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Original Paper

Short Message Service Text Message Support for Weight Loss in Patients With Prediabetes: Pragmatic Trial

Henry H Fischer[1], MD; Michael J Durfee[1], MPH; Silvia G Raghunath[1], BA; Natalie D Ritchie[1,2,3], PhD

[1]Denver Health and Hospital Authority, Denver, CO, United States

[2]Department of Psychiatry, University of Colorado School of Medicine, Aurora, CO, United States

[3]College of Nursing, University of Colorado, Aurora, CO, United States

Corresponding Author:
Henry H Fischer, MD
Denver Health and Hospital Authority
777 Bannock St
Denver, CO
United States
Phone: 1 3034364200
Fax: 1 3034364448
Email: henry.fischer@dhha.org

Abstract

Background: To reach all 84.1 million US adults estimated to have prediabetes warrants need for low-cost and less burdensome alternatives to the National Diabetes Prevention Program (NDPP). In a previous randomized controlled trial, we demonstrated the efficacy of a 12-month short message service text message support program called SMS4PreDM amongst individuals with prediabetes.

Objective: The study aimed to evaluate the implementation and effectiveness of SMS4PreDM in a pragmatic study following dissemination in a safety net health care system.

Methods: English- and Spanish-speaking patients at risk for diabetes (eg, glycated hemoglobin 5.7-6.4) were referred by their providers and offered either NDPP classes, SMS4PreDM, or both. This analysis focuses on weight change among 285 SMS4PreDM-only participants who began the year-long intervention between October 2015 and April 2017 with accompanying pre- and postweights, as compared with 1233 usual-care control patients at risk for diabetes, who were identified from electronic health records during this time but not referred. Weight outcomes included time-related mean weight change and frequency of either ≥3% weight loss or gain. Mixed linear models adjusted for age, gender, race, ethnicity, preferred language, and baseline weight. A secondary analysis was stratified by language. We also assessed implementation factors, including retention and cost.

Results: SMS4PreDM participants had high retention (259 of 285 patients or 91.0% completion at 12-months,) and a time-related mean weight loss of 1.3 pounds (SE 0.74), compared with the control group’s slight mean weight gain of 0.25 pounds (SE 0.59; *P*=.004). Spanish-speaking SMS4PreDM participants (n=130) had a time-related mean weight loss of 1.11 pounds (SE 1.22) compared with weight gain of 0.96 pounds (SE 1.14) in Spanish-speaking controls (n=382, *P*<.001). English-speaking intervention participants (n=155) had a comparable time-related mean weight change (–0.89 pounds; SE 0.93) as English-speaking controls (n=828; 0.31 pounds gained; SE 0.62, *P*=.14). Overall, frequency of achieving ≥3% weight loss was comparable between groups (54 of 285 or 19.0% of SMS4PreDM participants [95% CI 14.8-23.9] vs 266 of 1233 or 21.6% of controls [95% CI 19.3-24.0]; *P*=.33). Nonetheless, more controls had ≥3% weight gain compared with intervention participants (337 of 1233 or 27.3% of controls [95% CI 24.9-29.9] vs 57 of 285 or 20.0% of SMS4PreDM participants [95% CI 16.8-25.1]; *P*=.01). SMS4PreDM delivery costs were US $100.92 per participant.

Conclusions: Although SMS4PreDM was relatively low cost to deliver and demonstrated high retention, weight loss outcomes may not be sufficient to serve as a population health strategy.

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KEYWORDS

eHealth; prediabetes; texting; weight loss

Introduction

Background

To reach all 84.1 million US adults estimated to have prediabetes, low-cost and less burdensome alternatives to the NDPP are needed [1]. A 2015 review found median costs of US $417 per person for programs comparable with the NDPP [2]. A recent NDPP evaluation concluded that retention has been suboptimal [3], which may be because of the demands of year-long in-person meetings. In a previous randomized controlled trial (RCT), we demonstrated efficacy of a 12-month short message service (SMS) text message support program called SMS4PreDM in individuals with prediabetes [4]. Specifically, ≥3% weight loss was achieved by 30 of 79 or 38% of participants receiving the SMS4PreDM intervention (95% CI 27.7-49.3), compared with 17 of 81 or 21% of control group participants (95% CI 12.5-30.6; absolute difference of 17%; *P*=.02) [4]. Research suggests that such modest weight loss can prevent diabetes as every kilogram lost decreases risk by 16% [5]. Real-world NDPP implementation has appeared to result in less average weight loss (4.2% N=14,747 [3]) compared with that observed in its original RCT (4.9% N=1,079 [6], along with concerning disparities in outcomes for underserved participants [3]. Thus, it is important to similarly evaluate SMS4PreDM upon broader dissemination.

Objectives

We evaluated implementation and effectiveness and implementation of SMS4PreDM in a pragmatic study following dissemination in a safety net health care system.

Methods

English- and Spanish-speaking patients at risk for diabetes (eg, glycated hemoglobin 5.7-6.4) were referred by their providers and offered NDPP classes and/or SMS4PreDM. Outcomes from NDPP participants were recently published [7]. We focus here on evaluating effectiveness of SMS4PreDM. SMS4PreDM methodology has been described in detail [4]. In brief, SMS text message content was based on the NDPP curriculum and iteratively refined upon patient feedback. Messages promoted lifestyle change and modest weight loss and were delivered 6 days per week over 1 year. This analysis included 285 SMS4PreDM-only participants who began the intervention between October 2015 and April 2017, with accompanying baseline and follow-up weights available, as compared with a usual-care control group of 1233 patients at risk for diabetes and available weights, who were identified from electronic health record (EHR) data during the same time frame but not referred. Patients who became pregnant during the intervention or underwent bariatric surgery were excluded.

A repeating measure analysis used all weights available in the EHR from routine health care visits within a year of the individual's start date for SMS4PreDM participants or matched identification date for controls, as well as 12-month weights collected by study personnel upon invitation for participants without recent clinical visits. Weight outcomes included mean time-related weight change and realization of either ≥3% weight loss or gain. Mixed linear models adjusted for age, gender, race, ethnicity, preferred language, and baseline weight. A secondary analysis stratified by language. We also assessed implementation factors, including retention and cost. The Colorado Multiple Institutional Review Board approved this program as an evaluation project, which was not registered as a clinical trial.

Results

Participant characteristics are shown in Table 1. Retention in SMS4PreDM was high as only 20 of 285 or 7% dropped out in the first 4 weeks, with 259 of 285 or 91% completing the 12-month program. SMS4PreDM participants (n=285) had an average of 5.6 visits with weight assessments during the study period compared with 5.4 visits for the control group (n=1233; *P*=.72). Most SMS4PreDM participants (262 of 285 or 91.9%) exclusively had EHR-derived weights, with few patients having weights collected by invitation (23 of 285 or 8.1%).

The intervention group had a time-related mean weight loss of 1.3 pounds (SE 0.74), whereas the control group realized mean weight gain of 0.25 pounds (SE 0.59, *P*=.004). Spanish-speaking SMS4PreDM participants (n=130) realized time-related mean weight loss of 1.11 pounds (SE 1.22) compared with weight gain of 0.96 pounds (SE 1.14) in Spanish-speaking controls (n=382, *P*<.001). English-speaking intervention participants (n=155) did not achieve more time-related mean weight change (–0.89 pounds; SE 0.93) than English-speaking controls (n=828; 0.31 pounds gained; SE 0.62; *P*=.143). There was no significant difference between groups in frequency of reaching the ≥3% weight loss goal (54 of 285 or 19.0% of SMS4PreDM participants [95% CI 14.8-23.9] vs 266 of 1233 or 21.6% of controls [95% CI 19.3-24.0]; *P*=.33). However, more controls gained ≥3% weight compared with intervention participants (337 of 1233 or 27.3% of controls [95% CI 24.9-29.9] vs 57 of 285 or 20.0% of SMS4PreDM participants [95% CI 16.8-25.1]; *P*=.011). SMS4PreDM delivery costs were US $100.92 per participant.

Table 1. Demographics of short message service text message support (SMS4PreDM) and control group participants.

Demographic	Intervention (n=285)	Control (n=1233)	*P* value
Sex, n (%)			.003
Female	217 (76.1)	827 (67.1)	
Male	68 (23.9)	406 (32.9)	
Race, n (%)			.18
White	218 (76.5)	895 (72.6)	
Black	36 (12.6)	220 (17.8)	
Asian	7 (2.5)	27 (2.2)	
Other/unknown	24 (8.4)	91 (7.4)	
Ethnicity, n (%)			<.001
Hispanic/Latino	173 (60.7)	584 (47.4)	
Non-Hispanic/Latino	61 (21.4)	364 (29.5)	
Unknown	51 (17.9)	285 (23.1)	
Language, n (%)			<.001
English	155 (54.4)	828 (67.2)	
Spanish	130 (45.6)	382 (30.9)	
Unknown	0 (0)	23 (1.9)	
Age (years), mean (SD)	45.5 (12.2)	48.4 (14.6)	<.001

Discussion

Principal Findings

In this pragmatic study of SMS text message support for weight loss to prevent diabetes, SMS4PreDM afforded high retention at a lower cost than the NDPP. However, modest weight outcomes suggest that SMS4PreDM may not be clinically effective enough to serve as a population health strategy. Although nearly twice as many SMS4PreDM participants achieved ≥3% weight loss than controls in our previously published RCT [4], less robust weight loss outcomes were demonstrated in real-world dissemination, a trend also observed with the NDPP [3]. At the same time, fewer participants in this pragmatic trial gained ≥3% weight compared with controls (NNT 14), which may hold importance, given findings that weight gain of 1 kg/m^2 has been shown to increase glucose dysregulation [8], although more studies of this relationship are warranted. Weight loss results of SMS4PreDM were also generally within the range of outcomes found in prior systematic reviews of mobile phone apps and SMS text messaging interventions for weight reduction [9,10].

Limitations

Limitations include nonrandomization in our pragmatic study, which may have contributed to demographic differences observed between study groups (although analyses controlled for such factors). Analyses also excluded participants without available weights; however, conditions for weight collection were largely similar between groups overall (eg, the majority of all patients in the analysis had weights collected from approximately bimonthly, routine clinical visits). However, a potential bias is that SMS4PreDM participants who successfully lost weight may have been more likely to comply with requests for final weight measurement with study personnel. It is also unknown why Spanish-speaking individuals appear to respond better to SMS text message support than English-speaking individuals, as consistent with our prior RCT [4].

Conclusions

Future qualitative study may be needed to help explain why SMS4PreDM and similar interventions can yield less impact upon dissemination. An educational and motivational enhancement before NDPP enrollment was shown to increase efficacy in 1 study, although potentially by excluding less activated individuals [11]. Ensuring increased readiness for weight loss may potentially improve efficacy in a population that choose SMS text message support instead of in-person classes and possibly yield greater cost-effectiveness by more appropriately matching services with patients likely to benefit from them. Further research is also needed to better understand the extent to which supplemental coaching may be necessary to optimize weight loss and which extra-visit technology-based platforms (eg, apps) are most cost-effective. Future efforts to target reach among Spanish speakers may also be merited, particularly given there is likely less-than-adequate availability of Spanish-language NDPPs or comparable in-person interventions. More broadly, SMS text messaging may be especially beneficial during the maintenance phase following weight loss, given its acceptability for long-term contact [12], coupled with modestly beneficial outcomes and a relatively low cost. Retention during the maintenance phase of the NDPP has been especially problematic [3], necessitating identification of retention-bolstering strategies. In conclusion, SMS text messaging for weight-related support may continue to hold appeal, potentially for retention purposes, and further work may be merited to determine how to incorporate its desirable features along with more clinically effective components.

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Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health record
NDPP: National Diabetes Prevention Program
RCT: randomized controlled trial
SMS: short message service

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Original Paper

Web-Based Benefit-Finding Writing for Adults with Type 1 or Type 2 Diabetes: Preliminary Randomized Controlled Trial

Joanna Crawford[1,2], MPsychol(Clin); Kay Wilhelm[1,2,3], MBBS, MD; Judy Proudfoot[1], PhD

[1]Black Dog Institute, Sydney, Australia
[2]School of Psychiatry, University of New South Wales, Sydney, Australia
[3]Consultation Liaison Psychiatry, St. Vincent's Health Australia, Sydney, Australia

Corresponding Author:
Joanna Crawford, MPsychol(Clin)
Black Dog Institute
Hospital Road, Prince of Wales Hospital
Randwick, NSW
Sydney, 2031
Australia
Phone: 61 2 9382 8310
Email: joanna.crawford@blackdog.org.au

Abstract

Background: The high prevalence of diabetes distress and subclinical depression in adults with type 1 and type 2 diabetes mellitus (T1DM and T2DM, respectively) indicates the need for low-intensity self-help interventions that can be used in a stepped care approach to address some of their psychological needs. However, people with diabetes can be reluctant to engage in mental health care. Benefit-finding writing (BFW) is a brief intervention that involves writing about any positive thoughts and feelings concerning a stressful experience such as an illness, avoiding potential mental health stigma. It has been associated with increases in positive affect and positive growth and has demonstrated promising results in trials in other clinical populations. However, BFW has not been examined in people with diabetes.

Objective: This study aimed to evaluate the efficacy of a Web-based BFW intervention for reducing diabetes distress and increasing benefit finding in diabetic adults with T1DM or T2DM compared to a control writing condition.

Methods: Adults with T1DM or T2DM and diabetes distress were recruited online through the open access Writing for Health program. After completing baseline questionnaires, they were randomly allocated to receive online BFW or an active control condition of online writing about the use of time (CW). Both groups completed 15-minute online writing sessions, once per day, for 3 consecutive days. Online measures were administered at baseline, 1 month, and 3 months postintervention. Participants were also asked to rate their current mood immediately prior to and following each writing session.

Results: Seventy-two adults with T1DM or T2DM were recruited and randomly allocated to receive BFW (n=24) or CW (n=48). Participants adhered to the BFW regimen. Greater increases in positive affect immediately postwriting were found in the BFW group than in the CW group. However, there were no significant group-by-time interactions (indicating intervention effects) for benefit finding or diabetes distress at either the 1-month or 3-month follow-up. Both the BFW and CW groups demonstrated small, significant decreases in diabetes distress over time.

Conclusions: BFW was well tolerated by adults with diabetes in this study but did not demonstrate efficacy in improving diabetes distress or benefit finding compared to an active control writing condition. However, due to recruitment difficulties, the study was underpowered and the sample was skewed to individuals with minimal diabetes distress and none to minimal depression and anxiety at baseline. Future research should continue to investigate the efficacy of variants of therapeutic writing for adults with T1DM or T2DM, using larger samples of participants with elevated diabetes distress.

Trial Registration: Australiand New Zealand Clinical Trials Registry ACTRN12615000241538; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=368146

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KEYWORDS

diabetes; adult; distress; benefit-finding; depression; anxiety; emotions; internet; writing; surveys and questionnaires; treatment outcome

Introduction

Background

Diabetes mellitus is group of disorders posing a global public health challenge. In 2018, the International Diabetes Federation estimated that the global prevalence of diabetes in adults in 2017 was 8.4% (451 million adults) [1]. Psychological comorbidity is common and burdensome in people with type 1 or type 2 diabetes mellitus (T1DM or T2DM, respectively) [2-4], with many experiencing negative thoughts and emotions toward diabetes and its treatment [4,5]. Diabetes distress is a construct correlated with, but distinct from, depression in people with diabetes and includes distress associated with the treatment regimen, eating, hypoglycemia, complications, interpersonal relationships, and health care professionals [5,6]. Approximately 70% of people with T2DM display high levels of diabetes-related distress without meeting the criteria for major depressive disorder (MDD) [7,8]. Diabetes distress is associated with poor glycemic control and acts as a unique contributor to poor diabetes self-care [9,10]. Several studies have found that diabetes distress mediates the association between depressive symptoms and hemoglobin A_{1c} (HbA_{1c}) [11,12]. Further, diabetes distress is also a risk factor for depression [13].

Similarly, in people with diabetes, anxiety and depression are associated with poorer diabetes self-management [14-17] and increased disease severity and complications [16-19]. Of note, subthreshold depressive symptoms (which fall short of the full diagnostic criteria for MDD or dysthymia) are more common in people with diabetes than MDD, but are less likely to be diagnosed than MDD [20]. Approximately half of the people with T2DM will experience at least one episode of subthreshold depression over 5 years [19]. Subthreshold depressive symptoms in people with diabetes are associated with poorer quality of life [21,22] and poorer diabetes self-care [15]. These findings have increased attention to addressing diabetes distress and mild depressive symptoms in patients with diabetes and may provide an avenue for preventing MDD [13,21,23] and improving diabetes self-management [11,12,24].

The international guidelines for diabetes management now recognize the importance of psychological care [24]. Screening for both diabetes distress and depressive symptoms in people with diabetes, followed by appropriate interventions, has been recommended [21,25]. A stepped-care approach has been suggested, with mild distress or subthreshold depression managed within primary care, utilizing evidence-based self-help interventions [26,27]. Web-based interventions, predominantly clinician-assisted interventions, are effective for reducing comorbid depression in people with diabetes [28]. However, many interventions for diabetes distress or depression rely upon face-to-face group sessions [29], numerous telephone calls [30], or clinician support [28]. Overall, there is growing recognition of the need for low-intensity interventions to address diabetes distress or subthreshold depression, which are cost-effective and easily disseminated to large numbers of patients.

However, many people with diabetes are reluctant to seek mental health care [31]. This may be due to the stigma of mental ill health and the belief that distress associated with diabetes is normal and should not be pathologized [32]. Hence, interventions that do not explicitly refer to “depression” or “anxiety” may appeal more to some people with diabetes [32].

Therapeutic writing is a brief intervention that aims to improve physical or mental health [33]. The most common form of therapeutic writing is expressive writing (EW), in which thoughts and feelings regarding a stressful event are disclosed in writing, typically for 15-20 minutes for 3-4 days within a short period of time [34]. EW has been examined in over 250 studies investigating its effects on physical or mental health in a wide range of populations, including healthy participants, people with psychological problems, and people with chronic health conditions [33,35-37]. However, there are limitations to EW. Results of EW studies are quite variable, and the effect sizes are often small [33,35]. Further, EW often involves an immediate increase in distress [33], even when followed by longer-term benefits [38], which limits its suitability for wide dissemination without therapist support.

Indeed, trials of EW in people with diabetes have yielded mixed results. One study, for example, found fewer depressive symptoms at follow-up [39], while another found reduced stress but no effect on HbA_{1c} levels, diabetes self-care, or diabetes distress [40]. A later trial found that EW was associated with a *worsening* in depressive symptoms, with no change in diabetes distress [41]. Of note, in the latter study, the EW task involved writing about any stressful experience over the past month rather than a diabetes-specific task.

Such findings have led researchers to investigate other variations of therapeutic writing, to maximize benefits and increase positive affect (and reduce distress) during the intervention. By modifying writing instructions, researchers have sought to increase the likelihood that participants engage in desired cognitive processes, with the aim of increasing the benefits gained from the writing task [42,43]. The integration of positive psychology into therapeutic writing is one such modification [44].

Benefit-finding writing (BFW) involves writing about any *positive* thoughts and feelings about a stressful experience such as an illness. Until recently, research has largely overlooked the utility of positively focused writing following stressful events or illness. However, there is emerging evidence that the experience of a medical illness often has sequelae that patients view as positive or beneficial [45]. Benefit finding is defined as “identifying positive life changes resulting from adversity and negative life stressors, including illness” [46]. It is correlated with posttraumatic growth [47], which has recently been found to be associated with greater positive affect and less negative affect in the daily lives of people with some chronic health conditions [48]. Benefit finding has been associated with increased psychosocial well-being and decreased depression in a range of clinical populations [46,49]. Benefit finding in diabetes has been associated with lower symptoms of depression, increased adherence to diabetes self-care, and greater perceived coping effectiveness [50]. Therefore, interventions to increase benefit finding in people with diabetes could be useful [50].

Trials of BFW in both nonclinical populations [43,51-54] and clinical populations [55-58] have demonstrated promising results. Compared to EW, BFW has been found to result in less distress and increased positive affect immediately postwriting [51,59]. Results from pilot trials in clinical populations suggest that BFW has benefits with regard to the symptoms of depression [56], anxiety [55], fatigue [58], and the number of cancer-related medical appointments [57]. In addition, positive affect journaling has recently been found to reduce symptoms of depression and anxiety in general medical patients with elevated anxiety [44]. Thus, the limited research on BFW to date suggests that it may have the same longer-term health benefits as EW, but with the added advantage of immediate increases in *positive* affect. However, BFW has not been examined in people with diabetes.

To our knowledge, this is the first study of BFW in people in diabetes. We aimed to examine BFW in adults with T1DM or T2DM who were experiencing diabetes distress, but were not experiencing a mood or anxiety disorder. This is because people with diabetes who meet the criteria for MDD or an anxiety disorder are likely to require more intensive treatment, with several evidence-based interventions available [28]. Our study included participants reporting mild or minimal symptoms of depression or anxiety, in addition to any degree of diabetes distress.

Objectives

The primary aim of this randomized controlled trial (RCT) was to evaluate the efficacy of a Web-based BFW intervention for adults with T1DM or T2DM (compared to a CW condition) for reducing diabetes distress and increasing benefit finding in diabetes. The secondary outcomes examined were self-rated depression and anxiety symptoms, diabetes self-care, health, and health care utilization. It was hypothesized that participants randomized to the BFW condition would demonstrate significant decreases in diabetes distress and symptoms of depression and anxiety, and report reduced visits to health care professionals compared to those in the control group. It was also hypothesized that participants randomized to the BFW condition would experience significant increases in benefit finding in relation to diabetes and improvements in diabetes self-care and perceived health, relative to those in the control group, and that these effects would be evident at 1-month and 3-month follow-up assessments.

This study also aimed to conduct manipulation checks of the BFW intervention instructions by investigating immediate emotional responses to the writing tasks and their linguistic content. It was hypothesized that, compared to those in the CW group, participants in the BFW group would (1) have significantly greater increases in positive affect immediately after writing but not significantly different changes in negative affect; (2) use a significantly higher proportion of positive emotion words, negative emotion words, and cognitive processing words, in line with previous research [51]; and (3) rate their responses as significantly more personal and more meaningful, but not more distressing.

Finally, as people with diabetes can be reluctant to engage in psychological care [31], this study aimed to examine the feasibility of internet-based BFW by adults with T1DM or T2DM. Feasibility was assessed by adherence and acceptability of the intervention.

Methods

Design

The design consisted of a CONSORT-EHEALTH [60]–compliant, 2 (conditions) x 3 (time) RCT (Multimedia Appendix 1). The protocol for the trial has been published [61]. Participants were randomized to either internet-based BFW or internet-based CW (use-of-time writing). Both conditions involved an intervention of 3 days of online writing using the *Writing for Health* website (see below). Outcome measures were administered at three time points for both groups: baseline, 1 month, and 3 months postintervention. Self-rated current mood was also assessed immediately prior to and following each writing session. An online feedback questionnaire was administered postintervention.

Participants and Recruitment

Ethics approval was obtained from the Human Research Ethics Committee at St. Vincent’s Hospital, Sydney, Australia (HREC/13/SVH/379). All participants provided informed consent before engaging in any research-related activity. This study was prospectively registered with the Australia and New Zealand Clinical Trials Registry (ACTRN12615000241538).

The study was advertised from February 2015 to November 2016 on the websites, social media, and publications of Australian diabetes-related organizations and advertisements in waiting rooms of diabetes services and general practitioners throughout Sydney, Australia. Due to slow recruitment, the study was also advertised in Diabetes Australia’s printed Circle Magazine, which was mailed to 140,000 members. Finally, letters were mailed to 500 adult members of the National Diabetes Services Scheme in Australia, informing them of the study. In all advertising and recruitment materials, adults with T1DM or T2DM were directed to the *Writing for Health* website to find out more about the study.

Eligibility and exclusion criteria for adults with T1DM or T2DM living in Australia are shown in Textbox 1. The exclusion threshold was set at 8 or above on both the Generalized Anxiety Disorder-7 items (GAD-7) scale or the Patient Health Questionnaire-9 items (PHQ-9) scale, as sensitivity and specificity values have been found to be acceptable for a cutoff of 8 on the GAD-7 scale for identifying generalized anxiety disorder [62] and the PHQ-9 scale for identifying MDD [63]. Participants were not provided any compensation for taking part in the study.

Textbox 1. Eligibility and exclusion criteria.

Eligibility criteria:

- Consent to participate
- Age ≥ 18 years
- Living in Australia
- Type 1 or type 2 diabetes, self-reported as diagnosed by a general practitioner or endocrinologist
- Email address and access to the internet
- Ability to read and write in English with ease

Exclusion criteria:

- Patient Health Questionnaire-9 score >8 or Generalized Anxiety Disorder-7 score >8
- Current suicidal thoughts, as indicated by a response of >1 to item 9 on the Patient Health Questionnaire-9 scale
- Self-reported diagnosis of schizophrenia, bipolar disorder, or a psychotic disorder
- Self-reported diagnosis of dementia or another cognitive disorder
- Engagement in current psychological therapy

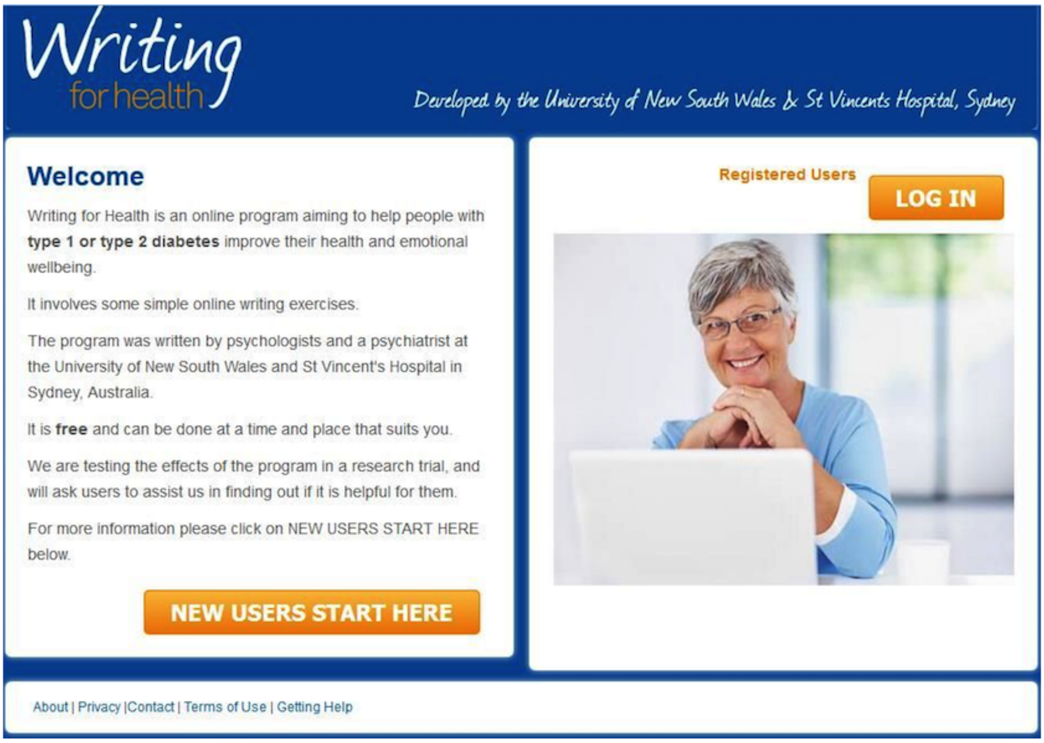
Procedure

Potential participants applied for the study via the open access *Writing for Health* website (Figure 1). All stages of this study were conducted online through *Writing for Health*, including information about the study, consent to participate, screening questionnaires with automated feedback, participant registration, randomization to one of two conditions, the writing interventions, feedback questionnaire, and follow-up questionnaires at 1 month and 3 months postintervention.

Potential participants read the study information in *Writing for Health* and provided informed consent online (by checking a box) to participate. The study was described as investigating whether the writing exercises in the *Writing for Health* program improve the mental and physical well-being of people with diabetes. Both types of writing exercises were described to potential participants. However, the research hypotheses were not revealed.

Potential participants completed automated screening questionnaires, which also provided baseline data. Excluded applicants received an onscreen message informing them that the program is not suitable for them, with links to appropriate resources. All potential participants were provided with online feedback on the severity of their depression and anxiety symptoms.

Figure 1. Homepage of Writing for Health.



Welcome

Writing for Health is an online program aiming to help people with **type 1 or type 2 diabetes** improve their health and emotional wellbeing.

It involves some simple online writing exercises.

The program was written by psychologists and a psychiatrist at the University of New South Wales and St Vincent's Hospital in Sydney, Australia.

It is **free** and can be done at a time and place that suits you.

We are testing the effects of the program in a research trial, and will ask users to assist us in finding out if it is helpful for them.

For more information please click on NEW USERS START HERE below.

Participants who met the eligibility criteria proceeded to online registration with the program, completed further online questionnaires (for further baseline data, see below), and were randomized to one of two online writing conditions (BFW or CW). Randomization (1:1) was automatically generated by *Writing for Health* after participants registered with the program. Although the randomization process was concealed from the researchers, they were not blinded to the condition of each participant. At the conclusion of the 3-day writing intervention, participants were invited to complete an online *Feedback Questionnaire*.

Automated reminder emails were sent by *Writing for Health* to participants on each day of their 3-day writing intervention and when it was time to complete their follow-up questionnaires at 1 month and 3 months postintervention. Participants were also provided automated feedback on the severity of their depression and anxiety symptoms at their online follow-up assessments.

Safety Protocol

Direct contact between participants and researchers did not occur in the standard course of the trial. However, in accordance with the study safety protocol [61], a study psychologist contacted a participant by email or telephone if he/she indicated distress after a writing session or scored in the severe range for depression or anxiety at the 1-month or 3-month follow-up, or indicated possible suicidal thoughts, to assess any need for psychological support and refer the participant to appropriate services, if required.

Intervention

The online *Writing for Health* website was developed for this study by mental health researchers (including psychologists and a psychiatrist) at St Vincent's Hospital, Sydney, Australia, and the University of New South Wales, and was hosted on a secure server at the university. Feedback on the usability of the website was previously provided by five adults with T1DM or T2DM during the development process.

Both the BFW and CW conditions involved participants in three 15-minute online writing sessions (once per day for 3 consecutive days), according to the instructions provided. Participants from both conditions continued to receive usual care from their health services.

Intervention Condition: Internet-Based Benefit-Finding Writing for Diabetes

Participants in the BFW condition were asked to write about any *positive* thoughts and feelings that they had had about their experiences with diabetes. The instructions (Multimedia Appendix 2) were adapted from those used by Stanton and colleagues (2002) in BFW for women with breast cancer [57]. The same instructions were provided for all three writing sessions, consistent with previous studies of BFW [57,58].

Control Condition: Internet-Based Use-of-Time Writing (Control Writing)

Participants in the CW condition were asked to write in detail about how their time was spent that day (first writing session) and the plans for how their time will be spent the following day (second writing session) and week (third writing session). Participants were instructed to be as objective as possible and to focus on the facts and details of how their time was spent (or will be spent), and not to focus on their emotions. These CW instructions were adapted from the control conditions used in previous trials of therapeutic writing [51,56,64,65].

Measures

Primary Outcome Measures

The 17-item Diabetes Distress Scale (DDS17) [61] is a self-report measure of psychosocial stress associated with diabetes, with four reliable subscales: Emotional Burden (feeling overwhelmed by diabetes), Physician-Related Distress (worries about access, trust, and care), Regime-Related Distress (concerns about diet, physical activity, and medications), and Interpersonal Distress (not receiving understanding and appropriate support from others). Cut-off points on the DDS17 have been established for little or no distress, moderate distress, and high distress [65].

The 17-item Benefit Finding Scale [45] was originally developed to investigate benefit finding in women with early stage breast cancer. In the current study, the stem question is modified from, "Having had breast cancer has..." to "Having had diabetes has..." Participants were asked to respond to each of the 17 perceived benefits, such as "has lead me to be more accepting of things" and "has brought my family closer together" on a 5-point scale: 1 - *not at all*, 2 - *a little*, 3 - *moderately*, 4 - *quite a bit*, and 5 - *extremely*. This scale has previously been adapted for use in diabetes (with one item removed) and found to have one large factor and good internal consistency (Cronbach alpha=0.89) in a population of adolescents with T1DM [50].

Secondary Outcome Measures

The PHQ-9 [66] was used in the initial online screening to assess current symptoms of depression. It is a brief, widely used, reliable, valid 9-item self-report measure of both severity of depression over the past 2 weeks and is used to make a Diagnostic and Statistical Manual of Mental Disorders-IV criteria–based diagnosis of depression. It has established cut-off scores of 5, 10, 15, and 20, representing mild, moderate, moderately severe, and severe depression, respectively. The total score ranges between 0 and 27, with scores ≥10 having a sensitivity of 88% and a specificity of 88% for major depression [66].

The GAD-7 [67] was used in the initial online screening to assess the current symptoms of anxiety. It is a brief, widely used, reliable, and valid 7-item self-report measure of the severity of anxiety. Scores range from 0 to 21; scores of 5, 10, and 15 represent mild, moderate, and severe anxiety symptoms, respectively. A total score of 8 has been identified as an important threshold for identifying the presence of an anxiety disorder [68].

The Summary of Diabetes Self-Care Activities (SDSCA) measure (revised) is an 11-item self-report measure of self-care of diabetes (including diet, exercise, blood sugar testing, foot care, and smoking) widely used both clinically and in research [69]. Items in the revised version were selected based on their psychometric properties, sensitivity to change, and ease of scoring and interpretation [69]. In a critical appraisal of 26 different measures of diabetes outcomes, the SDSCA measure (revised) was one of only three measures that meets all the criteria of suitability, validity, reliability, and sensitivity to change [70].

Self-rated health was assessed by the question, “In general, how would you rate your health at present?” The five response options were: *very good*, *good*, *fair*, *poor*, and *very poor*. Responses to this question have previously been found to be significantly associated with the blood glucose indicator HbA_{1c} (poorer self-rated health associated with higher HbA_{1c} levels) and number of self-reported diabetes-related symptoms in patients with T2DM [71].

Health care utilization was assessed by the question “In the past month, how many times have you visited a doctor or other health care professional?” at three time-points: baseline, 1-month follow-up, and 3-month follow-up.

Additional Measures

The measures below were assessed to conduct manipulation checks.

International Positive and Negative Affect Schedule—Short Form

The International Positive and Negative Affect Schedule Short Form (I-PANAS-SF) is a reliable and valid 10-item measure of positive and negative affect, comprised of 10 words that represent positive and negative affect [67]. The values of the correlations between this short-form and the positive and negative affect scales of the full 20-item form of the PANAS are 0.92 and 0.95, respectively [72]. Instructions were modified to assess state rather than trait affect, using the instructions of the 20-item PANAS - Immediate Version [73]. Participants were instructed to indicate the degree of specific affect they feel “right now, at the present moment” on a scale of 1 to 5 (1=very slightly/not at all, 5=extremely).

Essay Evaluation Measure

The Essay Evaluation Measure is a 3-item measure adapted from previous studies [57,74], which asks participants to rate, immediately after each writing session, how meaningful, personal, and distressing their writing exercise was, on a 7-point scale (0=not at all, 6=extremely). Similar questions have been used as manipulation checks in previous therapeutic writing studies [57,74]. Immediately after each writing session, participants in the BFW intervention condition were also asked if they were able to identify *any* positive thoughts or feelings about living with diabetes in their writing session.

Feedback Questionnaire

The Feedback Questionnaire is a 12-item self-report measure developed to assess participants’ experiences and perceptions of the *Writing for Health* program. Item content was informed by self-report measures from other evaluations of internet-based interventions [75,76] and included its usability, ease of use, credibility, and most and least helpful aspects.

Other Measures

Sociodemographic information (age, gender, education, and occupation) and diabetes-related information (type, duration of illness, management, and complications) were also collected.

Data Analysis

Statistical analyses were conducted using SPSS 22 (IBM Corp, Armonk, NY). Group differences in baseline characteristics were analyzed with two-sample *t* tests and Chi-square tests. The 1-month and 3-month follow-up data were analyzed on an intention-to-treat (ITT) basis using the SPSS mixed procedure. Time was treated as a repeated measures factor (3 levels: T1, T2, T3), with an unstructured residual variance-covariance matrix, and with fixed effects for group, time, and time-by-group interactions. This procedure allowed inclusion of individuals with missing data at follow-up assessments [77].

Planned contrasts were used to examine differences between the groups in changes in outcome variables between baseline and each of the two follow-up occasions and changes over time within groups. All effects were tested at $P<.05$. Within-group and between-group Cohen *d* effect sizes for the primary and secondary outcome measures were also calculated.

Prior to outcome analyses, the distribution of variables was examined for skewness, with variables transformed (log or square root) as needed to reduce skewness to between -1 and 1. All four DDS17 subscale scores and the Blood Sugar Testing subscale of the SDSCA required log transformation; the DDS17, PHQ-9 and GAD-7 total scores required square root transformation. Outliers (scores more than 3 SDs above the mean) were addressed using the winsorizing technique, in which outliers are replaced with the mean value plus 3 SDs [78]. Winsorizing is recommended to reduce the impact of outliers on the Type 1 error rate [78]. Only one outlier value was identified and winsorized.

In addition, manipulation check analyses were conducted to validate the writing intervention instructions in three ways:

- Scores on the Essay Evaluation Measure were compared between the two groups using analysis of variance (ANOVA).
- To examine immediate emotional responses to the writing interventions, scores on the I-PANAS-SF [72] administered immediately before and after each writing session were analyzed using a 2 (group) x 3 (session) x 2 (positive affect and negative affect) repeated measures multivariate ANOVA.
- The content of the written scripts in both groups was assessed using the Linguistic Inquiry Word Count 2015 software program (2015) [79] to examine for differences in positive emotion words and cognitive insight words. This validated method provides a content analysis of the language used in the scripts, quantifying the number of words used from specific categories (eg, emotions and cognitive processes) and has previously been used in numerous studies of therapeutic writing [51,59,80-82]. Linguistic Inquiry Word Count scores for word categories were compared between the two groups using ANOVAs.

Sample Size and Power Analysis

For this preliminary study, we powered the study to detect a moderately large effect size (Cohen *d*) of 0.7, consistent with previous BFW studies [52,57]. Based on a statistical power of 0.80 and a probability level (Cronbach alpha) of .05, a sample size of 34 per group (ie, 68 for the two groups) was needed for two-tailed tests to detect an effect size (Cohen *d*) of 0.7. Given the expected attrition rate of approximately 34% [41], our target total sample size was 104.

However, the unexpected difficulty encountered in recruiting participants to the trial caused extensive delays in the study timeline. Many different methods were employed to recruit the required sample size, and the recruitment period was extended to assist the effort. Yet, by the end of the extended recruitment period, only 88 of the 104 participants had been recruited (BFW: n=37; CW: n=51). Of these, 72 participants (BFW: n=24; CW: n=48) had completed their baseline measures and were therefore eligible for inclusion in ITT analyses. Revised power analyses were conducted to determine the effect sizes that could be detected with the obtained sample size. Moreover, the unintended unequal allocation of participants eligible for analyses in the two groups (resulting in a 2:1 ratio) would further reduce the statistical power, as a 2:1 ratio requires 12% more participants than a trial using 1:1 to detect the same effect size with equivalent power [83]. Therefore, for ITT analyses in this study (BFW: n=24; CW: n=48), moderately large effect sizes of Cohen *d* ≥0.73 could be detected by two-tailed tests, given a statistical power of 0.80 and a Cronbach alpha of .05.

