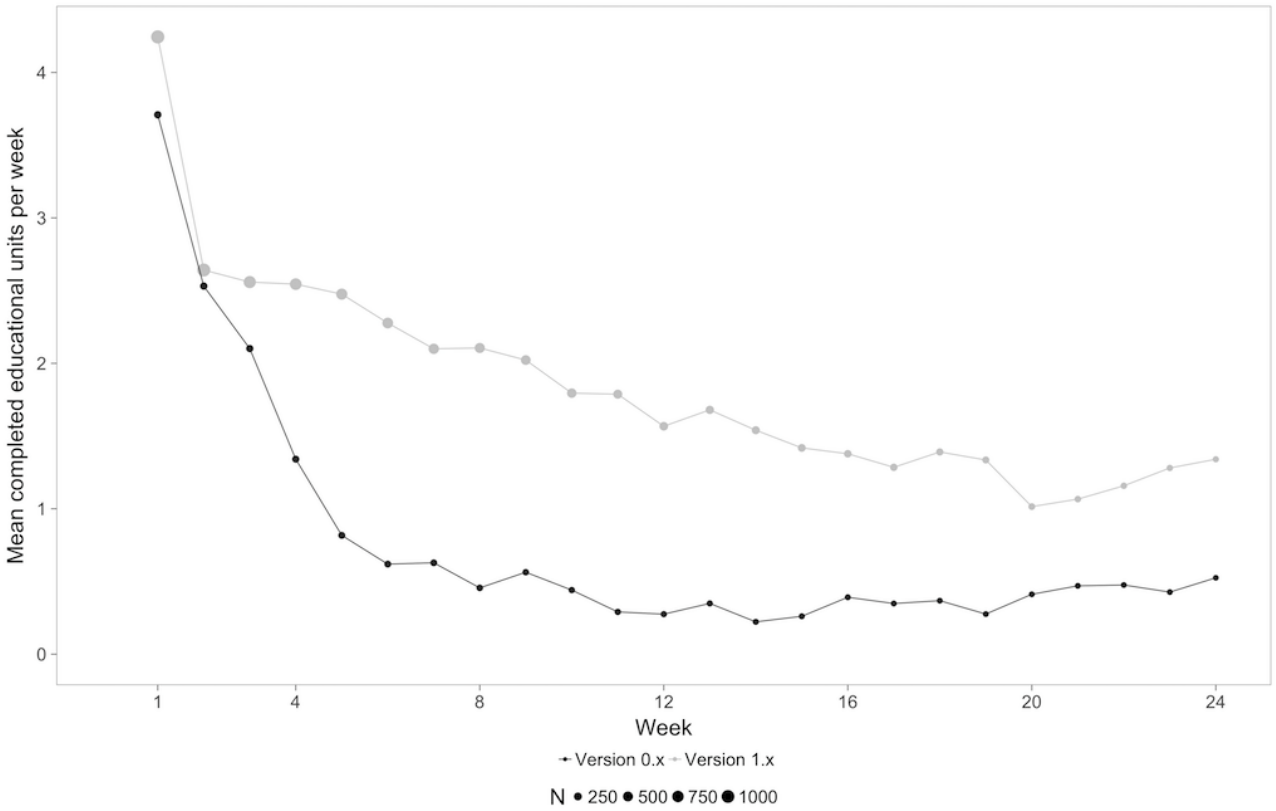

Figure 5. In-app reported pain levels of users on the NRS for both versions over time (weeks).

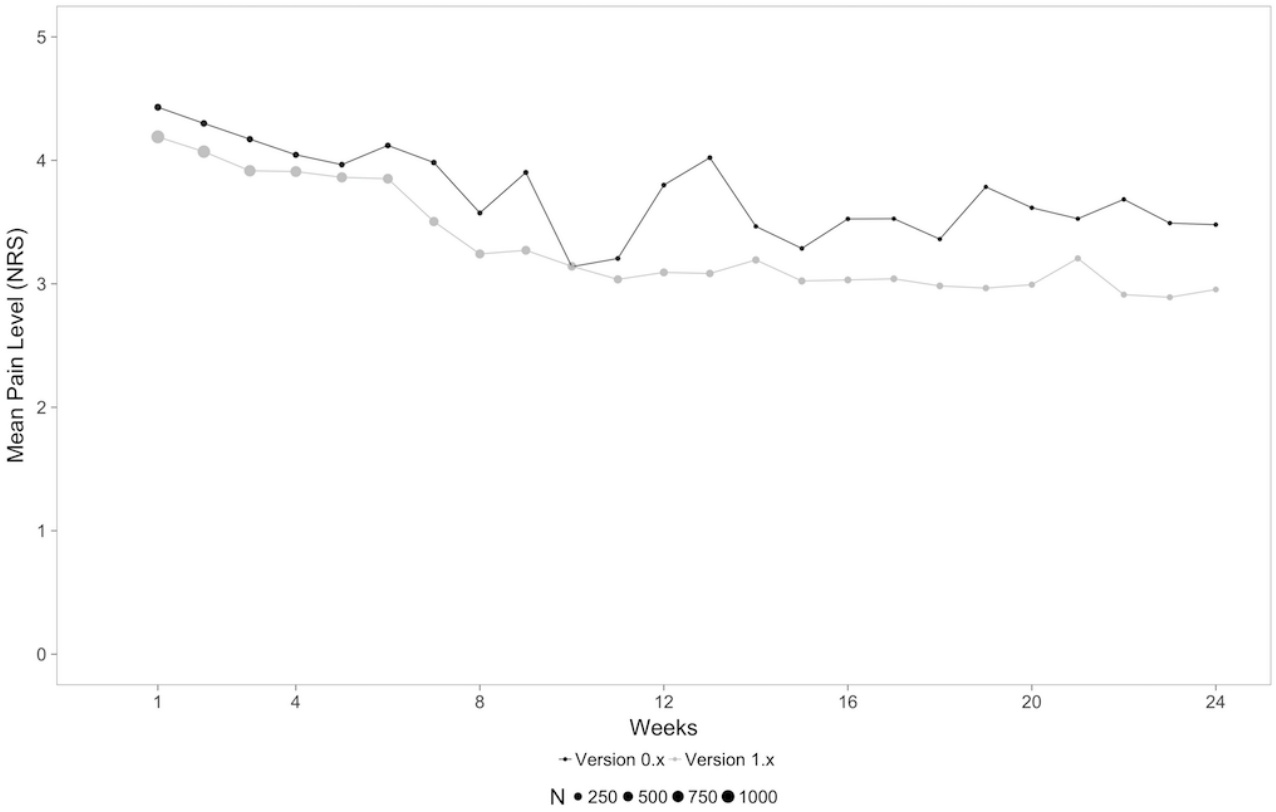

Table 4. Mean weekly in-app reported pain levels at baseline and at 12 and 24 weeks.

Week	Version 0.x (n=158), mean (SD)	Version 1.x (n=998), mean (SD)	*P* value[a]
1 (baseline)	4.43 (1.50)	4.19 (1.55)	.06
12	3.80 (2.17)	3.09 (1.78)	.07
24	3.48 (2.09)	2.95 (2.17)	.29

[a]*P* values are for nonpaired *t* test between groups.

Discussion

Findings of the Study

The development of a new version of an app integrating user feedback for self-management of low back pain can increase app use significantly and thus increase clinical benefit in terms of self-reported pain levels. The analysis of user data in this study reveals that users signing up for the updated version of the Kaia app did not remain active in the app for longer periods of time, but engaged in the individual exercises more often than users of the previous version. Of note, this translated into an increased benefit concerning pain levels as a clinical endpoint. Therefore, within the limitations of this retrospective report of user data, we propose that implementing systematically collected user feedback can serve as an effective measure to actively engage users in an app for self-management and even improve the clinical endpoint of user-reported pain.

The dropout rate in this study was significantly lower than that reported in a previous study on the Kaia app [10]. However, even though dropout rates improved in comparison to previous reports, they remain an incentive for further improvement of the Kaia app. In addition to remaining feedback from users still not accounted for in version 1.x, there are other factors potentially explaining the dropouts. On the one hand, the app features no long-term rewards or group interaction that may further increase retention. On the other hand, a prospective study design with inclusion in centers and defined follow-up visits may also contribute to higher retention in studies of other interventions, but are not present in the real-world data of this study.

This most likely reflects the fact that many users, who were listed as inactive in the previous study, became active again afterwards and the user retention improved with the new version of the app. Of note, the different duration of the observational period for both groups also introduces a potential bias in this analysis because users in the version 0.x group progressed over a longer period of time in the app. Nevertheless, the short-term rate of dropouts is comparable to observed rates for other interventions to treat musculoskeletal pain conditions with apps in a recent study [18]. The midterm retention at 24-weeks in this study shows that a significant proportion of users still engage in the app and that completion of body exercises per week only slightly decreases in app users following the first few weeks.

The pattern of users remaining engaged in the app also decreasing their pain levels on the NRS and retaining that benefit over time has been described before in a number of noninterventional studies evaluating the effect of digital interventions for rehabilitation of pain conditions [10,11,18]. The follow-up of this study is comparatively long and indicates that the self-management strategies conveyed by the Kaia intervention may indeed induce stable pain reduction well above the minimal clinically important difference for the NRS for chronic orthopedic pain conditions [19,20] with an absolute improvement of more than one point on the NRS and almost 30% relative improvement, which almost reaches the threshold for “much improved” musculoskeletal pain conditions [20].

However, given the limitations of this study, this finding will need to be reproduced by prospective studies. The authors would like to point out that, although current meta-analysis articles have found little evidence for a clinical effect of digital interventions in low back pain, the interventions in these reports have mostly consisted of cognitive behavioral therapy that was delivered via Web interfaces. None of the interventions in those studies focused on a multidisciplinary rehabilitative approach delivered via mHealth; therefore, they did not make use of the full potential of digital interventions in terms of content or design [21,22].

Digitalized self-management strategies offer a promising novel strategy for long-term patient engagement in chronic diseases. Retention and continuous behavioral change are crucial for this goal [8]. Some features, such as the inclusion of health care professionals, individualization of the app, and user-friendly design, have been found to increase the effectiveness of digital interventions for this goal in a recent review [23].

Integrating users in the design of apps and the continuous improvement process have been recognized as a crucial factor for app adoption. Various techniques, such as participatory design, have been developed for early user integration in development [24].

Many reports have previously described the collection of the feedback of prospective users in early app development or during focus groups [12,13,25]. In case of multidisciplinary concepts for disease management of musculoskeletal pain conditions, potential users interviewed in focus groups have indicated motivational traits, an introductory feature, and individualization to be important features [13]. Notably, all these topics were also mentioned as potential improvements by users of Kaia.

Compared to focus groups and other structured interviews, the collection of real-world feedback of users, as used in this study, offers many advantages as an alternative approach for participatory design. Most importantly, this approach makes use of the rapid development cycles of health apps in which potential improvements can be integrated quickly. Furthermore, potential users have often already spent a significant amount of

time with the software at home, where the software is intended for use. Therefore, feedback collected from real-world settings is likely to better reflect the problems encountered by users in their everyday patient journeys using digital interventions.

Another study has evaluated user preferences for desirable features of health apps and found structure, ease of use, personalized features, and accessibility to be the most important features for users [26]. Indeed, user feedback concerning the Kaia app dealt with many of these issues. Redefinition of structure, personalization of content in each of the categories, and simplification of app use were among the most frequent user requests, and all were addressed with new content or features in the novel 1.4 version.

Limitations

Limitations of this study arise for the largest part from the design as a retrospective cohort study. This design makes the study vulnerable for potential bias in the form of selection bias. There is also a significantly different demographic composition of the two cohorts compared in the study. Also, by definition, it is difficult to compare different types of cohorts with one another when no randomization has taken place. The methodology to compare cohorts with different observational periods makes the Kaplan-Meier plots less representative and introduces a potential bias that is likely to overestimate the dropout rate in the group with the shorter observational period. Because this analysis contains only very few users older than 60 years of age, this study cannot draw any conclusions about the efficacy and retention of the Kaia app in a population older than 60 years. This is a limitation of this study that should be addressed by prospective studies in selected populations of users older than 60 years.

Conclusions

This study indicates that, given the limitations of retrospective cohort studies, the implementation of systematically collected user feedback during development of updated versions can contribute to improvements in terms of use frequency and potentially even clinical endpoints such as pain level. The clinical efficacy of the Kaia app needs to be validated in prospective controlled trials to exclude bias.

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Conflicts of Interest

SH is an employee of Kaia Health Software and receives a salary and options. AP and IC are employees of Kaia Health. BU and AL declare no conflicts of interest.

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Abbreviations

NRS: numeric rating scale
QMS: quality management system

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Original Paper

Visualizing Collaboration Characteristics and Topic Burst on International Mobile Health Research: Bibliometric Analysis

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Abstract

Background: In the last few decades, mobile technologies have been widely adopted in the field of health care services to improve the accessibility to and the quality of health services received. Mobile health (mHealth) has emerged as a field of research with increasing attention being paid to it by scientific researchers and a rapid increase in related literature being reported.

Objective: The purpose of this study was to analyze the current state of research, including publication outputs, in the field of mHealth to uncover in-depth collaboration characteristics and topic burst of international mHealth research.

Methods: The authors collected literature that has been published in the last 20 years and indexed by Thomson Reuters Web of Science Core Collection (WoSCC). Various statistical techniques and bibliometric measures were employed, including publication growth analysis; journal distribution; and collaboration network analysis at the author, institution, and country collaboration level. The temporal visualization map of burst terms was drawn, and the co-occurrence matrix of these burst terms was analyzed by hierarchical cluster analysis and social network analysis.

Results: A total of 2704 bibliographic records on mHealth were collected. The earliest paper centered on mHealth was published in 1997, with the number of papers rising continuously since then. A total of 21.28% (2318/10,895) of authors publishing mHealth research were first author, whereas only 1.29% (141/10,895) of authors had published one paper. The total degree of author collaboration was 4.42 (11,958/2704) and there are 266 core authors who have collectively published 53.07% (1435/2704) of the total number of publications, which means that the core group of authors has fundamentally been formed based on the Law of Price. The University of Michigan published the highest number of mHealth-related publications, but less collaboration among institutions exits. The United States is the most productive country in the field and plays a leading role in collaborative research on mHealth. There are 5543 different identified keywords in the cleaned records. The temporal bar graph clearly presents overall topic evolutionary process over time. There are 12 important research directions identified, which are in the imbalanced development. Moreover, the density of the network was 0.007, a relatively low level. These 12 topics can be categorized into 4 areas: (1) patient engagement and patient intervention, (2) health monitoring and self-care, (3) mobile device and mobile computing, and (4) security and privacy.

Conclusions: The collaboration of core authors on mHealth research is not tight and stable. Furthermore, collaboration between institutions mainly occurs in the United States, although country collaboration is seen as relatively scarce. The focus of research topics on mHealth is decentralized. Our study might provide a potential guide for future research in mHealth.

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KEYWORDS

collaboration characteristics; topic bursts; international mobile health; mHealth; telemedicine; bibliometric analysis; bibliometrics; research trends

Introduction

Background

With continued economic and societal development worldwide, the traditional system of health care delivery has increasingly failed to satisfy human demand in providing efficient health care services. It should be noted that numerous constraints and barriers exist to providing high-quality, accessible, and timely health services, especially in low-resource settings [1-3]. In this context, mobile technologies have been introduced into health care service delivery, and, subsequently, mobile health (mHealth) has emerged, changing the situation by offering support via mobile communication technologies [4].

mHealth is an umbrella term that encompasses areas of networking, mobile computing, medical sensors, and other communication technologies within health care [5]. The first occurrence of the term "mHealth" in literature was in the special issue entitled "Unwired e-med" on wireless telemedicine systems, published in 2000 [6]. The World Health Organization Global Observatory for eHealth defines mHealth as "Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. mHealth involves the use and capitalization on a mobile phone's core utility of voice and short messaging service (SMS) as well as more complex functionalities" [7]. Obviously, mHealth technologies can facilitate more accessible and affordable health care to all; it has presented unprecedented advantages over the past years [8]. Subsequently, it has attracted great attention from scholars, experiencing rapid development in recent years, and has become a hot topic in the health care field.