Results

Participant Recruitment and Attrition

A participant flow diagram is displayed in Figure 2. Over a 21-month period, only 169 individuals provided consent to commence the screening procedure during that period. Of these, 162 commenced the online screening procedure and 102 were eligible to participate, 88 of whom proceeded to online registration and were randomized to either the BFW group (n=37) or the CW group (n=51). Of these participants, 25 allocated to the BFW group and 48 allocated to the CW group completed baseline assessment. One participant in the BFW group formally withdrew from the study after completing the baseline questionnaires but before commencing the intervention. Thus, 24 participants in the BFW group and 48 in the CW group were eligible for inclusion in the ITT analyses (N=72).

At the 1-month follow-up, 21 BFW participants and 33 CW participants completed the questionnaires, while at the 3-month follow-up, 17 BFW participants and 23 CW participants completed the questionnaires. Within the BFW group, 21 participants completed all three writing sessions (88% of those who completed baseline data and 95% those who completed the first writing session). In comparison, 37 of the CW participants completed all three writing sessions (77% of those who completed baseline data and 86% of those who completed the first writing session). There was no significant difference between the BFW group (95%) and the CW group (86%) in the proportion of participants who completed all three writing sessions, of those who commenced the first session (χ^2_1=1.341, *P*=.25).

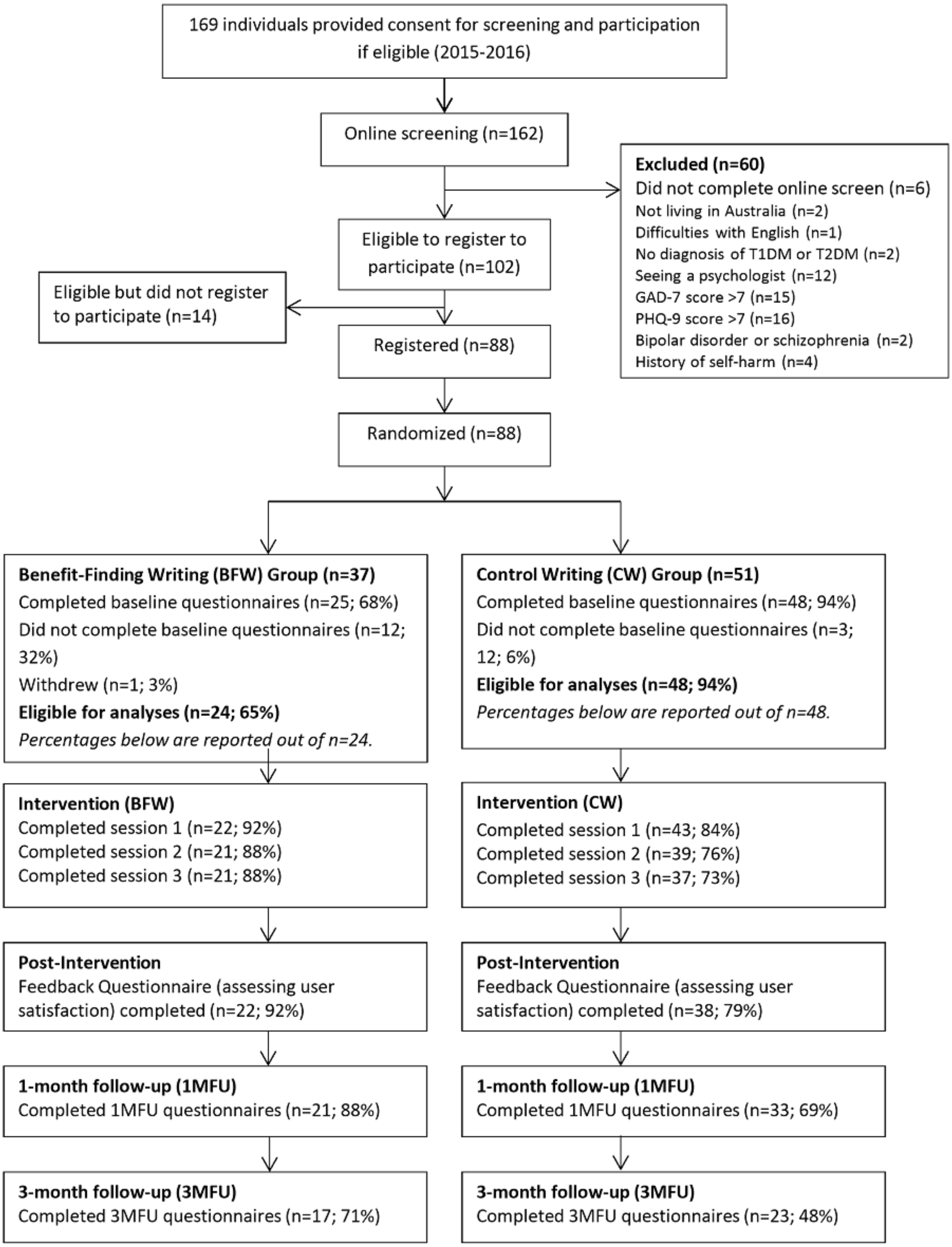


Figure 2. Participant flow diagram. GAD-7: Generalized Anxiety Disorder-7 items; PHQ-9: Patient Health Questionnaire-9 items; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus.

Baseline Characteristics

Table 1 displays the demographic and clinical baseline characteristics, and Table 2 shows the outcome measures at baseline. A total of 46 participants (64% of the sample) had T1DM and the remaining 26 participants (36%) had T2DM. The majority were women (n=57, 79%) and highly educated, with 63% (n=45) reporting that they had a university degree. Over one-third of the sample was retired (n=27, 38%). The mean response score of 3.96 (SD 0.82) on the current health item (ranging from 1=very poor to 5=very good) corresponded to “good” self-reported current health.

Table 1. Participant demographic and baseline characteristics in the benefit-finding writing and control writing groups and the total sample.

Characteristic	Total sample (N=72)	BFW[a] (n=24)	CW[b] (n=48)	*P* value[c]
Demographics				
Age (years), mean (SD)	53.79 (15.93)	53.54 (17.26)	53.92 (15.41)	.80
Female, n (%)	57 (79)	20 (83)	37 (77)	.64
Married/de facto, n (%)	44 (62)	15 (65)	29 (60)	.51
Employed (full-time or part-time), n (%)	30 (42)	9 (39)	21 (44)	.40
Retired, n (%)	27 (38)	10 (44)	17 (35)	.29
University educated, n (%)	45 (63)	14 (61)	31 (65)	.72
Clinical characteristics				
Type 1 diabetes, n (%)	46 (64)	15 (62)	31 (65)	.87
Years since diabetes diagnosis, mean (SD)	17.69 (14.26)	16.86 (13.68)	18.08 (14.65)	.78
Diabetes complications, n (%)	16 (22)	4 (17)	12 (22)	.69
Diabetes management[d], n (%)				
Insulin	51 (71)	17 (71)	34 (71)	.98
Medication	24 (33)	6 (25)	18 (38)	.60
Blood sugar testing	67 (93)	24 (100)	43 (90)	.68
Healthy eating plan	59 (82)	18 (75)	41 (85)	.73
Exercise	54 (75)	16 (67)	38 (79)	.61
Current antidepressant medication, n (%)	13 (18)	6 (25)	7 (15)	.24
Ever been depressed, n (%)	33 (46)	12 (50)	21 (44)	.50
Ever had a mental illness diagnosed, n (%)	22 (31)	7 (29)	15 (31)	.88

[a] BFW: benefit-finding writing.

[b] CW: control writing.

[c] *P* values for variables based on means are from a two-sample *t* test. *P* values for variables based on percentages are from a Chi-square test.

[d] Categories were not mutually exclusive and participants could indicate more than one management strategy to best describe their situation.

As reported in Table 2, participants' baseline levels of depression, anxiety, and diabetes distress were very low. Baseline scores on the PHQ-9 (mean 2.25, SD 1.62) indicated that most participants were in the "minimal to none" range (0 to 4) for depression symptoms [62]; similarly, baseline scores on the GAD-7 (mean 1.71, SD 1.73) indicated that most participants were in the "minimal to none" range (0 to 4) for anxiety symptoms [63]. Further, baseline scores on the DDS (mean 1.74, SD 0.66) and all four subscales of the DDS17 (means ranging from 1.65 to 1.95) were in the range of "DDS < 2.0: little or no diabetes distress" [65]. However, almost one half of the sample (n=33, 46%) reported ever experiencing depression for 2 weeks or more in the past (Table 1).

There were no significant differences between the intervention (BFW) and control (CW) groups in any baseline characteristics (demographics, clinical characteristics, or outcome measures), with the exception of a single item of the SDCSA measure (revised) assessing fruit and vegetable consumption (t_{70}=2.484, P=.02). The CW group had a significantly higher mean number of days (5.58 days, SD 1.41 days) than the BFW group (4.30 days, SD 2.34 days) in which they ate five or more serves of fruits and vegetables over the past 7 days.

Table 2. Baseline scores on primary and secondary outcome measures in the benefit-finding writing and control writing groups and the total sample.

Measure	Total sample (N=72)	BFW[a] (n=24)	CW[b] (n=48)	*P* value[c]
Primary outcome measures				
Benefit Finding Scale, mean (SD)	43.81 (16.67)	39.83 (17.16)	45.79 (16.23)	.45
Diabetes Distress Scale, mean (SD)				
Total score	1.73 (0.64)	1.74 (0.66)	1.73 (0.63)	.60
Emotional Burden	1.65 (0.68)	1.66 (0.66)	1.65 (0.70)	.49
Physician-Related Distress	1.68 (0.71)	1.70 (0.70)	1.67 (0.71)	.39
Regimen-Related Distress	1.73 (0.66)	1.80 (0.71)	1.69 (0.64)	.67
Interpersonal Distress	1.95 (0.87)	1.83 (0.77)	2.01 (0.92)	.56
Secondary outcome measures				
PHQ-9[d], mean (SD)	2.11 (1.59)	2.25 (1.62)	2.04 (1.58)	.31
GAD-7[e], mean (SD)	1.60 (1.71)	1.71 (1.73)	1.54 (1.71)	.24
Revised Summary of Diabetes Self-Care Activities				
General Diet, mean (SD)	5.29 (1.68)	4.93 (2.14)	5.46 (1.41)	.86
Specific Diet—Fruit and Veg, mean (SD)	5.17 (2.10)	4.30 (2.34)	5.58 (1.87)	.02[f]
Specific Diet—High-Fat Foods, mean (SD)	3.39 (2.16)	3.61 (2.45)	3.29 (2.03)	.56
Exercise, mean (SD)	3.79 (2.26)	3.39 (2.28)	3.98 (2.25)	.45
Blood Glucose Testing, mean (SD)	5.54 (2.28)	5.50 (2.27)	5.56 (2.31)	.76
Foot Care, mean (SD)	2.53 (2.52)	2.17 (2.67)	2.70 (2.45)	.19
Smoking Status, n (%)	7 (10)	1 (4)	6 (13)	.23
Self-reported health, mean (SD)	3.96 (0.82)	4.00 (0.80)	3.94 (0.84)	.78
Number of visits to a health professional in the past 30 days, mean (SD)	1.82 (2.17)	2.04 (1.97)	1.71 (2.28)	.56

[a] BFW: benefit-finding writing.

[b] CW: control writing.

[c] *P* values for variables based on means are from a two-sample *t* test. *P* values for variables based on percentages are from a Chi-square test.

[d] PHQ-9: Patient Health Questionnaire-9 items.

[e] GAD-7: Generalized Anxiety Disorder-7 items.

[f] Statistically significant at *P*<.05.

Manipulation Checks

Essay Evaluation Measure

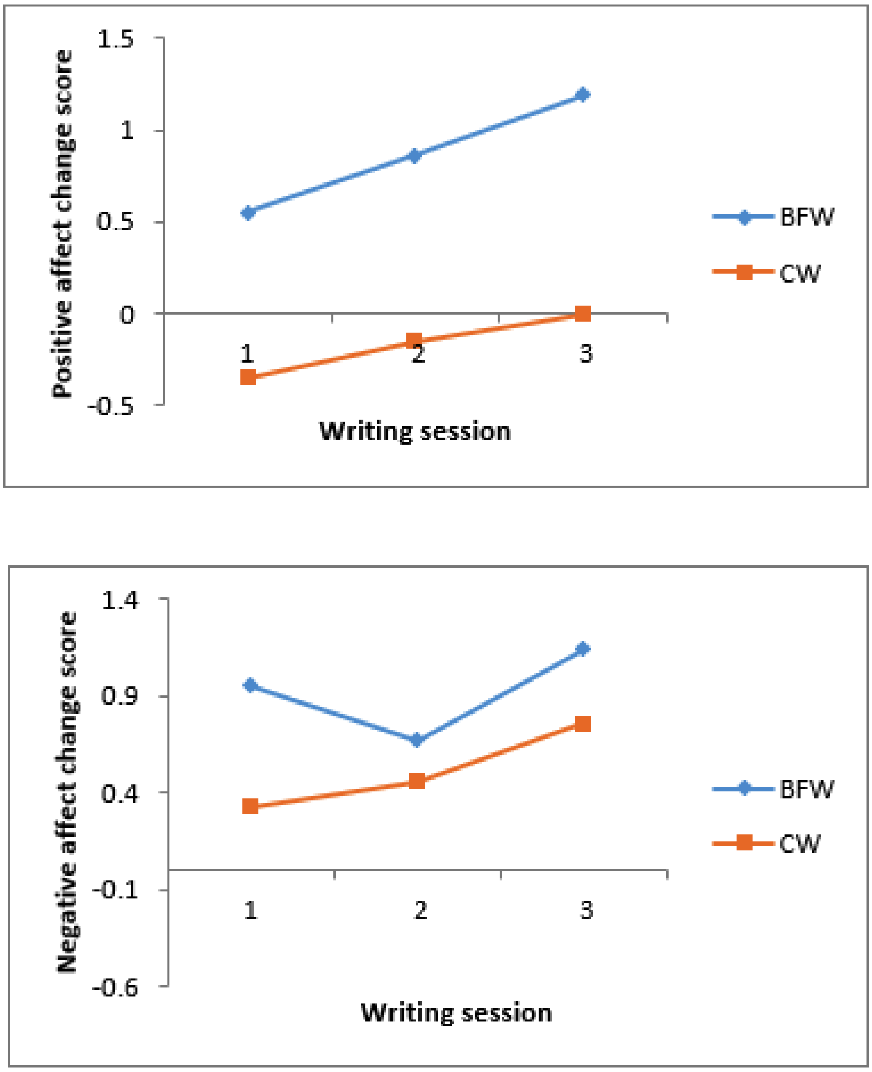
Consistent with predictions, participants in the BFW group rated their writing exercises as significantly more personal ($F_{1,56}$=6.00, *P*=.02, $_p{}^2$=0.09) and significantly more meaningful ($F_{1,56}$=6.87, *P*=.01, $_p{}^2$=0.11) than those in the CW group. The two groups did not differ significantly in terms of the ratings of how distressing the writing exercises were ($F_{1,56}$=2.76, *P*=.10, $_p{}^2$=0.05).

The majority of participants in the BFW group reported being able to identify positive thoughts or feelings about diabetes in their writing sessions: 20 (91%) in Writing Session 1, 21 (100%) in Writing Session 2, and 20 (95%) in Writing Session 3.

Linguistic Content Analyses

Consistent with predictions, participants in the BFW group used a significantly greater proportion of positive emotion words ($F_{1,56}$=128.37, *P*<.001, $_p{}^2$=0.70), negative emotion words ($F_{1,56}$=55.23, *P*<.001, $_p{}^2$=0.50), causal words ($F_{1,56}$=49.71, *P*<.001, $_p{}^2$=0.47), and cognitive insight words ($F_{1,56}$=180.32, *P*<.001, $_p{}^2$=0.76) than those in the CW group. The two groups did not differ in the total number of words used per session ($F_{1,56}$=0.13, *P*=.72, $_p{}^2$=0.00).

Figure 3. Mean positive and negative affect change scores on the International Positive and Negative Affect Schedule - Short Form in the benefit-finding writing and control writing groups. BFW: benefit-finding writing; CW: control writing.



Positive and Negative Affect

Change scores (post-pre) for the Positive Affect and Negative Affect subscales of I-PANAS-SF were computed for each of the three writing sessions (Figure 3). As predicted, the BFW group had significantly greater increases in positive affect than the CW group ($F_{1,56}$=7.76, P=.01 , η_p^2=0.12). The increases in negative affect following writing did not differ significantly between the BFW and CW groups ($F_{1,56}$=2.37, P=.13 , η_p^2=.04).

Effect of Writing Interventions on Primary Outcome Measures

Between-Group Differences in Primary Outcome Measures at 1-Month and 3-Month Follow-Ups

Table 3 presents the observed means and estimated marginal means for the primary outcome measures at baseline and 1-month and 3-month follow-ups. Table 4 reports the between-group results of the SPSS mixed procedure analyses and the Cohen *d* effect sizes. Figure 4 displays the estimated means of the primary outcome measures in the two groups at baseline, 1-month follow-up, and 3-month follow-up.

There were no significant group-by-time interactions in the mixed model analyses for the BFS or DDS17 scores ($F_{2,45.75}$=2.18, P=.12 and $F_{2,45.75}$=0.34, P=.97, respectively). As displayed in Table 4, there were no significant group-by-time interactions for any of the planned contrasts examining differences between the BFW and CW groups in changes from baseline to 1-month follow-up or 3-month follow-up for the BFS, total DDS17 score, or any of the four subscales of the DDS17 (all P>0.05). In addition, as displayed in Table 4, all between-group Cohen *d* effect sizes for the primary outcomes were minimal to small.

Table 3. Results of primary outcome measures: observed and estimated means with SDs at baseline and 1-month and 3-month follow-ups.

Primary outcome for each group	Observed means (SD)			Estimated means[a] (SD)		
	Baseline[b]	1-month follow-up[c]	3-month follow-up[d]	Baseline	1-month follow-up	3-month follow-up
Benefit Finding Scale						
BFW[e]	39.83 (17.16)	39.91 (18.68)	40.06 (18.22)	39.83 (16.52)	38.10 (18.78)	37.61 (19.07)
CW[f]	45.79 (16.23)	46.97 (19.12)	49.09 (19.77)	45.79 (16.56)	45.04 (19.61)	49.29 (20.58)
Diabetes Distress Scale Total						
BFW	1.74 (0.66)	1.62 (0.56)	1.54 (0.65)	1.30 (0.24)	1.25 (0.20)	1.23 (0.24)
CW	1.73 (0.63)	1.67 (0.57)	1.57 (0.48)	1.30 (0.21)	1.26 (0.21)	1.24 (0.28)
Diabetes Distress Scale Subscales						
Emotional Burden						
BFW	1.66 (0.66)	1.75 (0.81)	1.58 (0.62)	0.44 (0.39)	0.48 (0.44)	0.42 (0.39)
CW	1.65 (0.70)	1.83 (0.77)	1.79 (0.61)	0.43 (0.34)	0.51 (0.48)	0.52 (0.48)
Physician-Related Distress						
BFW	1.70 (0.70)	1.42 (0.91)	1.44 (0.81)	0.27 (0.20)	0.12 (0.20)	0.15 (0.20)
CW	1.67 (0.71)	1.34 (0.49)	1.26 (0.41)	0.27 (0.21)	0.14 (0.21)	0.11 (0.28)
Regimen-Related Distress						
BFW	1.80 (0.71)	1.74 (0.69)	1.58 (0.57)	0.52 (0.34)	0.48 (0.34)	0.42 (0.39)
CW	1.69 (0.64)	1.67 (0.66)	1.57 (0.63)	0.47 (0.28)	0.43 (0.35)	0.40 (0.35)
Interpersonal Distress						
BFW	1.83 (0.77)	1.46 (0.59)	1.55 (1.02)	0.39 (0.29)	0.24 (0.29)	0.21 (0.34)
CW	2.01 (0.92)	1.87 (1.07)	1.59 (0.89)	0.43 (0.28)	0.32 (0.35)	0.27 (0.35)

[a] Estimated means based on intention-to-treat sample of benefit-finding writing (n=24) and control writing (n=48), with variables transformed (log or square root) to address skewness, SDs, and CIs shown in parentheses.

[b] Benefit-finding writing: n=24, Control writing: n=48.

[c] Benefit-finding writing: n=21, Control writing: n=33.

[d] Benefit-finding writing: n=17, Control writing: n=23.

[e] BFW: benefit-finding writing.

[f] CW: control writing.

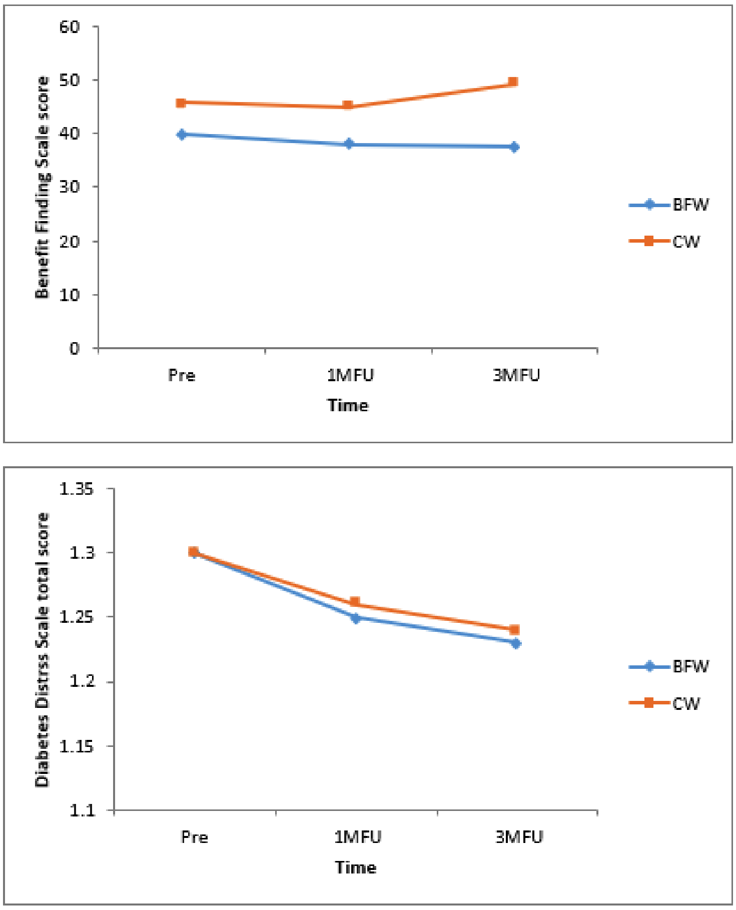
Table 4. Estimated differences in mean change of primary outcomes between baseline and 1-month or 3-month follow-up for the benefit-finding writing and control writing groups.

Outcome	Baseline to 1-month follow-up[a]			Baseline to 3-month follow-up[b]		
	Estimated mean difference (95% CI)	*P* value	Cohen *d* (95% CI)	Estimated mean difference (95% CI)	*P* value	Cohen *d* (95% CI)
Benefit Finding Scale	0.98 (–5.19 to 7.15)	.32	–0.06 (–0.63 to 0.50)	5.72 (–0.52 to 11.97)	.07	–0.34 (–0.80 to 0.19)
Diabetes Distress Scale, total score	0.01 (–0.07 to 0.09)	.82	–0.05 (–0.54 to 0.44)	0.01 (–0.06 to 0.09)	.83	–0.05 (–0.53 to 0.45)
Diabetes Distress Scale subscales						
Emotional Burden	0.05 (–0.16 to 0.25)	.65	–0.11 (–0.59 to 0.39)	0.11 (–0.07 to 0.29)	.23	–0.31 (–0.79 to 0.20)
Physician-Related Distress	0.02 (–0.10 to 0.13)	.74	–0.10 (–0.59 to 0.38)	–0.05 (–0.15 to 0.06)	.38	0.19 (–0.31 to 0.67)
Regimen-Related Distress	–0.00 (–0.12 to –0.11)	.95	–0.02 (–0.49 to 0.47)	0.02 (–0.11 to 0.16)	.74	–0.10 (–0.58 to –0.40)
Interpersonal Distress	0.04 (–0.11 to 0.19)	.61	–0.14 (–0.63 to 0.36)	0.01 (–0.14 to 0.16)	.88	–0.07 (–0.56 to 0.42)

[a] Difference = (baseline – 1-month follow-up [for benefit-finding writing]) – (baseline – 1-month follow-up [for control writing]).

[b] Difference = (baseline – 3-month follow-up [for benefit-finding writing]) – (baseline – 3-month follow-up [for control writing]).

Figure 4. Estimated means of the primary outcome measures in the benefit-finding writing and control writing groups at baseline (pre), 1-month follow-up, and 3-month follow-up using the Benefit Finding Scale and Diabetes Distress Scale. 1MFU: 1-month follow-up; 3MFU: 3-month follow-up; BFW: benefit-finding writing; CW: control writing.



Within-Group Differences in Primary Outcome Measures at 1-Month and 3-Month Follow-Ups

Table 5 displays the results of mixed procedure analyses for within-group changes on the primary outcomes from baseline to 1-month and 3-month follow-ups. There were no significant within-group changes from baseline in terms of benefit finding in relation to diabetes (BFS scores). However, significantly lower diabetes distress (DDS17 total score) was observed in both groups at the 3-month follow-up, but not the 1-month follow-up, compared to the baseline. The within-group changes in the four subscales of DDS17 were also examined. Both the BFW and CW groups displayed significant within-group reductions in two subscales of the DDS17 (Physician-Related Distress and Interpersonal Distress) at both 1-month and 3-month follow-ups. As shown in Table 5, medium effect sizes were observed for these within-group DDS17 subscale changes. However, neither group displayed any significant within-group changes in the other two subscales of the DDS17 (Emotional Burden and Regimen-Related Distress).

Table 5. Within-group estimated changes in primary outcomes between baseline and 1-month and 3 month follow-ups.

Outcome and group	Baseline to 1-month follow-up[a]			Baseline to 3-month follow-up[b]		
	Estimated mean difference (95% CI)	*P* value	Cohen *d* effect size *d* (95% CI)	Estimated mean difference (95% CI)	*P* value	Cohen *d* effect size *d* (95% CI)
Benefit Finding scale						
BFW[c]	1.74 (–3.13 to 6.60)	.48	0.10 (–0.47 to 0.66)	2.22 (–2.59 to 7.03)	.48	0.12 (–0.44 to 0.69)
CW[d]	0.76 (–3.04 to 4.55)	.69	0.04 (–0.36 to 0.44)	–3.50 (–7.48 to 0.48)	.08	–0.19 (–0.59 to 0.21)
Diabetes Distress Scale total						
BFW	0.05 (–0.20 to 0.11)	.14	0.23 (–0.58 to 1.03)	0.07 (0.01 to 0.13)	.03	0.29 (–0.51 to 1.10)
CW	0.04 (–0.01 to 0.08)	.13	0.19 (–0.38 to 0.76)	0.06 (0.01 to 0.11)	.02	0.24 (–0.33 to 0.81)
Diabetes Distress Scale subscales						
Emotional Burden						
BFW	–0.04 (–0.20 to 0.13)	.65	–0.10 (–0.90 to 0.70)	0.02 (–0.11 to 0.16)	.75	0.05 (–0.75 to 0.85)
CW	–0.08 (–0.21 to 0.04)	.18	–0.19 (–0.76 to 0.38)	–0.09 (–0.20 to 0.03)	.13	–0.22 (–0.78 to 0.35)
Physician-Related Distress						
BFW	0.15 (0.06 to 0.24)	<.001	0.75 (–0.08 to 1.58)	0.11 (0.03 to 0.20)	.007	0.60 (–0.22 to 1.42)
CW	0.13 (0.06 to 0.20)	<.001	0.62 (–0.04 to 1.20)	0.16 (0.09 to 0.22)	<.001	0.65 (–0.53 to 1.23)
Regimen-Related Distress						
BFW	0.03 (–0.06 to 0.13)	.49	0.12 (–0.68 to 0.92)	0.09 (–001 to 0.20)	.08	–0.27 (–1.08 to 0.53)
CW	0.03 (–0.04 to 0.11)	.36	0.13 (–0.44 to 0.69)	0.07 (–0.02 to 0.16)	.11	–0.22 (–0.79 to 0.35)
Interpersonal Distress						
BFW	0.15 (0.03 to 0.27)	.02	0.52 (–0.30 to 1.33)	0.17 (0.06 to 0.29)	.004	0.57 (–0.25 to 1.39)
CW	0.11 (0.02 to 0.22)	.02	0.35 (0.22 to 0.95)	0.16 (0.07 to 0.26)	<.001	0.51 (0.07 to 1.08)

[a] Change = baseline – 1-month follow-up.

[b] Change = baseline – 3-month follow-up.

[c] BFW: benefit-finding writing.

[d] CW: control writing.

Effect of Writing Interventions on Secondary Outcome Measures

Between-Group Differences in Secondary Outcome Measures at 1-Month and 3-Month Follow-Ups

Multimedia Appendix 3 includes the observed means and estimated marginal means for the secondary outcome measures at baseline and follow-ups. The results for the between-group differences in secondary outcomes are displayed in Multimedia Appendix 4. There was only one significant group-by-time interaction for any of the secondary outcome measures examined. For self-reported health, there was a significant difference between the BFW and CW groups in changes from baseline to 1-month follow-up (*P*=.04), reflecting an increase in self-reported health in the CW group and a decrease in the BFW group (neither of these within-group changes were significant). However, there was no significant difference between the two groups in changes in self-reported health from baseline to the 3-month follow-up (*P*=.81). There were no significant group-by-time interactions for scores of the PHQ-9, GAD-7, revised SDSCA, or health care utilization.

Within-Group Differences in Secondary Outcome Measures at 1-Month and 3-Month Follow-Ups

The results for the within-group differences in secondary outcomes are displayed in Multimedia Appendix 5. Both the BFW and CW groups displayed significant increases in depression (PHQ-9 scores) and anxiety (GAD-7) scores over time. In both the BFW and CW groups, there were significant within-group increases in both the PHQ-9 and GAD-7 scores from baseline to 1-month follow-up and a significant increase in GAD-7 scores from baseline to the 3-month follow-up. The CW group also displayed a significant increase in PHQ-9 scores from baseline to the 3-month follow-up. The effect sizes for these within-group changes ranged from small to moderately large. The observed mean PHQ-9 and GAD-7 scores in both groups at both follow-ups remained in the nonclinical range (2.79 to 4.47), which is in the "none-minimal" range (<5) for depression and anxiety severity.

There were few other significant within-group changes in the secondary outcomes. In the BFW group, there was a significant decrease in Exercise scores on the revised SDSCA at the 1-month follow-up, but not at the 3-month follow-up. In the

CW group, there was a significant increase in the Foot Care subscale of the revised SDSCA at the 1-month follow-up, but not at the 3-month follow-up. There were no significant within-group changes over time in either group for the General Diet, Specific Diet, or Blood Glucose Testing subscales of the revised SDSCA or self-reported health or health care utilization.

Safety

Mean distress ratings reported after each session were low for both groups in all three writing sessions, ranging from 0.14 to 1.05. Two participants in the BFW group (8%) and two in the CW group (4%) were contacted by email following a high distress rating (≥5/6); all four participants reported that their distress was short-lived. Four participants in the BFW group (17%) and two in the CW group (4%) were contacted by telephone due to elevated scores on the PHQ-9 or GAD-7 at follow-up(s), in line with the study safety protocol [61]. One participant (in the BFW group) was referred to a mental health service after reporting a recurrence of previous depression at the 3-month follow-up. All six participants contacted by telephone had reported a history of depression or a diagnosis of a mental illness at baseline. There were no privacy breaches or technical difficulties during the trial.

Acceptability

The BFW group (n=22) and CW group (n=38) did not differ in their mean total score for the Feedback Questionnaire (BFW: mean 16.18, SD 4.89; CW: mean 15.36, SD 5.34; t_{58}=0.59, *P*=.56). In the BFW group, 71% (n=15) of the participants reported that they were “mostly” to “very” satisfied with the *Writing for Health* program compared to 55% (n=21) in the CW group (χ^2_1=1.47, *P*=.23). Approximately half of the participants in both the BFW group (n=11, 51%) and CW group (n=18, 47%) reported that they would be “mostly” to “very” confident in recommending *Writing for Health* to a friend with diabetes (χ^2_1=0.14, *P*=.71). Further, approximately one-third of both groups (BFW: n=7, 33%; CW: n=13, 34%) reported that the writing exercises were “mostly” to “very” helpful in reducing stress (χ^2_1=0.01, *P*=.95).

Discussion

Principal Findings

This RCT examined the efficacy of BFW, compared to a CW condition, among adults with T1DM or T2DM who were not currently experiencing MDD or an anxiety disorder. It was hypothesized that participants randomized to the BFW group, compared to those in the CW group, would have significant increases in benefit finding, significant reductions in diabetes distress (primary outcomes), and significant improvements in the secondary outcomes at both the 1-month and 3-month follow-ups. However, these hypotheses were not supported by our results. In addition, there were no significant intervention effects on the primary outcomes.

All the hypotheses for the validation analyses were supported by our results. This suggests that the results for the outcome measures cannot be explained by participants not following the writing instructions or failing to engage with the writing tasks as expected. Specifically, consistent with other BFW studies [52,56,57], participants in the BFW group rated their writing sessions as significantly more personal and meaningful than those in the CW group. Second, as in previous findings [43,84,85], the BFW group had a significantly greater increase in positive affect following writing, relative to the CW group. Third, consistent with previous findings, linguistic analyses revealed that BFW participants had a greater use of positive emotion words [51,85-87], negative emotion words [51,85], and cognitive processing words [51,85,88,89] than CW participants. Further, the majority of BFW participants reported that they were able to identify at least one positive aspect of living with diabetes in their writing session that day. Overall, these findings suggest that the BFW participants followed their writing instructions and, as expected, engaged in both emotional expression and cognitive processing to a greater degree than control group participants. However, there were no significant between-group differences in the primary and secondary outcome variables. A second review of the literature produced several potential explanations.

To our knowledge, this was the first study to examine benefit finding as an outcome of therapeutic writing, so it is not possible to directly compare this finding with previous trials. However, posttraumatic growth, a concept closely related to benefit finding [90], has been found to increase following BFW to a greater degree than following EW [43]. Further, more intensive interventions have previously been found to increase benefit finding in medical populations [91,92]. For example, in adults with T2DM, benefit finding was found to increase following 14 sessions of telephone health coaching [92]. Our BFW intervention (of three 15-minute sessions) was substantially briefer, with less clinician contact. Although the intervention brevity and content were chosen to avoid potential resistance to psychological care by people with diabetes, it is conceivable that a more intensive, or simply more efficacious, intervention is required to increase benefit finding in people with diabetes.

Contrary to our hypotheses, the BFW group did not show significant reductions in diabetes distress, compared to the control group, at either the 1-month or 3-month follow-up. Rather, both groups had significant within-group reductions in diabetes distress, specifically in Physician-Related Distress and Interpersonal Distress, which are related to diabetes-related support from health professionals and family and friends, respectively. Thus, one possibility is that the process of participating in a research study about experiences of living with diabetes, albeit with limited clinician support, was sufficient to increase the level of perceived social support in relation to diabetes, regardless of the writing intervention instructions. This explanation is consistent with the findings of the REDEEM trial, in which three brief online interventions, all accompanied by support telephone calls, resulted in significantly reduced diabetes distress in nondepressed adults with T2DM [30]. As suggested by the authors [30], it appeared that nondepressed adults with diabetes distress were highly responsive to professional attention and normalization of diabetes distress. The finding of a small reduction in diabetes distress in both groups in this study is consistent with the findings of a meta-analysis of interventions for reducing diabetes distress [93], which found that even generalist and psychoeducation interventions resulted in small reductions in diabetes distress in adults with T1DM or T2DM.

Further, the lack of a significant reduction in diabetes distress, compared to a control group, is consistent with the findings of an RCT of standard EW for adults with T2DM [40] and a pilot RCT of EW about stressors occurring in the past month in nondepressed adults with T2DM [41]. It is also in line with the meta-analysis showing that only interventions of six or more sessions resulted in significant reductions in diabetes distress compared to a control group [93]. Thus, overall, it appears that while attention to diabetes distress and a generalist intervention may be sufficient to result in small reductions in diabetes distress in nondepressed adults, a longer or more efficacious intervention is required to provide significant reductions in diabetes distress compared to an active control condition.

This study did not find the predicted improvements in the secondary outcomes of depression, anxiety, diabetes self-care, self-reported health, and health care utilization. Of note, participants in both groups demonstrated significant increases in mean depression and anxiety scores over a period of 3 months, albeit with mean scores remaining in the "none-minimal" range for symptoms. There were no significant between-group differences in these changes. This finding was inconsistent with previous findings of a reduction in symptoms of depression or anxiety following diabetes-specific EW [39], writing about use of time [64], or online positive affect journaling in medical patients with elevated anxiety [44]. Given that the baseline depression and anxiety scores in our study were so low (2.11 and 1.60, respectively), the increase in mean scores may reflect a regression to the mean [94]. The baseline means were unexpectedly substantially below the inclusion criteria cut-off scores of 8 and lower than the normative means of adults with T1DM or T2DM in Australia (5.6 to 7.7 on the PHQ-9 and 4.0 to 5.3 on the GAD-7) [95]. Further, half of the sample reported a history of depression, and it is known that the adults with diabetes and past depression are at an increased risk of a recurrence of depression [96]. A minority of participants with a history of depression experienced worsening of depression or anxiety symptoms over the 3-month study period, which may have accounted for the increase in mean scores in both groups. Regardless of the reason for these changes, this finding highlights the need for monitoring of depression and anxiety in trial participants with diabetes and past depression.

Safety

Given that one of the key potential benefits of BFW, relative to EW, is the absence of short-term distress that typically accompanies EW [33], it was important for this study to assess immediate emotional responses to BFW in people with diabetes. This study found that participants in the BFW group reported no more distress than those writing about use of time and had greater increases in positive affect immediately after writing. This supports the hypothesis that BFW may be more suitable for online dissemination than forms of therapeutic writing that typically lead to short-term distress [36]. However, participants in this study had few symptoms of depression or anxiety, and it is not known how depressed adults with diabetes would respond to BFW.

Feasibility of the Intervention

Feasibility of Web-based BFW for adults with T1DM or T2DM was assessed by adherence to and acceptability of the intervention. Adherence to BFW was high, with 95% of those who commenced the first writing session also completing all three writing sessions. Further, manipulation checks indicated that those in the BFW group were able to write about the positive aspects of diabetes and engaged with the intervention as intended. However, acceptability of the intervention was only moderate. Although over two-thirds of the participants in the BFW group reported satisfaction with the *Writing for Health* program, only half of both groups would recommend it to a friend.

Further, given the small sample recruited over a 21-month period, there was no high level of demand for Web-based BFW in adults with diabetes. Other studies of therapeutic writing in participants with diabetes have also reported difficulty in recruiting their target sample sizes [39,41]. This is in line with the observation that participants' reasons for undertaking unfacilitated therapeutic writing are often unclear, particularly among those with a chronic illness [33].

Thus, this study identified some limitations to the feasibility of Web-based BFW for adults with diabetes, with apparent low interest in the intervention and only moderate acceptability, despite high adherence among those who commenced the writing sessions. Recent qualitative findings (published subsequent to this study) regarding the perceptions of written reflection about T2DM [97] have shed some light on the appropriateness of therapeutic writing for adults with diabetes. Specifically, it was found that while some adults with T2DM reported that writing about diabetes increased their commitment to diabetes self-management, others perceived that a written reflection was inapplicable to their diabetes. Some found that writing about diabetes was difficult, the timing in terms of their disease trajectory or life priorities was inappropriate, and they required a meeting with a diabetes nurse in order to benefit from the task. The authors concluded that written reflection about diabetes may only be suitable for some adults with T2DM and that it may be more appropriate as part of a "blended" approach rather than a standalone intervention [97]. The findings from this study regarding the feasibility of BFW for diabetes support this recommendation.

Limitations and Future Directions

There were several limitations to this study. A clear limitation was the small sample size, which reduced the statistical power such that only moderately large effect sizes for differences between the two groups, if present, could have been detected. Second, given the preliminary nature of this trial, multiple comparisons of several independent variables were conducted without control of the alpha levels to reduce the risk of Type 1 errors (ie, "false positive"). However, given that there were few significant results, this is unlikely to be a significant issue.

Perhaps, most importantly, the generalizability of the results of this study was limited by the profile of the sample who registered to participate. Although the conservative eligibility criteria were set in line with the exploratory nature of the study, baseline levels of diabetes distress, depression, and anxiety were low, leaving very little room for improvement. It has recently been suggested that therapeutic writing may offer the most benefit for those with moderate levels of symptoms, as those with very few symptoms cannot improve their symptoms with this treatment and those with severe symptoms may require stronger treatment [44]. Therefore, future trials of therapeutic writing in adults with diabetes should apply a minimum threshold for diabetes distress, to examine its efficacy among those with elevated symptoms, as well as the maximum cut-off scores for depression and anxiety to exclude those with a likely mental illness.

Physical symptoms and biological indicators such as HbA_{1c} were not assessed. However, given that physical symptoms tend to be more responsive to therapeutic writing interventions than psychological symptoms [33,35], future studies of therapeutic writing in people with diabetes should include a self-report measure of physical symptoms.

Finally, the current study found that BFW was only moderately acceptable to adults with T1DM or T2DM. Given the reluctance of many people with diabetes to engage in mental health care, future research should examine predictors of engagement with low-intensity interventions, especially those such as BFW, given that it appears to appeal to only some adults with diabetes. Further, since a participatory design is known to increase the acceptability and use of interventions [98], the development of future therapeutic writing interventions should include the participation of adults with diabetes at every design stage. Although this study set out to use BFW because previous research suggested that it may be suitable for online dissemination due to a lack of distress involved [36,51,59], one future direction could be the co-design of a “combined” therapeutic writing, which would allow users to express negative thoughts and feelings about diabetes as well as perceived benefits, with strategies to encourage cognitive change and coping [99,100].

Conclusions

The results of this preliminary RCT found that Web-based BFW for nondepressed adults with T1DM or T2DM was no more efficacious than a CW condition in improving diabetes distress or benefit finding over a period of 3 months. Possibly due to very low baseline levels of depression and anxiety in the sample, BFW in this study was not efficacious in improving the symptoms of depression or anxiety, diabetes self-care, self-reported health, or health care utilization compared to CW.

BFW was adhered to and was associated with increases in positive affect and no more distress than the control condition. This suggests that BFW for diabetes may be more suitable for online dissemination than traditional EW, which typically results in short-term distress. Hence, future research should continue to investigate the efficacy of BFW for adults with T1DM or T2DM, using a larger sample of participants with elevated diabetes distress. Further, engaging a co-design process may improve the perceived helpfulness of therapeutic writing in adults with diabetes. Despite these issues, further research in this population is warranted, as therapeutic writing offers potential as a simple and cost-effective low-intensity intervention, especially for people with diabetes who may not wish to consider mental health interventions.

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Authors' Contributions

JC, KW, and JP conceived of the study and initiated the study design and protocol. JC managed the trial implementation, under the supervision of KW and JP, and drafted this paper. All authors contributed to and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 3MB - diabetes_v4i2e13857_app1.pdf]

Multimedia Appendix 2

Instructions for Web-based benefit-finding writing for diabetes.

[PDF File (Adobe PDF File), 38KB - diabetes_v4i2e13857_app2.pdf]

Multimedia Appendix 3

Results of secondary outcome measures: observed and estimated means, with SDs at baseline and 1-month and 3-month follow-ups.

[PDF File (Adobe PDF File), 51KB - diabetes_v4i2e13857_app3.pdf]

Multimedia Appendix 4

Estimated differences in mean change of secondary outcomes between baseline and 1-month and 3-month follow-ups for the benefit-finding writing group and the control writing group.

[PDF File (Adobe PDF File), 58KB - diabetes_v4i2e13857_app4.pdf]

Multimedia Appendix 5

Within-group estimated changes in secondary outcomes between baseline and 1-month and 3-month follow-ups.

[PDF File (Adobe PDF File), 71KB - diabetes_v4i2e13857_app5.pdf]

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Abbreviations

BFW: benefit-finding writing
CW: control condition of online writing
EW: expressive writing
GAD-7: Generalized Anxiety Disorder-7
HbA_{1c}: hemoglobin A_{1c}
I-PANAS-SF: International Positive and Negative Affect Schedule - Short Form
ITT: intention to treat
MDD: major depressive disorder
PHQ-9: Patient Health Questionnaire-9 items
RCT: randomized controlled trial
SDSCA: Summary of Diabetes Self-Care Activities
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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Original Paper

Influence of Patient Characteristics and Psychological Needs on Diabetes Mobile App Usability in Adults With Type 1 or Type 2 Diabetes: Crossover Randomized Trial

Helen NC Fu[1], RN, PhD; Terrence J Adam[2,3], MD, PhD; Joseph A Konstan[4], PhD; Julian A Wolfson[5], PhD; Thomas R Clancy[6], RN, PhD; Jean F Wyman[1], RN, PhD

[1]Center for Aging Science and Care Innovation, School of Nursing, University of Minnesota, Minneapolis, MN, United States
[2]Department of Pharmaceutical Care & Health Systems, College of Pharmacy, University of Minnesota, MInneapolis, MN, United States
[3]Institute of Health Informatics, University of Minnesota, Minneapolis, MN, United States
[4]Department of Computer Science and Engineering, University of Minnesota, Minneapolis, MN, United States
[5]School of Public Health, University of Minnesota, Minneapolis, MN, United States
[6]Center for Nursing Informatics, School of Nursing, University of Minnesota, Minneapolis, MN, United States

Corresponding Author:
Helen NC Fu, RN, PhD
Center for Aging Science and Care Innovation
School of Nursing
University of Minnesota
308 Harvard Street SE
Minneapolis, MN, 55455
United States
Phone: 1 612 624 2132
Email: helen007@umn.edu

Abstract

Background: More than 1100 diabetes mobile apps are available, but app usage by patients is low. App usability may be influenced by patient factors such as age, sex, and psychological needs.

Objective: Guided by Self-Determination Theory, the purposes of this study were to (1) assess the effect of patient characteristics on app usability, and (2) determine whether patient characteristics and psychological needs (competence, autonomy, and connectivity)—important for motivation in diabetes care—are associated with app usability.

Methods: Using a crossover randomized design, 92 adults with type 1 or 2 diabetes tested two Android apps (mySugr and OnTrack) for seven tasks including data entry, blood glucose (BG) reporting, and data sharing. We used multivariable linear regression models to examine associations between patient characteristics, psychological needs, user satisfaction, and user performance (task time, success, and accuracy).

Results: Participants had a mean age of 54 (range 19-74) years, and were predominantly white (62%, 57/92), female (59%, 54/92), with type 2 diabetes (70%, 64/92), and had education beyond high school (67%, 61/92). Participants rated an overall user satisfaction score of 62 (SD 18), which is considered marginally acceptable. The satisfaction mean score for each app was 55 (SD 18) for mySugr and 68 (SD 15) for OnTrack. The mean task completion time for all seven tasks was 7 minutes, with a mean task success of 82% and an accuracy rate of 68%. Higher user satisfaction was observed for patients with less education (*P*=.04) and those reporting more competence (*P*=.02), autonomy (*P*=.006), or connectivity with a health care provider (*P*=.03). User performance was associated with age, sex, education, diabetes duration, and autonomy. Older patients required more time (95% CI 1.1-3.2) and had less successful task completion (95% CI 3.5-14.3%). Men needed more time (*P*=.01) and more technical support than women (*P*=.04). High school education or less was associated with lower task success (*P*=.003). Diabetes duration of ≥10 years was associated with lower task accuracy (*P*=.02). Patients who desired greater autonomy and were interested in learning their patterns of BG and carbohydrates had greater task success (*P*=.049).

Conclusions: Diabetes app usability was associated with psychological needs that are important for motivation. To enhance patient motivation to use diabetes apps for self-management, clinicians should address competence, autonomy, and connectivity by teaching BG pattern recognition and lifestyle planning, customizing BG targets, and reviewing home-monitored data via email.

App usability could be improved for older male users and those with less education and greater diabetes duration by tailoring app training and providing ongoing technical support.

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KEYWORDS

mHealth; diabetes; self-management; usability; Self-Determination Theory; mobile apps; user satisfaction

Introduction

Background

Patients with diabetes may benefit from self-management interventions to prevent complications including stroke and vision loss. Individuals with poor diabetes management have 2.3 times higher health care expenditures compared to those without diabetes [1]. Adhering to medical nutritional therapy and choosing what to eat are challenging for many patients with diabetes [2]. Using a diabetes app to record diet and track blood glucose (BG) shows promise to increase diet and medication adherence [3]. Small trials showed that using a diabetes app can improve glycemic control with a 0.4% to 1.9% reduction in hemoglobin A_{1c} (HbA_{1c}) levels [4-6], but few patients use apps, possibly due to design problems affecting usability [7]. Diabetes app usability is the degree to which a user (patient) feels satisfied and finds the experience to be efficient and effective to accomplish tasks such as tracking BG readings [8].

Patient characteristics are hypothesized to influence user experience, but there is limited evidence on how demographic and clinical characteristics affect app usability [9-11]. Patients aged 56 years and older tend to report lower user satisfaction [12]. Prior studies also noted women made more errors than men when entering BG readings [10]. Technology experience and confidence also influenced patient ability to use diabetes apps [13]. For two popular apps, Glucose Buddy and MyFitnessPal, designs were not tailored based on patient knowledge and technology ability, which led to complaints of the apps being too complicated [13]. Most apps provide information input and output only and are limited in their theoretical basis [14]. In prior usability studies, the frameworks of health behavior theories were not considered in relation to understanding patient perspectives in app use. Assessing app usability and its relationship with patient characteristics and health behavior needs will fill critical knowledge gaps in user-centered design and best practices to promote optimal diabetes self-management. To fill this gap, we used a health behavior theory focused on motivation as the framework to understand the mechanism of how patient factors can influence the use of diabetes apps.

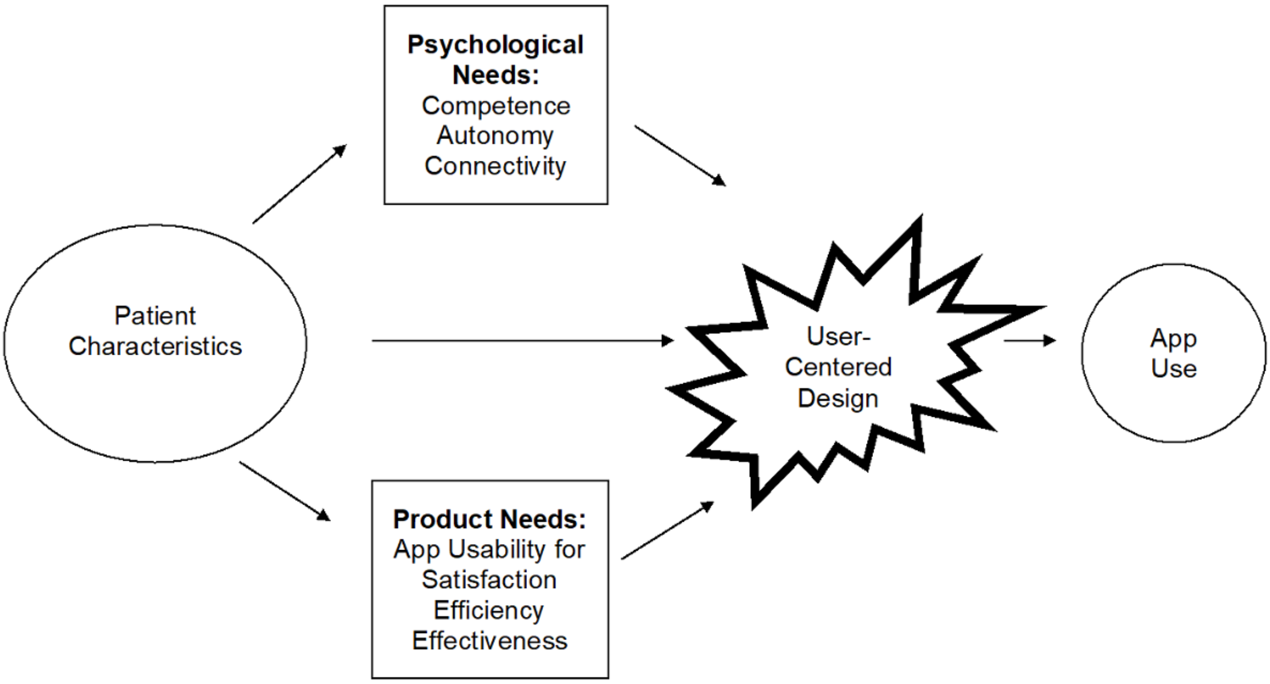
Theoretical Framework

We used Self-Determination Theory (SDT) on motivation to guide our hypotheses regarding how app functions and psychological needs influence app usability. Previous studies have shown that psychological needs are associated with adherence of healthy behaviors [15-18]. The motivation to adhere to healthy behavior is facilitated when patients experience satisfaction in three psychological needs: competence, autonomy, and relatedness [19]. Intrinsic motivation occurs when patients endorse personal benefits of healthy behaviors [20], which means that if patients perceive personal benefits of app use to assist them in adopting healthy behaviors, they can be motivated to use apps. Individual patient characteristics play a role in psychological needs and product needs that subsequently contribute to user-centered design and app use (Figure 1). Competence is the patient’s desire to be competent and experience confidence in keeping their BG in range [18]. App use can increase competence by displaying a report of out-of-range BG readings to increase patient understanding of BG numbers. Autonomy is a patient’s desire for empowerment in having options to change behaviors [20]. Using apps can increase autonomy by providing BG reports and carbohydrate (carb) intake patterns for all meals. Patients can visualize which meals require better carb control and health behavior changes in diet, insulin dose, or activity level. Relatedness or connectivity concerns the patient’s desire to be cared for by someone they trust [21]. Patients are more likely to adopt behaviors when they receive autonomous support and feel connected with people they trust such as a health care provider [20]. Apps can help patients connect with health care providers by supporting email communication and sharing home-monitored data.

Objectives

The overall goal of this study was to evaluate the influence of patient factors on the usability of two publicly available diabetes apps. Thus, we planned for two sets of usability observations (app A and app B) from the same patient to adjust for app design effects, ensuring the changes in usability ratings were effects of the patient’s characteristics. Aim 1 was to determine the relationships between patient characteristics (eg, age, sex, education, technology use, diabetes history, and motivation) and app usability. We hypothesized that patient characteristics would predict user satisfaction and user performance in task time, success, and accuracy. Aim 2 was to determine the relationship between psychological needs and app usability. We hypothesized that user satisfaction would be associated with the psychological needs for competence, autonomy, and connectivity with a health care provider—theoretical constructs from SDT on motivation.

Figure 1. Usability model of diabetes app use.



Methods

Study Design

A randomized crossover design was used to test two Android apps (OnTrack and mySugr) listed as “the Best Diabetes Apps 2016” by *Healthline*. This within-subject design (one group of patients to test two apps) allowed collection of two sets of usability observations and required a smaller sample size compared to a parallel group design. This design also adjusts for app design effects without worrying about between-subject differences in a two-group comparison. The Android platform was selected because it has the greatest number of users (52.7%) [22]. Because age was a potential confounder correlated with usability scores [23], and patients aged 56 years and older tend to give a lower satisfaction rating in apps [12], we created two age-based strata: adults age 56 years and older and adults younger than 56 years. A statistician randomly assigned the app testing order of AB or BA within each age stratum using a computer software program and provided group assignment in a sealed opaque envelope. These steps were to adjust for app effects and address potential bias due to learning effects and investigator preferences. The primary usability outcome was user satisfaction measured by the System Usability Scale (SUS) [24]. Secondary usability outcomes were user performance, including efficiency (task time) and effectiveness (task success and accuracy). The University of Minnesota Institutional Review Board approved the study. All participants signed an informed consent document and received a US $50 honorarium.

Participants

Participants were recruited by flyers posted at community or Veterans Affairs (VA) clinics, university campuses, community bulletin boards, diabetes support group meeting sites, and websites (Craigslist and Facebook). A total of 92 participants met all inclusion criteria: (1) age 18 years or older, (2) type 1 or type 2 diabetes, (3) insulin therapy for at least 6 months, (4) use of an Android mobile phone for at least 6 months to ensure familiarity with the testing app’s operating system, (5) English proficiency, (6) adequate vision to read email or text messages on their current mobile phone, and (7) mobile phone use proficiency. Individuals who used any diabetes app in the past 6 months or had ever used OnTrack or mySugr were excluded. Because OnTrack and mySugr are made available to the public, including patients with either type 1 or type 2 diabetes was important for generalizability. We verified mobile phone use proficiency by screening for app use and did not include typical mobile phone usage for calls, texting, emailing, or taking pictures.

Procedures

In-person app training and testing were conducted from July 26 to November 30, 2017. Individual study sessions were held in a private room. The sessions ranged from 1 to 3.5 hours. During app training, participants watched YouTube tutorial videos posted by the app developers and practiced following a checklist for seven tasks on a Samsung 5S study phone: (1) enter a carb intake, (2) enter an exercise activity, (3) enter an insulin dose, (4) enter a BG reading, (5) locate a BG report for days of the week, (6) locate a BG report for each meal, and (7) email a BG report. During app testing, participants followed a checklist to test app tasks in a randomized order with data units that were different from app training. Each participant completed a SUS questionnaire at the end of each app test. During a 30-minute break between the first and second app test, participants completed a background survey and were given an opportunity to eat a light snack and use the restroom. App training and testing were conducted by the first author (HNCF), who kept field notes that included nonverbal reactions to app testing and open responses of app preference. Another researcher checked fidelity from the audio recording of the study sessions.

Measurements

User satisfaction in app usability (primary outcome) was rated by the SUS, a 10-item questionnaire, at the end of app testing [24]. The SUS measures ease of use, app function integration, user confidence, learning needs prior to use, and app use intention. Survey items included “I felt very confident using this app” and “I would like to use this app frequently.” Responses are on a 5-point Likert scale (0=strongly disagree to 4=strongly agree). Even-numbered items are negative statements, such as “this app is unnecessarily complex.” The SUS is widely used in product usability evaluation with a reliability coefficient alpha of .91 [23] and a loading factor greater than 0.3 for construct validity [25]. Scores of 85 or higher are excellent; scores less than 70 are acceptable. Scores between 50 and 69 are marginally acceptable; scores 50 and lower are unacceptable [26]. Secondary outcomes were user performance in terms of efficiency (measured by task time) and effectiveness (measured by task success and accuracy). Task time is the total task completion time per app. Task success is the degree to which a user independently completed required tasks [27]. Each app task success was rated from 0% to 100%. The rating was zero when the app lacked a testing function or when a participant received more than 50% of standard technical support. The user success rate was calculated by averaging the success of all tasks. The user accuracy was whether the participant performed tasks correctly (eg, correct insulin dose) and was calculated by averaging the accuracy of all tested tasks.

Patient characteristics were self-reported in a 32-item background survey that included demographics (age, sex, race/ethnicity, and education), mobile phone brand, technology use, and diabetes factors (types, HbA_{1c}, duration, insulin use, BG testing, and prescribed BG testing). An established motivation scale, the Treatment Self-Regulation Questionnaire (TSRQ), was also included, which assessed patients’ reasons for engaging in diabetes self-management behaviors with 8 items for intrinsic motivation and 11 items for extrinsic motivation rated on a 7-point Likert scale [18]. Both types of motivation scores were calculated by averaging the response ratings, which ranged from 1 (not true at all) to 7 (very true). Overall motivation was assessed by the Relative Autonomy Index, which was calculated by subtracting the intrinsic motivation score with the extrinsic motivation score. Positive scores indicate greater intrinsic motivation, whereas negative scores indicate greater extrinsic motivation. The TSRQ has been validated across settings and for other health behaviors with an internal consistency alpha coefficient greater than .73 in a prior study [28] and .82 in this study.

Competence in diabetes self-management was measured by the Perceived Competence Scale, which ranged from 1 (not true at all) to 7 (very true) on a 7-point Likert scale with four items and scored by averaging the responses [29]. Its internal consistency alpha coefficient was greater than .80 in a prior study [18] and .88 in this study. Autonomy in diabetes care was measured by four items designed by investigators and validated by four experts (endocrinologist, physician-researcher in diabetes, and two PhD-prepared diabetes nurse educators). This scale measured patient interest in identifying personal BG readings and carb intake trends, which is a subcomponent of autonomy [30]. Patients who desire autonomy (intrinsic motivation) are proactive in their health behavior and choices for diabetes management [30]. Responses were rated on a 5-point Likert scale rating from 1 (strongly disagree) to 5 (strongly agree); an overall score was obtained by averaging all item responses. The alpha coefficient of .74 was deemed acceptable. Health care provider connectivity was rated by the Health Care Climate Questionnaire, which assessed the degree to which primary health care providers offer autonomous support in diabetes management [31]. The score is based on the average response to six items on a 7-point Likert scale rating from 1 (strongly disagree) to 7 (strongly agree). Its reliability alpha coefficient was .82 in a prior study [31] and .94 in this study.

Statistical Analysis

We targeted a sample size (n=92) for a regression model (n=84) with 10% attrition (n=8) based on 13 predictors with R^2 correlation of .20 and alpha of .05 in the calculation. Residual plots showed no evidence of heteroskedasticity. Analyses of *t* tests and chi-square tests were used to assess differences between the two age strata and sex groups. Paired *t* tests of mySugr and OnTrack usability scores showed significant differences ($P<.05$), hence all regression analyses were adjusted for app group and testing order with an interaction term. We set an alpha of .05 for statistical significance. All analyses were performed using R statistical software [32].

For aim 1, both random effect (repeated app testing) and fixed effect (app group) were analyzed by a linear mixed effect multiple regression model of analysis of variance (ANOVA). The full model was run separately for each usability outcome model, including 15 predictors of patient characteristics. Mobile phone brand and education variables were collapsed into dichotomous variables: (1) Samsung versus not Samsung Android, and (2) high school education or less versus education higher than high school. For aim 2, the model for aim 1 was used by adding a psychological need predictor (eg, competence) while adjusting for covariates of patient characteristics (key demographics, technology factors, diabetes history, and motivation), testing order, app group, and an interaction term between testing order and app group. We also assessed the individual mediation effect of task time, success, and accuracy on user satisfaction to explain all or part of the relationship between the psychological need and user satisfaction [33].

Results

Sample Recruitment and Characteristics

Diverse recruitment sites yielded 92 participants who completed the study from urban and suburban Minnesota: 46 were recruited from Facebook (50%), eight from patient referrals (9%), seven from a community clinic (8%), six from a university (6.5%), six from public housing (6.5%), five from Craigslist (5%), four from a VA clinic (4%), three from diabetes support groups (3%), and seven from miscellaneous sites (8%). Participant characteristics are summarized in Table 1.

Table 1. Sample characteristics and psychological needs (N=92).

Characteristics/psychological needs	Participants
Age (years), mean (SD)	54 (13)
Men, n (%)	38 (41)
Race, n (%)	
White	57 (62)
Black/African American	23 (25)
Native American	10 (11)
Asians	2 (2)
Highest completed education, n (%)	
Elementary	4 (4)
High school or equivalent	27 (29)
Community/technical school	31 (34)
Bachelor’s degree	19 (21)
Graduate degree	11 (12)
Device brand, n (%)	
Samsung	44 (48)
LG	19 (20)
iPhone	8 (9)
ZTE	7 (8)
Motorola	6 (6)
Other	8 (9)
Mobile phone comfort level, n (%)	
Very uncomfortable	23 (25)
Neither	12 (13)
Comfortable	33 (36)
Very comfortable	24 (26)
Diabetes types, n (%)	
Type 1	28 (30)
Type 2	64 (70)
HbA_{1c}[a] % (ranges 5-14), mean (SD)	8.2 (1.5)
Diabetes duration (years), mean (SD)	17 (11)
Insulin duration (years), mean (SD)	12 (12)
Insulin use types, n (%)	
Insulin pump	14 (15)
Long- and short-acting injection	46 (50)
Long-acting injection	28 (30)
Short-acting injection	2 (2)
None (stopped use)	2 (2)
Blood glucose testing prescribed per day, mean (SD)	3.8 (1.8)
Blood glucose testing per day, mean (SD)	6.2 (1.4)
Daily or less, n (%)	19 (21)
2 times a day, n (%)	34 (37)
4 times a day, n (%)	21 (23)

Characteristics/psychological needs	Participants
>4 times a day, n (%)	18 (19)
Overall motivation[b], mean (SD)	2.16 (1.3)
Intrinsic motivation, mean (SD)	5.43 (0.9)
Extrinsic motivation, mean (SD)	3.26 (1.2)
Competence, mean (SD)	5.38 (1.1)
Autonomy, mean (SD)	3.92 (0.6)
Connectivity with health care provider, mean (SD)	6.05 (1.2)

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

[b] Also known as the self-determination index obtained from intrinsic motivation score minus extrinsic motivation score.

More than half of the participants were women, nearly half used Samsung phones, and 70% (64/92) had type 2 diabetes. The mean age was 54 years (range 19-79) with a median age of 57, and the mean HbA_{1c} was 8.2% (range 5%-14%) or 66 mmol/mol (range 31-130). The only missing data was an HbA_{1c} level from one participant.

App Usability

The overall mean user satisfaction was 62 (SD 18) and mean task completion was 7 (SD 3.8) minutes. Participants had a mean task success rate of 82% (SD 19%) and mean accuracy rate of 68% (SD 21%). Participants rated the two apps as marginally acceptable in user satisfaction (SUS scores between 50 and 69) as shown in Table 2. OnTrack scored 68, which is considered a “D” grade (eg, scores between 60 and 69); mySugr received a score of 55, which is an “F” grade (eg, scores less than 60). User performance was better for OnTrack compared to mySugr: more efficient (mean time 6.6, SD 3.7 minutes versus mean time 7.5, SD 3.7 minutes, $P<.001$), more effective (mean task success 84%, SD 18% versus 80%, SD 20%, $P=.03$), and more accurate (mean accuracy 74%, SD 20% versus 63%, SD 22%, $P<.001$).

Patient Characteristics

Demographics, technology use, diabetes factors, and motivation were not predictors of user satisfaction as assessed by the SUS for the tested apps (Table 3). Age, sex, and education were predictors of user performance in task time and success rate. Adults older than 56 years took an extra 2.2 minutes (95% confidence interval [CI] 1.1-3.2) for task time, had lower task success rate (95% CI 3.5%-14.3%), and higher task error rate (95% CI 4.2%-16.4%) compared to adults aged 18 to 55 years. On average, for every 10 years of age, adult patients spent 0.8 minutes longer to use the app ($P=.02$), and the task success rate decreased by 4.6% ($P=.003$). Men were less proficient, took an extra 1.7 minutes ($P=.01$), and achieved 6.9% less success ($P=.04$) compared to women. Participants with education beyond high school had 6.4% less user satisfaction ($P=.04$) and greater success by 10.5% compared to participants who were not educated beyond high school ($P=.003$). Current Samsung mobile phone users were 7.3% more accurate ($P=.05$).

Diabetes type was not a predictor of task time or success, but diabetes duration negatively influenced user accuracy. The longer duration of diabetes, the less accurate participants were in using diabetes apps. A 10-year increase in diabetes duration was associated with an 8.5% drop in task accuracy ($P=.02$). A 10-year use of insulin increased accuracy by 7.1%, but it was not statistically significant ($P=.06$). Glycemic control of HbA_{1c} level showed no association with user satisfaction and performance. Self-reported BG testing frequency, prescribed BG testing frequency, and motivation for diabetes care were not associated with app usability.

Table 2. Diabetes app usability outcomes.

Usability	Overall (N=184), mean (SD)	mySugr (n=92), mean (SD)	OnTrack (n=92), mean (SD)	Difference (95% CI)	*P* value[a]
Practice time (minutes)	19 (8)	22 (9)	16 (6)	5.6 (4.0-7.2)	<.001
Satisfaction	62 (18)	55 (18)	68 (15)	12.7 (8.2-17.2)	<.001
Efficiency (minutes)	7.0 (3.8)	7.5 (3.8)	6.6 (3.7)	0.8 (0.3-1.3)	<.001
Success (%)	82 (19)	80 (20)	84 (18)	3.9 (0.3-7.5)	.03
Accuracy (%)	68 (21)	63 (22)	74 (20)	11.0 (6.0-16)	<.001

[a] Obtained from paired *t* test comparing two apps, mySugr and OnTrack.

Table 3. Adjusted associations between patient characteristics and app usability.

Predictors effect (coefficients)	Satisfaction (SUS)	Efficiency (minutes)	Success (%)	Accuracy (%)
Characteristics	Model 1	Model 2	Model 3	Model 4
Age per 10 years	−0.5	0.8[a]	−4.6[b]	−2.5
Men vs women	0.1	1.7[a]	−6.9[a]	−0.1
>High school vs ≤high school[c]	−6.4[a]	−1.2	10.5[b]	0.3
Samsung vs not Samsung	1.5	−0.8	5.3	7.3
Mobile phone comfort	0.6	−0.1	0.6	−0.3
Diabetes type 2 vs type 1	−5.5	1.6	−4.7	−7.4
Diabetes duration per 10-year diagnosis	3.6	0.5	−0.1	−8.5[a]
Insulin duration per 10-year use	−1.3	0.6	−3.1	7.1
HbA_{1c}[d]	0.4	−0.2	1.8	0.7
Blood glucose testing per day	−0.4	0.2	−1.7	−1.0
Blood glucose testing prescribed per day	−0.2	−0.2	0.9	−1.2
Motivation (TRSQ[e])	−0.4	−0.03	0.7	−0.1
Testing order	−3.9	−1.2	11.2[b]	3.6
App group	8.4[a]	−1.3[b]	9.8[b]	11.1[a]
Interaction order and app	8.3	0.9	−11.3	−0.5
Adjusted[f] R^2	.14	.35	.31	.17

[a] $P<.05$ statistical significance.

[b] $P<.01$ statistical significance.

[c] Highest completed education was high school or less.

[d] HbA_{1c}: hemoglobin A_{1c}.

[e] TRSQ: Treatment Self-Regulation Questionnaire.

[f] Obtained from linear regression model analysis without repeated measures.

Psychological Needs

Psychological needs were significantly associated with user satisfaction but not associated with user performance. This supports our hypothesis that patient ratings of competence, autonomy, and health care provider connectivity are related to user satisfaction with diabetes apps. Patients who rated high in diabetes care competence were more satisfied with diabetes apps: a 1-unit increase in diabetes competence score was associated with an increase of the SUS score by 3.1 points (*P*=.02; Table 4). Similarly, patients who reported greater autonomy or interest to learn their personal BG and carb patterns were more satisfied with the apps: a 1-unit increase in the autonomy score was associated with an increase of the SUS score by 5.9 points (*P*=.006). Patients who rated a higher connectivity with health care providers (receiving greater autonomous support) expressed higher user satisfaction: a 1-unit increase of connectivity score was associated with an increased SUS score of 2.5 points (*P*=.03). Patient autonomy, as an interest in learning personal patterns of BG and carbs, was also associated with greater successful task completion by 4.9% (*P*=.049). The effect of psychological needs on user satisfaction was not strongly mediated by task time, success, and accuracy (percent mediated 0.5%-19.7%).

Table 4. Adjusted associations between psychological needs and app usability.[a]

Psychological needs (coefficients)	Satisfaction (SUS[b])	Efficiency (minutes)	Success (%)	Accuracy (%)
Competence	Model 1A	Model 2A	Model 3A	Model 4A
Adjusted effect	3.1[c]	0.2	−0.1	−2.9
Adjusted[d] R^2	.16	.35	.31	.18
Autonomy	Model 1B	Model 2B	Model 3B	Model 4B
Adjusted effect	5.9[e]	−0.8	4.9[c]	1.2
Adjusted[d] R^2	.17	.37	.33	.17
Connectivity	Model 1C	Model 2C	Model 3C	Model 4C
Adjusted effect	2.5[c]	0.2	−0.02	−0.01
Adjusted[d] R^2	.16	.35	.31	.17

[a] N=184 observations from randomized 92 patients, adjusted all models with 15 covariates listed in model 1 from Table 3, which included age, sex, education, use of Samsung, mobile phone comfort, diabetes types, diabetes duration, insulin duration, hemoglobin A_{1c}, blood glucose testing per day, blood glucose testing prescribed per day, motivation, testing order, app group, and interaction term between order and app.

[b] SUS: System Usability Scale.

[c] $P<.05$.

[d] Obtained from linear regression model analysis without repeated measures.

[e] $P<.01$.

Discussion

Psychological Needs and User Satisfaction

To our knowledge, this is the first study to report a relationship between app usability and the characteristics and psychological needs of the patient. A strength of our approach was the relatively large and diverse study population (N=92) for usability testing because most mHealth usability evaluations have fewer than 30 participants and limited recruitment sites. Our study population resided in both urban and suburban settings and included African Americans, Native Americans, and Asians. Study findings indicate that psychological needs and education are important factors in app usability, whereas patient characteristics are important for user performance or the ability to use an app efficiently, successfully, and accurately. Diabetes app usability, as assessed by user satisfaction (SUS), was associated with three psychological needs important for motivation in diabetes care: competence, autonomy, and connectivity with a health care provider.

Competence in diabetes care was associated with greater app user satisfaction. In our study, patients wanted to use the app to increase their competence and preferred the convenience to track data on the go. Apps offering out-of-range BG reports can help patients identify whether their meals, insulin dose, and physical activities need to be adjusted. This perceived app benefit agrees with prior research that patients desired educational information and goal setting in apps to help them plan self-management activities [13]. Autonomy in diabetes care, as assessed by patient interest in personal patterns, correlated with greater user satisfaction and successful task completion. This is consistent with prior research showing that a diabetes app can help patients set realistic goals based on personal patterns and see choices to modify behavior [13]. Patients wanted a customized care plan within an app to help them control diabetes and learn to improve eating habits [34]. Addressing patient desire or need to connect with a health care provider is important for patient engagement in an mHealth intervention. Connectivity with a health care provider was positively associated with user satisfaction. Patients who were well-connected and reported autonomous support from their health care provider rated higher satisfaction. This is consistent with other studies that found patients were more motivated and would use mHealth tools for diabetes when they perceived their health care providers to be autonomously supportive [15]. Apps facilitate data sharing and patient-provider communication. Clinicians can view analysis reports emailed to them or view them on patients’ mobile phones during clinic visits; having real-time data facilitates discussions with patients and pinpoints exact areas for behavior changes.

Patient Characteristics and User Performance

Patient characteristics correlated with the individual’s ability to use an app. User performance in task time, success, and accuracy varied by age, sex, education, or diabetes duration when controlled for covariates (eg, education, diabetes types, HbA_{1c}, BG testing, and motivation). A 10-year age increment was associated with a slower time performance of 0.8 minutes and lower success performance by 4.6%; surprisingly, age did not correlate with accuracy even though younger users are typically more accurate with technology use. This may be explained by the design of this study, which provided as much technical support and time as desired.

In contrast to prior studies, women outperformed men in time efficiency and task success when accounting for other participant factors. This sex difference may be related to differences in mobile phone and app use. According to one study that tracked 75,000 people’s use of popular websites and apps, women spend more time than men on mobile phones (49% versus 39%) [35]. Women also use social media apps (eg, Facebook) more often than men (83% versus 75%) [36]. We ran a separate full model adjusted for Facebook recruitment, which did not affect results. Education beyond high school was significantly correlated only with user success performance. This suggests that if participants with high school education or less are provided with technical support, they can learn to use an app as efficiently and accurately as those with more education.

Diabetes duration was significantly related to user accuracy. A 10-year diabetes history decreased accuracy by 8.5%, perhaps because of diabetes complications. The rate of diabetic peripheral neuropathy increases by twofold for those with diabetes for longer than 10 years [37]. The prevalence of diabetic retinopathy 10 years after diagnosis is 60% [38]. Finger nerve pain can make it hard and painful to tap correct app icons. Icons and fonts on a small mobile phone screen could be hard to read for those with vision complications from retinopathy. In this study, most participants had suboptimally controlled diabetes with an elevated mean HbA_{1c} level of 8.2% (66 mmol/mol). The target HbA_{1c} level for adults older than 65 years is less than 7.5% (58 mmol/mol) [39] and 7% or less (53 mmol/mol) for adults younger than 65 years without a history of hypoglycemia [2]. HbA_{1c} level, BG monitoring frequency, and motivation in diabetes care did not correlate with app usability.

Clinical Implications

Our study provides new insights into the theoretical basis of health behavior in diabetes app usability. Application of SDT provided important insights on how patient needs and app designs are related. Psychological needs of competence, autonomy, and connectivity with a health care provider (motivational constructs) were associated with user satisfaction. These results suggest that clinicians should address these psychological needs when recommending the use of a particular diabetes app. Clinicians could help improve patient competence by providing education on BG and carb pattern recognition and planning for lifestyle modifications (eg, lowering carb intake). Clinicians who customize a care plan and a BG target range could help increase patient autonomy so that patients can set up a parameter in their apps to analyze BG accordingly. Autonomous support and home-monitored data received through email could promote connectivity with health care providers. Addressing psychological needs for competence, autonomy, and connectivity can potentially lead to long-term app use. Clinicians should screen for diabetes complications that may affect user accuracy.

Limitations and Future Directions

Several limitations in this study provide directions for future research. We were only able to evaluate two diabetes apps in a single study session with findings applicable for a short-term app experience. User satisfaction may change with long-term app use. Future research should include long-term follow-up, record app adherence rate, and assess factors affecting whether or not long-term app use will be sustained.

Fatigue with the 2-hour testing session could have affected participant performance. However, we provided a 30-minute rest break that included refreshments, and none of the participants complained about being tired at study completion. Another possible study limitation was related to the sample population. We recruited a diverse sample with different proportions of nonwhite participants from sites such as public housing and a federally qualified health center. This heterogeneity in race breakdown by recruitment site made it challenging to distinguish between the effects of race and recruitment; thus, we were unable to include race/ethnicity as a covariate.