Given the importance of mHealth, some scientific researchers have focused on reviewing related literature to identify the characteristics and status of mHealth research in recent years. However, much of this effort has only considered specific subfields of mHealth, with conclusions being drawn from descriptive analysis and systematic reviews. For example, some reviews have focused on mobile health apps [9,10] related to the most prevalent conditions (eg, headache disorders [11], heart failure [12], HIV/AIDS [13]), and short message service (SMS) text messaging for health improvement [14-16]. Other reviews have concentrated on the analysis of mobile health technologies [17] and mobile devices for assessment of physical activity [18]. In addition, some scholars have summarized lessons learnt from mHealth trials and studies using peer-reviewed journals, websites, and key reports [19]. However, a review of previous related literature shows some research limitations. There have been few papers that have focused on the bibliometric perspective of mHealth research, which refers to methods of analyzing the data of scientific literature quantitatively, to gain knowledge of the meta-information related to the research in question [20,21]; the combined use of methodologies that give information on different aspects of scientific output is generally recommended [22]. In addition, discussion relating to the collaborative status and overall topic burst still remains relatively scarce.

Objectives

The aim of this study, therefore, was to address these limitations by conducting a comprehensive exploration and analysis into the worldwide mHealth field, using quantitative analysis. Through this approach, major problems can be identified and raised. That is, what are the external characteristics of mHealth research, such as the growth in published literature and journal distribution? What is the status of collaboration between scholars in the field and trends in international mHealth research at the author, institution, and country level? What is the evolutionary process of the term bursts based on the high-frequency and highly bursting keywords set? What are the research topic bursts? The answers to these questions will not only supplement the previous research work completed but also contribute to further research on international mHealth.

Methods

Data Collection

In this study, we identified publications that are indexed in the Thomson Reuters Web of Science Core Collection (WoSCC) database, namely, the Science Citation Index Expanded, the Social Sciences Citation Index, and the Emerging Sources Citation Index. As WoSCC comprised most high-quality literature, and being updated continuously and dynamically, it has been identified as being most appropriate for the bibliometric analysis in this study [23].

To retrieve mHealth-related publications, as fully as possible, we formulated the following search strategy, on the basis of the above definition and reviews on mHealth (for further details on the search strategy employed, see Multimedia Appendix 1): #1 mobile health, #2 mHealth apps, #3 TS=((“mobile technolog*” OR “mobile device*”) AND “health*”), #4 TI=((“mobile phone*” OR “tablet comput*” OR “personal digital assistant*”) AND “health*”), #5 TI=(“mobile unit*” OR TI=“mobile health unit*”), #6 (#1 OR #2 OR #3 OR #4) NOT #5. Moreover, “document type” was limited to paper. The time span of publication was confined from 1985 to 2016.

On the basis of the above search strategy and restrictions, a total of 2902 bibliographic records were identified and downloaded on December 28, 2016. To perfect the research, the main inclusion and exclusion criteria were formulated after 2 researchers independently reviewed and evaluated the 500 pilot bibliographic records. The inclusion criteria were as follows: (1) the contents of the papers primarily concentrated on mobile health, and (2) all study designs. The exclusion criteria were as follows: (1) the record related to book review and notifications, instead of being a regular paper; (2) the content of the research focused on animal mobile health (eg, cattle [24]), rather than being focused on human-oriented mobile health; and (3) the

study mainly concentrated on mobile units (eg, mobile health facilities [25]), rather than integration of Information and Communication Technologies (ICT) with health care services. In this process, the titles, abstracts, and keywords of the publications in these records were screened with reference to the research objective. Any discrepancies or disagreements were discussed until consensus was reached. Then, 1 researcher screened the remaining records using the above selection criteria. Finally, a total of 198 irrelevant records were manually removed. In total, 2704 bibliographic records published from 1997 through 2016 were obtained for subsequent bibliometric analysis, so as to cast light on collaboration characteristics and research topic burst in the field of international mHealth. The entire selection process of bibliographic records on mHealth research is shown in Figure 1.

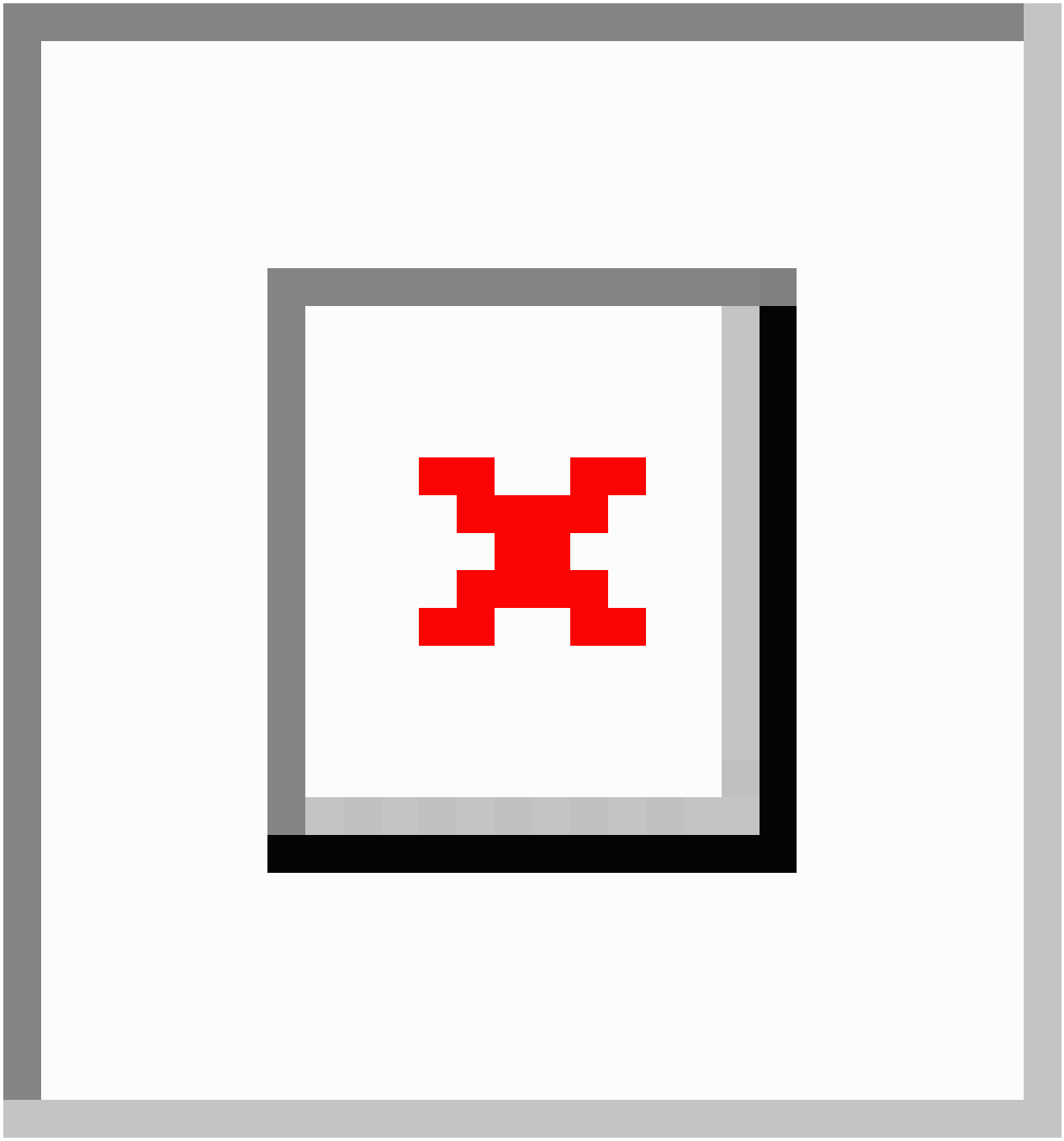
Design of Data Analysis Method

Similar to other bibliometric studies [26], a variety of analytic indicators have been employed in this research. Generally, bibliometric analysis can be used to depict and predict research trends and the direction of a given topic in a given field [27]. In this study, we analyzed literature distribution, including the growth in mHealth literature and journal distribution, using Bibliographic Item Co-occurrence Mining System (BICOMS) [28] and MS Excel 2010. In addition, core journals were identified, which normally refers to the most important journals with higher citation counts. That is, these core journals publish papers more frequently at a high academic level, which reflect the latest research findings, frontier research status, and developing trends of the subject; they are typically paid more attention by scientific researchers in the same research field.

In this research, the total number of published papers is regarded as an index of quantity of research productivity, whereas citation frequency is considered as an index of quality of research productivity. Therefore, the total local citation score (TLCS) and the total global citation score (TGCS) were calculated in this study. TLCS refers to the number of times that a set of papers included in a collection has been cited by other papers within the same collection, whereas TGCS refers to the number of times that a set of papers included in a collection has been cited in the WoSCC [29]. The average global citation score (AGCS) is the mean value of TGCS, which also indicates the average number of citations that papers in the mHealth field receive. Similarly, the average local citation score (ALCS) is the mean value of TLCS, which indicates the average number of citations that papers within the collection receive. In general, TLCS and TGCS have been the key indicators capable of evaluating the relevance of each research paper in our sample [30]. It is obvious that TLCS and TGCS can help us identify the most significant work on the topic. However, it should be noted that TLCS presents the important papers for a chosen research area, whereas TGCS mainly displays the effects of the papers related to a chosen research area on the papers in the WoSCC.

On the basis of the above indicators, HistCite, an analytical and visualization tool [31], was employed to analyze the research productivity of authors, institutions, and countries. Generally speaking, country collaboration, institution collaboration, and author collaboration are 3 primary forms of scientific collaboration. Coauthorship is fundamental in country collaboration and institution collaboration [32].

Figure 1. Selection process for obtaining bibliographic records on mHealth research.



The rate of collaborative papers published is defined as the proportion of collaborated papers to the total number of papers, whereas the degree of author collaboration refers to the average number of authors per paper during a certain period of time; both indicators reflect the trend in collaborative research, to some extent [33].

CiteSpace II [34] was used to directly visualize the 3 collaboration relationships. Visual maps generated by CiteSpace are composed of nodes and links. The node displays in a purple circle; nodes normally represent the author, institution, country, and so on, whereas links represent cocitation or co-occurrence between these nodes. On the basis of Chen's definition [35], the higher citation and centrality the node has, the larger impact the node has in the cocitation map. By studying these clusters and the relationships between them, valuable information can be drawn. Finally, 4 stages were completed, as follows, regarding the analysis of research hotspots.

First, we calculated the frequencies of each keyword and created a coword matrix using BICOMS. When we considered equivalent relations between keywords, a total of 5543 keywords were identified from the publications and subsequently merged to obtain more precise results based on the following 3 principles: (1) merging of some keywords, which are entry terms, into corresponding Medical Subject Headings terms using PubMed (eg, "mobile phone," "cellular phones," and "cellular telephone" were merged into "cell phones"); (2) replacement of the full keyword into its acronym (eg, "Personal Digital Assistant" was replaced with "PDA"); and (3) merging of

singular and plural keywords (eg, “mobile technology” and “mobile communication” were changed to “mobile technologies” and “mobile communications,” respectively). Then, 139 keywords, with the frequency not less than 10, were chosen to generate a 139 × 139 co-occurrence matrix. It should be noted that the data in diagonal cells were treated as missing data, and the values of nondiagonal cells were the co-occurrence frequency [36].

Second, burst detection was conducted on the cleaned bibliographic records, and a temporal bar graph for keywords was drawn. Kleinberg’s burst detection algorithm [37], which can identify sudden increases or “bursts” in the frequency of words used over time, is effective in detecting bursts in keyword popularity. We employed Science of Science (Sci2) [38], which can implement such algorithm, to detect the burst terms in the cleaned bibliographic records and calculate the burst strength which depicts the intensity of the burst, that is, how great the change is in the word frequency that triggered the burst. In total, 228 keywords with a burst strength not less than 1 were generated. However, these keywords only represented the possibility to be core keywords and needed to be further selected, according to the keyword frequency that reflects the degree of concern to some extent. The higher the number of keyword frequency, the more likely it is to become a hot topic in future. We further computed the intersection of the high-frequency (frequency≥10) keywords set and highly bursting (burst strength≥1) keywords set [39], so as to reduce the interference caused by low frequency keywords. As a result, 71 keywords were obtained. Next, a temporal visualization map for the 27 keywords with a frequency not less than 10 and burst strength not less than 2 was drawn using Sci2. Each row record is represented as a horizontal bar with a specific start and end date, with a corresponding keyword label on its left side in the temporal bar graph visualization. The area of each bar encodes a numerical value of burst strength.

Third, hierarchical cluster analysis was conducted, based on the 71 × 71 co-occurrence matrix. At first, we removed any rows or columns that did not correspond to any 1 of the 71 keywords from the 139 × 139 co-occurrence matrix. Finally, the 71×71 co-occurrence matrix was formed and then transformed into Pearson’s correlation matrix, using IBM SPSS Statistics 19. In this matrix, every value in the cell indicates the similarity of each keyword pair [40]. Considering the discrete matrix data, a dissimilarity matrix was created. Subsequently, hierarchical cluster analysis was performed using SPSS 19.0 [41], and the results display directly the keywords cluster.

Finally, the visualization map and its network characters were obtained by analyzing the original Pearson’s correlation matrix, using MS Excel 2010 and Ucinet6.6 [42,43]. The density of the network was calculated, with a social network map being drawn, using Ucinet6.6 and Netdraw (embodied in the Ucinet tool), to verify the result above. Furthermore, the relative size of nodes is proportional to the frequency of keywords, whereas the relative thickness of lines is drawn proportionally to the correlation between keywords [44].

Results

Literature Distribution

Growth of Literature

On the basis of the above search strategy and the cleaned data obtained, we found that the earliest paper on mHealth, indexed by WoSCC, was published in 1997. The publication output of mHealth-related research, from 1997 to 2016, is presented in Figure 2, indicating that the number of papers concerning mHealth research has risen yearly and produced from 2 in 1997 to 765 in 2016. In terms of publication language, most (98.08%, 2652/2704) are written in English, followed by German, Portuguese, and Spanish. Since the beginning of 2012, it should be recorded that the number of mHealth-related publications has increased considerably.

The cumulative annual number of publications has continually grown from 2 to 2704 (shown in Figure 3). A literature logical growth curve was obtained by a direct fit to the equation: $y = 3913.14 / (1 + 1929.18e^{-0.39t})$, ($R^2$>0.987), where y is the cumulative annual number of papers and t is the number of years since 1997. The time of the inflection point of the growth curve is: $t = ln(1929.18) / 0.39 = 19.4 \approx 20$ (ie, 2016 - 1997 + 1).

Figure 2. Number of publications related to mHealth in Web of Science Core Collection (1997-2016).

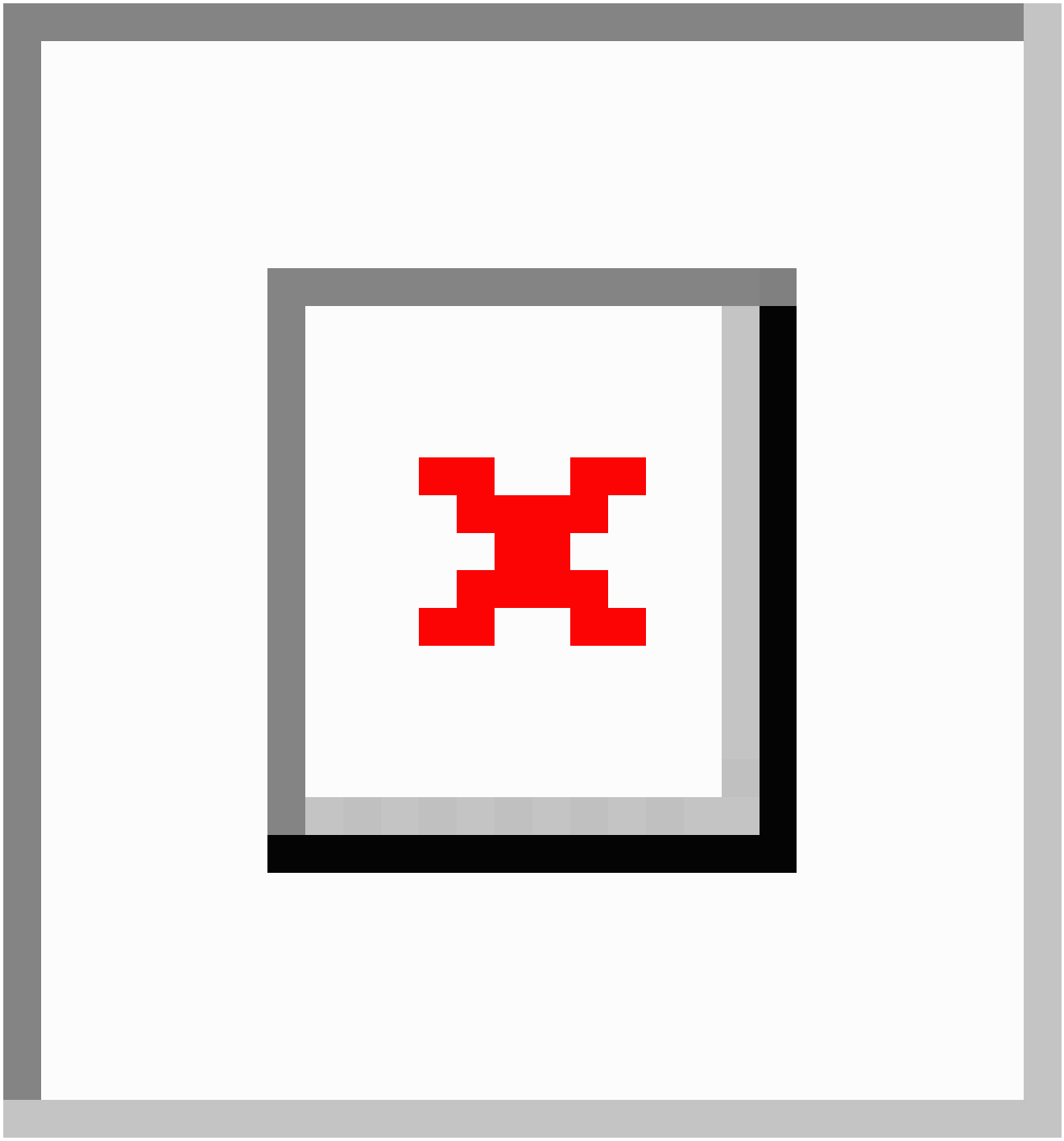
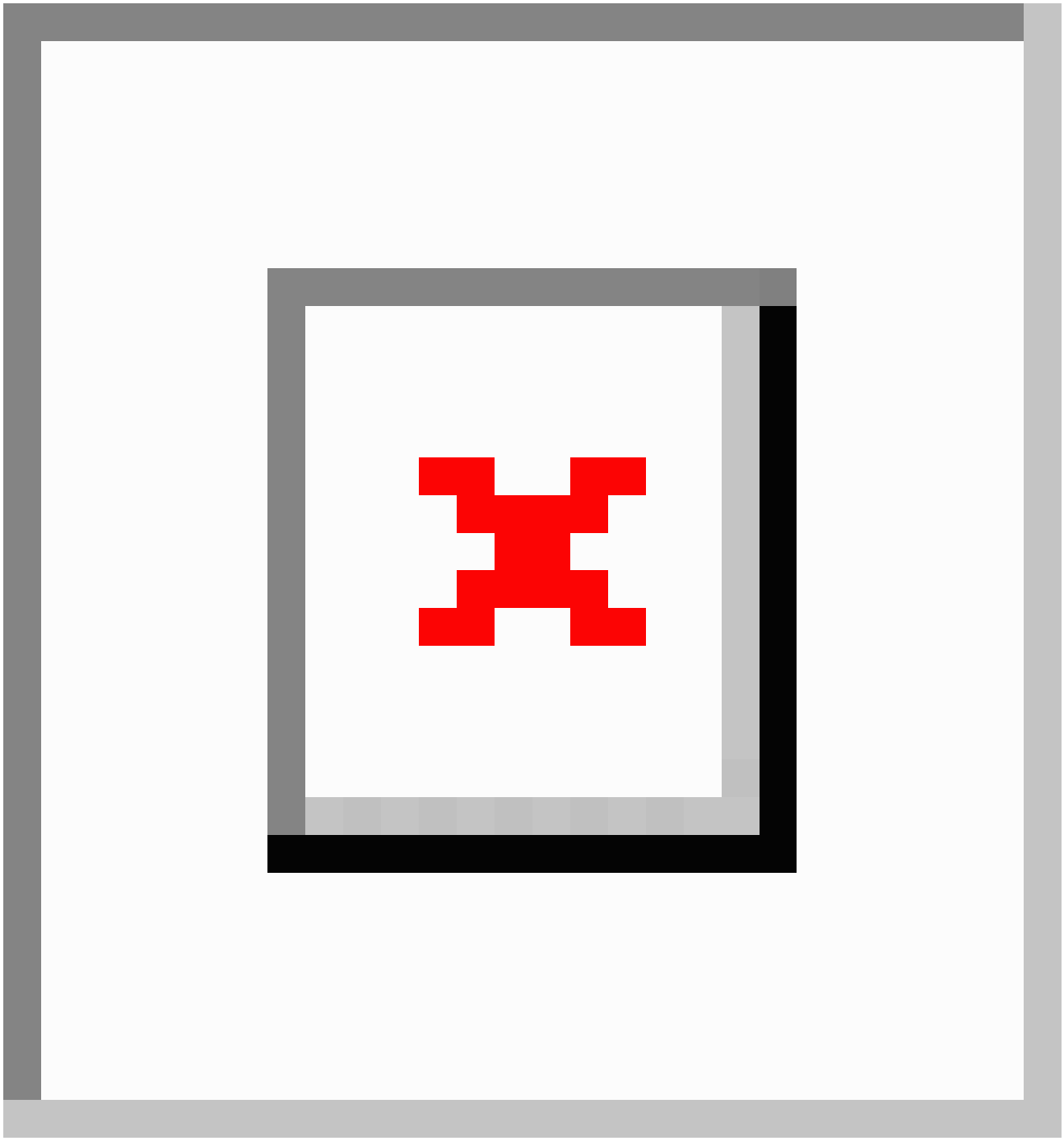


Figure 3. The relationship between cumulative number of publications and years since 1997.



Journal Distribution

From 1997 to 2016, research relating to mHealth has been published in 1008 journals. These journals were listed in a descending order by the productivity of publication and then divided into a nucleus of journals and 2 following groups, containing approximately the same number of publications as the nucleus. Note, the "Journal of Medical Internet Research" is the most productive journal, publishing a total of 125 papers on mHealth research.

As shown in Table 1, the nucleus, covering the Top 18 journals (1.79%, 18/1008), has 853 papers, accounting for 31.55% of all 2704 papers. The relationship among the number of journals in the nucleus and the 2 succeeding zones is approximately $1:7:7^2$; this follows Bradford's Law of scattering [45].

Table 1. Top 18 journals (by article count) on the topic of mobile health (mHealth).

No.	Top journals	IF[a] (2015)	IF (2016)	Articles, n (%)	Cumulative percentage
1	*Journal of Medical Internet Research*	4.532	5.175	125 (4.62)	4.62
2	*Telemedicine and E-Health*	1.791	2.031	120 (4.44)	9.06
3	*JMIR mHealth and uHealth*	N/A[a]	4.636	107 (3.96)	13.02
4	*Journal of Medical Systems*	2.213	2.456	71 (2.63)	15.64
5	*PLoS ONE*	3.057	2.806	49 (1.81)	17.46
6	*BMC Medical Informatics and Decision Making*	2.042	1.643	38 (1.41)	18.86
7	*International Journal of Medical Informatics*	2.363	3.210	38 (1.41)	20.27
8	*Journal of the American Medical Informatics Association*	3.428	3.698	37 (1.37)	21.63
9	*BMC Public Health*	2.209	2.265	36 (1.33)	22.97
10	*Journal of Telemedicine and Telecare*	1.377	2.008	34 (1.26)	24.22
11	*JMIR Research Protocols*	N/A[b]	N/A	32 (1.18)	25.41
12	*IEEE Transactions on Information Technology in Biomedicine*	N/A	N/A	32 (1.18)	26.59
13	*IEEE Journal of Biomedical and Health Informatics*	2.093	3.451	28(1.04)	27.63
14	*Journal of Health Communication*	2.013	1.614	24 (0.89)	28.51
15	*Trials*	1.859	1.969	24 (0.89)	29.40
16	*Health Informatics Journal*	1.578	3.021	21 (0.78)	30.18
17	*Sensors*	2.033	2.677	19 (0.70)	30.88
18	*Personal and Ubiquitous Computing*	1.498	2.395	18 (0.67)	31.55

[a]IF: impact factor.

[b]N/A: not applicable.

The journal impact factor (IF), in a given year, is defined as the number of citations received by papers published in the previous 2 years, divided by the number of papers published in the same time. Table 1 shows that the journal IF rose in 2016 for 13 of the 18 top journals, when compared with 2015, except for 4 journals, namely, *PLoS ONE, BMC Medical Informatics and Decision Making, Journal of Health Communication, IEEE Transactions on Information Technology in Biomedicine, and JMIR Research Protocols.* Moreover, the average IF of the top 16 journals in 2016 reached 2.82. A total of 9 of the 18 journals are in the category of Medical Informatics in the Journal Citation Reports 2016.

Collaboration Characteristics

Core Author and Author Collaboration

The total number of authors who have published research in the field of mHealth is 10,895, 21.27% (2318/10,895) of which have been as first author. However, 141 authors have published just 1 paper, comprising 1.29% (141/10,895) of the total. The top 7 most productive first authors with not less than 5 outputs were identified in the area of mHealth (shown in Table 2), which together contributed to the publication of 45 papers (for list of papers published, see Multimedia Appendix 2), that is, an average of 6.4 papers per first author during the period of 1997-2016. Table 2 also shows that the most productive first author in the field of mHealth is John D Piette with 11 papers, followed by Dror Ben-Zeev and David D Luxton.

In this study, a total of 2563 coauthored papers were identified, indicating that the rate of collaborative papers is 94.79% (ie, 2563/2704). The total publication frequency of authors, which refers to the cumulative result of the number of authors of each paper, is 11,958, indicating that the degree of author collaboration was 4.42 (11,958/2704) during the period of 1997 to 2016.

The visualization network of author collaboration was created using CiteSpace based on the g-index selection criteria in each slice (shown in Figure 4). Note that several authors tended to collaborate with a small group of collaborators, generating 4 major clusters with some highly active authors. Namely, Cluster 1, takes the top spot, which includes 5 core members, including Piette JD, Allman-Farinelli M, Bauman A, Aikens JE, and Chen J; Cluster 2 consists of Whittaker R, Maddison R, and Jiang YN; Cluster 3 contains Aschbrenner KA, Naslund JA, and Bartels SJ; and the core members of cluster 4 are Wang W, Wu Q, Chen L, and Li Y. Additionally, there are a large number of relatively smaller clusters in the collaborative map of authors (for list of relevant information for main authors of the 4 clusters, see Multimedia Appendix 3).

Table 2. The top 7 most productive first authors during the period 1997-2016.

Author name (full name)	ORCID[a]	Recs-first[b] (Recs-all[c])	Percentage[d]	Main affiliation	Country
Piette JD (John D Piette)	N/A[e]	11 (20)	0.41	Ann Arbor Department of VA, Center for Clinical Management Research, Michigan	United States
Ben-Zeev D (Dror Ben-Zeev)	0000-0001-6597-2407	8 (10)	0.30	Dartmouth Medical School, Hanover	United States
Luxton DD (David D Luxton)	N/A	6 (6)	0.22	The National Center for Telehealth and Technology, Tacoma, Washington	United States
Chib A (Arul Chib)	N/A	5 (5)	0.18	Nanyang Technological University	Singapore
Turner-McGrievy, GM (Gabrielle M Turner-McGrievy)	0000-0002-1683-5729	5 (7)	0.18	University of South Carolina, Columbia, South Carolina	United States
Aschbrenner KA (Kelly A Aschbrenner)	N/A	5 (9)	0.18	Geisel School of Medicine at Dartmouth, Lebanon, NH	United States
Akter S (Shahriar Akter)	0000-0002-2050-9985	5 (5)	0.18	University of Wollongong	Australia

[a]ORCID: Open Researcher and Contributor ID.

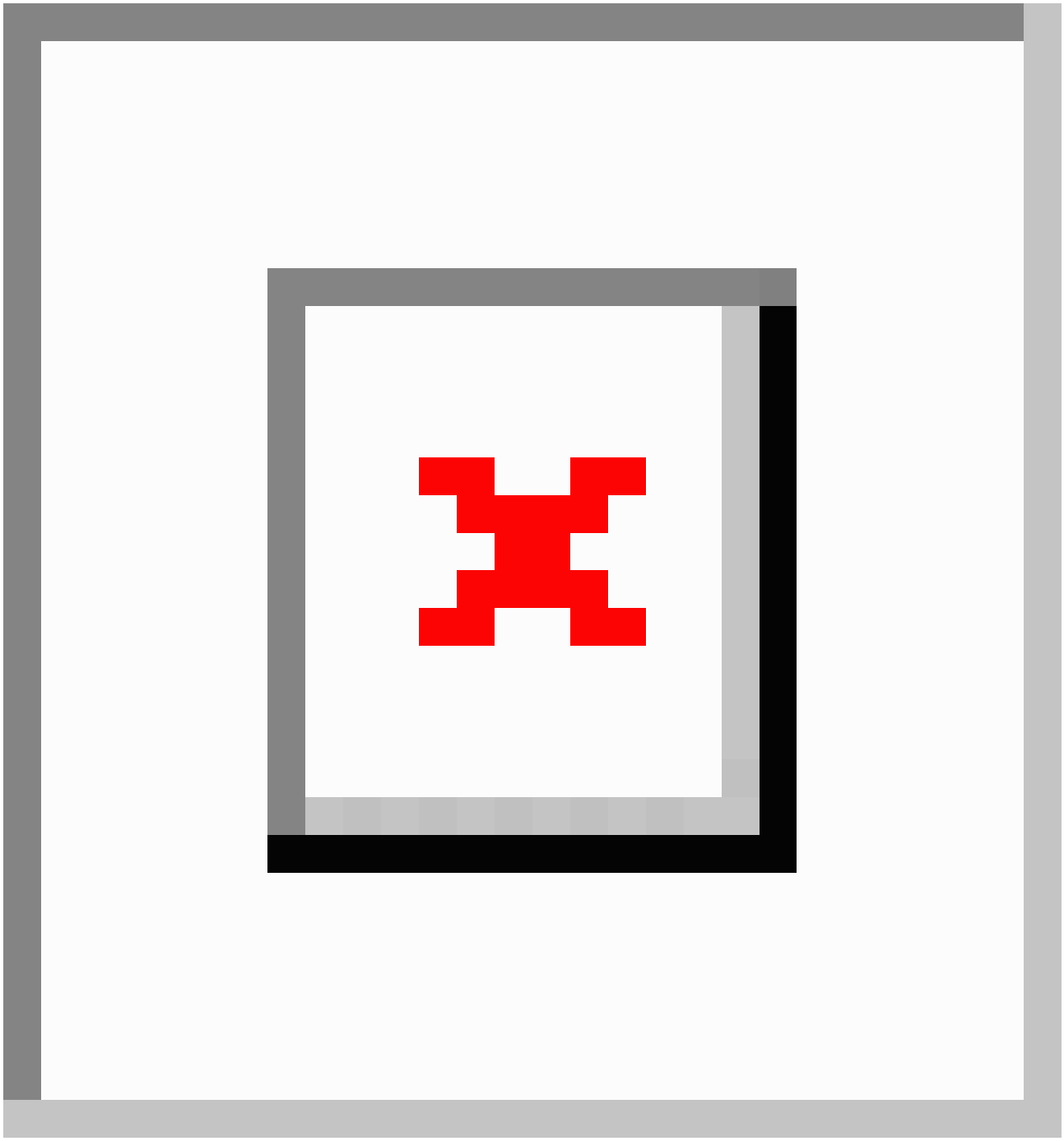
[b]Recs-first: number of papers published as first author.