Unmeasured covariates, such as socioeconomic status (eg, income), types of medical insurance, diabetes complications, and obesity, could influence results. However, our study included multiple recruitment sites and a variety of patient backgrounds with different education levels, insulin use types (pump users on private insurance and those on injection therapy on a public insurance program), and different housing facilities. Covariates, such as education and mobile phone model, may count as a proxy for socioeconomic status. A multiple variable model accounted for common demographics and diabetes history. Our study excluded adolescents with diabetes as well as family caregivers. Future studies should recruit minority patients, adolescents, and caregivers. We did not include laboratory-based usability measures. Future studies can further identify app use barriers through other methods of quantifying usability problems (eg, recording screen reaction, counting keystrokes, and tracking eye movements).

Conclusions

Applying SDT to diabetes app usability revealed that addressing psychological needs for diabetes care competence, autonomy, and connectivity with a health care provider may enhance patient motivation to use diabetes apps. Patient-centered training and ongoing technical support could improve usability for (1) older male users, (2) those with education levels of high school or less, and (3) those with a long duration of diabetes. User-centered apps are desired by patients. App designs and features should incorporate health behavior theoretical framework and be tailored to patients' ages and abilities.

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Authors' Contributions

HF wrote the manuscript and researched the data. JW, JK, TC, TA, and JW contributed to the Discussion and reviewed and edited the manuscript.

Conflicts of Interest

None declared.

Editorial notice: This randomized study was not prospectively registered. The authors explained this as follows: *While this study uses a randomized controlled design (ie, crossover design), participants did not receive a health-related intervention and the study does not involve a health-related outcome. Rather, the research is a "simulated experiment" to assess app usability and user satisfaction with using apps that contained fake/simulated data. Therefore, this study is not a clinical trial and is exempt from clinical trial registration.*
The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials because this study is formative and the risk of bias appears low; however, authors are reminded that educational outcomes in the context of disease self-management can be seen as health-outcomes, and prospective registration and publication of a protocol of any trial (clinical or not) is best practice to prevent *a posteriori* changes in outcomes.

Multimedia Appendix 1

CONSORT‐EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 88KB - diabetes_v4i2e11462_app1.pdf]

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Abbreviations

ANOVA: analysis of variance
BG: blood glucose
HbA_{1c}: hemoglobin A_{1c}
SDT: Self-Determination Theory
SUS: System Usability Scale
TSRQ: Treatment Self-Regulation Questionnaire
VA: Veterans Affairs

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Original Paper

Enhanced Self-Efficacy and Behavioral Changes Among Patients With Diabetes: Cloud-Based Mobile Health Platform and Mobile App Service

Dyna YP Chao[1*], MBA, EMBA, PhD; Tom MY Lin[2*], PhD; Wen-Ya Ma[3], MD

[1]Healthcare Solution Center, Health Inventor of Taipei, Taipei City, Taiwan

[2]Graduate Institute of Management, National Taiwan University of Science and Technology, Taipei City, Taiwan

[3]Department of Metabolism, Cardinal Tien Hospital, New Taipei City, Taiwan

[*]these authors contributed equally

Corresponding Author:
Dyna YP Chao, MBA, EMBA, PhD
Healthcare Solution Center
Health Inventor of Taipei
5F, No.22, Fushan Rd
Wenshan Dist
Taipei City, 116
Taiwan
Phone: 886 917508975
Email: dynachao@gmail.com

Abstract

Background: The prevalence of chronic disease is increasing rapidly. Health promotion models have shifted toward patient-centered care and self-efficacy. Devices and mobile app in the Internet of Things (IoT) have become critical self-management tools for collecting and analyzing personal data to improve individual health outcomes. However, the precise effects of Web-based interventions on self-efficacy and the related motivation factors behind individuals' behavioral changes have not been determined.

Objective: The objective of this study was to gain insight into patients' self-efficacy with newly diagnosed diabetes (type 2 diabetes mellitus) and analyze the association of patient-centered health promotion behavior and to examine the implications of the results for IoT and mobile health mobile app features.

Methods: The study used data from the electronic health database (n=3128). An experimental design (n=121) and randomized controlled trials were employed to determine patient preferences in the health promotion program (n=62) and mobile self-management education (n=28). The transtheoretical model was used as a framework for observing self-management behavior for the improvement of individual health, and the theory of planned behavior was used to evaluate personal goals, execution, outcome, and personal preferences. A mobile app was used to determine individualized health promotion interventions and to apply these interventions to improve patients' self-management and self-efficacy.

Results: Mobile questionnaires were administered for pre- and postintervention assessment through mobile app. A dynamic questionnaire allocation method was used to follow up and monitor patient behavioral changes in the subsequent 6 to 18 months. Participants at a high risk of problems related to blood pressure (systolic blood pressure ≥120 mm Hg) and body mass index (≥23 kg/m^2) indicated high motivation to change and to achieve high scores in the self-care knowledge assessment (n=49, 95% CI −0.26% to −0.24%, *P*=.052). The associated clinical outcomes in the case group with the mobile-based intervention were slightly better than in the control group (glycated hemoglobin mean −1.25%, 95% CI 6.36 to 7.47, *P*=.002). In addition, 86% (42/49) of the participants improved their health knowledge through the mobile-based app and information and communications technology. The behavior-change compliance rate was higher among the women than among the men. In addition, the personal characteristics of steadiness and dominance corresponded with a higher compliance rate in the dietary and wellness intervention (83%, 81/98). Most participants (71%, 70/98) also increased their attention to healthy eating, being active, and monitoring their condition (30% 21/70, 21% 15/70, and 20% 14/70, respectively).

Conclusions: The overall compliance rate was discovered to be higher after the mobile app–based health intervention. Various intervention strategies based on patient characteristics, health care–related word-of-mouth communication, and social media may be used to increase self-efficacy and improve clinical outcomes. Additional research should be conducted to determine the most influential factors and the most effective adherence management techniques.

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KEYWORDS

type 2 diabetes mellitus; self-management; health literacy; patient engagement; intervention; word-of-mouth

Introduction

Financial Burden

In China, noncommunicable chronic diseases not only are a critical health problem but also impose a major economic burden. Globally, diabetes mellitus (DM) has been diagnosed in 415 million people, and DM and its complications are a global health emergency, accounting for 12% of global health expenditure [1]. The MOST survey revealed that 11.6% of adults in China (approximately 114 million people) have received DM diagnoses. The prevalence of DM has resulted in a substantial financial burden on medical systems, families, and societies. DM is more prevalent in older age groups and among people living in economically developed regions. Overall, DM-related expenditure in 2013 was approximately US $548 billion, accounting for 10.8% of total health expenditure worldwide. DM-related expenditure is expected to exceed US $627 billion by 2035 [2,3].

Information Technology Transformation

Self-management has become a critical approach for improving health outcomes among patients with DM, and market demand has emerged for related innovations in information technology (IT). Specifically, patients have expressed interest in cloud-based Internet of Things (IoT) measurement devices to record various types of structured and unstructured data (eg, blood glucose, blood pressure, body mass index, body fat, sleep quality, fatigue [4], depressive symptoms, working pressure, and social engagement frequency) [5-7]. Providers hope to integrate patient data into records of patient history, which can be used to derive engagement models of health promotion for increasing patient motivation and adherence [7-9].

The use of mobile health apps as a lifestyle intervention for improving diabetes outcomes has become increasingly common. In 1 study, patients who underwent this intervention exhibited continual improvement in glycemic control compared with baseline values for the duration of the program (with approximately 50% of participants losing at least 5% of their body weight over 6 months). However, the benefits of the transtheoretical model (TTM) [8,10] and behavioral change [4] were not sustained above the control group setting at 3 months after completion of the program [11].

Patient-Centered Approaches

Patients with diabetes should be encouraged to change their lifestyles and synchronize their personal data recorded inside and outside of hospitals [12]. Thus, patient-centered approaches should be developed for new dynamic behavioral engagement models [13] and as enhancements to existing health promotion models. Personalized approaches should focus on transtheoretical methods as well as patients’ self-management skills, wellness knowledge [9,14], education, psychosocial assessments, satisfaction, and rate of adherence with treatment [6,15].

Adherence exhibits significant beneficial effects on fatigue and social interaction for insulin-using patients with diabetes, emotional well-being for patients with myocardial infarction [4], and glycated hemoglobin (HbA_{1c}) for patients with myocardial infarction and diabetes. In addition, researchers have indicated that higher rates of adherence (especially to diet-related recommendations) are associated with improved health outcomes among insulin-using patients with diabetes [11,16].

Observational studies have reported that educational programs for patients with diabetes do not succeed unless they are intensive and continued over a long period with monitoring of behavioral changes and interventions [17-20].

The aim of this study was to identify the personalized influence factors of goal setting, self-execution activities, and self-efficacy for patients with type 2 diabetes. In addition, we aimed to analyze the association of the identified factors with patient-centered health promotion behavior and to encourage patients to engage in electronic word-of-mouth communication [21,22] to motivate their therapy partners [23,24].

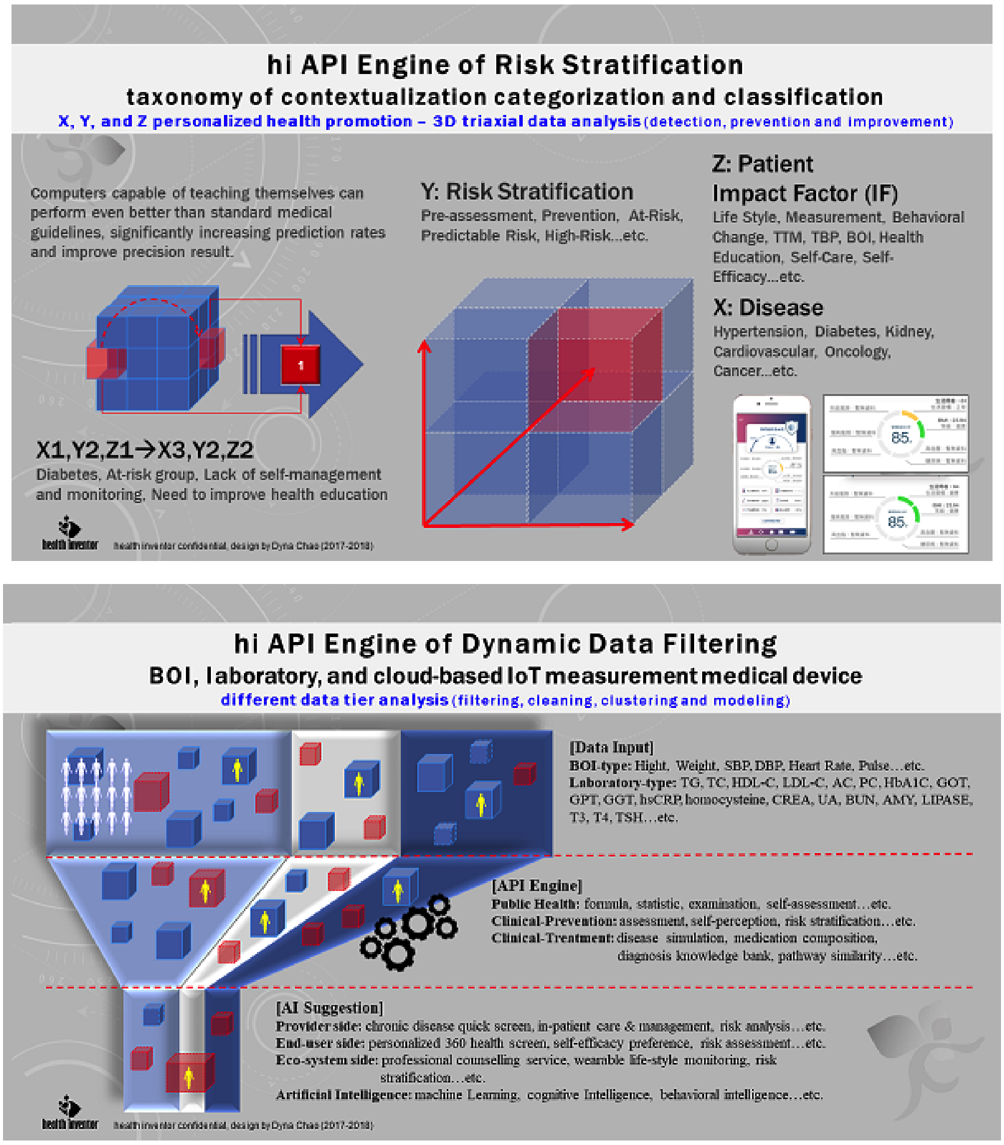
Methods

Overview

In this study, we developed a cloud-based interactive health care management mobile app, interactive personalized management framework (IPMF), and adopted a platform as a service tier. The platform integrates and displays patient information on a 360-degree dashboard. The dashboard may be used to monitor patient health status and facilitate engagement with physicians. Interactive wellness education is also offered through the mobile-based app and cloud-based interactive service platform [16,25-27]. In addition to genetic and environmental factors, patient behavior is a critical factor associated with chronic disease. The effectiveness of disease management depends not only on patients’ clinical status but also on their lifestyle, disease knowledge, health literacy, beliefs, cognitive state, behavior changes, and emotional state [28-32].

Previous studies have demonstrated that health educators and care managers must understand a patient’s disease literacy level, personal characteristics, and readiness for action to determine effective treatment [1,33]. Care providers should create a service environment that enables patients to adopt appropriate behavioral changes [34,35].

Figure 1. 360-Degree health management dashboard displaying three-dimensional triaxial data analysis of IPMF. x: disease, y: level, and z: patient impact factor. API: application programming interface; BOI: body of information; hi: health inventor; IoT: Internet of Things.



Hence, in the developed system, the application programming interface engine uses a three-dimensional analysis tool to aggregate individual patient data and health status. The x-axis denotes disease type and indicates undiagnosed but high-risk and at-risk status, early diagnosed disease, self-perceived symptoms, and diagnosed disease. The y-axis denotes the severity of each symptom. Finally, the z-axis mainly displays the factors that may influence patients' health in daily life, including family history, education, economic situation, lifestyle, and stress (see Figure 1).

Methodology

This study used the TTM under the theory of planned behavior to monitor patients' behavioral changes during the preintervention assessment, follow-up, and postintervention assessment periods [1,5].

Studies have indicated that IT and IoT measurement devices are valuable means of supporting disease management [9,33]. Studies have also reported the use of these technologies in the provision of evidence-based health education tailored to individual patients [16,36]. However, most relevant transtheoretical studies have not analyzed patients' self-knowledge or the effectiveness of patients' self-care behavior for health management. Specifically, studies have not compared the results of health knowledgeability analyses with continuous data on personal health measurement data and health outcome.

Recruitment

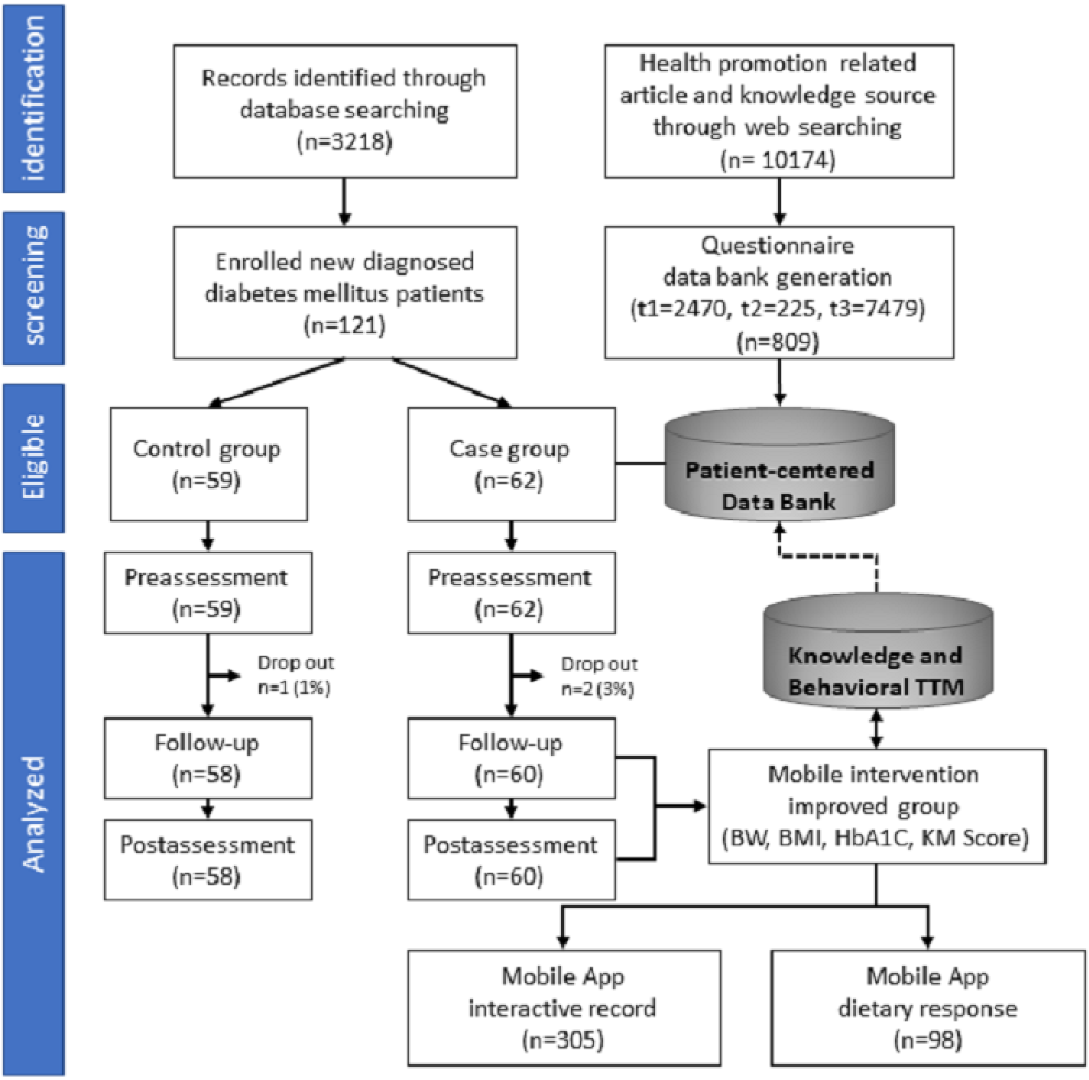
Inclusion and Exclusion

The purpose of this research was to assess the influence of patient insight on adherence to self-management recommendations for patients with new diagnoses and who were at high risk of additional health problems. Accordingly, patients with the following characteristics were eligible to enroll: (1) type 2 DM (T2D) diagnosis received within the prior 3 months, (2) HbA_{1c} % greater than 5.4%, (3) oral glucose tolerance test result greater than 140 mg/dL, and (4) capable to use mobile-based and IT interventions. Patients with DM were invited to participate in the study group based on their disease knowledge and self-management. For the assessment of self-efficacy and cognitive behavioral change, a suitable sample size was determined using the estimated SD of change in self-knowledgeable score versus body weight and HbA_{1c}. With an SD of alpha of .05, we estimated that a final sample of 120 participants would provide 85% power to reveal a minimum detectable difference in changes.

Randomization and Eligibility

In total, 3218 patients with diabetes were identified through a database. These patients were assessed according to the inclusion and exclusion criteria, and ultimately 121 patients (n=121) signed forms of consent and joined the study within 3 to 6 months of communication. Participants were stratified according to age and sex and were then randomly assigned to the case or control group. Case-group patients participated (n=62) in a 1-hour training and employed the IPMF system when they visited outpatient departments. Control-group patients (n=59) were provided with traditional care without support from IT, IoT measurement devices, or the mobile-based app system (see Figure 2).

Figure 2. Study enrollment criteria and selection flow. BMI: body mass index; BW: body weight; HbA_{1c}: glycated hemoglobin; KM: knowledge management; TTM: transtheoretical model.



Asian Race or Ethnic Lifestyle

All patients provided informed consent and were interviewed by a professional team comprising a physician, health educator, nutritionist, care manager, and service consultant. All recruited patients were provided with regular clinical advice and medication.

To test the effectiveness of the IPMF and mobile-based interactive results, especially in preferred food style, eating methods, nutrition, and cooking habits, the intervention behavior data bank collected in Taiwan and China. By considering lifestyle and eating habits, this study focused on Taiwan (n=3218) and lifestyle knowledge bank conducted in both China and Taiwan (n=10,174).

Process and Application Features

The investigation comprised beginning (3 months), follow-up (18 months), and closure phases (3 months). Each outpatient had a different return visit time; therefore, for preassessment, the participants completed self-assessments using the mobile-based app throughout the initial phase (the open period was from months 1-6). Subsequently, each patient collaborated with a physician to set a personal goal and define a health program for the follow-up phase (from months 6-18). By the time they had completed 4 to 6 visits to the outpatient department, each participant had finished the postassessment of the closure phase (from months 18-24). To integrate behavioral activities into the health promotion service flow, the mobile apps were provided to the participants through a mobile tablet while they were waiting to see a doctor or health educator (see Figure 3).

Mobile tablets, such as iPads and mobile phone, also served as supporting tools for physicians and health educators to access patients' integrated information. Patient compliance data were collected through the interface of the IPMF as the patient entered the start phase (1-6 months) for preintervention assessment and the closure phase (18-24 months) later for postintervention assessment. The patient self-assessment score was a taxonomy reference. The behaviors outlined in the American Association of Diabetes Educators (AADE) 7 Self-Care Behaviors program [14,34,37] were used as indicators. These behaviors comprise healthy eating, being active, blood-glucose and blood-pressure monitoring, medication use, problem-solving, use of healthy coping strategies, and risk reduction (see Figure 4).

Patient demographic data that were relevant to health promotion factors were provided by the hospitals providing care and inputted into the IPMF. Participants then received interventional DM education about the American Association of Diabetes Educators 7 Self-Care Behaviors (AADE7). Physicians and health educators conducted educational interventions according to patient's interests and specific requirements to enhance the patient's self-management abilities. The interactive mobile physician dashboard system improved patients' willingness to engage in continual health education.

Figure 3. Research design (initial stage, follow-up, and closure). A1C: HbA_{1c} (glycated hemoglobin); AADE: American Association of Diabetes Educators; BG: blood glucose; BMI: body mass index; HDL: high-density lipoprotein; IoT: Internet of Things; LDL: low-density lipoprotein.

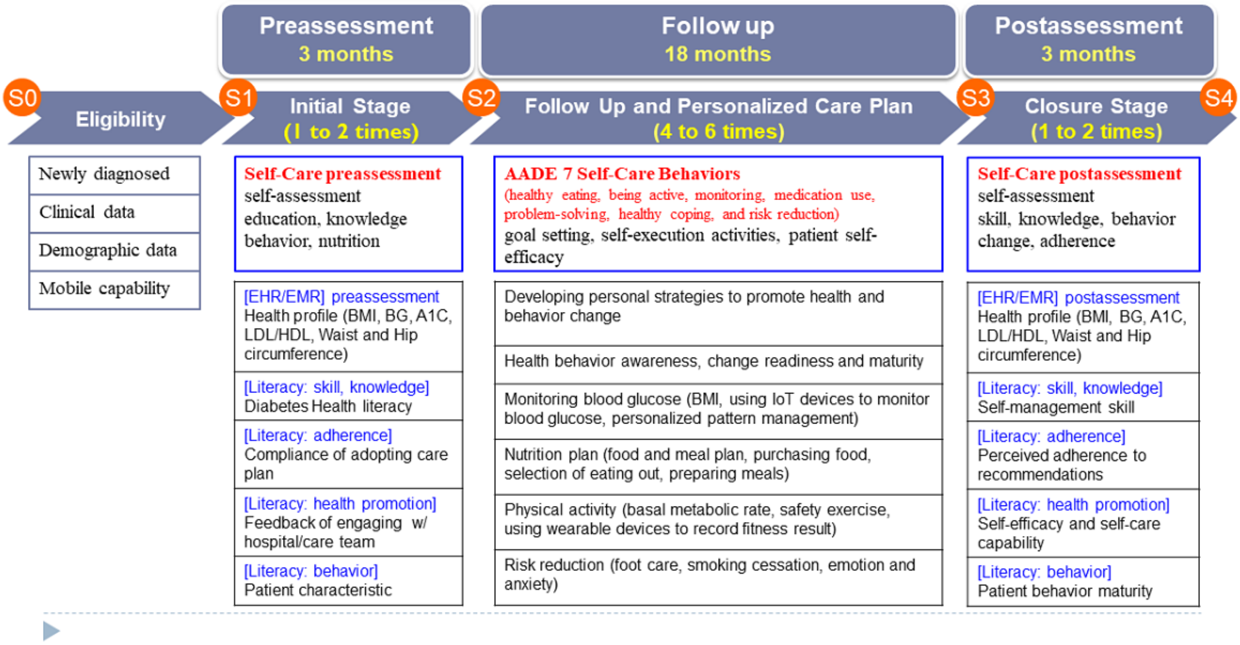
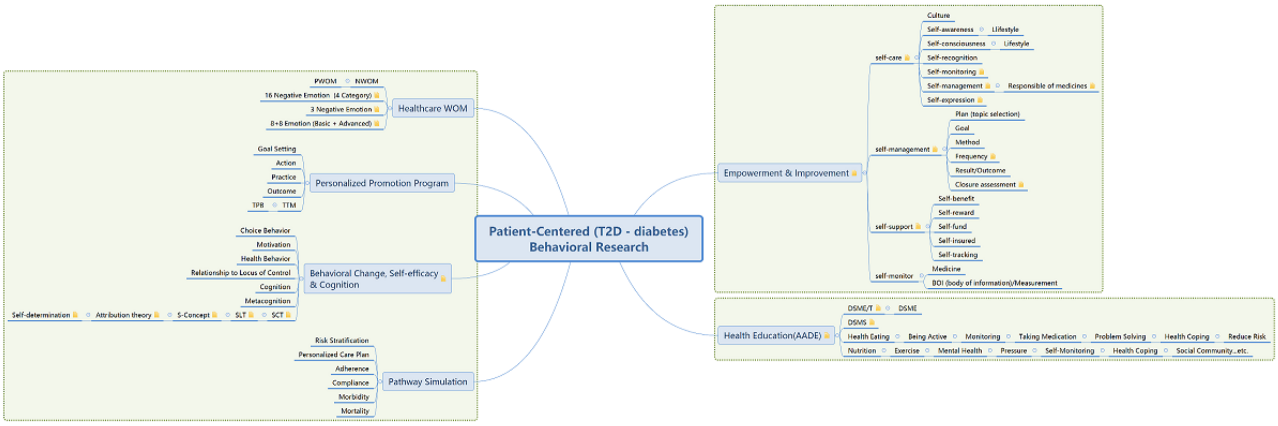


Figure 4. Patient-centered application framework and features. T2D: type 2 DM; TTM: transtheoretical model; WOM: word-of-mouth NWOM: negative word-of-mouth; PWOM: positive word-of-mouth; S-Concept: self-concept theory; SCT: social cognitive theory; SLT: social learning theory; TPB: teory of planned behavior.



Application Framework

The proposed framework was used to construct a DM education service platform that integrated the collected information. The platform also served as an automatic knowledge bank for aggregating patient learning behavior. The developed framework may be used to help physicians and health educators understand patients' specific needs and areas for improvement. The IPMF model not only aggregates information from clinical databases but also involves a questionnaire generation mechanism and knowledge bank feature for collecting information regarding patients' DM literature, DM-related beliefs and emotions, diet, glucose self-monitoring, self-motivation, self-education, and the influence of disease on patient productivity.

The developed mobile app was to analyze patient lifestyles and compliance tendencies and to use a knowledge simulation platform to determine factors for improvement. Analysis of these factors was used to improve clinical outcomes and to enhance patient-physician engagement [38-40].

Self-Management Preference

According to the frequency of their access of mobile app features, patients exhibit individual preferences for self-care management, and these preferences influence overall compliance and clinical outcomes. The system collected data regarding the heterogeneity of patients' lifestyles, knowledge and feelings about diseases, states of action readiness, self-motivation elements of health improvement, and risk conditions.

Intervention

An IPMF interactive system was used to observe the patient-insight factor and encompassed disease history, family history, and relevant characteristics. The system was presented through a 360-degree dashboard and provided personalized patient intervention suggestions to physicians and health educators.

Influence Factor

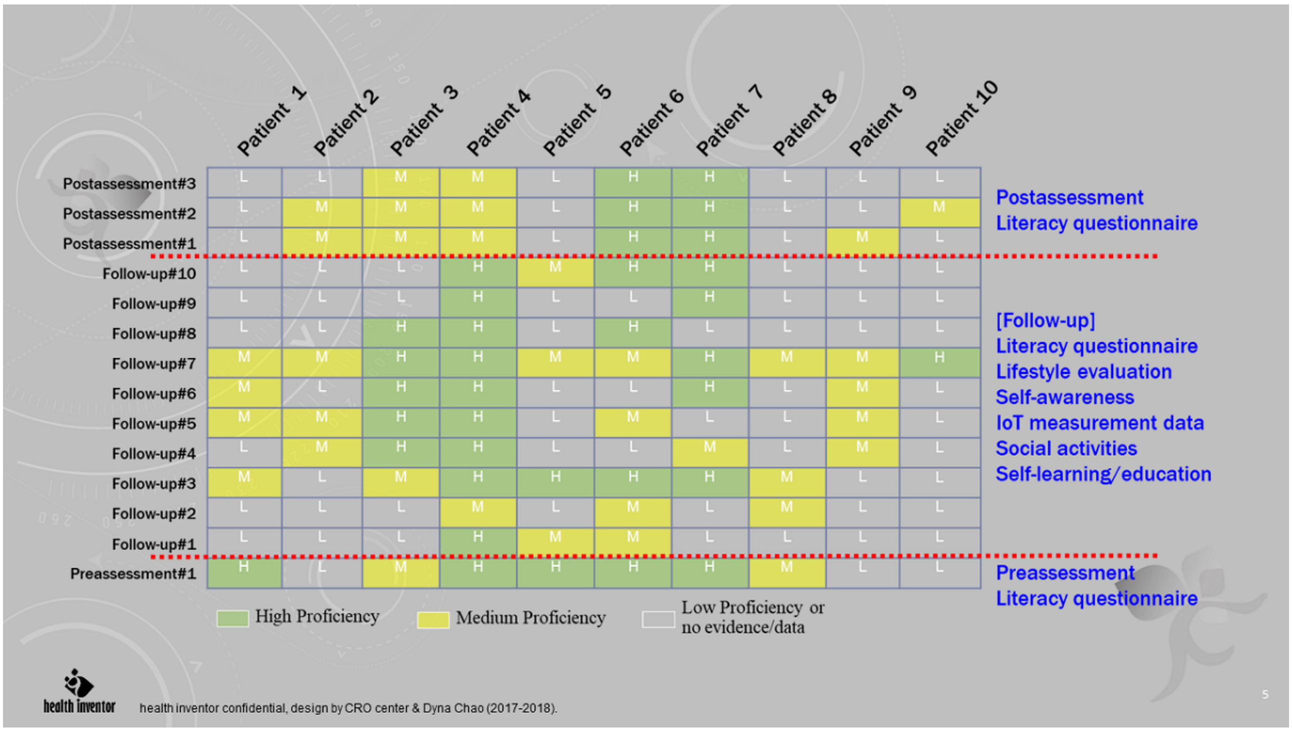
Patient characteristics and self-knowledge may have influenced compliance. Moreover, age, sex, education level, and income level affected patient acceptance of IT applications. The system identified the influential factors and their associations with compliance.

Data Collection Method

Interactive Patient Assessment System (Mobile App, iPad)

In the study, patients' health status, lifestyle, behavior change, and treatment preferences were collected through TTM framework for observing self-management behavior (see Figure 5). Pre- and postintervention assessments via mobile app were conducted (see Figure 6). Patient feedback was stored in a cloud-based IPMF platform and was used to determine factors that contributed to sustainable behavior changes.

Figure 5. Behavior maturity management (transtheoretical model): pre- and postassessment. IoT: Internet of Things.



	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10
Postassessment#3	L	L	M	M	L	H	H	L	L	L
Postassessment#2	L	M	M	M	L	H	H	L	L	M
Postassessment#1	L	M	M	M	L	H	H	L	M	L
Follow-up#10	L	L	L	H	M	H	H	L	L	L
Follow-up#9	L	L	L	H	L	L	H	L	L	L
Follow-up#8	L	L	H	H	L	H	L	L	L	L
Follow-up#7	M	M	H	H	M	M	H	M	M	H
Follow-up#6	M	L	H	H	L	L	H	L	M	L
Follow-up#5	M	M	H	H	L	M	L	L	M	L
Follow-up#4	L	M	H	H	L	L	M	L	M	L
Follow-up#3	M	L	M	H	H	H	H	M	L	L
Follow-up#2	L	L	L	M	L	M	L	M	L	L
Follow-up#1	L	L	L	H	M	M	L	L	L	L
Preassessment#1	H	L	M	H	H	H	H	M	L	L

Postassessment
Literacy questionnaire

[Follow-up]
Literacy questionnaire
Lifestyle evaluation
Self-awareness
IoT measurement data
Social activities
Self-learning/education

Preassessment
Literacy questionnaire

🟩 High Proficiency 🟨 Medium Proficiency ☐ Low Proficiency or no evidence/data

health inventor

health inventor confidential, design by CRO center & Dyna Chao (2017-2018).

5

Figure 6. Interactive patient pre- and postassessment.

我的健康儀表板

一般會員

Point：120

失能風險：暫無資料

慢病風險：暫無資料

高血脂：暫無資料

生存餘命：32.4
生活習慣：中危

BMI：26.06
等級：一級肥胖

高血壓: 126/80
等級：正常

糖尿病：暫無資料

85分

個人健康排名 20%

小組健康排名 X

平均互動紀錄 368%

自我學習 150%

平均健康紀錄 18hr

個人達標率 –60%

想做「線上生活評估嗎」？

我的紀錄

開始日期
2018/03/5

紀錄天數
21天

Patient Readiness Evaluation System (Mobile App, iPad)

As described, the AADE7 Self-Care Behaviors are critical to the management of DM (see Figure 7). Thus, in the study, the system collected the information of patients with T2D regarding healthy eating, physical activity, blood glucose and blood pressure monitoring, medication use, problem solving, risk reduction, and use of healthy coping strategies. The collected information was used to evaluate patients' mental readiness regarding the management of DM. After the readiness evaluation, patient score and disease level were transmitted to a physician dashboard for the next intervention stage.

Figure 7. The American Association of Diabetes Educators diabetes self-care behavior quiz.

以下有關糖尿病自我管理的七件主要事情，您這次想與醫師討論哪些事？(請先選一項)

Please select the categories of 7 dimensions that you want to discuss with your Physician.

Mary，您好!

Please select a period in sentences which is similar with you to help Physician to understand your situation.

☐ I usually eat out

✓ I like have some peanuts or cake when I drink coffee or tea

☐ Eating is important to me, I only eat my favorite foods

✓ I don't like that somebody decide for me what I should eat

✓ When I have dinner, I like to watch TW with meal.

Interactive Physician Dashboard System (Mobile App, iPad)

Patient clinical status, results from patient assessment, and readiness evaluation systems were presented on a physician dashboard. Patients interacted with the dashboard, and the system suggested an individualized education program based on evaluation results and patient lifestyle and preferences. Physicians and health educators used the comprehensive dashboard, wellness articles, and self-assessment tools to engage with patients. The dashboard tool illustrated the correlation between disease progression and patient's self-efficacy (see Figure 8).

Figure 8. Interactive physician and patient engagement dashboard.

性别: 男

职业 工程师

教育程度: 本科

身高/体重: 178.0CM / 72....

BMI:22.7

基础代谢率: 1539.7千卡

生化指标	结果	标识	参考范围	检查日期
糖化血红蛋白	5.5%		4.0-5.9	2014-07-07

Statistical Methods

The patient intervention activity and integrated data were recorded in the physician dashboard system. Data were analyzed using IBM SPSS Statistics version 19.0. A paired *t* test was used for pre- and postintervention assessment analysis, and the *t* test and chi-squared test were used for group comparisons.

Results

In total, 121 patients (n=121) were enrolled in the study. The case group included 62 participants (case group, n=62; control group, n=59), and these patients completed 27,479 intervention interactions by using the IPMF. Patients lost to follow-up were eliminated; 118 patients completed postintervention assessment (case group, n=60; control group, n=58). A total of 97 patients completed both the preassessment and postassessment (case group, n=49, retention rate=82%; control group, n=48, retention rate=81%).

Although for the duration of follow-up, patients were free to choose categories of DM self-management according to their interests, there were no change requests during the patient engagement. The results of the case group were better than those of the control group, especially those for knowledge score, weight, and HbA_{1c} (*P*=.05; *P*=.03; *P*=.003). Participants at a high risk indicated high motivation to change and to achieve high scores in the self-care knowledge assessment (n=49, 95% CI −0.26% to −0.24%, *P*=.052; Table 1).

Of the 305 of interventions, healthy eating was selected 98 times (see Figure 9) and thus was the most-selected category (32%, 98/305), with the second most selected category being taking medication (25%, 75/305).

The demographic characteristics of case group patients who finished the behavioral education course and completed postintervention assessments (n=28) in high score and improved group are listed in Table 2. The average age was 63.71 years, and the age range was 37 to 88 years.

Among the participants, 75% reported a high school education level. Compliance frequency from pre- and postintervention-assessments were compared for analyzing the effects of the IPMF intervention (Table 3). The *P* values reflect differences between pre- and postintervention assessments, and results indicate that patients were willing to set a dietary goal for self-management (*P*=.04).

Table 1. Self-care knowledge assessment.

Self-knowledge and behavior change	Control group (n=48, 81%)			Case group (n=49, 82%)		
	Preassessment, mean (SD)	Postassessment, mean (SD)	*P* value between groups	Preassessment, mean (SD)	Postassessment, mean (SD)	*P* value between groups
Knowledge score	56.22 (10.97)	57.78 (10.68)	.33	60.16 (19.24)	65.08 (12.24)	.048
Weight (kg)	66.67 (17.28)	65.65 (16.98)	.07	67.86 (16.84)	57.5 (15.33)	.03
Body mass index (kg/m^2)	25.29 (3.25)	24.94 (2.89)	.14	25.47 (3.31)	25.28 (2.93)	.23
Systolic blood pressure (mm Hg)	128.09 (17.36)	131.15 (18.24)	.57	130.24 (18.92)	131.37 (19.01)	.56
Diastolic bold pressure (mm Hg)	76.22 (12.11)	78.61 (12.98)	.52	74.99 (13.12)	75.58 (11.04)	.47
HbA_{1c}[a] (%)	8.95 (2.34)	7.82 (1.87)	.06	8.44 (2.28)	6.92 (1.27)	.03

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

Figure 9. The participant engagement frequency by Diabetes self-management of 7 categories. Interactive response (n=305).

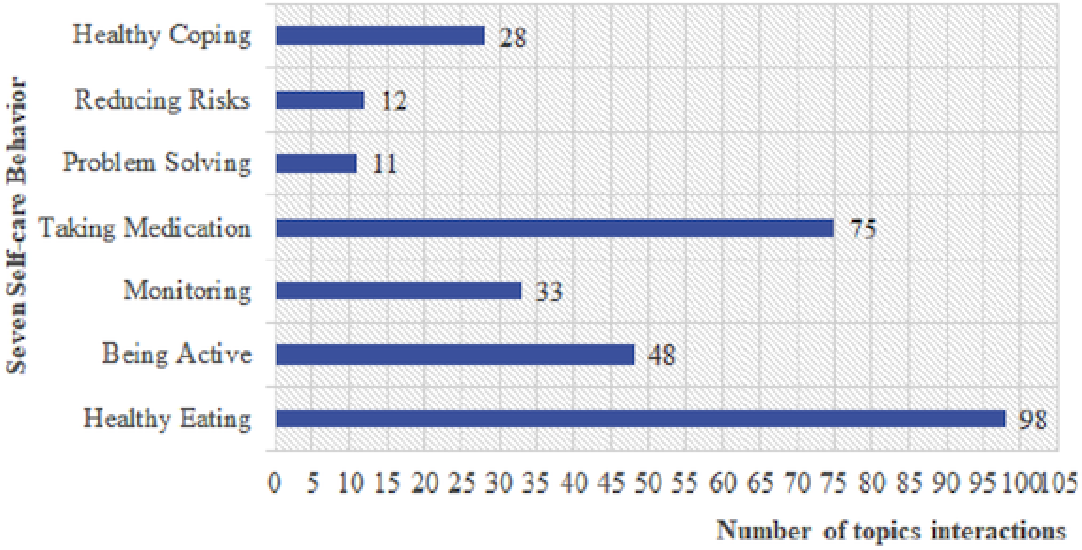


Table 2. Demographic characteristics of participants (N=120).

Characteristic	n (%)
Age (years)	
25≤years<40	1 (4)
40≤years<50	3 (11)
50≤years<60	6 (21)
60≤years<70	9 (32)
years≥70	9 (32)
Gender	
Male	17 (61)
Female	11 (39)
Education	
No education	1 (4)
Elementary school	6 (21)
Junior high school	4 (14)
High school	11 (39)
College	5 (18)
Graduate	1 (4)
Occupation (n=120)	
Unemployed	8 (7)
Public servant	5 (4)
Office worker	21 (18)
Businessman	17 (14)
Retired	64 (53)
Others	5 (4)

Table 3. Compliance comparison between pre- and postintervention assessments.

Compliance	Average (preassessment), mean (SD)	Average (postassessment), mean (SD)	*P* value
Dietary	3.5 (1.0)	3.8 (1.0)	.04
Exercise	3.0 (1.5)	3.3 (1.4)	.13
Medicine taking	4.6 (0.7)	4.4 (1.0)	.42
Blood glucose monitoring	3.2 (1.3)	3.4 (1.3)	.33
Blood pressure monitoring	3.2 (1.4)	3.2 (1.3)	.56
Health coping	3.8 (0.9)	4.1 (0.9)	.06

In addition to behavioral education compliance, the results of the Pearson chi-squared test indicate that patients' average compliance frequencies increased after intervention (Table 4), with improvements in dietary compliance reaching statistical significance (*P*=.07). The study results indicate that other surveyed health behaviors, including smoking status and drinking status, did not affect dietary behavioral compliance.

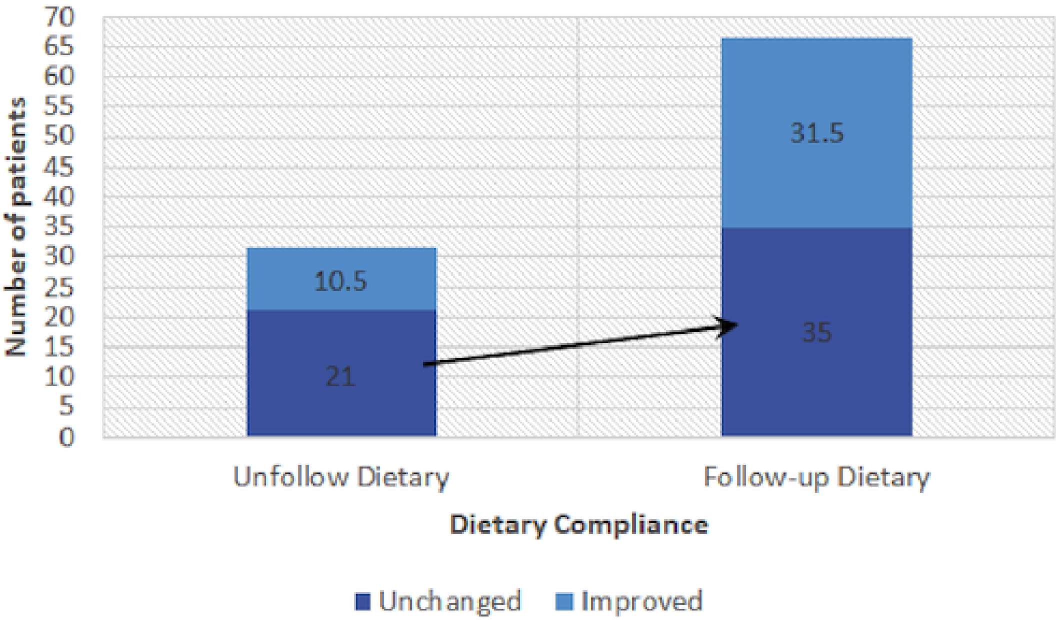
On the basis of the compliance changes, participants were then divided into an improved group (patients who exhibited improved compliance after the study) and an unchanged group (patients whose compliance was unchanged or decreased) for comparison. The improved group contained a higher number of patients who experienced diet-related intervention through the IPMF than the unchanged group (66.5% vs 31.5%; see Figure 10).

Table 4. Improved dietary compliance versus unchanged dietary compliance (n=16).

Behavioral education compliance (case group)	Dietary unchanged result, n (%)	Dietary improved result, n (%)	Pearson chi-squared *P* value
Gender			**.07**
Male	12 (75)	5 (42)	—[a]
Female	4 (25)	7 (58)	—
Drinking status			**.80**
Nondrinker	7 (44)	4 (33)	—
Occasional	3 (19)	2 (17)	—
Daily drinker	6 (37)	6 (50)	—
Mobile phone usage			**.63**
No	12 (75.0)	8 (67)	—
Yes	4 (25.0)	4 (33)	—

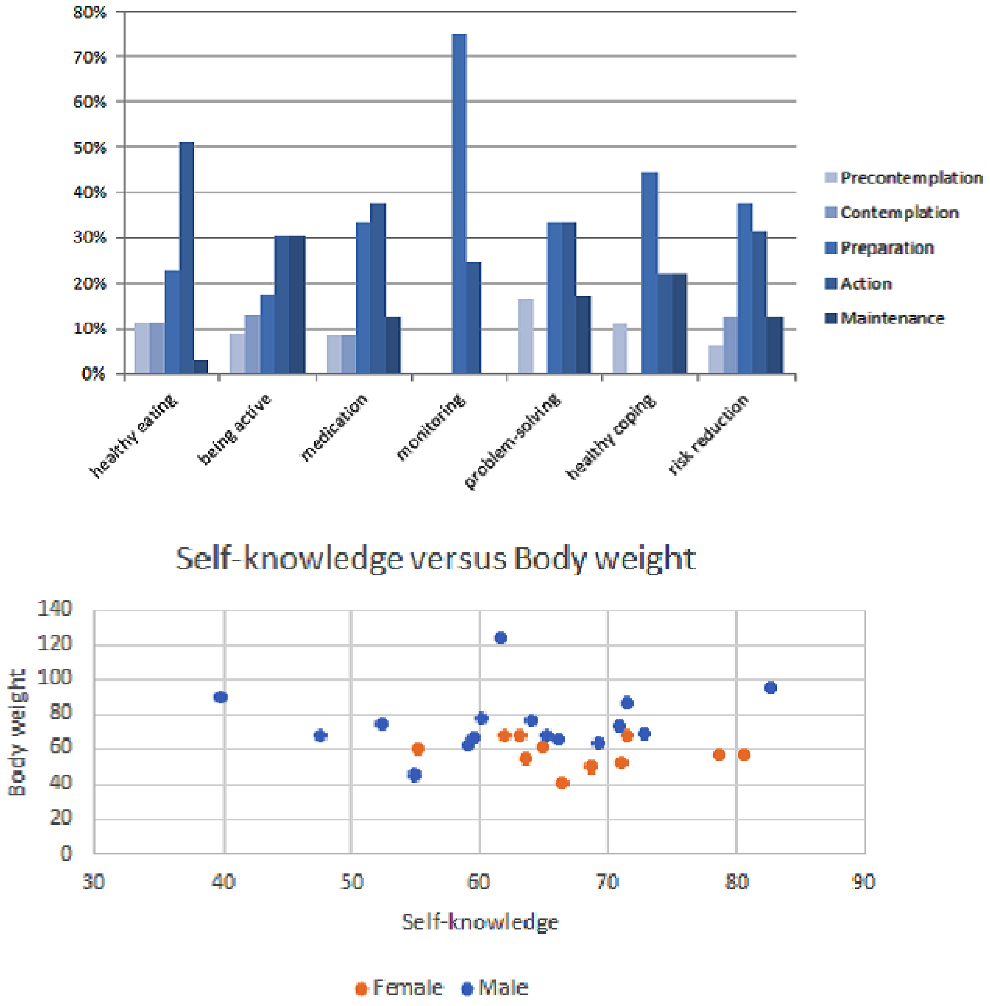
[a] Not applicable.

Figure 10. Compliance of improved patients among those using the intervention. Dietary response (n=98).



According to behavioral change of TTM data on monitoring, patients could enter the preparation stage directly (precontemplation, contemplation, preparation, action, maintenance; 0%, 0%, 75%, 25%, and 0%, respectively) without needing blood glucose monitoring. For healthy eating, more time was required for the precontemplation, contemplation, and preparation stages, but the time required for the action stage was markedly higher (precontemplation, contemplation, preparation, action, maintenance; 11%, 11%, 23%, 52%, and 3%, respectively). In the overall behavior change period, male participants with higher body weights and body-mass indexes exhibited greater motivation to change. Compared with male participants, female participants exhibited higher scores in self-knowledge and self-care (see Figure 11).

Figure 11. Intervention and self-behavior change (by transtheoretical model view).



Discussion

Principal Findings

This study indicates that overall patient compliance rate increased after the IPMF-based educational intervention [4,5,12,26]. Participants who completed postintervention assessments were older than 60 years. This finding demonstrates that age was not an impediment to mobile device usage.

The use of IPMF to improve patient compliance may help patient engagement and customer relationships and retain patients [12,13,33]. The personalized interactive education approach used in this study was associated with greater overall compliance with recommended health behaviors [1,19,27,34,35].

In addition, education level was not a barrier to using a mobile device (such as an iPad) for wellness education. Mobile phones are increasingly prevalent, but only a few participants owned a mobile phone. This low mobile phone ownership may have been correlated with average participant age [25].

Key aspects of self-efficacy for patients include the ability to use a mobile app to self-monitor progress and to be accountable for goals set [33]. In this study, the IPMF system may be particularly helpful for T2D patients with hypertension or who are overweight.

From another perspective, older people may encounter problems in engaging with interventions to reduce the risk of type 2 diabetes; the strong representation of this group in this study sample may be helpful for addressing relevant concerns [3]. This study indicated the participants were willing to join and complete the study regardless of whether they owned mobile phone, indicating that older patients can benefit from IoT resources [30]. This finding indicates that the intervention stimulated behavior changes in participants with greater interest in self-management.

Strengths and Limitations

A strength of this study was the inclusion of individual personalized goals and an execution plan; this study was not treated as a research study. All patient feedback data came from the real world as opposed to being generated from a research setting.

A limitation inherent in mobile app interventions is that patient responses may differ from those of normal behavior. This analysis was limited after follow-up, and the findings may not be applicable to patients with type 2 diabetes with low motivation to use a mobile app for self-management.

Implications

The results of this study indicated that persistent personal health management is correlated with positive feedback from physiological data [18,19]. In recent years, considerations of ethnic differences have served as the key element for providers designing treatment plans [7,16]. For example, investigating Chinese people's lifestyles—including elements such as diet, exercise, and stress-coping strategies—requires a wide variety of data obtained from user feedback [9,39].

Developers must address and acknowledge barriers to the use of mobile app interventions, such as low computer literacy and low health maintenance motivation [5,21,33].

Conclusions and Recommendation

This study found that (1) self-efficacy influences the factors of the IPMF intervention method and behavioral change model, and (2) a mobile app can be used to improve personalized care plans.

Despite the potential benefits of using a mobile app to support self-management of chronic diseases, we found that individual preferences can have a marked impact on personalized care plans and goal setting. As the mobile app for self-management in this study was developed and implemented rapidly, further work is necessary to produce a specific service that can enrich the quality of patient-centered care.

On the basis of this study, future related studies should consider the effects and continuity of behavioral changes resulting from interventions for enhancing self-efficacy. This research and the mobile interactive system will be revised and redeployed among an ethnic Asian population (eg, patients living in the United States with high motivation to use mobile apps to manage their personal health), and further evidence will be gathered to validate the effects of its use in health care self-management.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

AADE7: American Association of Diabetes Educators 7 Self-Care Behaviors
DM: diabetes mellitus
HbA_{1c}: glycated hemoglobin
IoT: Internet of Things
IPMF: interactive personalized management framework
T2D: type 2 DM
TTM: transtheoretical model

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Original Paper

Experiences of Patients With a Diabetes Self-Care App Developed Based on the Information-Motivation-Behavioral Skills Model: Before-and-After Study

Eunjoo Jeon[1], RN, PhD; Hyeoun-Ae Park[1], RN, PhD, FAAN

[1]College of Nursing, Seoul National University, Seoul, Republic of Korea

Corresponding Author:
Hyeoun-Ae Park, RN, PhD, FAAN
College of Nursing
Seoul National University
103 Daehak-ro, Jongro-gu
Seoul, 03080
Republic of Korea
Phone: 82 2 740 8827
Fax: 82 27654103
Email: hapark@snu.ac.kr

Abstract

Background: Mobile phones have been actively used in various ways for diabetes self-care. Mobile phone apps can manage lifestyle factors such as diet, exercise, and medication without time or place restrictions. A systematic review has found these apps to be effective in reducing blood glucose. However, the existing apps were developed and evaluated without a theoretical framework to explain the process of changes in diabetes self-care behaviors.

Objective: This study aimed to evaluate the diabetes self-care app that we developed by measuring differences in diabetes self-care factors between before and after using the app with the Information-Motivation-Behavioral skills model of Diabetes Self-Care (IMB-DSC).

Methods: We conducted a single-group pre- and postintervention study with a convenience sample of diabetes patients. A total of 38 adult patients with diabetes who had an Android smartphone were recruited. After conducting a preliminary survey of those who agreed to participate in the study, we provided them with a manual and a tutorial video about the diabetes self-care app. The app has functions for education, recommendations, writing a diary, recording, goal setting, sharing, communication, feedback, and interfacing with a glucometer, and it was applied for 4 weeks. We measured the general characteristics of participants, their history of diabetes self-care app usage, IMB-DSC factors, and blood glucose levels. The IMB-DSC factors of information, personal motivation, social motivation, behavioral skills, and behaviors were measured using an assessment tool consisting of 87 items extracted from the Diabetes Knowledge Test, third version of the Diabetes Attitude Scale, Diabetes Family Behavior Checklist, and Diabetes Self-Management Assessment Report Tool.

Results: The mean age of the participants was 43.87 years. A total 30 participants out of 38 (79%) had type 2 diabetes and 8 participants (21%) had type 1 diabetes. The most frequently used app function was recording, which was used by 34 participants out of 38 (89%). Diabetes self-care behaviors (P=.02) and diabetes self-care social motivation (P=.05) differed significantly between pre- and postintervention, but there was no significant difference in diabetes self-care information (P=.85), diabetes self-care personal motivation (P=.57), or diabetes self-care behavioral skills (P=.89) between before and after using the diabetes self-care app.

Conclusions: Diabetes self-care social motivation was significantly improved with our diabetes self-care app by sharing experiences and sympathizing with other diabetes patients. Diabetes self-care behavior was also significantly improved with the diabetes self-care app by providing an interface with a glucometer that removes the effort of manual input. Diabetes self-care information, diabetes self-care personal motivation, and diabetes self-care behavioral skills were not significantly improved. However, they will be improved with additional offline interventions such as reflective listening and simulation.

(JMIR Diabetes 2019;4(2):e11590) doi:10.2196/11590

KEYWORDS

diabetes mellitus; self-management; blood glucose self-monitoring; mobile applications

Introduction

Background

Diabetes mellitus is a chronic disease caused by an absolute or relative deficiency of insulin [1]. The number of patients with diabetes is increasing worldwide. According to the World Health Organization, 1.5 million deaths were directly caused by diabetes in 2014, and 422 million adults were living with diabetes [2]. The prevalence of diabetes in Korea was 13.7% in 2014, up from 8.6% in 2001 [1]. Diabetes can cause death because of inactivity of the heart, kidneys, eyes, and blood vessels if the blood glucose level is not properly controlled [3].

Antidiabetic medication such as an oral hypoglycemic agent plus insulin is used as an active regimen for blood glucose control to prevent diabetes and diabetes complications; however, drug therapy alone is not sufficiently effective [4]. Diabetes can be effectively treated when drug therapy is combined with appropriate diabetes self-care of lifestyle factors such as diet, exercise, and self-monitoring of blood glucose (SMBG) [5].

Mobile phones have recently been actively used for changing diabetes self-care behaviors. According to a health report from Intercontinental Marketing Services in 2015, diabetes self-care mobile phone apps were the second most common type of chronic disease management apps [6]. Diabetes self-care apps can provide various functions as listed below [6,7]:

1. Providing information in various formats such as text, images, and videos.
2. Allowing users to record their diabetes self-care behaviors.
3. Displaying diabetes self-care behaviors in charts and diagrams.
4. Providing tailored recommendations based on the history of diabetes self-care behaviors entered by users.
5. Providing reminders to perform diabetes self-care.
6. Enabling real-time communication between the medical provider and patient.

Diabetes self-care apps that manage lifestyle factors such as diet, exercise, and medication adherence have been shown to be effective in reducing the blood glucose level. A systematic review and meta-analysis of diabetes self-care apps found that they had a significant improvement in glycemic control [8,9].

However, existing diabetes self-care apps were developed without a theoretical framework to explain the process of changes in diabetes self-care behaviors [10]. Even though there are apps providing evidence-based interventions, they are not tailored to the level of knowledge and status of the diabetes self-care behaviors of the patients [11]. There are only a few apps reflecting user requirements [12] such as providing reminders, utilizing social media, and having an interface with a glucometer for facilitating diabetes self-care [13].

This study developed a diabetes self-care app based on the information-motivation-behavioral skills (IMB) model, which is a behavioral change theory for explaining the process of changing diabetes self-care behaviors and user requirements determined through focus group interviews. The app provides evidence-based tailored information, provides reminders, utilizes social media, and has an interface with a glucometer [14]. The American Association of Diabetes Educators (AADE) recommended evaluating changes in diabetes self-care using the IMB model [15]. On the basis of the AADE's recommendation, the developed app implemented an information factor to evaluate diabetes education, a motivational factor to evaluate cognitive changes, and a behavioral skills factor to evaluate the self-efficacy of diabetes self-care behaviors [16].

Objectives

This study evaluated the diabetes self-care app by measuring knowledge about diabetes and diabetes self-care as an information factor, individual and social motivation as a motivational factor, diabetes self-care skills as behavioral skills, and blood glucose levels as the outcomes.

Methods

Participants and Procedures

We conducted a single-group pre- and postintervention study with a convenience sample of diabetes patients to evaluate the diabetes self-care app developed in this study [14]. Participants were recruited by applying the following inclusion criteria: being older than 19 years, diagnosed with diabetes, and owning an Android phone. We recruited patients with diabetes regardless of diabetes types based on the previous intervention studies [15,16]. The sample size was 38, which exceeded the required sample size of 34 estimated for a 2-sided significance level of .05, a statistical power of .80, and an effect size for the intervention of .5 [8].

The research process consisted of the following steps (Figure 1):

1. We recruited study participants by posting a call for participation on 5 self-help websites for patients with diabetes from August 1 to 17, 2016.
2. We surveyed patients with diabetes who agreed to participate using a questionnaire to obtain information about their personal motivation, social motivation, behavioral skills, and behaviors.
3. We provided the subjects with a manual and tutorial video on how to use the diabetes self-care app.
4. The diabetes self-care app applied for 4 weeks provides educational material with recommendations about writing a diary, recording, goal setting, sharing, communication, feedback, and interfacing with the glucometer.
5. We surveyed the IMB-DSC factors after the 4-week intervention using the same questionnaire used in the first step.
6. We used an open-ended questionnaire to survey the subjects' experiences with using the diabetes self-care app and identify how functions of the app influenced the changes in IMB-DSC factors.

Figure 1. Research process applied in this study. DSM: diabetes self-management; IMB-DSC: Information-Motivation-Behavioral skills model of Diabetes Self-Care.

This study was approved by the institutional review boards at the Seoul National University (approval # 1510/002-009).

Theoretical Framework

The theoretical framework used in this study is presented below (Figure 2). The app was constructed by adding an index for the physiological outcomes to the IMB-DSC proposed by Osborn [17] adapted from the IMB model of Fisher et al [18]. It consists of 6 factors: information, personal motivation, social motivation, behavioral skills, behaviors, and physiological outcomes. Information, personal motivation, and social motivation are correlated with each other and affect behavioral skills and behaviors. Diabetes self-care behavioral skills affect diabetes self-care behaviors, whereas diabetes self-care behaviors affect blood glucose levels as the physiological outcomes.

Intervention

The app used in this study for intervention was developed by the authors, and the technical aspects such as its algorithm, heuristic, and usability were tested [14]. Our diabetes self-care app developed in the previous work was designed to be user-centered through focus group interviews, provided evidence-based tailored interventions with knowledge extracted from clinical practice guidelines, and integrated diverse functions such as education, recommendations, goal setting, recording, diary writing, social networking, feedback, reminders, and interface with a glucometer. We pilot tested the diabetes self-care app for usability with 14 diabetes patients.

Figure 3 shows how the diabetes self-care app functions are related to the components of the theoretical framework (Figure 3):

1. Evidence-based education and personalized recommendations were included to facilitate the provision of information.
2. Self-reflective diary writing, recording diabetes self-care behaviors, and individual goal setting were included to increase personal motivation.
3. Sharing with other patients and communication with health care providers were included to increase social motivation.
4. Feedback and visualizing blood glucose trends were included to improve behavioral skills.
5. Finally, a wireless glucometer interface (via Bluetooth) for receiving blood glucose data automatically was included to promote diabetes self-care behaviors.

Figure 2. The modified Information-Motivation-Behavioral skills model of Diabetes Self-Care.

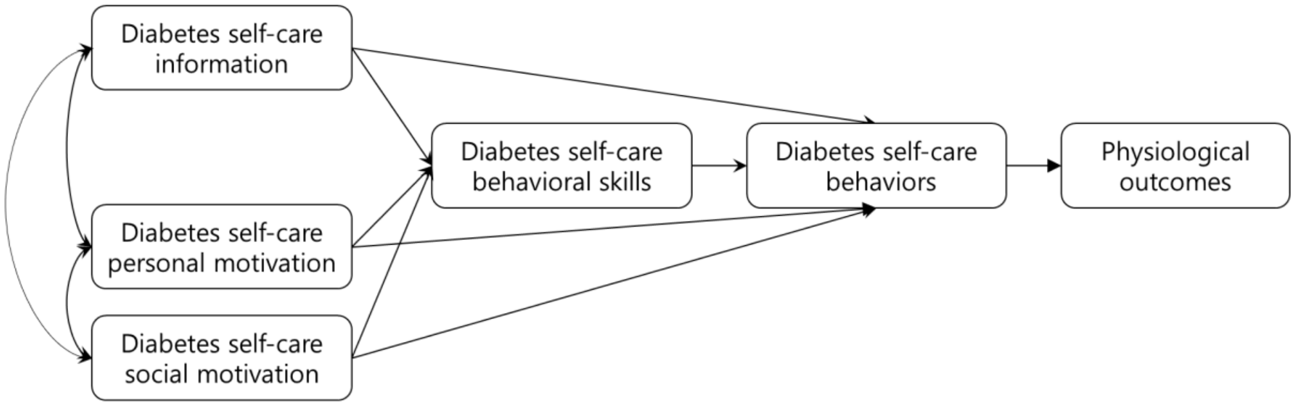
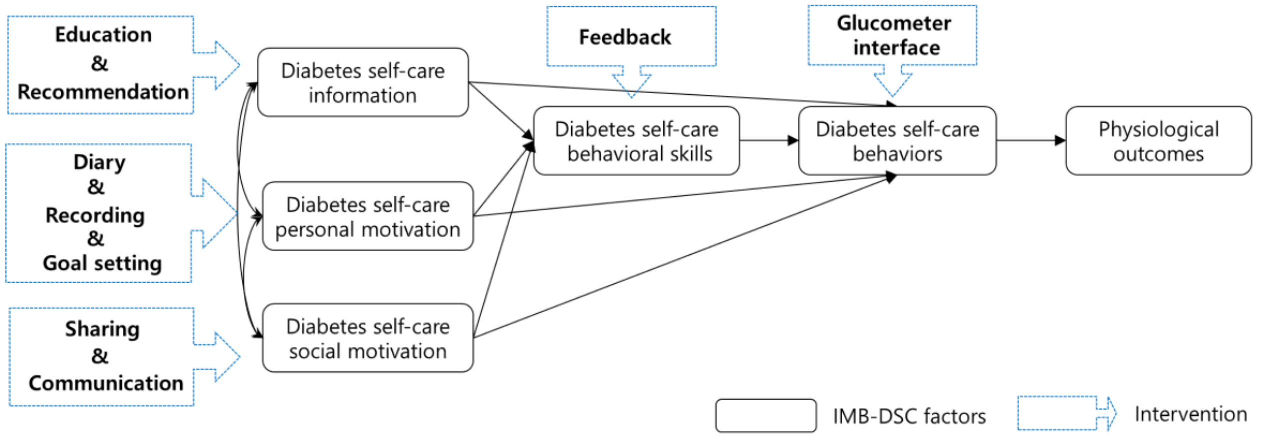


Figure 3. Relationships between the research framework and the diabetes self-care app intervention. IMB-DSC: Information-Motivation-Behavioral skills model of Diabetes Self-Care.



Measurements and Outcomes

We measured the general characteristics of the study participants, their history of diabetes self-care app usage, IMB-DSC factors, blood glucose levels, and surveyed their experiences with using the diabetes self-care app. We pilot tested the readability of the tools measuring 5 IMB-DSC factors with 14 diabetes patients [14].

General Characteristics and History of Using a Diabetes Self-Care App

Demographic and clinical information including age, gender, type of diabetes, and duration of diabetes were collected in the beginning of the study using a survey. The number of diabetes self-care app functions used was collected at the end of the study. The diabetes self-care app includes functions for recording diabetes self-care behaviors (diet, exercise, blood glucose level, medication adherence, blood pressure, and weight), providing reminders, glucometer interfacing, diary writing, and sending text messages to the health care provider.

Information-Motivation-Behavioral Skills Model of Diabetes Self-Care Factors and Physiological Outcomes

Diabetes self-care information was measured using the Diabetes Knowledge Test (DKT), which consists of 14 items measuring the general knowledge about diabetes and diabetes self-care [19]. The reliability of the DKT was measured by a Cronbach alpha of .67 in this study and of .71 in the study by Choi [20].

Diabetes self-care personal motivation was measured using the third version of the Diabetes Attitude Scale (DAS-3). The DAS-3 measures blood glucose control (3 items) and patient autonomy (8 items) using a 5-point scale ranging from 1 (strongly disagree) to 5 (strongly agree) [21]. The reliability of blood glucose control and patient autonomy in DAS-3 was measured by Cronbach alpha values of .57 and .71, respectively, in this study and .63 and .72, respectively, in the study by Choi [20].

Diabetes self-care social motivation was measured using the Diabetes Family Behavior Checklist (DFBC). The DFBC consists of 5 items with a 5-point scale ranging from 1 (“not at all”) to 5 (“at least once a day”) to measure social support in diabetes self-care [22]. The reliability of DFBC was measured by a Cronbach alpha of .84 in this study and of .87 in the study by Chang and Song [23].

Diabetes self-care behavioral skills were measured using the behavioral skills assessment tool that is part of the Diabetes Self-Management Assessment Report Tool (D-SMART). The tool consists of 20 items in 6 subcategories (diet, exercise, SMBG, medication, reducing risk factors, and problem solving) that are scored on a 4-point scale ranging from 1 (“I can’t do it”) to 4 (“I can do it for sure”) [24]. The reliability of the behavioral skills assessment tool of D-SMART was measured by a Cronbach alpha of .89 in this study and of .62 in the study by Choi [20].

Diabetes self-care behaviors were measured using the behaviors assessment tool of the D-SMART, which consists of 39 items in the 6 subcategories used to measure diabetes self-care behavioral skills [24]. The reliability of that behavior’s assessment tool was measured by a Pearson correlation coefficient of .79 in this study and of .73 in the study by Choi [20].

The physiological outcomes of the preprandial and postprandial blood glucose levels were measured by a glucometer.

Experiences With Using the Diabetes Self-Care App

We used an open-ended questionnaire to survey the experiences of the subjects with using the diabetes self-care app during the 4-week study period. The questionnaire asked whether IMB-DSC factors had improved, and if they had, which aspects of the app had contributed to these improvements.

Data Analysis

The collected data were analyzed using SPSS (version 22.0; SPSS Korea). The general characteristics of the subjects and the usage history of the diabetes self-care app were analyzed with descriptive statistics such as the mean and SD. Whether the IMB-DSC factors and the blood glucose level conformed to a normal distribution was tested using the Shapiro-Wilk test. Differences in IMB-DSC factors and the blood glucose level between pre and post intervention were analyzed using paired *t* tests when normality was satisfied and using Wilcoxon signed-rank tests in the other cases. We also analyzed the differences in IMB-DSC factors by gender, age (below average and above), diabetes type, and length of the condition (under 1 year and other). The normality in subgroups was tested, and a Wilcoxon singed-rank test was performed when normality was violated. Finally, the directed dependencies among the IMB-DSC factors were tested using the path analysis with postintervention values.

Results

General Characteristics of the Study Subjects

Demographic and clinical characteristics of the participants are presented (Table 1). More than half of them were male, their mean age was 43.87 years, and the largest proportion of them were in their 40s (n=18, 47%), followed by their 30s (n=11, 29%). Of the 38 participants, 30 (79%) had type 2 diabetes and 8 (21%) had type 1 diabetes. The mean duration of diabetes was 16.25 years in type 1 diabetes and 6.26 years in type 2 diabetes.

Usage History of the Diabetes Self-Care App

The diabetes self-care app was accessed an average of 21.79 times during the 4-week study period, ranging from 11 to 33. The most frequently used function was the recording function, with 34 out of 38 subjects (89%) using it. The next most frequently used functions were providing reminders and the glucometer interface, with 22 out of 38 subjects (58%) using these functions (Table 2).

Differences in Information-Motivation-Behavioral Skills Model of Diabetes Self-Care Factors

The preintervention scores, postintervention scores, and results of tests of the changes in IMB-DSC factors are presented in Table 3. Diabetes self-care social motivation differed significantly before (mean 12.16 [SD 5.48]) and after intervention (mean 13.87 [SD 6.81]; *P*=.05), as did diabetes self-care behaviors (mean 40.84 [SD 7.30] and mean 42.58 [SD 5.92], respectively; *P*=.02). However, there was no significant difference in information (*P*=.85), personal motivation (*P*=.57), or behavioral skills (*P*=.89) between before and after use of the diabetes self-care app.

Table 1. Demographic and clinical characteristics of the participants (N=38).

Characteristics	Participants
Gender, n (%)	
Male	23 (61)
Female	15 (39)
Age (years), n (%)	
20-29	1 (3)
30-39	11(29)
40-49	18 (47)
50-59	6 (16)
60-69	2 (5)
Type of diabetes, n (%)	
Type 1	8 (21)
Type 2	30 (79)
Duration of diabetes (years), mean (SD)	
Type 1	16.25 (14.83)
Type 2	6.26 (7.27)

Table 2. Numbers of subjects using the various diabetes self-care app functions (N=38).

Function	Total uses, n	Subjects, n (%)
Recording	3118	34 (89)
Reminders	55	22 (58)
Glucometer interface	1892	22 (58)
Sharing	56	10 (26)
Communication	10	10 (26)

Table 3. Comparison of independent variables between pre- and postintervention (N=38).

Variable	Maximum, n	Preintervention, mean (SD)	Postintervention, mean (SD)	*t* or *Z* value	*P* value
Diabetes self-care information	14	10.92 (1.78)	10.87 (2.37)	–.19	.85
Diabetes self-care personal motivation	45	33.29 (3.30)	33.36 (2.79)	–.57[a]	.57
Diabetes self-care social motivation	25	12.16 (5.48)	13.87 (6.81)	2.06	.05[b]
Diabetes self-care behavioral skills	72	54.89 (8.10)	54.08 (7.55)	–.14[a]	.89
Diabetes self-care behaviors					
Total	73	40.84 (7.30)	42.58 (5.92)	2.54	.02[b]
Diet	15	9.34 (2.08)	9.87 (2.27)	–1.32[a]	.17
Exercise	12	7.68 (3.20)	7.63 (2.79)	–.59[a]	.56
Self-monitoring of blood glucose	7	5.34 (2.23)	5.92 (1.44)	–1.93[a]	.05[b]
Problem solving	20	5.55 (2.91)	6.11 (3.09)	–2.07	.04[b]
Reducing risk factors	19	12.92 (3.23)	13.05 (2.85)	0.38	.71

[a] Wilcoxon signed-rank test done.

[b] $P<.05$.

Differences in Information-Motivation-Behavioral Skills Model of Diabetes Self-Care Factors by General Characteristics

There were no significant differences in changes of information, personal motivation, and behavioral skills before and after intervention by general characteristics such as sex and age. However, there were significant differences in changes of social motivation and behavior before and after intervention by type of diabetes and length of condition. In detail, diabetes self-care social motivation in the type 1 diabetes group differed significantly before (mean 11.38 [SD 5.37]) and after the intervention (mean 14.75 [SD 5.52]; *P*=.05), as in length of condition less than the 1-year group differed significantly before (mean 11.40 [SD 4.54]) and after the intervention (mean 13.36 [SD 6.02]; *P*=.03; Table 4).

Diabetes self-care behavior in the type 2 diabetes group differed significantly before (mean 40.87 [SD 7.89]) and after the intervention (mean 42.89 [SD 6.41]; *P*=.02), as in length of condition over the 1-year group differed significantly before (mean 38.15 [SD 8.28]) and after the intervention (mean 41.54 [SD 6.50]; *P*=.02; Table 5).

Diabetes-Related Physiological Outcomes

The preprandial blood glucose level was not different significantly before and after the intervention using the diabetes self-care app (*P*=.67), but there was a trend in decreasing the postprandial blood glucose level (mean 162.65 [SD 52.91] and mean 137.29 [SD 34.63] mg/dL, respectively; *P*=.09; Table 6).

Table 4. Differences in social motivation factor by general characteristics (N=38).

Variable	Samples, n	Preintervention, mean (SD)	Postintervention, mean (SD)	*t* or *Z* value	*P* value
Type of diabetes					
Type 1	8	11.38 (5.37)	14.75 (5.52)	–1.90[a]	.05[b]
Type 2	30	12.37 (5.44)	13.63 (7.18)	1.28	.21
Duration of diabetes					
Under 1 year	13	13.62 (6.92)	14.85 (8.31)	.67	.51
Over 1 year	25	11.40 (4.54)	13.36 (6.02)	2.29	.03[b]

[a] Wilcoxon signed-rank test done.

[b] *P*<.05.

Table 5. Differences in diabetes self-care behavior factor by general characteristics (N=38).

Variable	Samples, n	Preintervention, mean (SD)	Postintervention, mean (SD)	*t* or *Z* value	*P* value
Type of diabetes					
Type 1	8	40.63 (4.81)	41.00 (2.93)	–.34[a]	.73
Type 2	30	40.87 (7.89)	42.89 (6.41)	2.58	.02[b]
Duration of diabetes					
Under 1 year	13	38.15 (8.28)	41.54 (6.50)	2.91	.02[b]
Over 1 year	25	42.20 (6.46)	43.04 (5.58)	1.03	.31

[a] Wilcoxon signed-rank test done.

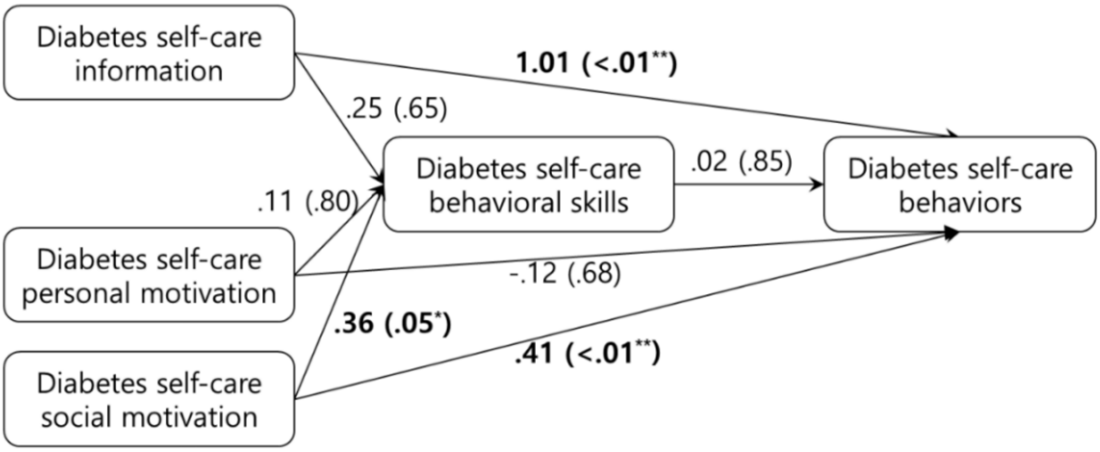
[b] *P*<.05.

Table 6. Comparison of blood glucose levels between pre and postintervention.

Time	Preintervention (mg/dL), mean (SD)	Postintervention (mg/dL), mean (SD)	*t* or *Z* value	*P* value
Preprandial (n=8)	125.70 (53.99)	129.14 (34.56)	–.42[a]	.67
Postprandial (n=18)	162.65 (52.91)	137.29 (34.63)	–1.79	.09

[a] Wilcoxon signed-rank test done.

Figure 4. The result of path analysis for Information-Motivation-Behavioral skills model of Diabetes Self-Care. Asterisk signifies significance at *P*<.05 and double asterisk signifies significance at *P*<.01.



Path Analysis of Information-Motivation-Behavioral Skills Model of Diabetes Self-Care

Diabetes self-care behavior was significantly affected by information (coefficient=1.01; *P*=.008) and social motivation (coefficient=.41; *P*=.002), and diabetes self-care behavior skills were significantly affected by social motivation (coefficient=.36; *P*=.05; Figure 4).

Experiences With Using the Diabetes Self-Care App

The narratives of the 28 participants who responded to the open-ended questionnaire about their experiences with using the diabetes self-care app are presented (Table 7).

Table 7. Comments from the survey of experiences with using the diabetes self-care app (N=28).