[c]Recs-all: total number of papers published by the author.

[d]Percentage: Percentage of papers published as first author.

[e]N/A: not applicable.

Figure 4. The collaboration relationship of productive authors publishing mHealth research.



The core authors group is recognized as those authors with more publications and influence than others. On the basis of Price Law [46] (for the equation, see Multimedia Appendix 4), the minimum output of core author is obtained, namely, approximately 3.35 (ie, 0.749 x $20^{1/2}$), which means that the publication output of every core author is not less than 4. From this research, we can identify 266 core authors who have collectively published 1435 papers or 53.07% (1435/2704) of the total number of publications.

Institution and Collaboration

Statistical data analysis shows that the 2704 identified publications in the mHealth field were distributed among 3040 institutions. As shown in Table 3, authors from top 10 research institutions have published 449 (16.61%, 449/2704) papers. The University of Michigan performed well, being seen as the most productive institution in mHealth research, followed by The University of Washington and Harvard University. All 10 institutions are universities, with 9 being based in the United States. The TLCS and TGCS of the University of Washington can be seen as the highest among the universities. Harvard University has the highest AGCS, with high academic influence and collaboration in mHealth research, followed by the University of Washington.

Compared with other forms of collaboration, institutional collaboration provides a measure to examine the interactions between institutions on a more granular level [47]. After being pruned [48], the major collaboration relationship of institutions

related to mHealth research is shown in Figure 5, in which the institution labeling is shown based on the citation frequencies with 20 threshold levels (for list of the corresponding relations between the abbreviations and the full forms of the main institutions, see Multimedia Appendix 5). It is noted that there are 5 universities that present higher centrality with the purple circle, namely: The University of Michigan, University of California San Francisco, Stanford University, University of Pittsburgh, and The University of Pennsylvania, which demonstrated the central position and academic importance in the collaborative network of mHealth research. The links between institutions are relatively few, which coincides with the foregoing analysis.

Country and Collaboration

In total, scholars from 111 countries and territories have contributed to research on mHealth. A total of 10 countries and territories have contributed to the publication of 2477 papers (shown in Table 4). The United States, which is the most productive country in mHealth research, ranks the first in publication outputs, accounting for 46.97% (1270/2704) of the total. The United Kingdom, Australia, Canada, and China are not far behind. Moreover, when combining with the report released by the World Bank [49], it can be acknowledged that there are 20 lower middle-income countries (LMICs) that have contributed to mHealth research. A total of 197 (7.29%, 197/2704) papers were contributed to by authors in LMICs.

Furthermore, the TLCS and TGCS of the United States are the highest, followed by the United Kingdom and Canada. The top 6 countries in a descending order by AGCS, which indicates the high average quality of these papers, are the United States, Canada, the United Kingdom, China, Australia, and Germany.

Figure 6 shows the collaboration relationship of the most productive countries and territories. Country and territory labeling is shown based on the citation frequencies with 10 threshold levels (for list of the corresponding relations between the abbreviations and the full forms of the main countries and territories, see Multimedia Appendix 6). The United States is obviously the most active country in mHealth research worldwide. In the mHealth field, the United States plays an irreplaceable leading role, although the collaboration of authors inside the country is relatively scarce. It is also noteworthy that there are another 4 countries and territories that demonstrate higher centrality with the purple circle, namely, England, Australia, South Korea, and China.

Table 3. Top 10 institutions on mobile health (mHealth) research.

No.	Institution	Recs[a]	Publication, %	Cumulative percentage	TLCS[b]	TGCS[c]	AGCS[d]
1	University of Michigan	60	2.22	2.22	101	462	7.70
2	University of Washington	56	2.07	4.29	176	818	14.61
3	Harvard University	53	1.96	6.25	91	775	14.62
4	University of California, San Francisco	48	1.78	8.03	56	401	8.35
5	Columbia University	44	1.63	9.65	66	275	6.25
6	University of Sydney	40	1.48	11.13	42	339	8.48
7	Johns Hopkins Bloomberg School of Public Health	39	1.44	12.57	46	220	5.64
8	University of California, Los Angeles	39	1.44	14.02	83	540	13.85
9	Johns Hopkins University	35	1.29	15.31	22	137	3.91
10	University of Pittsburgh	35	1.29	16.60	84	334	9.54

[a]Recs: number of published papers.

[b]TLCS: total local citation score.

[c]TGCS: the total global citation score.

[d]AGCS: average global citation score.

Figure 5. The collaboration relationship between institutions related to mHealth research.

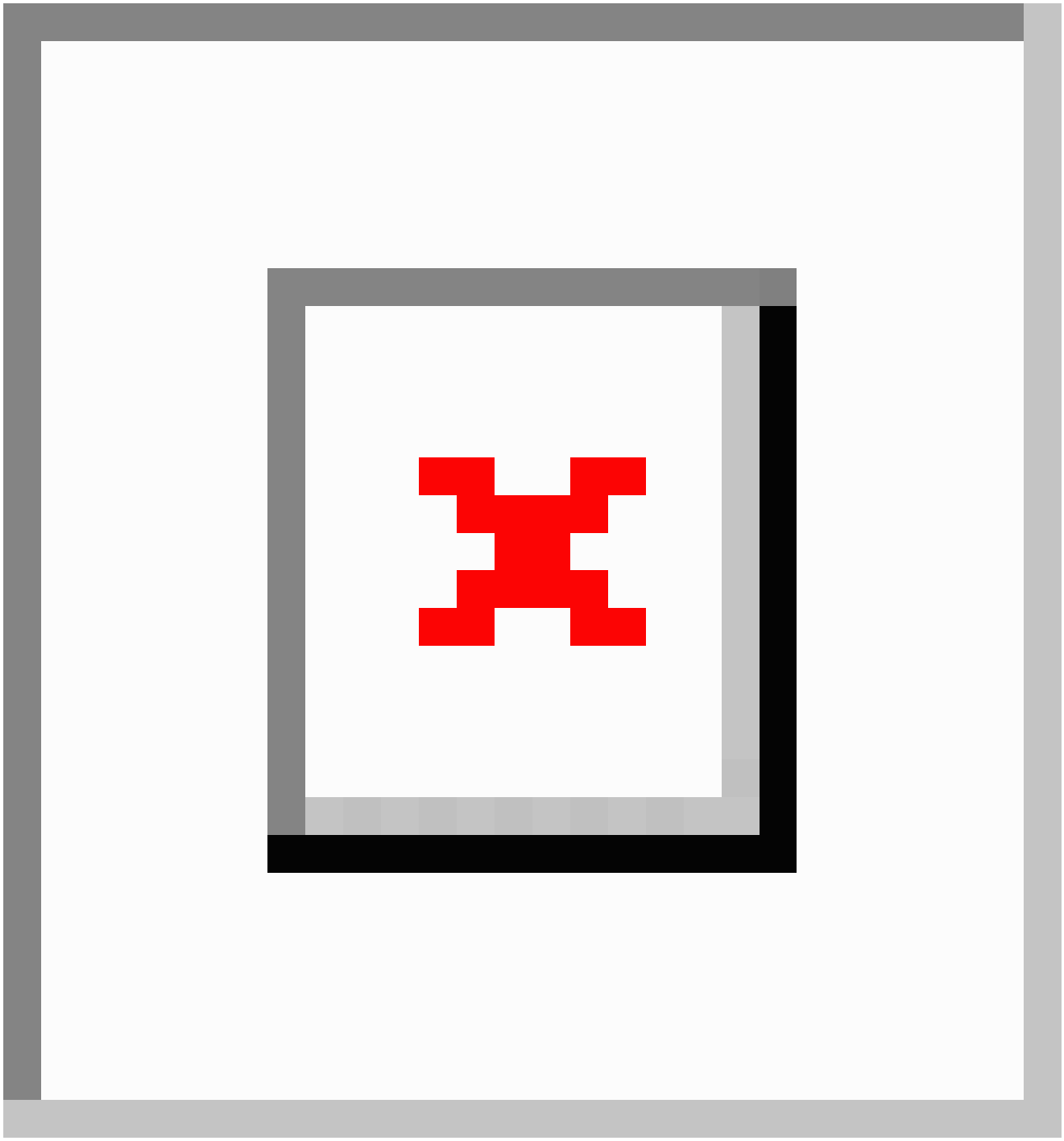


Table 4. Top 10 countries and territories.

Country and territory	Recs[a]	TLCS[b]	TGCS[c]	ALCS[d]	AGCS[e]
United States	1254	1721	11648	1.37	9.30
United Kingdom	263	171	2141	0.65	8.14
Australia	178	150	1371	0.84	7.70
Canada	175	243	1583	1.39	9.05
People's Republic of China	136	98	1061	0.72	7.80
South Korea	116	62	577	0.53	4.97
Spain	106	39	573	0.37	5.41
Taiwan	88	94	818	1.07	9.30
Germany	83	27	499	0.33	6.01
Netherlands	78	36	442	0.46	5.67

[a]Recs: number of published papers.

[b]TLCS: total local citation score.

[c]TGCS: the total global citation score.

[d]ALCS: average local citation score.

[e]AGCS: average global citation score.

Research Hotspots

Temporal Bar Graph for High-Frequency and High-Burst Keywords

There are 71 keywords with a burst strength more than 1 and frequency not less than 10, which were ranked according to the frequency of keyword (for the details, see Multimedia Appendix 7). Each of these keywords holds the intervals of date in which the bursts occurred. All 71 keywords cover the research frontier of mHealth to a great extent. In addition, the frequencies of these keywords are 2028 times, showing that 1.28% (71/5543) of keywords accounted for 16.46% (2028/12,318) of the total 12,318 frequencies.

The temporal bar graph for the 27 burst terms clearly represents an evolution in topics over time, demonstrating the updating and interacting of the literature. In Figure 7, we can see that mobile telemedicine, mHealth units, and PDA were run through the research on mHealth in the period between 2000 and 2012, suggesting that the application of mobile technologies in health care has begun to receive greater attention. This phenomenon corresponds to the widespread application of information technology in every walk of life in the early 21st century. In this body of knowledge, we can identify some main devices that have been applied to the health care field during the period of 2005 to 2010, including Bluetooth, body sensor networks, and mobile computing.

Figure 6. The collaboration relationship of country and territory related to mHealth research.

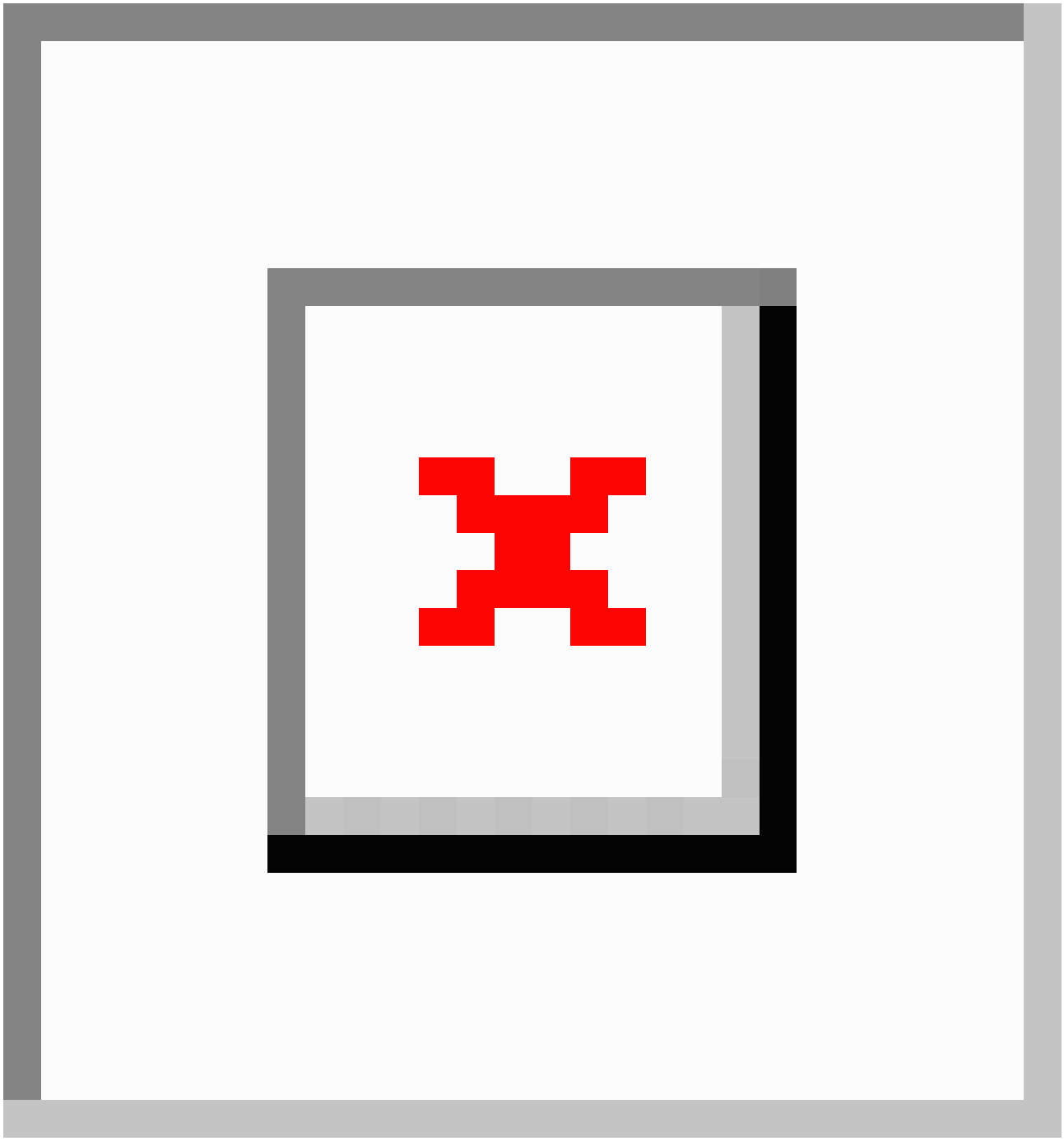
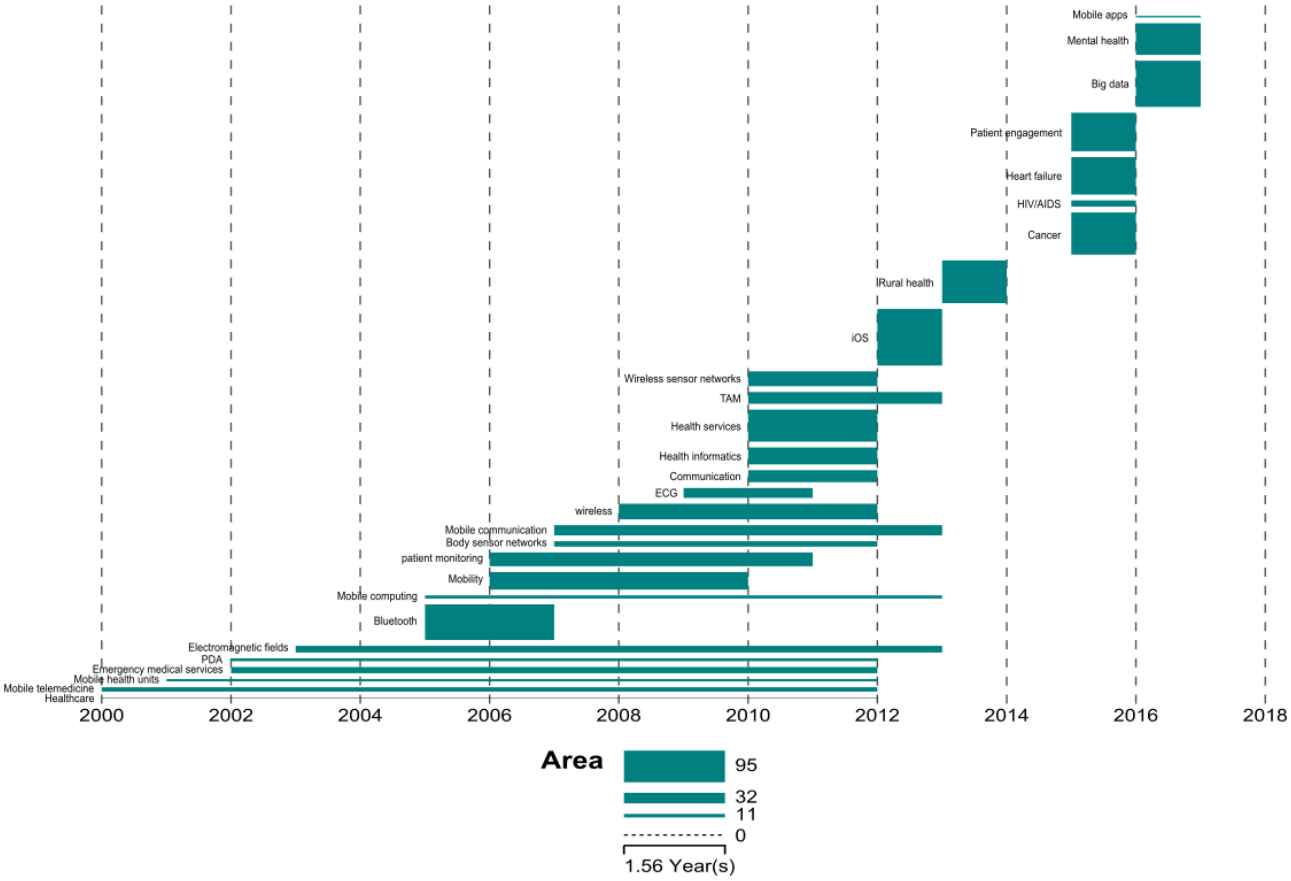


Figure 7. Temporal bar graph for burst terms. ECG: electrocardiogram; PDA: personal digital assistant; TAM: technology acceptance model.



From 2010 to 2014, the major burst terms were technology acceptance model (TAM), iOS, health services, and rural health. It showed that the research focus had turned to the integration of health technology with health services, and that researchers had begun to explore how to improve technological acceptation from users. The representative burst terms from 2015 to 2016 were patient engagement, mental health, illness, and big data, suggesting that patient engagement and smart prevention methods have been a major research focus in the current new technology environment in the recent years.

Research Topic Distribution

The 71 keywords identified in the mHealth field were divided into 12 clusters through hierarchical cluster analysis, indicating the topics are broad and varied. The cluster name of each cluster was refined, based on the keywords in the respective cluster, all of which are presented in Table 5. That is, Cluster 1 refers to security and privacy; Cluster 2 focuses on health monitoring and u-health; Cluster 3 is associated to health care and mobile computing; Cluster 4 is related to body sensor networks and patient monitoring; Cluster 5 refers to cell phones and health surveillance; Cluster 6 is about text messaging and health intervention; Cluster 7 focuses on social support, social media, and health promotion; Cluster 8 is related to mobile apps and mental health; Cluster 9 refers to mobile technology, nursing, and data mining; Cluster 10 is associated to self-care and patient engagement; Cluster 11 focuses on health services and health education; and Cluster 12 is related to TAM, chronic disease, and home health monitoring.

Social Network Analysis

On the basis of the 71×71 similarity matrix, it was possible to calculate the density of the network, which is 0.007, a relatively low level. To explicitly demonstrate the networking relationship and obtain more powerful and intuitive results, we formed the 52×52 co-occurrence matrix based on the original 71×71 co-occurrence matrix, of which the keyword that correspond to any row or any column has not less than 12 frequencies. On the basis of the new matrix, a network was generated using Netdraw2.0 embedded in Ucinet6.6 (shown in Figure 8), which intuitively reflects the relationships among the high-frequency and highly bursting keywords.

The graph shown in Figure 8 semantically interrelates and chronologically links diverse fields of mHealth research. A total of 4 major areas can be identified: (1) the top left subnetwork is related to patient engagement and patient intervention research, which mostly covers Clusters 5-7; (2) the top right topics deal with health monitoring and self-care research, which roughly include Cluster 2, Cluster 8, Cluster 10, and Cluster 12; (3) the bottom right is linked to mobile device and mobile computing research, which mainly contains Clusters 3-4 and Cluster 9; and (4) the bottom left relates to security and privacy studies, which includes Cluster 1.

Table 5. Twelve clusters of mobile health (mHealth) research.

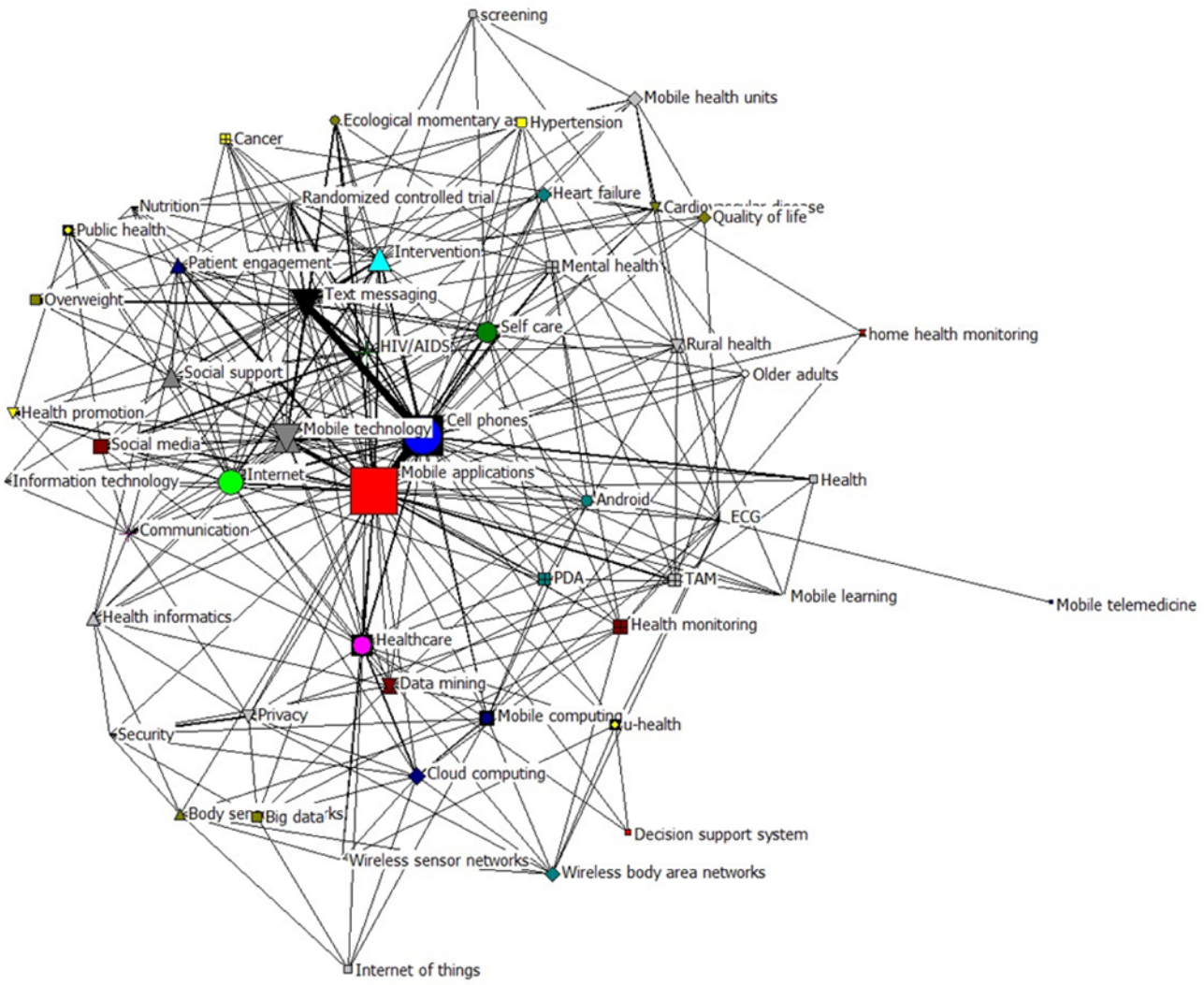
Cluster	Number of keywords	Cluster name	Keywords
1	2	Security and privacy	Security; privacy
2	8	Health monitoring and u-health	ECG[a]; cloud computing; wireless body area networks; health monitoring; big data; mobile telemedicine; u-health; wireless
3	4	Health care and mobile computing	Health care; mobile computing; Internet of things; ubiquitous computing
4	4	Body sensor networks and patient monitoring	Body sensor networks; wireless sensor networks; decision support system; patient monitoring; mobility; Bluetooth
5	6	Cell phones and health surveillance	Cell phones; health; surveillance; epidemiology; informatics; electromagnetic fields; maternal health
6	7	Text messaging and health intervention	Text messaging; HIV/AIDS; randomized controlled trial; cancer; overweight; nutrition; intervention study
7	7	Social support, social media and health promotion	Internet; intervention; social support; social media; health promotion; communication; public health
8	4	Mobile apps and mental health	Mobile apps; ecological momentary assessment; mental health; bipolar disorder
9	7	Mobile technology, nursing, and data mining	Mobile technology; PDA[b]; health informatics; Android; data mining; nursing; iOS
10	4	Self-care and patient engagement	Self-care; patient engagement; heart failure; quality of life
11	4	Health services and health education	Information technology; health services; emergency medical services; health education
12	11	TAM[c], chronic disease, and home health monitoring	Mobile health units; cardiovascular disease; TAM; rural health; home health monitoring; older adults; hypertension; mobile learning; screening; implementation; mobile communication

[a]ECG: electrocardiogram.

[b]PDA: personal digital assistant.

[c]TAM: technology acceptance model.

Figure 8. Social network map of the original 52 × 52 co-occurrence matrix. ECG: electrocardiogram; PDA: personal digital assistant; TAM: technology acceptance model.



Discussion

Principal Findings

This study has demonstrated that the growth of literature related to mHealth research has accelerated in recent years, and that the influence is continually increasing. As we know, with the emergence of mobile phone technologies from 2006 to 2010, the field of mHealth entered a phase of rapid innovation and, in parallel, unfettered proliferation. In addition, mHealth Alliance, founded in 2008, has played an important role in advancing the field of mHealth through thought leadership and by convening a range of stakeholders, which focuses on advancing mHealth technology in global health care through policy research, advocacy, and outreach [50]. Obviously, all of these events present a large research scope on mHealth, and the number of publications started to increase dramatically during the period from 2009 to 2016, although it was less before 2008. In addition, based on the logical growth curve equation of mHealth literature, combined with the fact that some important papers published before December 28, 2016, are not indexed in WoSCC, it is reasonable to infer that mHealth literature published in 2017 is expected to reach more than 1000, and that the average annual growth rate of literature on mHealth will reach nearly 60% (648/410-1) after 2016.

Additionally, IF is seen to be a metric of excellence for journals, that is, journals with higher IF are often deemed to be more important than those with lower IF. In the past 2 years, there is an increase of IF for major journals related to mHealth, which further reflects the concern of researchers to mHealth.

Our study showed that the degree of author collaboration is relatively high, that the core author group is fundamentally formed, and that collaboration between the core authors should be further strengthened. Scientific collaboration has become prevalent in various disciplines [51]. In this study, the total degree of author collaboration was more than 4 during the past 2 decades and, compared with other disciplines, the collaboration degree of international mHealth stays above the average level in scientific collaboration [52]. As we understand, with the development of science and the explosion of knowledge, nobody is an expert in everything [53]. It is an arduous task for an individual to fully understand the extensive knowledge of various fields in the information era. Research on mHealth is no exception and this requires more experts from different field to collaborate together to answer important

questions. Additionally, collaboration can facilitate the sharing and dissemination of knowledge and attract more attention to the field [54,55].

Obviously, some specific authors played very important roles and had a big impact in the mHealth field and on future development, representing "core strength" in this field. The output of core authors in the mHealth field represents approximately 50% (1435/2704) of the total number of publications. According to the Law of Price, we can find that the core authors group has fundamentally been formed and that the publication output of the core authors will increase over time. However, there are only 4 major clusters of authors, which can be regarded as the backbone in the field, indicating that the current collaboration of core authors is not tight and stable. Moreover, when combined with the analysis above, it can be concluded that the core researchers in the mHealth field should further strengthen their collaboration to form a more stable and core collaborative group.

In our study, it can be seen that the leading research power is in the United States and that the collaborative relationship of institutions or countries is not relatively tight. Although 3040 institutions have been involved in research on mHealth, indicating a remarkable concern, publication output on mHealth research is distributed unevenly between institutions. Links between institutions are relatively few, according to the collaborative relationship map, which means less collaboration among institutions and less willingness to collaborate, except for the network consisting of numerous American colleges and universities. Additionally, it can be inferred that universities are major research forces, similar to other research fields. Institution collaboration, in general, should be further strengthened in future. Moreover, combining the sparse institution collaboration, it can be further inferred that the collaboration mainly occurs among authors with different academic professional backgrounds from the same institution.

Furthermore, the major industrialized countries (such as G7 countries: the United States, the United Kingdom, Germany, Canada, Italy, France, and Japan) are mostly in the core of the country collaboration network, suggesting that economic development and scientific investment have much contribution to the publication outputs in mHealth. However, China, which is representative of the developing countries, also pays more attention to public health and plays a prior role in the mHealth studies. Additionally, based on the country collaboration graph, it can be inferred that institutions located in the United States are more inclined to collaborate with domestic institutions, suggesting institutions in the United States have a relatively low tendency toward international collaboration. In fact, scientific collaboration relationships are highly resource-dependent [56] and internationalization of science, to a certain degree, depends on the attractiveness of a partner in the global network. Therefore, the international collaboration for institutions in mHealth research encounters challenges as well, particularly for developing countries that are confronted with critical internal conditions (eg, policy and funds) that often prevent them from collaborating with high scientific capacity. To change this situation, measures should be taken which will benefit the developing country itself from the application of mHealth in the near future. For example, more scholars related to mHealth research from the developing country should be supported by related countries or institutions to study and communicate in the United States, or some advanced experts could be invited to guide the research in the developing country.