Factor	Comments
Diabetes self-care information	“The diabetes self-care app provided general information about diabetes care.”
	“The information provided by the diabetes self-care app may be helpful to the early onset diabetic.”
	“More specific information is needed.”
Diabetes self-care personal motivation	“I am managing myself before using the diabetes self-care app, so I am not sure about the change.”
	“Seeing my records of diet and exercise is motivating me.”
	“Through the diabetes self-care app, the goal of blood glucose control was re-recognized.”
	“I was more interested because I had to check daily in the diabetes self-care app about foot care.”
Diabetes self-care social motivation	“With the diabetes self-care app, I felt like sharing similar experiences.”
	“I liked the ‘Like’ function.”
	“I was stimulated by watching other people’s blood sugar on the bulletin board.”
Diabetes self-care behavioral skills	“The diabetes self-care app has helped me realize that it is difficult to lower an elevated blood glucose level.”
Diabetes self-care behaviors	“The glucometer interface made it possible to conduct blood glucose tests at both work and home.”
	“It is convenient to input the blood glucose value via the glucometer interface.”

Discussion

Overview

The purpose of this study was to improve the factors of IMB-DSC, which was validated from previous papers [17,18,25]. As a result, the diabetes self-care app developed in this study was effective in promoting diabetes self-care behaviors and diabetes self-care social motivation and in reducing the blood glucose level. However, it did not have a significant effect on diabetes self-care behavioral skills, diabetes self-care information, or diabetes self-care personal motivation. In addition, the causal relationship of factors of the IMB-DSC was analyzed by path analysis with postintervention measurements. As the number of subjects in this study was small, it was not possible to perform a structural equation modeling (SEM) analysis which can handle measurement error and indirect effect.

Diabetes Self-Care Information

Diabetes self-care information did not change significantly between before and after use of the app. Our study subjects had high initial scores for diabetes self-care information, so there was not much room to improve after using the app. The initial diabetes self-care information score was much higher in this study than that by Choi, which found significant changes between before and after use of an app [20]. This difference in the initial diabetes self-care information scores between the 2 studies could have been because of the present subjects being younger, making them better able to acquire information using their mobile phones compared with the participants in the study by Choi.

Another possible reason for the absence of a significant increase in the diabetes self-care information could be the large variance in the duration of diabetes. The survey of experiences with using the diabetes self-care app revealed that the participants who had a long history of diabetes considered the app to be more useful for people with early-stage diabetes than for long-term patients. It, therefore, appears to be necessary to provide different sets of diabetes self-care information tailored to patients at different stages. For example, more general information about diabetes and diabetes complications could be provided to early-stage patients and more advanced and specific information about diabetes self-care behaviors could be provided to long-term patients [20,25].

Diabetes Self-Care Personal Motivation

Diabetes self-care personal motivation did not change significantly between before and after use of the app. This could have been due to the intervention period of 4 weeks being too short to change personal motivation. Previous studies have suggested that long-term interventions lasting more than 6 months are needed to change diabetes self-care personal motivation [25]. Besides, it is difficult to change personal motivation by an online intervention such as writing a diary, recording, and setting a goal alone. A previous study suggested using face-to-face consultation such as reflective listening [17].

Diabetes Self-Care Social Motivation

Diabetes self-care social motivation differed significantly between before and after use of the app. We introduced a bulletin board where the participants could use to share their diabetes self-care experiences and express empathy with other participants, with the aim of promoting social motivation. Increase in social motivation with using the bulletin board is consistent with the findings of previous studies in which the participants shared their know-how about diabetes self-care and feelings with other patients with the same disease [25-27]. This finding was also confirmed in the open-ended diabetes self-care app experience survey in which study participants expressed that they felt like sharing similar experiences using the bulletin board.

Diabetes Self-Care Behavioral Skills

Diabetes self-care behavioral skills did not differ significantly between before and after use of the app. Previous studies have recommended the need to demonstrate skills to promote behavioral skills [20,28]. However, we did not provide face-to-face education to increase diabetes self-care behavioral skills; instead, information on diabetes self-care was provided on an app. We suggest providing diabetic patients with information about diet and exercise planning as well as blood glucose measurement scheduling using the simulation technique proposed by Osborn [17].

Diabetes self-care behavioral skills was not significantly affected by diabetes self-care information, which is similar to the findings of Choi [20]. Diabetes self-care behavioral skills were not significantly affected by personal motivation either. However, diabetes self-care social motivation significantly affected diabetes self-care behavioral skills (coefficient=.36; *P*=.05). These findings were different from those of the previous study [20]. However, it is difficult to directly compare the results of this study with those of the previous study as Choi combined personal motivation and social motivation into a single motivation metric [20].

Diabetes Self-Care Behaviors

There were significant changes in diabetes self-care behaviors between before and after use of the app, especially in SMBG and problem solving. We provided a wireless glucometer interface to receive data on the blood glucose level automatically to minimize the amount of manual input required, which is in accordance with the suggestion of Intercontinental Marketing Services to improve SMBG [6]. A wireless glucometer interface function could have improved SMBG in this study.

Our path analysis showed that information (coefficient=1.01; *P*=.008) and social motivation (coefficient=.41; *P*=.002) significantly affected diabetes self-care behaviors in this study. The effect of social motivation on diabetes self-care behaviors was consistent with the findings of previous studies [25,29]. Increasing social motivation will contribute to increasing diabetes self-care behaviors, but the effect of diabetes self-care information on diabetes self-care behaviors varied in previous studies [20,25,30]. These discrepancies could have been because of diabetic knowledge measurement tools often requiring more general knowledge on diabetes or diabetic complications than the knowledge required to perform diabetes self-care behaviors [20].

Diabetes self-care personal motivation did not significantly affect diabetes self-care behaviors in this study, which contrasts with the findings of Osborn and Egede [28]. This could be because of a difference in how the motivation of the IMB model was measured: Osborn and Egede measured diabetes self-care personal motivation based on diabetes fatigue [28], whereas it was measured based on the attitude to diabetes in this study.

Diabetes self-care behavioral skills did not significantly affect diabetes self-care behaviors in this study. This directly contradicts the finding of Choi [20], which is the only other study that has measured behavioral skills in the same way as in this study.

Physiological Outcomes

There was a trend toward significant changes in physiological outcomes before and after using the app, especially in the postprandial blood glucose level. This is consistent with the systematic review of Liang et al finding that a diabetes self-care app was effective at improving glycemic control [8,9]. The diabetes self-care app developed in this study appears to reduce the blood glucose level by improving diabetes self-care behaviors. According to the AADE, improvements in diabetes self-care behaviors such as diet, exercise, SMBG, problem solving, and reducing risk factors are effective for blood glucose control [5].

The limitations of this study are as follows: First, it was developed based on Android and so excluded other mobile phone operating systems such as iOS, Windows, and Blackberry OS. Second, although there are some studies that performed a short intervention for 4 to 6 weeks to improve diabetes self-management [16,31,32], the long-term effect of diabetes self-care app cannot be confirmed in this study. Therefore, a long-term study of at least 3 to 6 months is necessary to evaluate the change of glycated hemoglobin reflecting the blood glucose level over the previous 3 months and the personal motivation factor representing belief and attitude about health. Finally, a structural equation model could not be established to explain the effect of the functions provided when using the diabetes self-care app because of the small number of study subjects. A future study needs to conduct an SEM analysis to identify the relationships of IMB-DSC factors with the diabetes self-care app.

Conclusions

We have developed a diabetes self-care app based on the IMB model that provides personalized education and information to promote diabetes self-care information according to the knowledge level and behavior status of patients, a bulletin board that allows patients to communicate and sympathize with other diabetes patients, and an interface with a glucometer to improve diabetes self-care behavior factors. This study found that the intervention did not produce any significant changes in personal motivation or behavioral skills; these factors could be improved by providing face-to-face counseling or practicing strategies in combination with using the diabetes self-care app.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

AADE: American Association of Diabetes Educators
DAS-3: Diabetes Attitude Scale
DFBC: Diabetes Family Behavior Checklist
DKT: Diabetes Knowledge Test
D-SMART: Diabetes Self-Management Assessment Report Tool
IMB-DSC: Information-Motivation-Behavioral skills model of Diabetes Self-Care
SEM: structural equation modeling
SMBG: self-monitoring of blood glucose

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Original Paper

Achieving Value-Based Care in Chronic Disease Management: Intervention Study

Nilmini Wickramasinghe[1,2,3], BSc, MBA, PhD; Blooma John[4], PhD; Joey George[5], PhD; Doug Vogel[6], PhD

[1]Swinburne University of Technology, Hawthorn, Australia
[2]Epworth HealthCare, Richmond, Australia
[3]Peter MaCallum Cancer Centre, Melbourne, Australia
[4]University of Canberra, Canberra, Australia
[5]Iowa State University, Ames, IA, United States
[6]Harbin Institute of Technology, Harbin, China

Corresponding Author:
Nilmini Wickramasinghe, BSc, MBA, PhD
Swinburne University of Technology
PO Box 218
Hawthorn,
Australia
Phone: 61 04 5773 7173
Email: nilmini.work@gmail.com

Abstract

Background: The World Health Organization notes that diabetes, a chronic disease, is a silent epidemic, and by 2020 there will be a 54% rise in the total number of individuals diagnosed with this disease. These are alarming figures that have significant repercussions for the quality of life of individuals and their families as well as for the financial stress of health care systems globally. Early detection and proactive management of diabetes is essential. The Diamond solution provides diabetes self-management by enabling patients to send details about their blood sugar readings at specific times to their nominated care coordinator to receive recommendations for diet and exercise and insulin titration.

Objective: The aim of the study was to assess the usability, acceptability, and fidelity of the Diamond diabetes monitoring device for patients with gestational diabetes mellitus (GDM). Specifically assessed were (1) patient compliance, (2) patient satisfaction, (3) level of glycemic control achieved, and (4) health professional satisfaction.

Methods: Using a design science research perspective, the Diamond diabetes monitoring device solution was adapted to the Australian health care environment. Once the solution was deemed fit for purpose by the director of the OB/GYN clinical institute and on securing all relevant ethics approvals, a 2-period 2-arm nonblinded crossover clinical trial was conducted for 8 weeks total time with crossover at 4 weeks to establish proof of concept, usability, and fidelity. The patient perspective was assessed by using structured questionnaires at 4 specific stages of the project, while the clinician perspective was captured via semistructured interviews and unstructured questionnaires.

Results: The 10 patients studied reported preferring standard care with the technology solution to standard care alone. Further, all clinicians involved concurred that the technology solution greatly assisted their ability to provide higher value patient-centered care. They also noted that it was extremely helpful for assisting in systematically monitoring glucose levels and any/all changes and trends.

Conclusions: Based on these initial findings, we offer a holistic pervasive approach to enable the achievement of value-based, patient-centered care in chronic disease management. Key lessons include the importance when designing such solutions to focus on the two primary user groups (patients and clinicians).

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KEYWORDS

diabetes; gestational diabetes; chronic disease management; value-based care; mobile health; power knowledge; Australian health care system; 2-period 2-arm crossover; clinical trial

Introduction

Diabetes mellitus is one of the leading chronic diseases, and its prevalence continues to rise exponentially. The number of diabetes patients worldwide is estimated to rise to 366 million in 2030 from 171 million in 2000 [1]. Australia is expected to be a significant contributor to this projected trend. As of June 2016, more than 1.2 million Australians had been diagnosed with diabetes and were registered with the National Diabetes Services Scheme [2]. This number represents those diagnosed with type 1, type 2, and gestational diabetes.

An estimated 280 Australians develop diabetes every day [2,3]. Moreover, for every person diagnosed with diabetes, it is estimated that there is another who has yet to be diagnosed, which doubles the number of people with diabetes. If uncontrolled or poorly managed, diabetes can lead to chronic vascular and kidney diseases, strokes, heart attacks, eye diseases, and neuropathy and, for some individuals, amputations of extremities and limbs [4,5]. Furthermore, diabetes and its complications incur significant costs for the health system in Australia, including costs incurred to careers, government, and the entire health system.

Treatment of women with gestational diabetes mellitus (GDM) aims to control maternal, and therefore fetal, hyperglycemia and the associated tendency of fetal hyperinsulinemia, which is at the root of fetal complications [6]. After many years of uncertainty as to the value of such treatment in GDM, two key trials have now shown benefit for both mother and fetus for antenatal initiation of lifestyle modification and glucose monitoring coupled with insulin therapy as necessary [7,8]. Antenatal treatment of detected mild GDM was also associated with improved health status for women during the antenatal period and at 3 months after birth, with less postnatal depression [8]. Specifically, there is agreement in the literature that specific self-management activities including glucose monitoring, dietary restrictions, and exercise regimes can result in good outcomes for mothers and babies, suggesting that self-management behaviors can be critical [7,9]. More recently in Australia, there has been a lowering of the threshold level for when a pregnant woman is classified as having GDM, which immediately led to a significant increase in the number of women diagnosed with GDM over and above the growing trend that has been occurring. This change in classification makes it even more pressing to find a suitable solution.

Early detection and proactive management of diabetes is essential [10,11]. A critical treatment imperative is to provide patients with diabetes appropriate monitoring to enable better assessment and control of blood glucose and prevent further complications [12]. It is also essential that a cost-effective solution convenient to patients and clinicians and least disruptive to the patient lifestyle be adopted [13].

Inet International developed a pervasive technology solution to facilitate patient empowerment with their care [14-17]. The solution uses pervasive mobile technology to transfer critical information between patient and providers, ensuing in superior monitoring. This solution has proved successful in assisting to lower hemoglobin A_{1c} (the universally recognized marker for diabetes) in trials in Canada and the United States [12].

We report on the findings of our clinical study, based on our holistic pervasive approach, to enable the achievement of value-based care in chronic disease management that is patient-centric and focuses on the two primary user groups (patients and clinicians). Given that health care costs are an important aspect of all health care agendas today, we frame our recommendations against a value-based paradigm, as we believe this a responsible approach to take. Moreover, a key emergent aspect of the study was the power-knowledge dynamic that exists between patients and their clinical care team. We expand on this finding, noting how it might influence adoption and use of the technology solution. In particular, we note that when developing technology solutions, it is important to engage both user groups; without clinician support and engagement, it is unlikely that patients will be willing to adopt or use a technology solution.

The aim of this study was to assess the usability, acceptability, and fidelity of the pervasive technology solution (Diamond, a diabetes monitoring device) for patients with GDM and thereby establish proof of concept. Specifically, the study was designed to assess (1) patient compliance, (2) patient satisfaction, (3) level of glycemic control achieved, and (4) health professional satisfaction. From this, we expected it would be possible to develop a deeper understanding of the benefits, barriers, and facilitators as well as any possible negative impacts of such pervasive mobile solutions in supporting and enabling superior chronic disease management. In addition, the study served to answer the following research questions:

- How does a mobile solution enable and support the value-based care paradigm in the context of chronic disease management?
- What are the benefits and suitability of such a pervasive technology solution to self-care?
- What are the key barriers and facilitators for the application of a pervasive technology solution to support GDM patient care?
- What are the possibilities of applying the tools and techniques of data science to enable precision health care delivery and inform public health care initiatives regarding better chronic disease management practices and protocols?
- Are patients influenced and persuaded by their clinician to adopt the solution and is this important in choosing the solution?

Methods

Study Site

The data site chosen to conduct our study, a large tertiary, not-for-profit health care system, is situated in Melbourne, Australia. The Australian health care system is essentially a two-tier complementary system [18]. This means that all citizens and permanent residents have basic health care provided by a national government scheme called Medicare and can choose to take on additional coverage via private health care insurance. In Australia, the health care system has historically been centered on the practitioners and service providers. It is a highly fragmented system with both state and federal government jurisdiction. Hence, there exist many types of health care providers from solo practice to public hospitals (government hospitals) to various types of private hospitals. The chosen data site is in the private system; hence, patients receiving treatment at this hospital must have private insurance. In addition, the hospitals in this system are tertiary, which means they conduct leading research to strive to discover better ways to treat medical issues, and their not-for-profit status means that any surplus is reinvested into the system.

Diamond Diabetes Monitoring Device

The Diamond solution was developed by the Canadian company Inet International to provide diabetes self-management and monitoring to all patients diagnosed with diabetes. Key aspects of the solution include full compliance with the US Health Insurance Portability and Accountability Act; it is totally pervasive in that it works on any mobile platform (Android, iOS, etc) and it requires co-use or coadoption by the patient and their clinical care team.

Diabetic patients provided with the Diamond solution are able to send details about their blood sugar readings at specific times (ie, before breakfast, 2 hours after breakfast, 2 hours after lunch, and 2 hours after dinner) to their nominated care coordinator (typically a diabetic educator or endocrinologist or other doctor). On receiving this information, the care coordinator will respond to the patient with recommendations for diet and exercise and insulin titration. This exchange happens in real time. In addition, the solution keeps a log of diet and exercise activity and insulin use and graphs the blood sugar readings over time so that both patient and care coordinator can observe what is happening at any time.

Ethics

The Australian research code of ethics classifies any clinical intervention on pregnant women at the highest risk and, hence, the ethics process is at a national approval level and very strict. Ethics approval was received from the Epworth Human Research Ethics Committee, but the ethics committee limited the sample to 10 patients given that the clinical study was the first of its kind to be administered on pregnant women, and thus, fell into a high-risk category; if a patient dropped out, for whatever reason, we were able to add another patient.

To tailor the chosen pervasive technology solution, Diamond, to the specific health care context of the data site as well as comply with legal and ethical requirements for use of a technology solution in a study with pregnant women, it was necessary to make several tweaks to the technology solution so that it was both compliant and fit for purpose. We complied with all requirements and secured all necessary ethics clearances; to do this in a systematic fashion, we employed a design science research methodology approach (Multimedia Appendix 1).

Research Design

A 2-period, 2-arm crossover clinical trial strategy [19] with an 8-week duration per patient was adopted with two equal periods of 4 weeks each (Figure 1). As we wanted to understand the benefits, if any, of using a technology solution in addition to standard care protocols, it was necessary to have 2 arms to the crossover study design so that all patients experienced standard care and standard care plus technology. One arm was the control (ie, standard treatment of GDM by the hospital) and the other arm was the intervention (ie, standard care plus technology). In compliance with ethics regulations and laws in Australia, no patient can be denied standard care, so the intervention arm was designed as standard care plus the technology solution.

Patients were offered the opportunity to participate in the trial once a diagnosis of GDM had been made based on a glucose tolerance test administered between 26 and 28 weeks of pregnancy. Enrollment in the study was done by the endocrinologist under the supervision of the consultant obstetricians and was totally optional. At the time of enrollment, all pertinent information regarding the study was shared with patients including the crossover strategy employed. Patients were asked to complete a short questionnaire exploring demographic details, their familiarity with technology in general, and their understanding of GDM. Following enrollment in the study, patients were randomly allocated to either the standard care or standard care plus technology arm of the study. All patients were then educated in the technique of blood glucose monitoring by a diabetic educator as per standard clinical practice. They were also educated in the use of traditional or technology-based recording techniques for blood glucose.

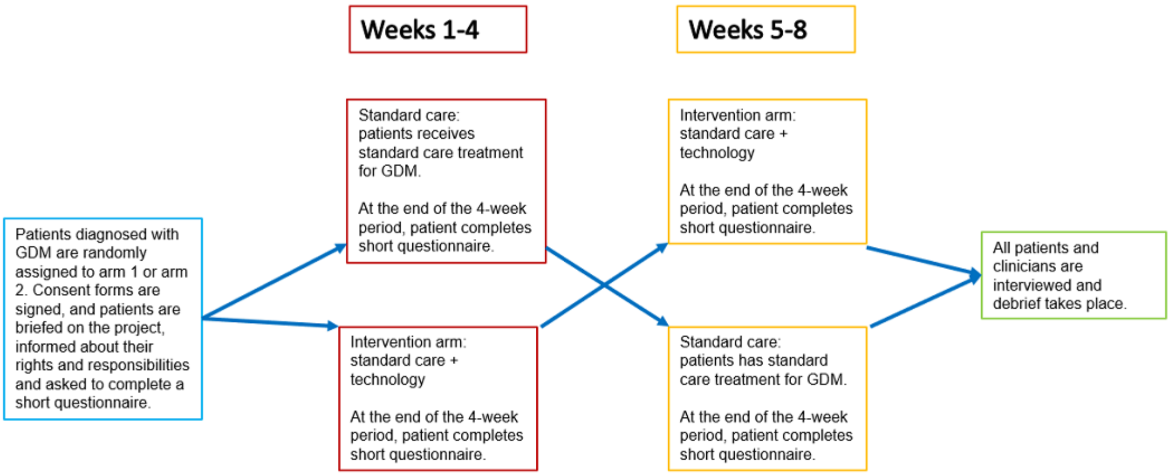
On the advice of the obstetrics and gynecology professionals, the duration was set at 8 weeks. This was deemed suitable as it was unlikely a baby would be delivered during this time frame and we would have time for the patient to experience both arms of the study. Hence, crossover was set at 4 weeks. As noted by Rigby [19], it is ideal to have a crossover time so that all participants can experience treatment with and without the technology and then comment on the differences. It is also recommended to have participants start with the technology solution and cross to without and vice versa so that it is possible to identify any biases more easily with technology use. The patient perspective was assessed at four specific stages of the project (Multimedia Appendix 2, part A):

- Structured questionnaire at the start of the project
- Structured questionnaire at the end of using standard care
- Structured questionnaire at the end of using the technology solution in conjunction with standard care
- Structured questionnaire at the end of the project

We note that to comply with ethics requirements, we did not interview patients at the completion of the study as it was considered too much stress and imposition on a new mother.

As there were two key user groups, patients and clinicians, it was necessary to also understand findings from the clinical team. The clinical care perspective included a focus on three key members of the patient care team: obstetrician, endocrinologist, and diabetes educator. These individuals were presented unstructured questionnaires to complete at the start and end of the study and were also invited to an interview where they were asked unstructured and semistructured questions about the study and their opinions on the role and benefit of the technology solution (Multimedia Appendix 2, parts B and C).

Figure 1. Study design. GDM: gestational diabetes mellitus.



Clinicians participated in both arms of the study and were asked about the crossover aspects during their interview at the end of the study. It was our desire to have questionnaires for the clinicians at the point of crossover, but ethics reviewers stated that this was superfluous and clinicians should not be given more questionnaires than necessary, so they were removed to comply with ethics requirements. The objective of the questionnaire at the start of the study was to assess ease of use with technology in day-to-day life determined by mobile solution used and frequency of use. The questionnaire at the conclusion of the study was designed to ascertain overall satisfaction with the technology solution and allow for any recommendations moving forward.

Results

To address the stated aims and answer the research questions, this study analyzed the data from two key perspectives: patient and clinician. Subscribing to the directives of Boyazis [20], the qualitative data were analyzed by examining the occurrence and frequency of the a priori themes and then any emergent themes. Qualitative and qualitative data were collected from the surveys conducted for both patients and clinicians as well as from performing basic statistical analysis on the numbers of patients in the study.

From the patient perspective, the key a priori themes included: (1) health literacy and understanding regarding diabetes management, (2) general familiarity with and use of mobile solutions, (3) standard care, (4) technology solution, and (5) suggestions to enhance the technology solution. Further, thematic analysis served to uncover other results from the patient data collected: (1) their supportive care team played a big role in their being comfortable with the technology solution because they trusted their doctor and were confident with the doctor's decision and (2) they were committed to doing whatever was best for their unborn baby's health, so having timely advice made them feel they were doing the best for their baby.

> *Overall, a wonderful initiative. This app makes it easier for patients with GDM as it's quick to enter readings, easy to track trends using graph on website and an effective and efficient way to communicate with doctors/nutritionists. For busy mums-to-be especially this is a fantastic tool, easier than remembering to call with readings each week. Excellent concept!* [Patient 02]
>
> *I could do it [record and check blood glucose levels] any time of day that was suitable and convenient to me. Knowing that someone was on the other end and would contact me if there was a concern/further information required. Info would be in writing. Could maintain privacy at work, no need to duck out to have conversations and report BGL [blood glucose level]. Didn't need pen and paper.* [Patient 07]

In addition, all patients preferred to have standard care with the mobile solution rather than the standard care approach only. All patients used mobile phones daily and felt very comfortable entering the required data. They all had a good understanding of the protocols they should follow for GDM once they were explained by their health care professional, and they complied as best as they could. This is not uncommon, given most mothers-to-be try to do what is in their unborn baby's best interests. At the conclusion of the study, many ideas for further enhancement were provided by the patients, including having a recommended food diary, assistance on where to get the needed food, recommendations for alternate exercise, and voice recognition to avoid data entry. All patients completed the four questionnaires.

For consistency, the same a priori themes were used to examine data collected from the clinicians. Overall, all the clinicians preferred the technology solution over the standard care only scenario. A total of 60% (6/10) of clinicians were totally happy using the app, and it was acceptable "as is" for them, while 40% (4/10) were happy with the solution but thought it could be further enhanced and was only useful for typical GDM patients.

They had reservations about using the solution in the case of complicated GDM patients. We note that, given ethics clearances obtained, we could not include high-risk patients in the study, so we cannot show any results for high-risk patients. Enhancements included keeping track of weight and blood pressure on an ongoing basis and graphing these together with the blood glucose levels.

Further, the clinicians concurred that the technology solution greatly assisted their ability to save time and made the monitoring of gestational diabetes more efficient and effective and was extremely helpful to assist in systematically monitoring glucose levels, changes, and trends any time regularly. This enabled them to provide better/optimal care for their patients; as they noted, having the key data at the right time greatly assisted them in making prudent decisions. They noted that even 1- to 2-point differences in blood glucose in pregnancy can have a severe impact on the fetus as it develops, given the resulting relatively much higher concentration of fetal blood glucose. For a tiny fetus, every extra second of exposure to a higher concentration of blood glucose can lead to major issues at birth and even throughout life.

In terms of usability, there were suggestions to change the format of patient entry so that it was clear when blood levels were seriously out of range versus slightly out of range. The only concern from the diabetes educators pertained to communicating with patients through the app rather than face-to-face appointments when dealing with a large sample size and the likely time requirements this would involve. It is anticipated that with appropriate staffing and workflow processes in place, this should not be an added burden, and it will also lend itself to capturing large amounts of data in a systematic fashion. These data can then be analyzed, so potential benefits at a more population health–level might ensue, which in turn might lead to new insights into diabetes management, treatment, and even prevention.

The clinicians in the study were particularly interested to further investigate the potential of the data and how data analytics might be used to identify key trends. They noted that GDM is the least understood form of diabetes and having cohorts of data on GDM patients would provide immense value in assisting to better understand this disease. They believe that the data collected could be helpful to examine what diets and exercise and when these occurred was best with GDM management as well as other factors including ethnicity and age. To get such a rich picture and understanding would assist them to develop better protocols for their patients and even contribute to public health protocols.

The clinicians identified as a major barrier hospital regulations and legal and government aspects.

> *In obstetrics there is always much focus if things go wrong—it is not good for the hospital, and the government and legal issues are complex, and it tends to get quite emotional too. Thus it tends to be quite conservative. Without hospital executive support, it is not possible to move forward with technology solutions. This is key, especially in our area.* [OBGYN 01]

In addition, emergent themes developed that focused on the need for coaching and education, need to redesign existing operations to make the best use of the efficiency and effectiveness potential the technology solution affords, and concerns about time commitments required and managing expectations regarding response rates by a member of the clinical care team. Finally, clinicians identified that it would be good to further enhance the solution to provide monitoring and management postdelivery to ensure that the mother still controls her blood glucose levels.

Discussion

Principal Findings

On analysis of the collected data, we contend that acceptability, usability, and fidelity were established as was initial proof of concept of the solution. Specifically, all patients using the technology solution with standard care had better management of blood glucose levels and were able to monitor and manage their GDM together with their clinician more effectively and efficiently when compared with standard care only. This was based on daily readings, examination of medical records and reports, and patient and clinician feedback. We note that the sample size was small (and this was due to ethics restrictions as already mentioned); however, we believe that by running further confirmatory studies we can develop a larger evidence base to further demonstrate the benefits of the Diamond solution for supporting and enabling superior care for patients with GDM. Moreover, the study establishes the benefits of such mobile solutions to both patients and their clinical care team to be used as an adjunct with standard care protocols. Specific answers to each of the posed research questions are provided in Multimedia Appendix 3. We note that while the results obtained may only be pertinent in the context of GDM, the developed framework can be generalized to other types of diabetes and even other types of chronic care interventions that use mobile solutions. We plan to expand on this in our future work.

Limitations

Like all studies, this study had a few limitations Sample size was limited due to ethics requirement. This in turn means that with such a small sample size generalizability is not possible. However, this directional data gives insights as to what might be appropriate in other contexts, which our follow-up research will investigate more fully. In addition, only one hospital site was used, and thus the patient catchment was limited not just by sample size but also by hospital location; it would not be unsurprising if hospitals located in different socioeconomic areas had different demographics for the patient population. But as noted earlier the results obtained serve to provide us with initial insights and directional data for our follow-up research.

Conclusions

We presented data from an exploratory clinical study designed to establish proof of concept, in an Australian context, of a specific pervasive mobile solution, the Diamond diabetes monitoring device. All patients reported preferring standard care with the technology solution over standard care alone.

Further, all clinicians reported that the technology solution greatly assisted their ability to save time and made the monitoring of GDM more efficient and effective and was extremely helpful to assist in systematically monitoring glucose levels, changes, and trends at any time more regularly. Based on these findings, we contend that a pervasive technology solution that is consistent with a value-based care paradigm for chronic disease management is important. Moreover, such a solution should be patient-centric, focused on the two primary user groups (patients and clinicians), and be used in conjunction with standard care protocols. We believe such a solution has the potential to represent a paradigm shift for diabetes care and chronic disease management in general. It is likely that the consequent paradigm shift in the approach to treating chronic diseases such as diabetes will provide the needed impetus to address the rising costs and better means to manage the current state.

In closing, we note that it is essential with all technology solutions, but most especially those in health care, to examine potential risks or negative aspects, if any. Based on the study, no significant risks became apparent, and given the extensive rigor applied in the ethics process, we believe any potential risks were identified during this process and addressed. However, with scale there may be an impact on clinician workload, and this should be investigated in future studies. Thus, establishment of usability, acceptability, and fidelity is clearly a necessary but not sufficient condition for universal adoption of a technology solution in health care contexts.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Design science research methodology.

[PDF File (Adobe PDF File), 140KB - diabetes_v4i2e10368_app1.pdf]

Multimedia Appendix 2

Questionnaires.

[PDF File (Adobe PDF File), 234KB - diabetes_v4i2e10368_app2.pdf]

Multimedia Appendix 3

Detailed answers to the posed research questions.

[PDF File (Adobe PDF File), 138KB - diabetes_v4i2e10368_app3.pdf]

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Abbreviations

DAAD-ATN: German Academic Exchange Service–Australian Technology Network of Universities
GDM: gestational diabetes mellitus

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Original Paper

Text Messaging and Type 1 Diabetes Management: Qualitative Study Exploring Interactions Among Patients and Health Care Professionals

Francesco Miele[1], PhD; Silvia Clementi[2], BD; Renzo Gennaro[3], MD; Ilaria Nicolao[2], BD; Tiziana Romanelli[2], MD; Katja Speese[3], BD; Enrico Maria Piras[1], PhD

[1]e-Health Research Unit, Bruno Kessler Foundation, Trento, Italy
[2]Azienda Provinciale per i Servizi Sanitari, Diabetes Center, Trento, Italy
[3]Azienda Provinciale per i Servizi Sanitari, Diabetes Center, Rovereto, Italy

Corresponding Author:
Francesco Miele, PhD
e-Health Research Unit
Bruno Kessler Foundation
Via Sommarive 18
Trento, 38122
Italy
Phone: 39 0461314129
Email: miele@fbk.eu

Abstract

Background: The diffusion of information and communication technologies (ICTs) in type 1 diabetes (T1D) management has generated a debate on the ways in which ICTs can support the patient-provider relationship. Several studies have focused on text messages. Most of the literature proposes quantitative analysis of the impact of text messaging on the clinical conditions of patients and/or their satisfaction with the technology, while the qualitative studies have focused mainly on patients' perceptions about strengths and weaknesses of this technology.

Objective: In contrast to past studies, we adopted a qualitative approach for the in-depth examination of patient-health care professionals' interactions in text messaging.

Methods: The study focused on the use of the Trento Cartella Clinica del Cittadino Diabetes System (TreC-DS), a digital platform with a built-in messaging system, in two diabetes centers, integrating message analysis with interviews with patients and health care professionals. Each center focused on a specific patient profile: the first one focused on pregnant women with T1D and the second one focused on adult patients with poorly controlled diabetes.

Results: The main results of the study were as follows: (1) Health care professionals and patients perceived the messaging system as useful for sharing information (ie, pregnant women for prescriptions and adults with poorly controlled diabetes for advice); (2) The content and communication styles of the two centers differed: in the case of pregnant women, interactions via text messaging were markedly prescriptive, while in the case of adult patients with poorly controlled diabetes, they were conceived as open dialogues; and (3) Conversations were initiated mainly by professionals; in the cases considered, it was mainly the diabetes center that decided whether a messaging conversation was needed.

Conclusions: The results show how the features of interactions of text messaging changed based on the patient profiles in two different centers. In addition, in both diabetes centers that were involved, the system seems to have laid a foundation for a closer relationship between patients and health care professionals.

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KEYWORDS

mHealth; text messaging; type 1 diabetes; diabetes in pregnancy; qualitative research

Introduction

Type 1 diabetes (T1D) is an autoimmune disease characterized by deficient insulin production in the body that tends to develop in childhood. T1D self-management can be challenging for patients and their relatives, including the following daily tasks [1]: self-monitoring blood glucose levels, managing insulin treatment, observing the symptoms of hypoglycemia (eg, constant hunger, tiredness, and blurred vision), and conducting other activities meant for preventing diabetes complications (eg, self-monitoring foot health and screening for eye complications).

The diffusion of information and communication technologies (ICTs) in health care has generated a polycentric debate on how ICTs can support patients with diabetes, providing services that empower them in self-management (eg, electronic logbooks or reminder functions for medications), enable communication with health care professionals (eg, messaging systems and rule-based alarms), and offer information on self-management (eg, tutorials for blood glucose tests). In particular, this debate has addressed issues such as the clinical impact of ICTs [2-9], the effects of ICTs on the patient-professional relationship [10,11], and their consequences on the workload of hospital staff [12-15].

The existence of a specific strand of studies on ICTs and diabetes is due to some characteristics of this illness, such as the significant workload required of patients and the vital role of patient education [16]. For this reason, although the use of messaging systems in health care is a topic already investigated with regard to other conditions [17-21], various contributors have focused explicitly on the role of text messaging in supporting and educating patients with diabetes. These studies often focus on the impact of text messaging on clinical outcomes and on the self-care capabilities of diabetic patients [22-27]. Other researchers have paid attention to patients' perceptions of the usefulness of text messaging [28-31], privileging quantitative techniques to assess users' satisfaction. Finally, another group of studies has adopted qualitative techniques to explore patients' perceptions regarding strengths and weaknesses of text messaging [32-37]. These works underline that text messaging is perceived by patients as a tool that is useful for resolving nonurgent issues with health care professionals [32], accessing and managing their own clinical data [37], receiving information and analytics for self-management [33,36], and feeling monitored [34,35]. Qualitative studies have also performed in-depth analysis of the factors perceived by patients that discourage the use of text messaging, such as their unfamiliarity with digital devices [21] or slow responsiveness of professionals [24].

As Holtz and Laukner argue [38], studies on text messaging have several limitations. The reports of provider interactions with diabetic patients through text messaging are limited and poorly documented, while health care professionals' perceived usefulness and the integration of mobile apps in organizational workflows are underinvestigated. This work intends to contribute to fill in the first gap, adopting a qualitative approach for documenting and examining, in depth, the interactions of patients and health care professionals via text messaging.

We consider the case of the Trento Cartella Clinica del Cittadino Diabetes System (TreC-DS), a digital platform with a built-in messaging system that supports communication between health care organizations and T1D patients. The study investigates the use of the messaging system in two diabetes centers in the Province of Trento, Italy. These two diabetes centers used the TreC-DS to support patients who would benefit from strict monitoring: pregnant women with T1D and adults with poorly controlled diabetes.

In the next section of this paper, we introduce the TreC-DS and the methods used to gather and analyze data. The findings, preceded by an overview analysis of the frequency of message exchanges, are organized into two subsections, one for each diabetes center. We conclude with some final remarks about the use of text messaging in T1D management and discuss limitations to this study.

Methods

The TreC Diabetes System

The Trento Cartella Clinica del Cittadino (TreC), a citizen-controlled clinical record system, was introduced to the Province of Trento in 2010 with the aim of empowering Italian citizens to manage their own health, facilitating their communication with health care institutions and the management of health information [39]. The platform has two TreC services: *basic* and *composite*. The former consists of data management and other common Web-based functions, and the latter includes higher integrated functions, such as a structured health diary and monitoring tools for specific pathologies [40].

The TreC-DS was developed to deliver mHealth services to citizens with T1D and to diabetes centers (see Figure 1). A mobile phone app enabled patients to keep track of all their diabetes information (eg, measurements, therapy, symptoms, and diet); it also included functions to support decision making (ie, a carbohydrate-count feature, a bolus calculator, graphs, and trend-tracking indexes). Through a Web-based dashboard, health care professionals (ie, doctors and nurses) could monitor patients' data remotely. Finally, the platform had a built-in messaging system that worked as a secure text-messaging service between patients and professionals.

Figure 1. A conceptual model of diabetes patient home monitoring: (1) daily diary compilation; (2) data stored in a central database; (3) data displayed on a dashboard; (4) health care professionals from the diabetes center access patient dashboards to evaluate patient problems; (5) conversation between patient and professionals about diabetes management.

Clinical Trial

This work is a part of a trial aimed at quantifying the effectiveness and acceptability of the TreC-DS for T1D patients. The trial was approved by the Research Ethics Committee of the Health Authority of the Autonomous Province of Trento, and written consent was obtained from the participants. The consent forms were included among other signed documents upon registration of the clinical trial at Ministero della Salute Direzione Generale dei Dispositivi Medici del servizio Farmaceutico e della Sicurezza delle Cure (DGDFSC) (trial number 0032830-P-22/04/2014).

The trial involved three diabetes centers in the Province of Trento. Each center focused on a particular patient profile and involved 10-15 patients:

1. The *Diabetes Center-Pediatrics* selected 15 children and adolescents who had poorly controlled diabetes, had a recent diagnosis, or used an insulin pump.
2. The *Diabetes Center-Adults* chose 15 patients with poorly controlled diabetes.
3. The *Diabetes Center-Pregnancy* selected 10 pregnant women with pre-existing T1D.

During the definition of the clinical trial protocol, these diabetes centers targeted patient profiles that would, according to the involved health care professionals, benefit from the stricter monitoring and frequent reminders about correct disease management that the platform could provide.

While the evaluation of the trial focused on the self-management practices of patients, changes in organizational practices arising from the introduction of the new technology to the diabetes centers and changes in the patient-professional relationship were also examined [11]. Here we present part of the results yielded from this research project, focusing on the use of the messaging system utilized by the Diabetes Center-Adults and Diabetes Center-Pregnancy, which were chosen for their frequency of use, integration of analyses of these messages, and interviews between health care professionals and patients. Characteristics of patients from these centers are summarized in Table 1.

Data Gathering

The use of the TreC-DS was explored through the analysis of text messages exchanged between patients and professionals via the system. The messages consisted of analyses of patient data, as well as inquiries and comments on insulin therapy, diet, and diabetes self-management. We analyzed 396 conversations within message threads exchanged between the patients and centers.

After a preliminary analysis of message exchanges, we conducted semistructured interviews with health care professionals and patients (see Textbox 1).