In this study, we find that modern ICT is increasingly being integrated with health care systems, and that research topic burst on mHealth is relatively decentralized. The 71 identified keywords demonstrate the research frontier of mHealth field to a very great extent. From the temporal bar graph, it can be seen that research focus has already begun to shift from acceptance and feasibility to outcome of mHealth to some extent and that patient engagement through social media and mobile computing has started receiving more attention in recent years. Generally, mHealth has been seen to be a new effective approach to increasing means and efficiency of care delivery in the health domain using ICT. Additionally, mHealth would provide support for medical service decisions by means of second development and utilization of medical and health care data, such as mobile computing and data mining.

The hierarchical cluster analysis intuitively displays the 12 keyword clusters and the relationship between topics, each of which represents a research direction on mHealth. Compared with other studies, mHealth research topics are relatively decentralized at present, and social network analysis presents the 4 major areas, each of which covers 1 or several of 12 clusters. In addition, the top left subnetwork receives more attention than others. Generally, research on mHealth should be further strengthened in these 4 areas, and the research topics would also need to be further focused in future, which will be beneficial to health care services.

Limitations

Although findings are based on the above analysis, there are still several potential limitations that may encourage further research efforts. First, this study only focuses on literature indexed by WoSCC. Although WoSCC emphases paper quality to ensure accurate and meaningful data, it leads to some papers related to mHealth not being covered. Moreover, there are several high-quality papers that are still not indexed by WoSCC due to time-lag, especially those published at the end of 2016. All of these will have some impact on the accuracy of research output on mHealth.

Second, there might be some biases of understanding for author collaboration because some different authors with the same name or abbreviation exist, who are affiliated to different institutions. In addition, some authors are simply "token co-authors" included in some papers. Therefore, the result of author relationship analysis for mHealth research would be influenced by the accuracy of the indexing author.

Finally, although temporal analysis and hierarchy cluster analysis are quite useful methods for exploring topic evolution and identifying hotspots in 1 field, the results may be affected by the accuracy of keywords. We used 3 main methods of cleaning keywords in this research, but there still exists some keywords with the same meaning, which will affect the cluster results to some extent.

Conclusions

In this study, a comprehensive bibliometric analysis on mHealth research was conducted, with the data source being the WoSCC, using various tools. Different visualization methods were used to interactively explore and understand the specific datasets. On the basis of the above results and discussion, some valuable results for mHealth research were obtained, including information on collaboration characteristics and research topic bursts. Meanwhile, with the deep contingency of mobile technologies and health care services, it is reasonable to believe that the literature related to mHealth research will grow at an exponential rate in future and that the collaboration of core authors will strengthen after core author groups officially form. In addition, although the United States has the leading research power in mHealth area, the collaborative relationship of institutions or countries should be reinforced to promote the global mHealth field. In general, the focus of research topics on mHealth should be enhanced in the future.

It should be noted that mHealth has begun to be an important part of digital health, which is the convergence of digital and genomic technologies with health, health care, living, and society to enhance the efficiency of health care delivery and make medicines more personalized and precise [57]. The broad scope of digital health includes categories such as mHealth, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine [58-60]. All of these are helpful to promote the emergence and development of quality research and provide a potential guideline for scientific researchers when launching new projects in the future.

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Authors' Contributions

LS, the first author, designed and conducted the study into literature distribution and topic bursts in the mHealth field. BX, the second author, contributed to the research into collaboration characteristics. All other authors contributed to the manuscript’s preparation and approved the final accepted version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Detailed search strategy of WoSCC.

[PDF File (Adobe PDF File), 38KB - mhealth_v6i6e135_app1.pdf]

Multimedia Appendix 2

List of papers published as top 7 most productive first authors.

[PDF File (Adobe PDF File), 126KB - mhealth_v6i6e135_app2.pdf]

Multimedia Appendix 3

List of relevant information for main authors of the 4 clusters in collaboration relationship map of productive authors.

[PDF File (Adobe PDF File), 56KB - mhealth_v6i6e135_app3.pdf]

Multimedia Appendix 4

The equation for the minimum output of core author.

[PDF File (Adobe PDF File), 13KB - mhealth_v6i6e135_app4.pdf]

Multimedia Appendix 5

List of the corresponding relations between the abbreviations and the full forms of the main institutions.

[PDF File (Adobe PDF File), 46KB - mhealth_v6i6e135_app5.pdf]

Multimedia Appendix 6

List of the corresponding relations between the abbreviations and the full forms of the main countries and territories.

[PDF File (Adobe PDF File), 46KB - mhealth_v6i6e135_app6.pdf]

Multimedia Appendix 7

List of keywords with burst strength more than 1 and frequency not less than 10.

[PDF File (Adobe PDF File), 125KB - mhealth_v6i6e135_app7.pdf]

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Abbreviations

AGCS: average global citation score
ALCS: average local citation score
BICOMS: Bibliographic Item Co-Occurrence Mining System
ECG: electrocardiogram
ICT: information and communication technologies
IF: impact factor
LMICs: lower middle-income countries
mHealth: mobile health
PDA: personal digital assistant
Sci2: Science of Science
SMS: short messaging service
TAM: technology acceptance model
TGCS: total global citation score
TLCS: total local citation score
WoSCC: Web of Science Core Collection

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Original Paper

User Requirements for Technology to Assist Aging in Place: Qualitative Study of Older People and Their Informal Support Networks

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Abstract

Background: Informal support is essential for enabling many older people to age in place. However, there is limited research examining the information needs of older adults' informal support networks and how these could be met through home monitoring and information and communication technologies.

Objective: The purpose of this study was to investigate how technologies that connect older adults to their informal and formal support networks could assist aging in place and enhance older adults' health and well-being.

Methods: Semistructured interviews were conducted with 10 older adults and a total of 31 members of their self-identified informal support networks. They were asked questions about their information needs and how technology could support the older adults to age in place. The interviews were transcribed and thematically analyzed.

Results: The analysis identified three overarching themes: (1) the social enablers theme, which outlined how timing, informal support networks, and safety concerns assist the older adults' uptake of technology, (2) the technology concerns theme, which outlined concerns about cost, usability, information security and privacy, and technology superseding face-to-face contact, and (3) the information desired theme, which outlined what information should be collected and transferred and who should make decisions about this.

Conclusions: Older adults and their informal support networks may be receptive to technology that monitors older adults within the home if it enables aging in place for longer. However, cost, privacy, security, and usability barriers would need to be considered and the system should be individualizable to older adults' changing needs. The user requirements identified from this study and described in this paper have informed the development of a technology that is currently being prototyped.

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KEYWORDS

aging in place; informal support; smart home; home monitoring technology

Introduction

Since the 1990s, there has been a move to promote "aging in place", in which individuals continue living in their place of residence in later life [1]. Aging in place is preferred by most older people [2,3] and is seen as a way to maintain autonomy and connection with friends and family who provide both practical and emotional support [4]. Moving into residential care can be detrimental for older people, as it can lead to increased immobility and a loss of independence [5]. At the

same time, there is growing recognition that neighborhoods and communities are crucial for enabling older people to age in place [2,6].

Various technologies have been used to support older people as they age in place, including home monitoring devices [7], purpose built smart homes [8], intelligent cognitive assistants [9], and online health information resources [10]. However, many technologies have the limitation of treating only one condition in isolation, rather than the older person as a whole, who may be dealing with a range of health issues. Additionally, there are various barriers to the uptake of these technologies among older people, including the cost, privacy concerns, and the perception that it is not required [11-13]. As older people are more likely to experience physical and cognitive decline associated with aging, this can also limit their ability to use technology [11,14].

Technologies used to assist older adults aging in place tend to be focused on providing communication pathways with formal health care providers, which neglects the older adults' informal support networks of friends, neighbors, and family members who provide ongoing practical and emotional support such as personal care, housework, company, and emotional assistance [15]. This informal support is often under-recognized, even though it is often essential for enabling older people to age in place. A recent report determined that informal caregivers across Europe assume 50-90% of the responsibility for the long-term support of elderly, dependent people and most of them have limited access to formal support services [15]. According to Fischert et al [16], "Tools for the elderly should consider the whole care network and take into account who will be using the tool, who has access to what information, and how these factors may change over time" (p. 630). The involvement of friends and family members is also beneficial because these individuals can influence whether an older person will adopt a technology [11]. Accordingly, Luijkx et al [17] emphasized the importance of including family members, including grandchildren, when implementing technologies into the lives of older adults.

This paper presents some of the findings from an exploratory project that investigates how technologies that connect older adults to their informal and formal support networks could assist aging in place and enhance older adults' health and well-being. The term "informal support networks" in this project refers to individuals identified by older adults as helping them age in place, which may include friends, neighbors, and family members, while "formal support networks" refers to organizations that provide health care services to the older adults. We present the findings from in-depth interviews with 41 participants, made up of 10 older adults and 31 members of their self-identified informal support networks. These participants were asked questions concerning their information needs and how technology could support older adults to age in place. The findings from focus groups conducted with health care professionals working with older adults, which formed part of this study, will be presented in a separate paper.

The findings of this study identified a series of user requirements for the technologies that have informed the development of a technology currently being prototyped in a later phase of the project. The work reported here adds to the scholarly body of knowledge by examining how technologies that assist older adults in their residences could be tailored to end users and how reported barriers could be overcome. This study is significant because the information needs of older adults' informal support networks have been largely neglected in health informatics research to date.

Methods

Overview

Semistructured interviews were conducted with older adults and members of their informal support networks between March and June 2017. In-depth interviews were selected because they can allow for an in-depth understanding of participants' perspectives of a chosen phenomenon [18]. Research ethical approval was obtained from the Massey University Human Ethics Committee (SAO 16/65).

Recruitment

Older adults were recruited using convenience sampling of individuals who indicated an interest in participating in the study. Community organizations were contacted about the study and asked to display posters on notice boards and distribute information to potential participants. Interested participants then contacted researchers directly. The older adults were required to be aged 70 years or older, live alone in the Manawatu region in New Zealand, and have at least one chronic health condition. They were excluded if they lived in a retirement village or in residential care. These criteria were selected so that the older adults recruited were likely to be nearing the stage of requiring assistance to age in place. Participating older adults additionally needed to identify at least 3 members of their informal support networks of friends, neighbors, and family members who provide them with ongoing practical and emotional support and were willing to participate in the study.

Ten older adults and 31 informal support network participants were recruited. The older adults were aged 74-92 years; 8 were female and 2 were male. The support network participants ranged in age from 22-80 years old; 25 were female and 6 were male. They included the older adults' family members (siblings, children, and grandchildren), friends, and neighbors who were providing practical and/or emotional support.

Interview Design and Content

The interviews with the older adults were face-to-face, while the interviews with the support network participants were a mixture of face-to-face, over the phone, and via Skype. They were all conducted by two members of the research team. The face-to-face interviews took place at public places where privacy could be maintained. A semistructured interview design was used [18], which meant that the interviews could focus on the subject at hand, while still allowing for some spontaneity and expansion on complex issues.

An interview guide with probes was developed to identify information needs and how these could be met through technologies, partly guided by a workshop conducted with

participants attending a health informatics conference in 2016 [19]. The interviews focused on home monitoring and information and communication technologies, as the study's goal is on enhancing older adults' wellness and assisting aging in place, rather than treating medical conditions. The interview questions were piloted during the development stage and are provided in Multimedia Appendix 1.

Analysis

The interviews were transcribed and then anonymized with unique identifiers that linked the older adults to their support network participants. The transcripts were thematically analyzed [20] manually in NVivo Version 11.0. The coding and theme development was inductive, using an iterative process that involved reading and rereading the datasets to establish initial codes that covered key ideas discussed and then combining similar codes under themes. Following this process, the themes were reviewed alongside the original dataset. During the analysis, the codes and themes were discussed within the research team and finalized.

Results

The analysis of the interviews identified three overarching themes: (1) social enablers, (2) technology concerns, and (3) information desired. Each theme has several subthemes described below.

Theme 1: Social Enablers

Almost all the participants expressed an acceptance of some home monitoring technology if it were needed to allow the older adults to age in place and avoid residential care. This theme includes their descriptions of factors that help increase the uptake of home monitoring and information and communication technologies among the older adults. As the title of this theme suggests, many of these concerns were related to the older adults' social well-being, as opposed to specific medical conditions. For instance, some older adults discussed how they already use a range of digital technologies, such as email, text messaging, Skype calls, and social media sites to connect with members of their informal support network and how this network has helped them use technology. This theme encompasses participants' discussions about how timing, the informal support network, and safety concerns can assist the uptake of technology among the older adults.

Timing and the acceptance of technology were closely related for both the older adult and support network participants. While some participants thought that technology would already be useful to assist aging in place, many others felt that it should be used in the future when required. A number of support network participants thought that technology could assist them in monitoring the older adults in the future. One participant stated:

> *If it came to the stage where I did have to look after her that would be when I would want to "technology-up" with the sensors and that.* [daughter of Older Adult 9, 45-year-old female]

Another stated:

> *I would consider that [technology] if we were trying to keep Mum at home because she had advanced cognitive issues.* [daughter of Older Adult 3, 59-year-old female]

The older adults' informal support networks were another enabler for their uptake of technology. For some older adults, technology was a way of connecting with members of their support network in modern terms, sometimes at a geographical distance. Many support network participants actively encouraged the older adults to use technology and assisted them in doing so. One participant described her experience in helping the older adult use a mobile phone, stating:

> *It was quite a lot of perseverance getting her to use it. But…she's got grandkids overseas and my aunt and uncle overseas and so she texts them and it's great.* [granddaughter of Older Adult 2, 29-year-old female]

An older adult discussed how her son remotely assists her in using technology, stating:

> *When I wanted some help with the computer…he said, "invite me on to your computer" and I would sit there, and he would fix the computer from California while I looked on.* [Older Adult 8, 77-year-old female]

However, some older adults raised concern about disturbing or burdening their support network. As one participant stated:

> *My network people or my neighbors are all busy rushing around doing whatever they want to do. They might not be there* [Older Adult 5, 83-year-old female]

Many participants considered technology to be a way to monitor and maintain the older adults' safety within the home, which was presented as being of high significance. In some cases, technology was already used for monitoring the older adult's well-being, such as with the support network member texting or emailing the older adult daily for a welfare check. Some older adults even indicated that they would be willing to forego what they would consider an invasion of privacy to keep themselves safe at home and avoid residential care. For instance, the possibility of falling seemed to change one older adult's mind about having cameras in the home as indicated in the following quotation:

> *I don't think I'd like a camera following me around all day! But then, if you're falling and you can't, well, push your [emergency] alarm.* [Older Adult 2, 85-year-old female]

Theme 2: Technology Concerns

Although most participants accepted the idea of technology being used to assist the older adults when required, there were concerns raised about some possible functions of the technology, how it would be managed, and the social consequences. The main issues raised were cost, usability issues, information security and privacy, and fears that technology could supersede face-to-face interpersonal communication.

A significant, and perhaps the strongest, concern expressed by older adults was the cost of the technology. For many older

adults, finances already hindered their uptake of technology. This was acknowledged by many support network participants. As one stated, "Cost of anything is a problem to [Older Adult 10]" (friend of Older Adult 10, 46-year-old male). Similarly, a support network participant of Older Adult 6 stated:

> *Oh, actually, that [the cost] could be a huge factor. One of the main ones.* [granddaughter of Older Adult 6, 21-year-old female]

Another participant discussed the issue of the cost of technology for elderly more generally, stating:

> *A lot of elderly people, they've got very little money…who's going to pay for it?* [daughter of Older Adult 3, 56-year-old female]

Usability issues were strongly raised by both the older adult and support network participants. Overall, the older adults were more concerned with whether technology would work within their home and lifestyle, while the support network participants were concerned with the older adults' ability to use technology. A few support network participants commented that they had observed older adults worsen in conditions associated with aging, such as vision and dexterity impairment, which might reduce or limit the older adults' ability to continue to use the technology. As one participant stated:

> *Older people losing their sight, losing their hearing, both of which worsen with age, is a real challenge for digital, because what's okay to start with may not be okay a year later.* [daughter of Older Adult 5, 60-year-old female]

The most common ethical issue raised was the security and privacy of personal information. Some participants did not seem to trust the security of information systems and raised concerns that individuals could access information without gaining informed consent from the older adults. Significantly, this was raised more strongly by the support network participants. For instance, one participant stated:

> *You have to trust somebody, and if St John's comes and takes you off to hospital, you have to trust that they're not going to tell the neighborhood that that house is empty…you have to trust somebody, but somebody up in the cloud?* [friend of Older Adult 3, 75-year-old female]

Additionally, both the older adult and support network participants expressed concern that technology could inadvertently replace face-to-face interaction. For example, support network participants described how they check on the older adults' well-being during visits, such as their mood and the temperature of the home, and so if technology could electronically replace this, these visits could become less pressing and decrease. This is significant as many participants, particularly those that were older, emphasized that technology does not facilitate communication of the same depth compared to face-to-face interaction. As one participant stated:

> *You can have one of those devices and that will tell [name] or [name] or some guy what's happening, but they're not close enough to make her a cup of tea.* [friend of Older Adult 3, 75-year-old female]

Theme 3: Information Desired

A crucial topic discussed by the participants was how much information should be collected so that the technology is both useful and does not impinge on the older adults' privacy. Views about this were diverse, although there was consistency among many participants in the idea of the information being processed and the technology being individualized to the older adult. This theme includes discussions about what information should be collected and transferred and who should make decisions about this information.

The information that the participants wanted to be collected and transferred varied significantly. Some support network participants wanted to receive a large quantity of information, such as a granddaughter (29-year-old female) who wanted to be notified each time that Older Adult 2 (85-year-old female) has a medical appointment, the outcome of each medical appointment, information about her diet, and her whereabouts. Others preferred to receive only information that they considered to be of a serious nature, such as a daughter (56-year-old female) who wanted to be notified when Older Adult 3 (81-year-old female) is in hospital, her condition after surgery, and information about serious falls. There were some older adults who were accepting of any information being transferred, while others, like the support network participants, wanted only information of a serious nature transferred. For instance, one older adult stated:

> *Well, if I've had a fall in the middle of the street somewhere and I've grazed my leg or something and I'm not trotting off to hospital, no, I wouldn't want her notified about that. But if the ambulance has come and I've knocked my head and I've lost consciousness or something, that might be a good idea!* [Older Adult 1, 82-year-old female]

However, many participants thought that information should be transferred only when there is a change in the older adults' usual routine. For example, rather than notifying the support network when the older adult gets out of bed in the morning, they would be notified only if the older adult is not up when it is past their usual time. This idea of processing the information before it is transferred was popular among all the participants—it was considered less intrusive for the older adults and the informal support networks would have less information to sort through. One support network participant stated:

> *I don't need to know that she's opened the fridge 10 times today, like if she hasn't opened the fridge at all today then I do…and then also if the fridge door stays open the whole time.* [daughter of Older Adult 5, 60-year-old female]

With a few exceptions, the participants thought that the older adults should decide what information is collected and transferred and to whom. Although some support network participants wanted more information than the older adult would be willing to have collected, they still thought that the technology should be individualized to the older adults' self-determined needs. On the whole, the older adults wanted to be in control of how the technology would be used and managed. As one older adult stated:

I would want control, yeah. Yeah, somebody told me once that I like being in control! And it's true. Don't we all? [Older Adult 3, 81-year-old female]

Discussion

Principal Findings

The work reported in this paper is part of the first phase of an exploratory project that investigates how technologies that connect older adults to their informal and formal support networks could assist aging in place and enhance older adults' health and well-being. Semistructured interviews were conducted with 10 older adults and 31 members of their self-identified informal support networks. The limited size of the study means that care should be taken not to overgeneralize the conclusions, but several common themes emerged within the findings. Overall, participants were accepting of the idea of technologies that monitor older adults in the home when required to enable aging in place.

However, concerns were raised that could hinder the uptake of this technology, pertaining to cost, usability, information security and privacy, and fears that it could supersede face-to-face interpersonal communication. This aligns with research that has demonstrated that older people have concerns about cost and privacy regarding these technologies [11-13] and that physical and cognitive decline associated with aging can limit their ability to use technology [11,14].

To date, health informatics scholarship has largely overlooked the role of informal support networks for aging in place and how their information needs could be assisted through technologies within the home. This study has shown that older adults' informal support networks want more information about the older adults' well-being, and in many cases older adults are accepting of certain home monitoring technologies transferring this information if it would allow aging in place longer. A number of support network participants already use available information and communication technologies to monitor the older adults on a daily basis, such as email or text messaging as a form of welfare check. Furthermore, support network participants actively encourage the uptake of technology among the older adults, aligning to existing literature that has determined that friends and family members influence whether an older adult will adopt a technology [11]. From the analysis, several user requirements can be deduced for a technology that assists older people to age in place. A list of high-level user requirements for the technology that have been derived from the analysis themes are summarized in Table 1 and discussed below.

First, as much as possible, the technology needs to be low cost. The concern about financial barriers was strongly expressed by most of the older adults interviewed. One way to achieve this could be to use technologies that already exist within the home, including televisions, computers, and home appliances that, with modification, transfer information about the older adults' well-being. This could also help address some of the older adults' concerns about the technology being adaptable to their home and lifestyle.

Table 1. User requirements derived from the analysis themes.

Theme and subthemes	Number	User requirement
Social enablers		
Compatibility	1	The technology needs to be easy to install.
Compatibility	2	The technology needs to be adaptable to different home layouts.
Compatibility	3	The technology should be adaptable to meet older adults' changing needs.
Usefulness	4	The technology should save users' time.
Compatibility	5	The technology should be able to use a variety of technologies to connect older adults to members of their nominated support network.
Technology concerns		
Cost	6	The technology needs to be at a low cost.
Cost	7	When possible, the technology should utilize objects already present within the home.
Privacy	8	The information needs to be stored securely.
Privacy	9	The security of the information needs to be clearly communicated to potential users.
Usability	10	The interface needs to be stable and easy to navigate, with large text.
Information desired		
Control	11	The information collected needs to be decided by the older adult.
Control	12	Access to information should be limited to individuals nominated by the older adult.
Control	13	It should be possible to send different information to different support network members.
Processing	14	The technology should be able to send raw and processed data.
Processing	15	It should be possible to only send information "outside of the norm" to the support network.

Second, the retrieved information needs to be stored and transferred securely. As the security of personal information was a concern raised by most of the participants, this should be clearly communicated to potential users.

Third, the technology needs to be designed for ease of use. It should be automated where possible. Any interface designed for the older adults should be stable and easy to navigate, with large text. For older adults with impairments that limit their ability to use technology, a direct user interface in their homes may not be required, the technology could simply monitor the environment so that the older adult would not need to actively engage directly with the system.

Fourth, the technology should be individualized to the older adults' self-determined needs. Most of the participants emphasized that older adults should be in complete control of the technology. Thus, the older adults should determine what information is collected, sent, and who would receive this information. The technology should also be adaptable to meet the older adults' changing needs, both in terms of the usability and the information collected and transferred.

Finally, the technology should be able to process information so that nominated members of the support network may be notified only when the older adults act outside of their usual routine, such as when there is no movement in the home during certain hours or if the oven is on for an extended period. This may require initial monitoring to establish the older adults' routine or it could be self-identified. As the participants discussed, the advantages of processing information in this way are twofold—it can be less intrusive for the older adults and less burdensome for the support network.

Limitations

With the nature of qualitative research, the findings are limited to the 41 participants recruited and care should be taken not to overgeneralize the conclusions drawn from the study. Future research examining this topic should certainly take a wider scope. Nevertheless, the user requirements from this study have informed the development of a technology that is currently being prototyped. The intention is to assist aging in place and to enhance older adults' health and well-being.

Conclusions

While various home monitoring and information and communication technologies can support people in their homes [7,8,10], these are often underused [14]. With any technology, the user needs are paramount, and for older people these needs can be complex. The whole care network should be considered [14], which includes the informal support network, such as friends, neighbors, and family members. This study has identified that home monitoring and information and communication technologies could help connect older adults to their informal support networks to assist aging in place if specific barriers are overcome.

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Authors' Contributions

All authors made a direct substantial intellectual contribution to this study. All authors approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Interview questions.

[PDF File (Adobe PDF File), 22KB - mhealth_v6i6e10741_app1.pdf]

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Original Paper

Feasibility of Using a Smartwatch to Intensively Monitor Patients With Chronic Obstructive Pulmonary Disease: Prospective Cohort Study

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Abstract

Background: Acute exacerbations of chronic obstructive pulmonary disease (COPD) are associated with accelerated decline in lung function, diminished quality of life, and higher mortality. Proactively monitoring patients for early signs of an exacerbation and treating them early could prevent these outcomes. The emergence of affordable wearable technology allows for nearly continuous monitoring of heart rate and physical activity as well as recording of audio which can detect features such as coughing. These signals may be able to be used with predictive analytics to detect early exacerbations. Prior to full development, however, it is important to determine the feasibility of using wearable devices such as smartwatches to intensively monitor patients with COPD.

Objective: We conducted a feasibility study to determine if patients with COPD would wear and maintain a smartwatch consistently and whether they would reliably collect and transmit sensor data.

Methods: Patients with COPD were recruited from 3 hospitals and were provided with a smartwatch that recorded audio, heart rate, and accelerations. They were asked to wear and charge it daily for 90 days. They were also asked to complete a daily symptom diary. At the end of the study period, participants were asked what would motivate them to regularly use a wearable for monitoring of their COPD.

Results: Of 28 patients enrolled, 16 participants completed the full 90 days. The average age of participants was 68.5 years, and 36% (10/28) were women. Survey, heart rate, and activity data were available for an average of 64.5, 65.1, and 60.2 days respectively. Technical issues caused heart rate and activity data to be unavailable for approximately 13 and 17 days, respectively. Feedback provided by participants indicated that they wanted to actively engage with the smartwatch and receive feedback about their activity, heart rate, and how to better manage their COPD.

Conclusions: Some patients with COPD will wear and maintain smartwatches that passively monitor audio, heart rate, and physical activity, and wearables were able to reliably capture near-continuous patient data. Further work is necessary to increase acceptability and improve the patient experience.

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KEYWORDS

chronic obstructive pulmonary disease; monitoring; physiologic disease management; wearable; telehealth

Introduction

Chronic obstructive pulmonary disease (COPD) affects 251 million people worldwide. In 2015, it was estimated to have caused 3.17 million deaths, 5% of all deaths globally [1]. People with COPD have exacerbations or episodes when their breathing, cough, or sputum production worsens, and treatment is warranted. Such acute exacerbations of COPD (AECOPDs) accelerate the decline in lung function, diminish quality of life, and lead to death [2-8]. Early treatment can reduce the severity of AECOPD and prevent hospitalizations, reduce morbidity, and likely reduce mortality [4,9].

Early treatment of AECOPD can be provided with early detection. Patients may be able to detect exacerbations earlier with information from frequent or continuous monitoring of physiologic parameters such as heart rate, respiratory rate, coughing, oxygen saturation, and physical activity. A recent systematic review examined the effectiveness of home telemonitoring for predicting an AECOPD [10]. Of the 16 studies that evaluated the predictive ability of systems that recorded physiologic parameters or symptoms, none appeared to be clinically reliable in predicting AECOPDs. One reason may be that most data are collected too infrequently. Most systems collected data once daily, potentially missing the sensitivity required to detect early AECOPDs [10].

The emergence of consumer wearables such as smartwatches offers a potential practical and affordable method to monitor and collect early signs frequently, even continuously, to detect concerning symptoms. However, such devices can only work if they are worn and maintained. While elderly patients have said they would be willing to use telemonitoring devices to improve their care [11], studies have found recruitment difficulties, with up to 80% refusing to use the device and low patient adherence [12,13]. The difficulty in reliably measuring physiologic data has been another reason attributed to the inability of telemonitoring to predict AECOPDs [10].

Our overall goal is to improve the care of people with COPD and reduce hospitalizations by providing patients with a practical way to monitor their condition to detect early exacerbations, allowing for timely intervention. In this study, we sought to determine whether patients with COPD would use, wear, and maintain a smartwatch for extended periods of time and whether such a device could reliably capture near-continuous sensor data.

Methods

Patient Recruitment

Participants with COPD aged 40 years and older were recruited from 3 hospitals—Sunnybrook Health Sciences Centre, Toronto General Hospital, and Toronto Western Hospital—and from 3 sources: hospital inpatient wards, respirology clinics, and responses to posters soliciting people with COPD. We excluded those who could not speak English, those who resided in a long-term care facility, those who had a medical condition that impaired their ability to participate in the study, and those who did not provide informed consent. Ethical approval was obtained from the University Health Network and Sunnybrook Health Sciences Centre research ethics committees.

Intervention

Our wearable system consisted of 3 main components: Android Wear smartwatch, Android phone, and remote server. Participants were provided with instructions on the use and charging of the watch and the phone and how to fill out the symptom survey. The smartwatch collected sensor data that included audio from a microphone on the watch, heart rate, accelerometer, and gyroscope recordings. To avoid depleting the battery, the smartwatch recorded 2 out of every 10 minutes. This strategy resulted in an average battery life of 16 hours, which proved sufficient for a full day's use. The accelerometer and gyroscope were sampled at 20 Hz. We used 2 smartwatch models: the LG Watch Urbane W150 (LG Electronics) and the Moto 360 2nd Generation (Motorola Mobility LLC; all 42 mm variations, including the sport and women's models), both running Android 6.0.1. The phone acted as a relay between the smartwatch and server and also prompted the user to fill out the symptom survey. We used LG Nexus 5 (LG Electronics; Android 6.0.1) or Moto G 3rd Generation (Motorola Mobility LLC; Android 6.0) phones. Each mobile phone is equipped with a 5 GB per month data plan, and our recording frequency and sampling rates were selected to fit within this limit. Phones were secured to prevent installation of other apps. The smartwatch sent sensor information to the mobile phone. These data were sent encrypted to a secure server, stored, and later made available for processing and analysis.

Outcomes

The primary outcome was whether patients with COPD were able to wear and maintain the smartwatches for 90 days. Secondary outcomes included the availability of heart rate, activity, and daily symptom surveys and qualitative feedback from participants at the end of the study. The heart rate and accelerometer data were collected directly from the smartwatches. Participants were also asked to complete a validated London COPD cohort daily symptom questionnaire consisting of 8 questions on the following symptoms: increased breathlessness, increased sputum color, increased sputum amount, a cold (such as runny or blocked nose), increased wheeze or chest tightness, sore throat, increased cough, and fever [3,14]. In accordance with the previous definitions, symptoms were classified as major (dyspnea, sputum purulence, and sputum volume) or minor (nasal discharge/congestion, wheeze, sore throat, cough, and fever). This survey has been validated to identify AECOPDs [3]. Patients who either dropped out or completed the study were also asked for their feedback on the wearable system, how they would want to interact with the system, and how the system could be improved.

Data Analysis

User behavior was analyzed to determine whether the participants filled out the daily questionnaires on the mobile phone. Questionnaires were scored using the previously validated scoring process to determine the occurrences of AECOPDs [14]. To calculate the daily symptom score, each major symptom was weighted 5 points and minor symptoms were 1 point each. AECOPD was defined when the participant had a score greater than 5 for 2 consecutive days. Resolution of AECOPD occurred when the score was at 0 for 5 days.