We interviewed all patients selected by the Diabetes Center-Pregnancy, except one that did not consent to the interview, as well as the first 8 patients to give their availability who were selected by the Diabetes Center-Adult with the aim to have comparable numbers of interviewed patients from each center. Patients were interviewed at home. Interviews lasted 45-60 minutes and were transcribed verbatim. All health care professionals involved in the clinical trial were interviewed. The main topics of the interviews are summarized in Table 2.

Table 1. Characteristics of patients and their use of text messaging.

Diabetes center and patient number	Gender	Age in years	Number of conversations with professionals via text messaging	Interviewed
Pregnancy				
1	Female	38	17	Yes
2	Female	32	16	Yes
3	Female	26	4	No
4	Female	37	9	Yes
5	Female	38	6	Yes
6	Female	28	20	Yes
7	Female	32	9	Yes
8	Female	36	12	Yes
9	Female	22	21	Yes
10	Female	33	9	Yes
Adults				
1	Male	39	27	Yes
2	Male	23	13	Yes
3	Male	41	5	No
4	Male	40	15	Yes
5	Male	49	17	Yes
6	Female	27	18	No
7	Female	37	17	Yes
8	Female	20	23	Yes
9	Male	32	22	No
10	Male	50	25	Yes
11	Female	50	19	Yes
12	Male	29	25	No
13	Male	42	36	No
14	Male	21	4	No
15	Male	31	7	No

Textbox 1. Target populations involved in the interviews.

Diabetes center and Interview participants

- Adults
  - 8 patients
  - 2 doctors (diabetologists)
  - 1 nurse
- Pregnancy
  - 9 patients
  - 1 doctor (diabetologist)
  - 1 nurse

Table 2. Interview guide.

Interview topics	Interview subtopics	
	Patients	Health care professionals
Patient-professional relationship (before TreC-DS[a])	• Disease onset • Self-management practices • Use of self-tracked data	• Education at onset and during clinical encounters • Use of patient-tracked data
Use of TreC-DS	• Collection and data analysis • Use of text messaging • Relationship between the use of TreC-DS and other care practices • Changes in relationship with professionals	• Use of patient-tracked data • Use of text messaging • Relationship between the use of TreC-DS and other organizational practices • Changes in relationship with patients
General evaluation of TreC-DS	• Usefulness of TreC-DS • Intention to use TreC-DS after the trial	• Usefulness of TreC-DS • Intention to use TreC-DS after the trial

[a] TreC-DS: Trento Cartella Clinica del Cittadino Diabetes System.

The interviews focused on reconstructing the ways in which patients and professionals used the different features of the TreC-DS, including text messaging, during the trial. In addition, during the interviews we investigated elements not directly connected with the use of the system. This latter focus was investigated, since it is assumed that the ways in which people use and incorporate a new technology into their daily lives are shaped by social circumstances, such as patients' attitudes toward their illnesses, pre-existing relationships and practices, and emerging social representations about the new technology [41].

Data Analysis

Overview

Data gathered were coded using template analysis, through which “the researcher produces a list of codes (‘template’) representing themes identified in their textual data. Some of these will usually be defined a priori, but they will be modified and added to as the researcher reads and interprets the texts” [42]. Preliminary categories based on the interview outline and literature analysis were used to segment the texts [32-38].

Message Analysis

At the end of message analysis, we created two general categories. The first category was labelled “communication style of the health care professional-patient interaction,” which was concerned with how much the interactions between professionals and patients were prescriptive or open. The second one was labelled “contents of the health care professional-patient interaction,” which was concerned with topics of the text messages. The contents of the conversations (ie, the message threads) were subdivided into the following subcategories:

1. Therapy: management of glycemia through insulin therapy.
2. Diet: management of glycemia through food intake.
3. Education: general rules for self-management.
4. Motivation: reinforce adherence to treatment.
5. Context: gathering information regarding patients’ daily lives (eg, exceptional events and comorbidities) that could affect diabetes management.
6. Technical issues: problems that emerged in data tracking.

Conversations often covered multiple topics at once. In these cases, we coded the single conversation more than once.

Interview Analysis

Interviews were also analyzed using template analysis. The purpose of this second step of analysis was to explore patients’ and professionals’ use and social representations of the TreC-DS, enriching the content of the categories described above. During the analysis of the interviews, another category emerged, which was labelled “representations about text messaging." This last category concerned the meaning given to text messaging by both patients and health care professionals (eg, how the system improved doctor-patient communication or self-care capabilities).

Results

Overview

We conducted a preliminary analysis of the frequency with which the patients and diabetes centers used the TreC-DS messaging feature during the trial. We focused on two topics: the direction of each conversation (ie, who initiated the interaction) and the shared content of the messages using the categorization described above. Regarding the direction of conversation (see Table 3), there were no remarkable differences between the messages from the two diabetes centers. In both cases, the majority of the conversations were initiated by the center; the percentage of center-initiated messages was somewhat higher among the adult patients with poorly controlled diabetes (231/273, 84.6%) than it was among the pregnant patients with diabetes (100/123, 81.3%).

Table 3. Direction of text-message conversations.

Diabetes center	Conversations, N	Direction of conversation, n (%)	
		Diabetes center to patient	Patient to diabetes center
Pregnancy	123	100 (81.3)	23 (18.7)
Adults	273	231 (84.6)	42 (15.4)

Table 4. Text-message conversation content.

Diabetes center	Conversation content, n (%)					
	Education	Motivation	Insulin therapy	Diet	External context	Technical issues
Pregnancy (N=156 conversations)	0 (0)	14 (9.0)	80 (51.3)	22 (14.1)	25 (16.0)	15 (9.6)
Adults (N=341 conversations)	24 (7.0)	104 (30.5)	94 (27.6)	27 (7.9)	25 (7.3)	67 (19.6)

In contrast, if we consider the content of the conversations (see Table 4), many differences can be observed between the Diabetes Center-Pregnancy and Diabetes Center-Adults groups. In the Diabetes Center-Pregnancy group, more than half of the content (80/156, 51.3%) of the conversations focused on therapy. This focus can be explained by the pregnant women's need to keep their glucose values within a fixed range by the center. Exchanges regarding these patients' external context (25/156, 16.0%) and diet (22/156, 14.1%) were quite frequent, likely for the same reason. In contrast, in the Diabetes Center-Adults group, the conversations were mainly comprised of motivational content (104/341, 30.5%) aimed at pushing patients with poorly controlled diabetes to achieve good results in the self-management of blood glucose levels. Messages concerning insulin therapy (94/341, 27.6%) and technical issues (64/341, 19.6%) were also frequent; the high percentage of technical issues is probably due to the sporadic access of adult patients to their hospital ward (ie, one or two face-to-face visits in a year). Drawing on our qualitative analysis of text-message exchanges and interviews, we will illustrate the ways in which the patients and health care professionals used and represented the built-in messaging system.

Diabetes in Pregnancy

T1D has several potential negative effects on the fetus, including overgrowth [43], the development of congenital malformations [44], and premature death [45]. To avoid these negative events, doctors generally recommend strict control over blood glucose levels and over the patient's lifestyle.

> *The goal of pregnancy was so important that I began to take many more medical exams and check-ups. [Before the pregnancy] I spent two or three years under strict control and, in the end, I entered the pregnancy with good blood sugar levels.* [Patient 1, Diabetes Center-Pregnancy]

> *I'm always scared to do what comes into my head arbitrarily, even when I know these injections can be managed autonomously.* [Patient 7, Diabetes Center-Pregnancy]

A stricter monitoring of clinical parameters may begin before the pregnancy and continue until childbirth, during which time women may partially renounce their autonomy. The temporary loss of autonomy is justified by both the clinical risks and the loss of relevance of self-management skills due to the physiological changes related to pregnancy. Therefore, the relationship between patients and their diabetes center changes dramatically. While health care professionals shift from an approach based on the empowerment of patients to a more prescriptive one, patients usually accept, and often openly appreciate, this change. In this context, the TreC-DS is represented by both professionals and patients as a technology that is useful for supporting diabetes center-patient communication remotely during a stage of illness in which communication is vital.

> *Without doubt, it [the use of TreC-DS] is a time-consuming activity...However, the quality of care has changed. If we see the patient after two weeks with the system, it is not like it is when we see a patient after two weeks without the system. It is resuming something that, actually, has never stopped.* [Nurse, Diabetes Center-Pregnancy]

> *The relationship with the ward was not as strong as it was previously: the visits, instead of being held once a week, were held twice a month. Nevertheless, weekly advice about therapy still arrived. I felt well monitored, and it [the TreC-DS] has been a great tool.* [Patient 4, Diabetes Center-Pregnancy]

The TreC-DS was represented by both patients and health care professionals as a system that improves the quality of care. By using it, the diabetes center could monitor patients strictly, request additional information, send prescriptions, and have more-focused conversations during the face-to-face visits with patients, having already acquired information about the patient's health status from the TreC-DS. For the patients, the system improved the quality of care and reduced the frequency of face-to-face visits, while ensuring continuous interaction with the diabetic center by receiving prescriptions and advice through the system.

The general representations of the system seemed to affect the communication styles of the messages, as shown in the conversation below between Patient 5 and the Diabetes Center-Pregnancy:

> *Hello. We checked your glucose values, and we noticed that they tend to increase both before dinner and when you wake up. In the afternoon, when you have a snack, try to increase your intake of NovoRapid [short-acting insulin] to 3 units; in the evening, you should increase your Levemir dosage [long-acting insulin] to 17 units. See you soon!* [Diabetes Center-Pregnancy, message sent to patient]

> *Good morning. Lately when I wake up, my glucose values are in the 120-138 range before breakfast. I usually take 6 units of Levemir at 11 p.m. In your opinion, do I need to increase my insulin dosage from 6 to 7 units? Thanks, and see you soon!* [Patient 5, question posed to Diabetes Center-Pregnancy]

> *Good morning. Your insulin treatment plan has been changed in the following manner: take 4 units of NovoRapid at breakfast, 7 units at lunch, and 7 at dinner; take 8 units of Levemir before bed.* [Diabetes Center-Pregnancy, in response to patient's question]

The reported messages, although they contain different directions, are characterized by a prescriptive communication style. The patients with "bad" glycemic values, whether directly observed by health care professionals or reported by the patients, received therapeutic prescriptions, as shown in the conversation below between Patient 7 and the Diabetes Center-Pregnancy:

> *Good morning. I need information about something that happened this afternoon: 2 hours after lunch, at 5 p.m., I measured my glycemic value at 188. Therefore, I walked for an hour and a half. Then I took a vitamin supplement and two candies labelled "without sugar." At 8 p.m., my glycemic value was 197! I do not understand. Why have my blood sugar values not decreased? In 3 hours, my values have remained high, even though I walked a lot.* [Patient 7, question posed to Diabetes Center-Pregnancy]

> *Hello. The walk was a good idea. You should always check the carbohydrates indicated on packages of food such as candy. The inscription "without sugar" means that the candy does not contain any added sugar, but it still does contain sugar.* [Diabetes Center-Pregnancy, in response to patient's question]

Nutrition was an area of autonomy that was rarely touched. However, the professionals did discuss the sugars contained in foods and how to handle them, whether through insulin therapy or physical activity. The communication style was less prescriptive on this topic, but the advice of the ward was generally considered authoritative.

> *Hello! Maybe you did not read the message written by the doctor. We are waiting to receive your blood sugar values, including those from the last few days.* [Diabetes Center-Pregnancy]

Given the high attention of the diabetes center on diabetic women in pregnancy, messages similar to the one above were quite common. Through these messages, the center aimed at continuous monitoring of patients; however, monitoring was only accepted for the duration of pregnancy.

> *No! After the pregnancy, I would not use the system every day. Right now, I have a goal I care about, and I am alert to everything. But after the pregnancy, I would feel really sick [using it].* [Patient 10, Diabetes Center-Pregnancy]

The women with diabetes who were interviewed agreed that continuous use of the TreC-DS would be unacceptable and too onerous after pregnancy. Therefore, the suspension of diabetes self-management was interpreted as temporary. Some patients claimed that if they were not pregnant, they would not use the system at all, while others favored a more limited use of the system. For the latter, the system was represented as useful for sending specific data to the diabetes center, allowing them to receive feedback from professionals about their self-management strategies.

Poorly Controlled Diabetes

In the medium-to-long term, patients with poorly controlled diabetes may develop serious health issues, such as cardiovascular diseases [46,47], retinopathies [48,49], or renal diseases [50,51]. Therefore, health care professionals have included adults with a history of poor self-management in the study, with the aim of monitoring them remotely.

> *My history with diabetes started out badly. When I was hospitalized, I was barely saved. From that moment on, I began to have practical issues with diabetes management: my life is fast-paced and stressful, and for a long time, I did not accept my illness. I approached the Diabetes Centre of Trento, which I frequented for some time, but then I abandoned it. Then, several years ago, I realized that I had to regain control over my life.* [Patient 7, Diabetes Center-Adults]

The above excerpt exemplifies why many patients experience difficulties accepting their illness and reconciling it with their social and work lives. Consequently, friction often arises between these patients and health care organizations. The TreC-DS was adopted by patients who had tried several times to improve their self-management capabilities after being alerted by a diabetes center that, in the future, their health conditions could become worse. The patients' histories were marked by various failures, and the system was an opportunity to regain control over their condition.

> *Over the last few years, diabetes management has changed dramatically. We have to monitor our patients, explaining to them, "Be careful: for injections, you now have to use a needle." Other times, it can happen that [we need to intervene].* [Doctor, Diabetes Center-Adults]
>
> *I greatly appreciated that clinicians and nurses were monitoring me...[Name of nurse] is very active; she gives me suggestions and, if I am in doubt, she answers my questions...and she does so on the basis of the values that I have input into the system!* [Patient 5, Diabetes Center-Adults]

Both for professionals and patients, the TreC-DS was useful for improving diabetes center-patient relationships, renewing and expanding the self-management skills of patients. From the professionals' perspective, poor control of diabetes occurs largely because patients have developed a bad relationship with their illness and because they have gaps in knowledge of diabetes. Given these assumptions, the system is useful for monitoring patients, acquiring information about their self-management capabilities, and giving them information and advice.

Yet the patients emphasized that through the TreC-DS, they felt constantly monitored, receiving messages with useful "tricks" for improving their self-management capabilities and feedback on trends in their blood glucose levels. For many of these patients, the system made face-to-face visits less necessary, reducing their frequency. After the introduction of the TreC-DS, patients rapidly shifted from a state characterized by poorly controlled diabetes to one characterized by daily interaction with a diabetes center, receiving feedback and advice.

> *While you had the flu, you managed your blood sugar values excellently! I hope that you'll get well so that you can celebrate the New Year. Happy New Year! Goodbye.* [Diabetes Center-Adults]
>
> *When the nurse writes me a message saying "Well done!" I like it, even if I don't know who is talking to me. I don't care; I know that, in any case, it is someone knowledgeable.* [Patient 9, Diabetes Center-Adults]

The system was useful for patients to receive feedback on their self-management skills. As noted previously, the majority of the conversations contained motivational messages sent by the health care department, with the aim of praising patients for the achievement of good blood glucose values. Another aim was to reassure patients who did not reach their clinical goals. The health care providers seemed interested in being noticeable to patients, pointing out to patients that they were monitoring them remotely and encouraging them to track their values daily. It was difficult for these patients to learn self-management skills; for the professionals, the use of the TreC-DS helped to support these patients on their journey.

> *Hi! Do you know "the rule of 15" for hypoglycemia management? When you have lowblood glucose levels, you have to adjust them with 15 grams of sugar, and after 15 minutes, you have to recheck your blood sugar values: if they are under 100, you have to take 15 grams of sugar again...* [Diabetes Center-Adults]

Encouraging messages were often followed by educational ones that provided general rules about diabetes management, such as in cases of incorrect patient behaviors observed remotely by health care professionals. Unlike the observations in the case of diabetes in pregnancy, the goal was not to drive patients remotely through prescriptive guidelines, but rather to provide them with advice and rules meant to improve their self-management skills. Consequently, messages concerning insulin therapy and diet took the form of suggestions that the patient could accept, refuse, or follow partially.

> *Hi! Have you checked your blood sugar values? I noticed that you are not taking the 8 units of Humalog [short-acting insulin] I prescribed for you because you need more insulin. Try taking 10 units of Humalog in the morning, 10 units in the middle of the day, and 10 units in the evening. Try this out for a few days, and let me know how it goes.* [Diabetes Center-Adults, message to patient]
>
> *Okay, but for the middle of the day, I'd like to stay at 8 units of Humalog because I don't eat much.* [Patient 6, message to Diabetes Center-Adults]
>
> *Okay. This is up to you.* [Diabetes Center-Adults, in response to patient's message]

The above conversation reveals that the patient only partially accepted the nurse's recommendations on modifying her insulin therapy, maintaining that before lunch, she would preserve the pre-existing plan. The suggestions provided by the diabetes center, following the analysis of data tracked in the TreC-DS, were renegotiated by patients in light of their eating habits and living conditions.

Discussion

Principal Findings

This paper analyzed how the TreC-DS, an mHealth platform with a built-in messaging system, was used by two diabetes centers to assist two types of patients with T1D. The main findings of this study are summarized in Table 5.

Sharing Information for Resolving Different Problems

Health care professionals and patients thought of the messaging system and the overall platform as useful for sharing information. Perceptions about text messaging were strongly influenced by the patients' histories and by the ways in which professionals and the patients themselves interpreted the patients' needs. On the one hand, for the women with T1D, pregnancy was a tough decision, as these patients were informed about the need for their diabetes to be under strict control during pregnancy; on the other hand, the adults with poorly controlled diabetes had a history of failure in diabetes management, and they gradually became aware of the clinical risks of this situation. Consequently, in the diabetes centers, the same system was considered a useful tool to address very different problems.

Constructing a Closer Relationship With the Patient

ICTs have long been associated with the standardization and depersonalization of patient-professional relationships [52]. Several recent studies, however, underlined how ICTs can foster more intimate relationships, where professionals better understand patients' clinical and emotional conditions and can provide personalized interventions [53,54]. Similarly, our results show how through a messaging system, a hospital department can continuously observe patients' data, guiding patients remotely in the management of diabetes. Despite some differences in the use of text messaging, in both diabetes centers, the messaging system was used by professionals to construct a closer relationship with patients and guide them to avoid clinical complications.

Table 5. Patient-health care professional interactions using text messaging.

Diabetes center	Content of message exchanges	Communication styles	Social representations about text messaging
Pregnancy	Most of the messages were about therapy (80/156, 51.3%).	Interactions were initiated mainly by professionals and were markedly prescriptive.	Useful for transmitting prescriptions from diabetes centers to patients. Face-to-face visits decreased and became more focused on patients' data.
Adults	Most of the messages were about motivation (104/341, 30.5%) and therapy (94/341, 27.6%).	Interactions were initiated mainly by professionals and were conceived as open dialogues.	Useful for empowering patients' self-management skills. Face-to-face visits decreased.

Emerging Asymmetrical Interactions

In our study, we showed how the conversations were mainly initiated by the health care professionals. Most likely, the shared perceptions of the system's use, interpreted from both sides as useful for transmitting information from professionals to patients, laid a foundation for asymmetrical interactions in which professionals analyze the data input by the patients. Clinicians and administrative staff often express concerns about using telemonitoring technologies because of the possible increase in patient requests [12-15]; however, in the considered cases, it is mainly the diabetes center that decides if a text message conversation is necessary, choosing when and how to begin a conversation with a patient.

Limitations and Future Work

This study aims to break new ground in the analysis on patient-provider relationships emerging from text-message exchanges. However, it suffers from some limitations that should be addressed by future research. Firstly, the study involved only two target groups of patients with TD1. More research is needed regarding the use of text messaging by other target groups of diabetic patients with different monitoring needs and different socioeconomic backgrounds. Secondly, the number of patients, the time frame of the trial, and, consequently, the workload are limited. The overall positive perceptions by health care professionals about text messaging should be reassessed in the prolonged care of a larger set of users. Thirdly, our work focused on patient-health care professional interactions using text messaging without a systematic comparison of these interactions in the absence of text messaging. The lack of a baseline impeded the ability to make specific considerations regarding the consequences of text messaging on the workflow of the health care professionals. Future research on this topic would benefit from an analysis combining observational methods and performance metrics (eg, frequency of visits and the time spent by professionals for each patient) before and after the introduction of the technology.

Conclusions

In recent years, a debate has emerged on the role of ICTs in diabetes management. Some studies have focused on text messages. Most of the literature proposes quantitative analysis of the impact of text messaging on the clinical conditions of patients and/or their satisfaction with the technology. Qualitative studies have focused mainly on patients' perceptions about strengths and weaknesses of this technology. In contrast, we used qualitative techniques for documenting in-depth, patient-health care professional interactions using text messaging, combining message analysis and semistructured interviews. The results show how the features of interactions and perceptions of text messaging changed based on the patient profiles in two different centers. In addition, in both diabetes centers considered, the system seems to have laid a foundation for a closer relationship between patients and health care professionals.

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Conflicts of Interest

None declared.

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Abbreviations

DGDFSC: Direzione Generale dei Dispositivi Medici del servizio Farmaceutico e della Sicurezza delle Cure
ICT: information and communication technology
T1D: type 1 diabetes
TreC: Trento Cartella Clinica del Cittadino
TreC-DS: Trento Cartella Clinica del Cittadino Diabetes System

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Original Paper

Glycated Hemoglobin Differences Among Blog-Reading Adults With Type 1 Diabetes Compared With Those Who Do Not Read Blogs: Cross-Sectional Study

Sean M Oser[1], MD, MPH; Heather L Stuckey[2], DEd; Jessica A Parascando[1], MPH; Erin L McGinley[1], BS; Arthur Berg[3], PhD; Tamara K Oser[1], MD

[1]Department of Family and Community Medicine, Penn State College of Medicine, Hershey, PA, United States

[2]Department of Internal Medicine, Penn State College of Medicine, Hershey, PA, United States

[3]Department of Public Health Sciences, Penn State College of Medicine, Hershey, PA, United States

Corresponding Author:
Sean M Oser, MD, MPH
Department of Family and Community Medicine
Penn State College of Medicine
500 University Drive, H-154
Hershey, PA,
United States
Phone: 1 717 531 8187
Fax: 1 717 531 5024
Email: soser@pennstatehealth.psu.edu

Abstract

Background: Of the estimated 23.1 million individuals diagnosed with diabetes, approximately 5% have type 1 diabetes (T1D). It has been proposed that this number will triple by 2050. With increases in technology use and resources available, many individuals are using insulin pumps and continuous glucose monitors (CGMs) to help manage their T1D. They are also using online resources such as social media to find more information and advice based on real-life experiences from peers. Blogs are a particular social media modality often used by people with T1D but have not been widely investigated.

Objective: The purpose of this study was to assess glycated hemoglobin (HbA_{1c}) differences between blog readers and blog nonusers in a population of adults with T1D. This study also looked at differences in technology use in these two groups, as well as HbA_{1c} differences in blog use and technology subgroups.

Methods: Participants were recruited both by mail and by online T1D-themed blog postings. Respondents completed a secure online eligibility assessment and were asked questions related to their T1D, blog and internet use, and insulin pump and CGM use. Demographics were also collected. Differences between blog readers and blog nonusers were tested via chi-square and *t* tests. Mann-Whitney *U* tests, Fisher exact tests, and analyses of variance (ANOVA) were used to test for differences in self-reported HbA_{1c} between groups and subgroups.

Results: A total of 282 eligible participants completed the survey (214 blog readers, 68 blog nonusers). Average duration of diabetes was 21.2 years, 77.7% (219/282) were female, 81.2% (229/282) used an insulin pump, 66.3% (187/282) used a CGM, and 95.7% (270/282) were white. HbA_{1c} was lower for blog readers (7.0%) than blog nonusers (7.5%), *P*=.006; for insulin pump users (7.0%) than multiple daily injections (7.7%), *P*=.001; and for CGM users (7.0%) than CGM nonusers (7.5%), *P*=.001. After adjusting for significant covariates, the association between blog use and HbA_{1c} remained significant (*P*=.04). ANOVA modeling also demonstrated significant differences in HbA_{1c} between blog users and nonusers among subgroups by pump use and CGM use (*P*<.001).

Conclusions: These results suggest that reading blogs is associated with lower HbA_{1c} values. While association does not prove causation, blog readers have the benefit of learning information from peers and having 24/7 access to a community of individuals with similar daily life struggles, where they are able to ask questions and seek advice.

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KEYWORDS

type 1 diabetes; blogs; continuous glucose monitor; insulin therapy; HbA1c; social media

Introduction

Approximately 1.25 million persons in the United States have been diagnosed with type 1 diabetes (T1D) [1], with incidence increasing in recent years [2]. It is estimated that annual and lifetime costs are greater for individuals with T1D than for individuals with type 2 diabetes, as complications associated with T1D are more dire and often involve more intensive medical care [3]. The complications associated with dysregulation of blood glucose levels can lead to long-term and devastating health consequences. While it has been shown that maintaining blood glucose levels as close to normal as possible is associated with better health outcomes [4], most people with T1D do not achieve recommended blood glucose targets [5,6].

In efforts to combat fluctuating blood glucose and glycated hemoglobin (HbA_{1c}) levels and reduce the incidence and severity of complications, T1D management has been facilitated by the introduction and evolution of diabetes technology such as self-monitoring of blood glucose and, more recently, continuous glucose monitors (CGMs) and increasingly automated insulin pumps.

Self-monitoring of blood glucose has demonstrated its fundamental importance: higher frequency of daily checks is correlated with lower HbA_{1c} [7,8]. Likewise, the use of an insulin pump has also demonstrated benefit in improving HbA_{1c} and decreasing risk of severe hypoglycemia and diabetic ketoacidosis [9], but pumps remain in use by a minority of patients [10,11,12]. As CGMs have evolved for patient use, earlier mixed results [13,14,15] have shifted to show benefits [16,17], especially when using CGM to augment insulin pump therapy [18-21].

In addition to these advances, social media has become a technology-based tool for health self-management for numerous conditions [22-29]. The Diabetes Online Community (DOC) has emerged as a popular, self-vetted community for caregivers of and persons with T1D, facilitating discussion of management strategies and personal experiences [30]. Specifically, the DOC provides patients and their caregivers with peer support in managing their T1D [31,32]. Data on social media use in diabetes continues to emerge. Health benefits have been shown when patients interact with their health team via social media [33]. Positivity and perceived benefit have been demonstrated among T1D patients connecting via social networking sites such as Instagram [34], Twitter [35], and Facebook [36]. Many have sought diabetes-related health information from social media platforms such as YouTube, Twitter, and Facebook [37,38,39] as well as from blogs [40,41,42]. And while there are limited data on an association between glycemia and social media engagement [43], no studies to date have examined a potential relationship between glycemia and blog use specifically.

Blogs allow extended and asynchronous sharing of personal experiences and reflections. They are available publicly and allow other readers to comment, or simply to read without commenting, when and where convenient for them. Blogs provide a particularly efficient source for retrospective analysis of data produced in a natural setting, gradually and without prompting. The methodology of blog analysis provides a foundational, time-efficient advantage over coordinating, conducting, and transcribing individual and/or focus group interviews.

The blogging community is broadly comprised of three types of users. Bloggers are those individuals who journal their experiences for others. Commenters read and actively comment on others' posts. Lurkers read others' blogs without commenting and are thought to comprise the largest of the three groups [44]. This study focused on lurkers and sought to determine whether there might be an association between HbA_{1c} and reading T1D-themed blogs. This paper describes key differences between HbA_{1c} and technology use among blog readers and blog nonusers.

Methods

Study Approval

This study used an online survey of adults with T1D and was approved by the Penn State College of Medicine Institutional Review Board. Implied consent was obtained online prior to the user being directed to the secure online survey. A summary explanation of the research served as implied consent and described the survey purpose and procedures, length of time to complete the survey, data storage and protection plans, and study team contact information, including name and phone number of the principal investigator. It was stated in the consent that the survey was voluntary.

Recruitment

In efforts to reach a broad and varied sample of participants, recruitment was conducted via online announcement on two popular adult T1D blogs, as well as through mailing to all people over 18 years old and listed as having T1D in a diabetes registry hosted at an academic medical center. Both online and via mail, a link to the online survey was provided; following the link to the survey was entirely voluntary. Inclusion criteria were (1) at least 18 years of age, (2) a diagnosis of T1D, and (3) agreement to participate. Active writers of T1D blogs or active commenters on such blogs were excluded (by self-identifying as such in an eligibility question), as the focus of this study was on lurkers who read but do not contribute to blog content. The number of responses was based on a convenience sample, as this was an open survey, available to an unlimited number of persons who had access to the blogs and social media platforms where the survey link was available for two weeks. Duplicate complete responses were not allowed from the same IP address, as automatic IP detection by the online survey platform prevented this, although it did allow an incomplete response to be restarted until a complete response was received. Participants were not compensated for completion of the survey.

Survey Instrument

Survey questions and results were housed in REDCap [45], a secure survey management research tool, at the Penn State Clinical and Translational Science Institute. Responses were automatically captured in REDCap and given a unique, sequential participant number. REDCap also captured date and time of survey responses, as well as completeness or partial completeness of surveys. Participants were asked inclusion and exclusion questions at the start of the survey, and access to the full survey was conditional upon meeting the aforementioned inclusion criteria. The survey included items assessing T1D-related blog use, insulin pump use, CGM use, internet access, mobile phone use, self-reported HbA_{1c}, and demographics. The questions were tested among a subset of adults with T1D, refined, and retested until they were clearly understood and unambiguous. It was estimated that survey completion would take 5 to 10 minutes. Participants were not able to go back to the survey and edit their responses.

Statistical Analysis

Statistical analysis was conducted using SPSS Statistics version 24 (IBM Corp). Chi-square tests and *t* tests, as appropriate, were used to test for differences in participant characteristics between blog readers and blog nonusers. Differences in self-reported HbA_{1c} between blog readers and blog nonusers were tested using the Mann-Whitney *U* test and Fisher exact test for continuous and categorical data, respectively. Analysis of variance (ANOVA) was used to identify statistical associations of HbA_{1c} levels across various subgroups of the survey participants.

Results

Recruitment

Response to online recruitment efforts was brisk, with the first response coming within minutes of the opportunity being posted on one blog. There were 65 responses within the first 24 hours of that posting and 185 within 24 hours of posting to a second blog (48 hours after the first one). Responses to the letters mailed to registry patients were fairly brisk as well, with 30 responses within 3 days of the letters being mailed. There was a slowdown over the Thanksgiving holiday, when there was no mail delivery, totaling 41 responses through the first week, and then response continued at a steady pace of about 15 per week until the survey closed two weeks later, with 70 responses to the mailed letters.

Sample Demographics

Of the 472 people who began the survey, 74 did not meet the inclusion criteria, and 116 did not complete the survey. Of the 282 who completed the survey (59.7% [282/472] of those who started the survey, 70.9% [282/398] of those eligible), 214 were blog readers and 68 were blog nonusers. Table 1 shows characteristics of the entire sample and divided by blog use/nonuse. Mean duration of diabetes was 21.2 [SD 13.7] years, 77.7% (219/282) were female, 81.2% (229/282) used an insulin pump, 66.3% (187/282) used a CGM, and 75.9% (214/282) were blog readers; 97.9% (276/282) were non-Hispanic, 95.7% (270/282) were white, and 75.9% (214/282) were employed. Comparing blog readers to blog nonusers, there were significant differences between the two groups in age, gender, employment, insulin pump use, CGM use, marital status, and mobile phone use, with blog readers more likely to be under age 45, female, and employed and more likely to use an insulin pump, CGM, and mobile phone. Blog nonusers were more evenly split by gender and had a higher proportion of students and retirees than the sample of blog readers. In both groups, the most common marital status was married or domestic partnership, but blog readers were slightly more likely to be single/never married, and blog nonusers were slightly more likely to be divorced or separated. There were no significant differences between the groups in education, ethnicity, race, time since diagnosis, or method of internet access. Income information was surveyed but is not reported due to an especially large proportion of respondents who declined to answer this question in particular.

Hemoglobin A_{1c} Associations

HbA_{1c} was significantly lower for blog readers than for blog nonusers (7.0% vs 7.5%, P=.006). After adjustment for significant covariates, this difference retained significance (P=.04). HbA_{1c} was also significantly lower for insulin pump users than for multiple daily injections (7.0% vs 7.7%, P=.001) and for CGM users than for CGM nonusers (7.0% vs 7.5%, P=.001). Other than these three variables (blog reading, pump use, CGM use), no significant differences in HbA_{1c} were found across any of the other variables collected.

To evaluate HbA_{1c} by blog use and a second independent variable (eg, blog use and insulin pump use), respondents were divided into four groups across the two variables (eg, blog readers on insulin pump, blog readers not on insulin pump, blog nonusers on insulin pump, blog nonusers not on insulin pump). Similar subgroups were also constructed with the binary variables blog use and CGM use. Differences in HbA_{1c} were seen across these groups as well, as depicted in Figure 1. HbA_{1c} was lowest among blog readers who use an insulin pump (7.0%) and highest among blog nonusers who do not use an insulin pump (8.0%); intermediate levels were seen among insulin pump users who do not read blogs (7.2%) and blog readers who do not use an insulin pump (7.4%). ANOVA evaluation of HbA_{1c} by insulin pump use and blog use revealed a strong statistical association between blog/insulin pump use and HbA_{1c} (P<.001). In addition to this strong association, there was no significant interaction between blog use and pump use (P=.22).

Two-factor ANOVA also showed differences in HbA_{1c} by blog use and CGM use, which is also demonstrated in Figure 1. HbA_{1c} was lowest among blog readers who use a CGM (6.9%) and highest among blog nonusers who do not use a CGM (7.5%); intermediate levels were seen among CGM users who do not read blogs (7.4%) and blog readers who do not use a CGM (7.4%). ANOVA evaluation of HbA_{1c} by blog/CGM revealed a strongly significant statistical association with HbA_{1c} (P<.001). Additionally, there was no statistically significant interaction between blog use and CGM use (P=.24).

Table 1. Sample description by blog use group.

Characteristics	Total sample (n=282)	Blog readers (n=214)	Blog nonusers (n=68)	*P* value
Age (years), n (%)				.009[a]
18-24	27 (9.6)	20 (9.3)	7 (10.3)	
25-34	94 (33.3)	80 (37.4)	14 (20.6)	
35-44	73 (25.9)	57 (26.6)	16 (23.5)	
45-54	42 (14.9)	25 (11.7)	17 (25.0)	
55-64	29 (10.3)	24 (11.2)	5 (7.4)	
65-74	16 (5.7)	8 (3.7)	8 (11.8)	
75+	1 (0.4)	0 (0)	1 (1.5)	
Gender, n (%)				<.001[a]
Male	62 (22.0)	34 (15.9)	39 (57.4)	
Female	219 (77.7)	180 (84.1)	28 (41.2)	
Unspecified	1 (0.4)	0 (0)	1 (1.5)	
Education level, n (%)				0.12
High school graduate	11 (3.9)	5 (2.3)	6 (8.8)	
Some college	53 (18.8)	37 (17.3)	16 (23.5)	
College graduate	104 (36.9)	82 (38.3)	22 (32.4)	
Postgraduate degree	114 (40.4)	90 (42.1)	24 (35.3)	
Ethnicity: Hispanic, n (%)	6 (2.1)	5 (2.3)	1 (1.5)	0.64
Race, n (%)				0.49
Asian	5 (1.8)	4 (1.9)	1 (1.5)	
Black or African American	6 (2.1)	3 (1.4)	3 (4.4)	
Native American	1 (0.4)	1 (0.5)	0 (0)	
White	270 (95.7)	206 (96.3)	64 (94.1)	
Employment, n (%)				<.001[a]
Employed	214 (75.9)	175 (81.8)	39 (57.4)	
Student	21 (7.4)	14 (6.5)	7 (10.3)	
Retired	18 (6.4)	6 (2.8)	12 (17.6)	
Years since diagnosis, mean (SD)	21.2 (13.7)	20.3 (12.9)	24.0 (15.7)	0.13
Insulin pump use, n (%)	229 (81.2)	181 (84.6)	48 (70.6)	.009[a]
CGM[b] use, n (%)	187 (66.3)	156 (72.9)	31 (45.6)	<.001[a]
Marital status, n (%)				.045[a]
Single, never married	73 (25.9)	58 (27.1)	15 (22.1)	
Married/domestic partnership	182 (64.5)	141 (65.9)	41 (60.3)	
Separated/divorced	23 (8.2)	13 (6.1)	10 (14.7)	
Internet access method, n (%)				0.52
Desktop	69 (24.6)	48 (22.4)	21 (31.3)	
Laptop	70 (24.9)	58 (27.1)	12 (17.9)	
Tablet	35 (12.5)	26 (12.1)	9 (13.4)	
Mobile phone	107 (38.1)	82 (38.3)	25 (37.3)	
Mobile phone use, n (%)	258 (91.5)	202 (94.4)	56 (82.4)	.004[a]

[a]Significant at the $P<.05$ level.

[b]CGM: continuous glucose monitor.

Figure 1. Hemoglobin A_{1c} (HbA_{1c}) among blog readers and blog nonusers, by insulin pump and continuous glucose monitor (CGM) use.

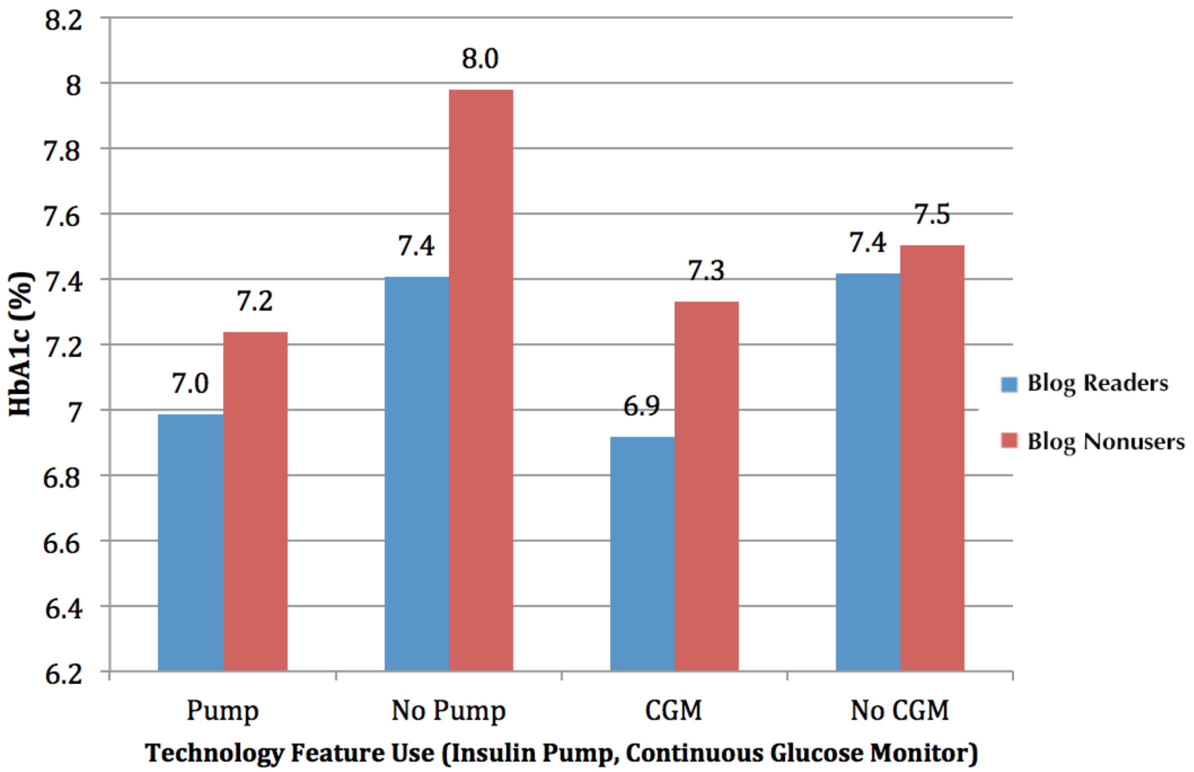

Table 2. Analysis of variance of hemoglobin A_{1c} by blog use status and a second variable.