Heart rate and accelerometer data were only considered if the device was not charging and their sensor status reading was reported as reliable. Audio data were collected and processed to detect coughing but will be described in another paper. We applied previously established methods to process raw accelerometer sensor data to determine sedentary behavior and physical activity [15]. Initially, raw data were converted to a motion summary count using an area under the curve calculation after removing the effects of gravity, which provided activity counts per minute. Thresholds for sedentary behavior (<50.92 counts per minute) and moderate-vigorous physical activity (>305.36 counts per minute) were used from a validation study of Android devices [16]. Python and the pandas, NumPy, and Scikit libraries were used for analysis.

Two authors (TS and RW) first independently analyzed participant feedback to look for common themes and then met and agreed upon common themes.

Results

Patient Recruitment

Out of 179 approached, 28 patients were recruited. People were primarily excluded for having a medical condition that impaired their ability to participate or being unable to speak English (Figure 1). The main reasons that eligible patients declined participation included privacy concerns and that they were uninterested in participating in a research study. Of the 28 enrolled patients, 16 completed the 90-day follow-up. The major reasons for dropping out of the study were that they were too sick (5 patients), they experienced technology issues (2), and they had privacy concerns (2). The baseline characteristics are shown in Table 1. Of the 28 participants, the average age was 68.5 (range 41 to 84) years, and 10 participants were women. For the 16 participants who completed follow-up, the average age was 69.3 (range 52-84) years, and 4 were women.

Figure 1. Enrollment and outcomes.

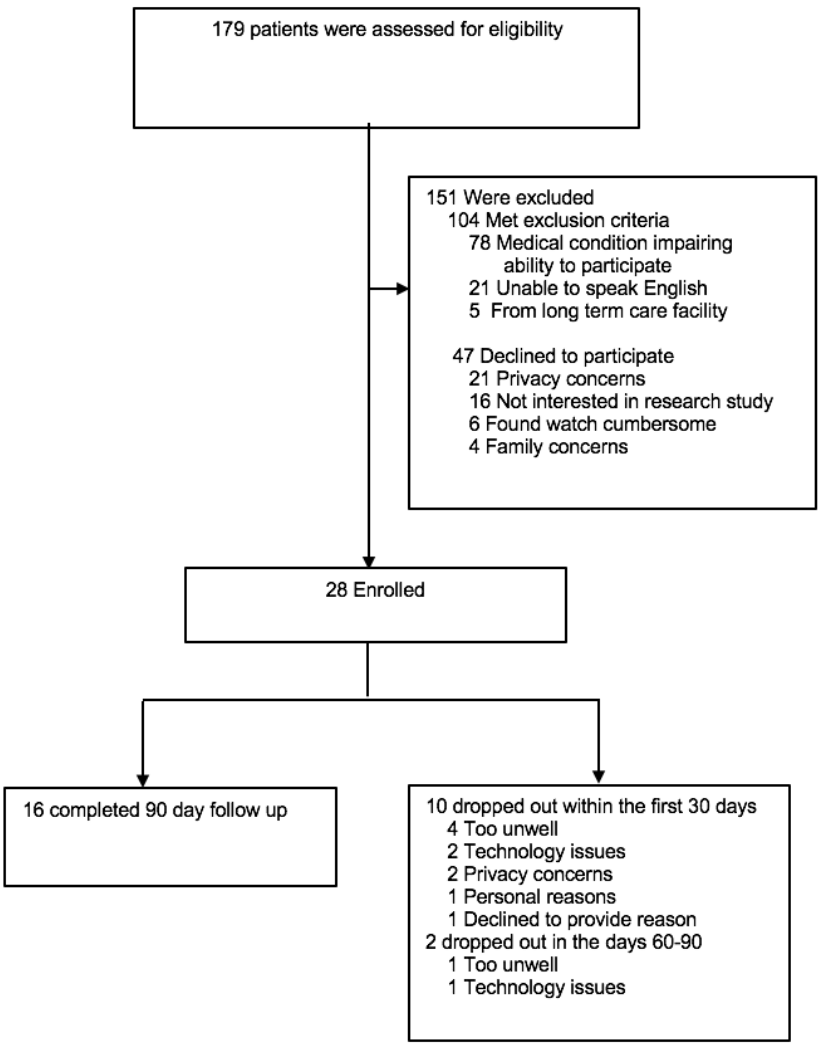


Table 1. Patient demographics.

Characteristics	All participants (n=28)	Participants who completed 90 days (n=16)
Age, years, mean	68.5	69.3
Women, %	35	25
FEV_1[a]/FVC[b], %	53	56
FEV_1, %	57	63

[a]FEV_1: forced expiratory volume in 1 second.

[b]FVC: forced vital capacity.

Intervention

There were several significant technical issues that occurred and were resolved in the initial 6 months. These issues prevented data to be uploaded and displayed errors on the watch. This caused 3 people to drop out as well as heart rate and accelerometer data to be unavailable for approximately 13 and 17 days, respectively. Other technical issues occurred intermittently in some smartwatches and mobile phones throughout the study period.

Outcomes

The daily survey questionnaires were completed an average of 47.5% of the time for all participants. For participants who completed the study, surveys were completed 71.7% of the time (range 21.1% to 100%), and the scoring of these surveys indicated 24 exacerbations which lasted an average of 32 (SD 24) days. There was a large variation in how patients scored their symptoms; 6 of 16 patients were considered to be in exacerbation for more than 75% of the time monitored.

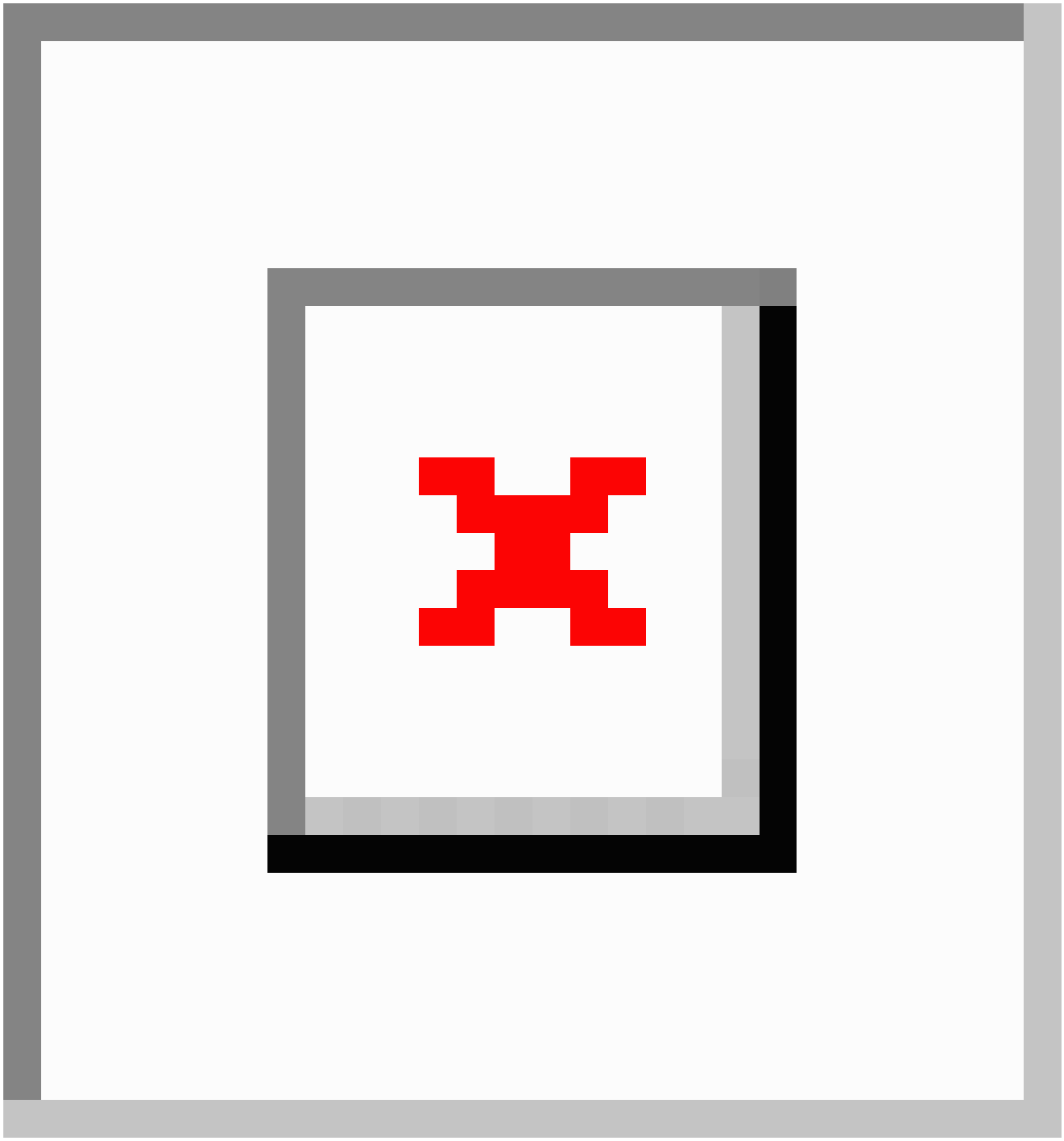
Patients had an average of 65.1 days of heart rate data available. For those days when data were available, there were on average 3170 heart rate recordings available per patient per day. Accelerometer data were available for 60.2 days on average. Due to the aforementioned technical issues, data were available for only 13 patients. For these patients, there were 592,000 accelerometer data points available per patient per day on average. After processing these to obtain sedentary behavior and moderate-to-vigorous physical activity, there were variations in patient activity (Table 2). An example of 1 patient's daily average heart rate, percentage of sedentary behavior and physical activity, and questionnaire responses is shown in Figure 2.

Table 2. Summary of survey, heart rate, and activity data by patient.

Patient number	Survey		Heart rate		Activity		
	Score, mean (SD)	Days completed	Mean (SD)	Days of available data	MVPA[a], mean %	Sedentary behavior, mean %	Days of available data
1	1.4 (2.7)	90	79.7 (8.7)	51	—	—	0
2	5.2 (4.8)	19	74.8 (6.1)	15	—	—	0
3	6.5 (4.8)	90	84.8 (5.4)	12	—	—	0
4	1.1 (2.5)	90	90.2 (9.5)	90	6.0	70.3	90
5	7.1 (5.4)	89	72.6 (7.8)	90	8.6	67.3	90
6	2.1 (3.8)	75	74.2 (5.8)	90	5.4	79.3	90
7	4.3 (4.0)	79	79.4 (10.7)	90	2.4	76.1	89
8	1.2 (2.1)	53	83.7 (16.5)	71	11.1	60.9	69
9	9.5 (4.7)	60	79.8 (10.2)	78	12.3	61.6	75
10	3.0 (4.3)	59	78.2 (11.3)	62	4.6	62.5	61
11	8.4 (4.8)	60	83.4 (7.4)	63	8.4	65.1	68
12	3.1 (3.7)	90	80.4 (6.4)	90	13.3	64.2	90
13	4.5 (4.0)	59	85.1 (8.2)	51	10.1	37.7	61
14	11.5 (4.8)	90	85.0 (5.7)	90	13.0	56.9	90
15	9.1 (3.4)	35	82.9 (15.8)	29	10.6	69.0	26
16	7.1 (5.3)	62	78.6 (4.0)	64	18.9	52.7	64
All	5.2 (5.3)	64.5	80.6 (10.4)	65.1	9.4	64.1	60.2

[a]MVPA: moderate to vigorous physical activity.

Figure 2. A participant's heart rate, activity, and symptom scores over 90 days.



Fifteen participants provided feedback on issues concerning using a COPD wearable and what would make them regularly use a COPD wearable. Those who dropped out expressed privacy issues with the study specifically recording audio and others noted technology issues with the smartwatch system that made them want to stop participating. There were concerns with the bulky smartwatch, and some expressed desire for a thinner, lighter, and more stylish wristband.

Participants expressed that they wanted an app and a device that could provide more feedback. This feedback would include information about themselves in terms of their heart rate, coughing data, and oxygen saturation. Participants were also interested in gaining knowledge by accessing COPD educational material, breathing exercises, and physical activity exercises. Some participants also liked the idea of their health care provider being alerted if their symptoms were getting worse while others worried their health care provider would find it a nuisance.

Discussion

Principal Findings

We conducted a feasibility study of smartwatches in people with COPD and found that they will wear and maintain smartwatches that passively monitor audio, heart rate, and physical activity data almost continuously. Thus, smartwatches appear to be a viable platform for the intensive sensor data collection that may be required to detect AECOPDs early.

The frequency of sensor data collected was much greater than the frequency of other previously described interventions, as we collected data for 2 minutes out of every 10 minutes. While most previous COPD telemonitoring studies collected data daily [10], the one study with more frequent collection used a custom wristband that was designed to perform 5 measurements of their oxygen saturation, heart rate, body temperature, and physical activity every 3 hours [17]. However, they obtained on average only 4 recordings per patient day, and data were available for only 60% of patient days, seemingly due to lack of use of their system.

We found that there were a high percentage of patients who were not interested in participating. While telemonitoring studies have not consistently reported their recruitment rate [18,19], our recruitment rate was lower than the rate found in the custom COPD wristband study (16% vs 57%) and our dropout rate was higher (43% vs 22%) [17]. This may have been due to privacy concerns of recording audio or the differences in recruitment settings, as one of our sources of patients was hospitalized patients who were often too sick to participate. We heard from participants that to increase enrollment, we should provide patients with feedback about their activity, their heart rate, and how to better manage their COPD because they did not just want a passive monitoring device.

We found that we can collect symptom data through the daily symptom card, but this was not consistently completed even in our motivated participants. The availability of symptoms surveys that our patients provided was similar to the literature (70% in our study vs 77% in a similar study) [20]. This may support the approach for data collection through passive sensors because it may be problematic to reliably obtain symptom surveys from patients with COPD on a long-term basis [13].

We found gender differences in recruitment with more men agreeing to participate and more men completing the study. This may be due to the large size of the smartwatches as several people commented on the bulkiness of the smartwatches. These gender differences should be explored further to determine if there are other factors which may deter women from using a wearable to help manage their COPD.

Limitations

There were significant limitations to our study. Many patients approached were not interested in participating. While this may partially be due to being part of a research study, it does call into question the generalizability of our results. We also had significant technical issues that negatively affected the retention of users and availability of data. Specifically, we found that the Android Wear platform was not a stable platform due to constant updates and operating system changes. Unfortunately, we were unable to definitively determine how much physiologic data were unavailable due to technical issues as opposed to not charging the device. As well, while the daily symptom score has been previously correlated with AECOPDs, we found a large variation in how patients would report symptoms. Some reported symptoms that were above their baseline, but some appeared to report any symptoms despite instruction. While the daily diary cards have been validated on paper [14], their use on a mobile phone app should be validated prior to further use. Finally, we collected heart rate and activity data but their accuracy is unclear because the smartwatches did not contain medical grade sensors.

Now that we have confirmed that some patients with COPD will use wearable devices that can obtain physiologic data, our next step is to engage patients in further depth to determine what they would like to see in a wearable device to help manage their COPD. This should increase the uptake and retention of both men and women with COPD. Further work would also include the validation of physiologic signals including cough detection, heart rate, and physical activity in predicting early AECOPDs.

Conclusion

We found that patients with COPD will wear and maintain smartwatches that passively monitor audio, heart rate, and physical activity, and we were able to reliably capture near-continuous patient data. Further work is necessary to increase acceptability and improve the patient experience.

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Conflicts of Interest

None declared.

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Abbreviations

AECOPD: acute exacerbation of chronic obstructive pulmonary disease
AGE-WELL NCE: Aging Gracefully across Environments using Technology to Support Wellness, Engagement and Long Life—Networks of Centres of Excellence

COPD: chronic obstructive pulmonary disease
MVPA: moderate to vigorous physical activity

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