Second variable	*P* value			
	Model	Blog use	2nd variable	Interaction
Pump use[a]	<.001[b]	.012[b]	.001[b]	.22[c]
Continuous glucose monitor use[a]	<.001[b]	.04[b]	.03[b]	.24[c]
Marital status	<.001[b]	.45	.006[b]	.20[c]
Employment	.001[b]	.58	.25	.10[c]
Age	.002[b]	.09	.11	.66[c]
Education	.007[b]	.04[b]	.19	.09[c]
Gender	.008[b]	.001[b]	.23	.17[c]
Time since diagnosis	.02[b]	.01[b]	.10	.07[c]
Ethnicity	.03[b]	.37	.20	.83[c]
Smartphone use	.04[b]	.11	.37	.75[c]
Race	.01[b]	.40	.40	.03
Internet access method	.15	.03[b]	.95	.44[c]

[a]No significant interaction; significance achieved for ANOVA model and additive effects of blog use and second variable.

[b]Significant at the $P<.05$ level.

[c]No interaction of the two test variables ($P>.05$).

Analysis of HbA_{1c} by blog use and other variables is summarized in Table 2. This table provides *P* values associated with the overall effect of the two variables (blog use and the second variable), the additive effects associated with blog use and the second variable, and the interaction effects of the two variables. For example, in ANOVA modeling of HbA_{1c} by blog use and age, the ANOVA model was significant (*P*=.002) and there was no significant interaction (*P*=.66) but neither variable had a significant individual additive effect (*P*=.09, *P*=.11).

Discussion

Principal Findings

In this study, blog use—but not interacting with insulin pump use or CGM use—was found to be a predictor of HbA_{1c}. To the best of our knowledge, this is the first study to evaluate blog use and HbA_{1c} and, therefore, the first to find an association between these two variables.

HbA_{1c} was 0.5% lower among blog readers than among those who don't read blogs. Beside being statistically significant, this is a clinically significant difference approaching the magnitude seen in this study with CGM use (0.5%) and insulin pump use (0.6%). The HbA_{1c} differences among pump users and CGM users in this study are similar to associations found by others, which are also acknowledged to be clinically important [6,9,46-49]. Likewise, the HbA_{1c} difference seen here between blog readers and blog nonusers may have significant clinical implications as well.

This raises the question of why this was seen, as it is not possible to determine any causal relationship here. It could be that more technologically inclined individuals are more likely to use insulin pumps and/or CGMs than those less technologically inclined, and it would therefore stand to reason that they would likewise be more likely to go online (including to read blogs and to respond to an online survey to determine study eligibility). It could also relate to insurance, financial, and/or policy differences that make some more and some less likely to have access to technology. These could be areas for future research—for example, to investigate whether there is a true clinical benefit to blog use or other internet-based technology use, as appears may be the case in this study's technologically inclined sample.

It is also possible that the results may be understood in the context of dynamic social impact theory, which posits that communication can more effectively increase an individual's likelihood of changing behavior if (1) the communicator is credible and similar to the reader, (2) the communication is temporally immediate, and (3) there are multiple persuasive change agents communicating [50]. In the context of reading blogs, it may be that as individuals living with T1D observe the experiences described by peers on readily available blogs, which are reinforced by commenters, they are more likely to change behaviors related to T1D self-management, resulting in improvements in HbA_{1c}. Further research is needed to better understand the role blogs may play in T1D self-management.

Limitations

A limitation of this study is that HbA_{1c} values here are self-reported; although this is more likely to have an effect on the absolute values themselves than on the magnitude of the differences observed, and self-report has been shown to be highly reliable elsewhere [51]. Another limitation is the inability to determine and report response rate—it is impossible to know how many people viewed the online announcement, as it was spread via social media. However, the ability to recruit significant numbers of respondents online was remarkable, as was the speed with which they responded—an emerging phenomenon [52]. In some contrast, the letters mailed to individuals from the diabetes registry produced a good response, but it was more gradual, over the course of a few weeks. This resulted in a disparity in sample size between the two groups, as those recruited online outnumbered those recruited by direct mail. Despite this, both sample populations in this study demonstrate a substantially higher proportion of insulin pump use and CGM use than has been reported for the general population of patients with T1D in the United States [10,11,12]. Finally, when considering the HbA_{1c} differences between blog readers and blog nonusers, it should be noted that there were also demographic differences between the sample populations, for example, in age and employment status. The blog nonusers were more likely to be students or retired than blog readers, for example; although the implications of this are not clear. Blog readers were also more likely to be female, which is consistent with general statistics about blog users but does represent a difference between the two groups. However, even with these demographic differences, there were no significant associations between HbA_{1c} and any of these demographic factors.

Future Directions

Other factors to study in the future might include potential differences in activation levels among blog readers compared to blog nonusers, as has been suggested elsewhere [53,54], as well as differences in levels of social support and/or instrumental support among blog readers compared to nonusers, in efforts to identify the reasons for the observed differences between adults with T1D who do and do not read T1D-themed blogs. As the social media landscape changes quickly and as blogs change in their popularity relative to other social media formats, a broader examination of potential relationships of HbA_{1c} to other types of social media could be informative. Other areas for future study could include replicating the study for adults with type 2 diabetes or for parents of children with T1D and examining how lurkers interact with blog content and the impact of these interactions on behaviors.

Conclusions

This study found that blog readers had lower HbA_{1c} than blog nonusers. One possible explanation for these results is that access to blogs provides valuable information and experiences related to T1D. We also found that blog readers who used insulin pumps or CGMs had lower HbA_{1c} compared to blog nonusers who did not use insulin pumps or CGMs, suggesting that being technologically inclined, or having access to technology, is beneficial for T1D health outcomes. Clinicians may wish to consider recommending blogs or specific blog posts to their patients with diabetes if they are comfortable with the content.

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Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
CGM: continuous glucose monitor
DOC: Diabetes Online Community
HbA$_{1c}$: glycated hemoglobin
T1D: type 1 diabetes

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Review

Diabetes, Care Homes, and the Influence of Technology on Practice and Care Delivery in Care Homes: Systematic Review and Qualitative Synthesis

Rebecca Mathews[1*], RN, MSc, BSc; Chris O'Malley[2*], MA, BA; Jenny M Hall[1*], PhD, BSc (Hons); Leah Macaden[3*], PhD, MSc, BSc, RN, RM, SHFEA; Sandra MacRury[1*], MBChB, MD, FRCP

[1]Division of Rural Health and Wellbeing, Centre for Health Science, University of the Highlands and Islands, Inverness, United Kingdom
[2]Highland Health Sciences Library, Centre for Health Science, University of the Highlands and Islands, Inverness, United Kingdom
[3]Department of Nursing, Centre for Health Science, University of the Highlands and Islands, Inverness, United Kingdom
[*]all authors contributed equally

Corresponding Author:
Sandra MacRury, MBChB, MD, FRCP
Division of Rural Health and Wellbeing
Centre for Health Science
University of the Highlands and Islands
Old Perth Road
Inverness, IV2 3JH
United Kingdom
Phone: 44 1463279583
Email: sandra.macrury@uhi.ac.uk

Abstract

Background: Diabetes is increasing in prevalence and complexity in the care home setting, affecting up to a quarter of care home residents. Health outcomes for these residents are impacted by management of the disease, health care professionals (HCPs)' decision-making skills within the care home setting, and access to specialist services. The use of technology has the potential to recognize opportunities for early intervention that enables efficient responsive care, taking a fundamental role in linking the care home community to wider multidisciplinary teams for support.

Objective: The aim of this paper was to identify evidence that explores factors relevant to the use of technology in and around the care home setting to aid in the management of diabetes.

Methods: Databases searched using a structured prespecified approach included: PubMed, CINAHL (Cumulative Index to Nursing and Allied Health Literature), OVID Nursing database, Scopus, MEDLINE, the Cochrane Library, and the King's Fund from 2012 to 2017: handsearching was undertaken additionally for any gray literature. Preferred Reporting Items for Systematic review and Meta-Analysis Protocol was used as protocol with Risk of Bias in Systematic reviews a tool to assess the risk of bias across studies. Studies had to include interventions that combined technology to or from the care home setting to support residents living with diabetes.

Results: The combined search strategy identified a total of 493 electronic records. Of these, 171 papers were screened for eligibility, 66 full papers were accessed, and 13 have been included in this study. Qualitative synthesis has identified different strands of research evidence in what and how technology is currently being used in and around care homes to enhance diabetes management. New initiatives and implementations of technology and emerging models of care that included the use of technology have also been included.

Conclusions: By triangulating the perspectives of HCPs, practitioners, specialists, and members of the care home community, the authors anticipate that this review will represent an up-to-date, evidence-based overview of the potential for using technology within the care home setting for diabetes management as well as stimulate research in this area.

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KEYWORDS

diabetes mellitus; technology; residential facilities; nursing homes

Introduction

Background

The prevalence of diabetes is increasing in parallel with population aging within the Scottish Highlands [1-3]. It has been identified that more than a quarter of care home residents have some kind of diabetes, whether diagnosed or undiagnosed [4-6] bringing challenges for nursing practice and specialist care services, accordingly, the need to access specialist services is increasing. The population in Scotland is projected to rise by 7% by 2039, with an increase of 85% in those living over the age of 75 years [7]. With huge increases predicted in the prevalence of diabetes in elderly persons, and the likelihood of developing diabetes as they age [8], management of this disease in the care home setting is of paramount importance.

Access to specialist services for care home residents living with comorbidities is limited [9] leaving care home staff continually seeking to deliver treatments more independently, sometimes with expectations and demands more than they feel competent to provide. Residents may be dependent on care home staff in relation to interventions around diabetes management, particularly with tasks such as blood glucose monitoring or insulin injections [10]. Most nursing home residents are unable to initiate access to doctors or community health care independently or make their own decisions about self-care [1,4,11]; therefore, care home staff must become both advocates and facilitators of care interventions. Today, the advancement of technology has the potential to influence practice in the delivery of safe, effective, quality, and seamless care [12] as well as to promote communication and provide access to multidisciplinary specialist care [13] aiding clinical support for residents within the care home community. Moreover, there is a need for trained staff to lead care planning, initiate treatment, and make independent decisions to support those living with diabetes. In turn, this should empower care home staff to contribute to better diabetes management, thus raising the standards of care within the care home setting. Residents living with diabetes represent one of the most difficult challenges to health professionals and care home staff in advancing care [14] and may need to receive care from multiple medical services. Given that the complications of diabetes and the associated comorbidities alongside the aging process [1] make residents potentially more vulnerable, care home staff are challenged in the provision of care to manage the disease effectively and influence outcomes.

To support staff and residents in care homes, clear structure and collaboration between care home and health care services is of importance. Standardized education and training in relation to diabetes care and management for care home staff would aid this process, thus reducing complications and improving quality of care for residents [15]. This should include clear access with good communication and support between specialists, primary and secondary services, and the implementation of defined standards of care for residents living with diabetes. Diabetes UK [16] has recognized the importance of providing standards of care for residents in care homes and published guidance in 2010 setting standards for diabetes care in residential homes, and multiple care home–specific policies, statements, guidelines, and recommendations [5,6,17-20] exist to support this approach. Nevertheless, at least in the Highlands in Scotland, there is currently no mandatory diabetes training for staff in care homes, no defined standards of care for residents living with diabetes, and no clear protocol for accessing specialist services in the care home setting, highlighting the need for tighter regulation to improve care for those living with diabetes in care homes [14].

There are many emerging and existing solutions to the provision of better support for health care professionals (HCPs) incorporating the use of technology within care delivery. The Joint Asia Diabetes Evaluation program advocates a nurse doctor team with a Web-based portal that uses care protocols and a validated risk engine to provide decision support and regular feedback [21]. Taking technology-enabled care (TEC) services forward, lessons need to be learned from good practice to adopt long-term organizational change on care pathways for the management of long-term conditions [22]. Health information technology has been shown to assist in decision support, improving care co-ordination, communication and therefore outcomes for older adults [23,24]. Electronic-health technologies, electronic health records, electronic medical records, and the use of electronic decision support enabling collaboration of care, communication and information sharing between HCPs [25,26] have been found to have a positive impact in caring for people living with diabetes [27] by enabling an overview of clinical information and prompts for diabetes care and management. The Informatics for Diabetes Education and Telemedicine project individualizes care by using video conferencing (VC), demonstrating a centralized support approach in the use of technology to promote education with personalized behavior goal setting accomplished through televisits with a nurse manager and dietitian [28]. Despite poor technology infrastructure and lack of user-friendly technology training reported by Kolltveit [29], it is also recognized that the use of telehealth technology holds considerable potential in the care home setting, enabling both proactive and reactive approaches, teamwork, partnership, and harmonization between allied HCPs granting distant interaction, working in different settings promoting communication, and, therefore, enabling early implementation of interventions [29,30]. Furthermore, the importance of the use of technology to aid social interaction for older people remains, with evidence suggesting that older people can successfully learn new technological skills, enhancing the quality of life while being mentally alert and engaged with wider communities [31-33].

Objective

This study aimed to systematically review the literature to identify evidence relevant to the use of technology in and around the care home setting to aid in the management of diabetes as well as to explore the nature of technologies and how they are being used to support staff and residents living with diabetes, identifying and synthesizing existing and new models of care that hold potential to enhance care and aid management in care homes.

Methods

For the purpose of this study, and to clarify, the words *care home community* will relate to individuals associated with a care home, nursing home or residential home. These may include residents, carers, managers, staff, nurses, and those who are connected to the home.

Eligibility Criteria

Studies were selected according to the criteria outlined below.

Study Design

Study characteristics of published or unpublished, controlled or uncontrolled research study design including both qualitative and quantitative studies; reports; and case studies have been selected. Additional methods to capture further studies included handsearching and reference and citation checking, which were undertaken by author 1 (RM).

Included Studies

We considered interventions using any type of technologies provided by, to, or from the care home setting, that had an influence on practice assisting in care delivery and interventions that involved engagement with specialist services, ongoing treatment management, or communication with wider health services. Also of interest were new and emerging technological models of care that provided support for long-term condition management currently being used in different health regimens that could be applied to the care home setting. Studies included were dated from 2012 to 2017. Articles were not restricted to English language. One article of another language was translated by Microsoft Edge, developed by Microsoft.

Excluded Studies

We excluded studies that involved any form of self-management technology, self-monitoring and self-reporting, mobile digital platforms, community setups, care at home, home care services, telecare assistive devices, mobile phone technology, smart care, smartphones, and smart homecare technology.

Participants

Care home managers, staff, residents, patients, carers, older persons, and those representing the care home community as well as General Practitioners, specialists, experts, nurse practitioners, allied HCPs, and those with a specific interest in diabetes management were included in this study.

Types of Interventions

We considered any interventions using any types of technologies provided to, or from the care home setting; the influence of technology on clinical practice and care delivery to or from the care home; and interventions that involved engagement with specialist services, ongoing treatment, management, or communication with wider health services.

Information Sources

To ensure literature saturation, 7 electronic bibliographic databases holding peer-reviewed publications of specialist research design and trusted evidence in health care were identified for their relevance. The databases included were MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), the Cochrane Library, PubMed, the King’s Fund, OVID nursing base, and Scopus.

Search Strategy

To illustrate methodological rigor in this systematic review, a robust protocol, the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA P 2015) [34] (Multimedia Appendix 1) was used for all potentially relevant articles to enhance quality, transparency, and strength. This approach provides an explicitly planned document supporting consistent evidenced-based research integrity in health care as well as reduced duplication of effort. In addition, Risk of Bias in Systematic reviews (ROBIS) 2016 [35], a new tool designed to specifically assess the risk of bias in systematic reviews has been utilized.

Electronic Search Strategy

This specific search strategy has been developed, performed, reviewed, and completed by author 1 (RM) with input from a Highland Health Sciences Librarian (CoM), not otherwise associated with the project, but with expertise in systematic review searching to ensure legitimacy. The structured databases were searched using a combination of subject headings and keywords. Concepts were banded together as described in Table 1, with the intent of covering the range of inclusion criteria for searching, to provide consistency in the searches across the databases. A list of the databases is provided in Table 2.

The King’s Fund was contacted directly after performing a basic search using the keywords: diabetes, technology, care homes and telehealth. This specific database developed an advanced search using keywords that were then adapted into broader categories by the King’s Fund: (1) care homes and technology; (2) diabetes and technology in health and social care; and (3) telehealth, telecare, and telemedicine. Textbox 1 shows an example search for one database.

Table 1. Electronic search terms and clustering of components.

Diabetes OR Diabetes Mellitus	Diabetes type 1 OR Diabetes type 2	DKA OR Hetoacidosis	Hypo OR	Hypoglycemia
AND Technology OR	AND Residential care OR Nursing care OR	AND Specialist Services OR	AND Residential home Nursing home Care home OR	AND Nursing home community OR
Email	Delivery of care	Integrated	Access to services	Care home staff
Laptop	Specialist care	Interdisciplinary	Support	Nurse
Tablet	Specialist nurse	Integra	Guidelines	Senior nurse
Video conference	Continuity of care	Seamless	Diabetes knowledge	Senior nurse carer
Digital	Primary care	Interprofessional	Educational package	Senior nurse care assistant
eHealth	Secondary care	Shared	Resources	Carer
Telephone	Service delivery	Model of care	Frameworks	Nursing home staff
Personal computer	Manage	Community	Protocols	Care assistant
Educational program	Management	Information sharing	Policy or policies	Support worker
Telehealth	Intervention	Collaborative	Information	

Table 2. Database table.

Database	Date search complete	Papers identified and titles screened	Duplicate papers	Result and total number of abstracts screened	Full papers accessed	Studies included (N)
PubMed via the National Center for Biotechnology Information	April 3, 2017	60	10	37	1	1
CINAHL via EBSCO	April 3, 2017	23	2	5	5	1
Scopus via Elsevier	April 3, 2017	118	8	35	11	3
OVID nursing	April 3, 2017	3	0	0	0	0
MEDLINE via EBSCO	April 3, 2017	1	1	1	1	0
The Cochrane Library	April 3, 2017	Basic search: 9	3	3	0	0
	April 3, 2017	Advanced search: 99	6	22	8	1
The King's Fund	April 3, 2017	Basic search: 3	1	3	1	3
	June 9, 2017	Advanced search: 50; 55; 52	3	12; 10; 23	5; 12	3
Additional searches	April to August 2017	20	0	20	8	2; 1 (to be published)
Total	—[a]	493	34	171	66	13

[a] Not applicable.

Textbox 1. Database search for Scopus.

(TITLE-ABS-KEY (diabetes OR “diabetes mellitus” OR “diabetes type 1” OR “diabetes type 2” OR “diabetes type one” OR “diabetes type 2” OR dka OR hypoglycaemi* OR ketoacidosis)) AND ((TITLE-ABS-KEY((technolog* OR email OR laptop OR tablet OR telephone OR digital OR ehealth OR videoconference OR vc OR pc OR “ personal computer” OR telehealth OR “educational program””))) AND (TITLE-ABS-KEY((“resident”* care” OR “nurs* care” OR “delivery of care” OR “specialist care” OR “specialist nurse” OR “continuity of care” OR “primary care” OR “secondary care” OR “service delivery” OR “manag” OR interven*))) AND (TITLE-ABS-KEY ((“specialist care” OR integrated OR interdisciplin* OR intergrat* OR seamless OR inter*profession* OR shared OR “model of care” OR community OR “information sharing” OR collaborative))) AND (TITLE-ABS-KEY((“resident* home” OR “nursing home” OR “care home” OR “access to services” OR support OR guideline* OR framework* OR protocol* OR resource* OR “diabetes knowledge” OR “education* package” OR policy OR policies OR information))) AND (TITLE-ABS-KEY((“nursing home community” OR “care home staff” OR nurse OR “senior nurse” OR “senior nurse carer” OR snca OR carer OR “nursing home staff” OR “care assistant” OR “support worker”)))) AND (LIMIT TO (PUBYEAR2017) OR LIMIT- TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR, 2015) OR LIMIT-TO PUBYEAR ,2014) OR LIMIT-TO (PUBYEAR, 2013) OR LIMIT-TO PUBYEAR, 2012))

Study Records

Selection Process

To enhance objectivity, 2 reviewers (authors 1 and 3) independently screened titles of electronic records generated by the search against the inclusion and exclusion criteria. Full abstracts were obtained for all the titles that appeared to meet the inclusion criteria. This process is shown in Figure 1 [36]. Author 1 independently reviewed abstracts followed by an independent review by author 3. Authors 1 and 3 were not blind to the journal titles or study authors. For neutral papers, decisions were made through discussion, and full-text articles were then accessed for inclusion.

Data Collection Process

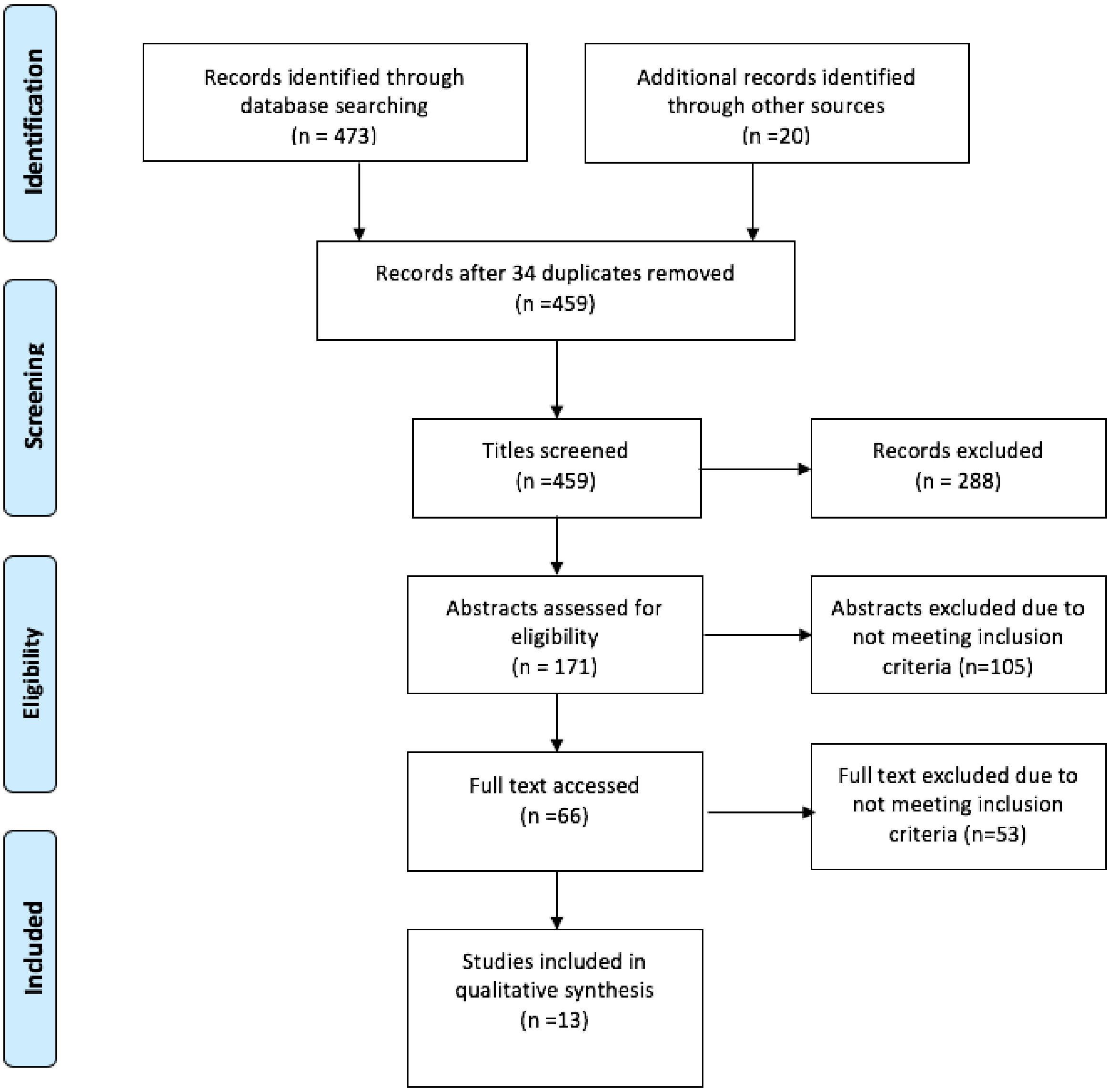
To extract relevant data from included studies, a data extraction form was developed before the search by author 1, adapted and based on an extended PICO (population, intervention, comparison, outcome) design [37-40] as a framework before proceeding with qualitative synthesis to identify themes (Multimedia Appendix 2). Elements of the studies addressed the following: author, study year, country, title, group covered/participants, study design, aim or discussion of the project or service, intervention, key findings, and planned or actual effectiveness. Individual studies or reports that consisted of multiple interventions were combined.

Outcomes and Prioritization

Primary Outcomes

The primary outcomes were to pull together existing forms of technology that are being designed to facilitate integrated working between allied health professionals and the care home community, and to highlight and expand the understanding of the use of technology-enabled approaches to diabetes management within the care home setting.

Figure 1. Selection process using Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA P 2009).



Secondary Outcomes

The secondary outcomes included informing health care policy decisions by standardizing diabetes education and training within the care home setting for staff and bringing in defined standards of care for those residents living with diabetes. Undertaking evidence reviews for new and emerging models of care will help us to understand preconditions for success, learning from other care settings and countries.

Risk of Bias of Individual Studies

To determine the risk of bias within included studies and identify any concerns with the review process, the methodological quality of studies was assessed using ROBIS 2016. As bias can arise at all stages of the review process, assessment was executed for each study throughout using the ROBIS tool and was completed in 4 domains as shown in Table 3. However, no studies have been excluded based on the quality of bias. Phase 1: assessing relevance: this process was covered by devising a prespecified data extraction form adapted and based on an extended version of PICO. Phase 2 identified concerns with the review process and phase 3 judges the overall risk of bias and are shown in Table 3.

Table 3. Determining Risk of Bias of Studies

Domain	1. Study eligibility criteria	2. Identification and selection of studies	3. Data collection and study appraisal	4. Synthesis and findings	Risk of bias in the review
Signaling questions	1.1 Did the review adhere to predefined objectives and eligibility criteria?; 1.2 Were the eligibility criteria appropriate for the review question?; 1.3 Were eligibility criteria unambiguous?; 1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate?; 1.5 Were any restrictions in eligibility criteria based on sources of information appropriate?	2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports?; 2.2 Were methods additional to database searching used to identify relevant reports?; 2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible?; 2.4 Were restrictions based on date, publication format, or language appropriate?; 2.5 were efforts made to minimize error in selection of studies?	3.1 were efforts made to minimize error in data collection?; 3.2 Were sufficient study characteristics available for both review authors and readers to interpret the results?; 3.3 Were all relevant study results collected for use in the synthesis?; 3.4 Was risk of bias (or methodologic quality) formally assessed using appropriate criteria?; 3.5 were efforts made to minimize error in risk of bias assessment?	4.1 Did the synthesis include all studies that it should?; 4.2 Were all relevant study results collected for use in the synthesis?; 4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs, and outcomes across included studies?; 4.4 Was between-study variation minimal or addressed in the synthesis?; 4.5 Were the findings robust, for example, as demonstrated through funnel plot or sensitivity analysis?; 4.6 Were biases in primary studies minimal or addressed in the synthesis?	A. Did the interpretation of findings address all the concerns identified in domains 1 to 4?; B. Was the relevance of studies to the reviews research question appropriately considered?; C. Did the reviewers avoid emphasizing results on the basis of their statistical significance?
Judgement	Concerns regarding specification of study eligibility criteria	Concerns regarding methods used to identify and/or select studies	Concerns regarding methods used to collect data and appraise studies	Concerns regarding the synthesis	Risk of bias in the review

Results

Overview

A summary of all the information studies is provided in Table 4.

Data Synthesis

Summary of Using Risk of Bias in Systematic Reviews

Due to the diversity of mixed-methods studies included in this analysis, the use of ROBIS 2016 proved challenging. The risk of bias was rated as low for 10 studies; the findings from these studies are *likely to be reliable* according to ROBIS. Phase 2 did not raise concerns with the review process; concerns were identified by the authors and addressed in the study conclusions. For the 3 studies viewed as the unclear risk of bias, these included reports of various implementations of telehealth, telemedicine, and telecare, such as TEC services across the United Kingdom, including case studies, pilot programs and vision statements; therefore, there was insufficient information reported to make a judgment on biases. However, these studies were included in the synthesis.

Table 4. Summary of information of studies.

Study; location	Groups, participants covered and sample size	Study design	Aim or discussion	Types of technology intervention	Key findings and planned or actual effectiveness
Study 1: Fox et al (2013) [41]; United Kingdom	Care home managers; Senior nurses from care homes; Health care assistants from care homes; Domiciliary managers from care homes; Combined sample of n=779 (20 studies)	Mixed-methods approach	Diabetes management in care homes and the use of guidelines for good standards of care in residential and nursing homes in the United Kingdom	Workshops led by health care professionals including focus group to identify key educational needs; educational presentation using VC[a]; and electronic learning	Identification of lack of written policy for diabetes management, knowledge, and training for staff in diabetes care, inadequate assessment of residents, lack of communication and specialist support from diabetes team, lack of resources for identification of risk of diabetes, access to specialist services, care planning and quality indicators. Educational needs supported by electronic learning seen as an inferior form of education when compared with a skilled, experienced educator.
Study 2: Benetos et al (2013) [42]; France	Elderly, frail residents in care homes living with diabetes and related comorbidities; sample size n=339 and n=675 (15 studies)	Mixed-methods approach, compilation of simple pragmatic advice for HCPs.	Initiatives for diabetes management in nursing homes.	Pragmatic advice for HCPs[b] concerning the management of elderly, frail diabetic patients tailored by a multidisciplinary team of French experts; eye slit lamp technology used by visiting HCP to the care home	To prevent complications associated with diabetes and comorbidities with emphasis on personal individual care planning for residents to adapt and individualize treatment together with education and training of patient, family, physician, nurses, and carers including individualized monitoring of glycemic targets. Access to specialists is recommended to be onsite.
Study 3: Kilvert & Fox (2015) [43]; United Kingdom	Older people living with diabetes with reference to the care home setting; sample size audit: 49,000; 2 case studies	Case studies, focus groups, and audit.	Recommendations and acknowledgment of policies and guidelines relating to diabetes management.	Improved technology using smart glucose meters; basal bolus regimes; insulin pumps and CGM[c].	CGM could be employed to alert carers of undesirably low or high blood glucose levels, recognition of the need to individualize treatment, inability to access education, and training and communication between care home and primary care poor. Guidance produced by Diabetes UK
Study 4: Hausken & Graue (2013) [44]; Norway	HCPs in nursing homes who care for older people with diabetes; sample size: 20 HCPs	Mixed-methods approach	Adequate training and support for enhanced professional competence of diabetes management in nursing homes and home-based services.	Educational training using a pilot program for health care workers; online learning and Web-based technology a potential source.	In Norway, it is a legal requirement to educate specialist health care workers to promote enhanced professional competence and ensure knowledge transfer between HCPs. Nurses and nursing aides are recognized as having different educational needs. This program provided enhanced evidence-based practice skills. Further research is recommended in this area.

Study; location	Groups, participants covered and sample size	Study design	Aim or discussion	Types of technology intervention	Key findings and planned or actual effectiveness
Study 5: NHS England (2015) [45]; United Kingdom	Care homes and the care home community; sample NHS[d] reports and case studies about care services in England representing 9 areas across the United Kingdom (Sunderland, Nottinghamshire, London, Sussex, Stoke-on-Trent, Shropshire, Telford, Calderdale, Airedale, and Blackpool)	Case studies and reports	Various implementations to develop technological initiatives between care home and care provider to ensure multidisciplinary team engagement and reshape how care is delivered across England	Teleswallowing to provide Remote Assessment Providing Interventions for Dysphagia (RAPID); telehealth system using a tablet to aid caregiver using the National Early Warning Score (NEWS) as monitoring tool across the board; Using FLO with Skype by live streaming with General Practitioners' for ward rounds. Promoting communication by fax, android tablet, two-way video links, telecare monitoring equipment with online toolkits for all HCPs. Secure email accounts; shared directory created; standardized documentation with structured messages developed to a national care standard to ensure MDT[e] engagement and support with each other. Android tablets for monitoring telehealth system alerting staff early to initiate early interventions aiding to avoid admission to hospital. Care homes using secure email to improve the flow of information and communication in and out of care homes; online toolkit for staff; telehealth system to alert changes in patients' observations, for example, monitoring the risk of falls. Two-way video link between care home and clinicians.	Various implementations of telehealth, telemedicine, and telecare including technology-enabled care services across the United Kingdom between care homes and care providers. New and proactive ways of the delivery of safe, effective care.
Study 6: Carlisle & Warren (2013) [30]; Australia	Health practitioners and patients; sample size; 2-arm prospective RCT[f]; n=210	Mixed-methods	To explore the implementation of a telehealth service within a coordinated model of care for chronic disease management.	Telehealth using home monitoring and videoconferencing with the diabetes care coordinator and GP[g] to resolve emerging clinical complications; regular emailed reports; broadband communication; telephone contact as required	Definitive conclusions not possible because of limited sample size. However, results showed that participants were keen to engage in telehealth, interpersonal skills, and operational factors were identified as key enablers. Positive working relationships were identified as important for sustaining engagement with telehealth. Benefits of telehealth such as greater access to health care services, improved health outcomes, and effective service delivery. It also highlighted the complexity of chronic disease management positively influenced by the effective implementation of telehealth.
Study 7: Cook et al (2017) [46]; United Kingdom	Residential and nursing home community; GPs and allied health care professionals; sample size (study 1) n=45; (study 2) n=28	Qualitative using constructionist methodology	Aligning access to GP, practice and older people, nurse specialists with care homes using the whole systems service delivery model approach.	Enhanced health care infrastructure for care home residents using a community-based virtual ward providing regular case management. MDT health professionals are then drawn into the group on a case-by-case basis.	Multiple competencies are required by the HCP to provide preventative care, the complex management of frailty, comorbidity, and end-of-life care can only be achieved through multisector and multi-professional working. The whole systems approach enables practitioners to share information and knowledge, problem solve and deliver coordinated care.

Study; location	Groups, participants covered and sample size	Study design	Aim or discussion	Types of technology intervention	Key findings and planned or actual effectiveness
Study 8: Brown et al (2016) [47]; United States	NPs[h] and RNs[i] caring for the older population of patients with longstanding diabetes; sample size n=52	Quality improvement project and pilot intervention longitudinal cohort evaluation	New model of diabetes management in chronic care delivery.	Care coordination using telehealth, for education and virtual outreach clinic; Communication between veterans and health care providers using protocols and documentation template; registered nurses provided patient education coaching in addition to protocol-adjusted medications; and transmission of blood glucose management via telephone	RNs use of didactic training, access to NP team leader partnering with patients, the use of a mentor, the use of medication titration using protocols and support from a clinical team to ensure safe, timely, and efficient care.
Study 9: Spanakis et al (2012) [48]; Europe	Allied professionals, patients, and specialists; sample: doctors, nurses, social scientists, technical personnel, patients, carers, nutritionists, and lawyers	Qualitative using focus groups	New care models incorporating advanced ICT[j] to support diabetes management in clinical applications CGM in different health care regimes, to integrate clinical and organizational workflows with external health information systems.	REACTION Platform via the Web to integrate care; insulin pumps; electronic health for integrated care space; closed-loop system aiding management of diabetes using ICT; glucose monitoring system; ICT tools for health care support; feedback provision to the point of care; integrative risk assessments Web-based; and electronic patch sensors	Technology allowing for a more accurate, faster response to crisis as well as better overall management in the prevention of complications of the disease. Advanced ICT and wireless technologies to enable continuous monitoring and automated closed-loop delivery of insulin via an insulin pump. The REACTION platform endeavors to provide integrated, professional, management, and therapy services using new chronic care models for diabetes patients in and across Europe.
Study 10: Wild et al (2014) [49]; United Kingdom	Care home community including staff, relatives, residents, and carers attached to the care home; sample care staff: n=20; residents n=10; and relatives n=10	Qualitative	Views and perceptions of the care home community on the role of technology design and the potential value of using technology for the care of older residents.	Future development of technologies within care homes considering: environment; assistive devices links to the community associated with a therapeutic approach; assessment tools; links to MDT; telecare; wireless sensors; telehealth; and virtual external access; speech recognition	Considerations for the development of design and technology, preparation for the introduction of technology would increase uptake, older people can learn new technological skills. To create technology that recognizes residents' long-term care needs enabling and empowering residents with the aim of improving the overall quality of life. Lack of research in this area is a limitation.
Study 11: Mason (2012) [50]; United Kingdom	Care Home Community; sample workshop participants	Report: Vision of the Care Home of the Future	Central to meeting the needs of older people in care homes, with a focus on the delivery of care using technology to improve the lives of residents.	Technology for staff supporting care delivery in the care home setting. Technology to keep people mentally alert and engaged with the outside world; checking systems for staff and residents; tablets and computers; GPS[k] trackers; medication reminders; epilepsy monitors; lifestyle and behavioral monitoring; video conferencing; telemedicine; information sharing via the Web; and environmental technologies technology tailored to meet individual needs	Future aspirations and visions for the future of care homes to primarily improve the quality of lives of residents promoting changing the landscape of care homes, workshops, staffing developments, care regulation and environment. A clear vision for the care home setting to be seen as a community hub enabling world-class coordinated leading quality care.
Study 12: Brittain et al (2016) [51]; United Kingdom	Care home community; 761 studies mapped	Rapid evidence synthesis	To underpin the spread of new models of care by conducting a rapid synthesis of evidence relating to enhancing health in care homes.	Technology: cost, ease of use, and staff demands; Workforce: interventions promoting positive joint working within the care home; Communication and engagement- tools to structure communication have the potential to enhance clinical outcomes; and Evaluation: insufficient data reported.	Digital technology has multiple potential applications in care homes. The use of SBAR[l] as a standardized tool to structure communication. Cost, ease of use and staff demands identified as both barriers and facilitators to the implementation and use of technology.

Study; location	Groups, participants covered and sample size	Study design	Aim or discussion	Types of technology intervention	Key findings and planned or actual effectiveness
Study 13: Benhamou et al (2013) [52]; France	Patients living with diabetes; sample: n=163, older diabetic individuals	Mixed-methods review	Current developments of information technology for the management of diabetes	Telemedicine delivery platform involving doctors and nurse educators; telemonitoring; Web-based programs to enable collaborative access to patient medical records. Downloadable capillary glycemic data; feedback with GPs via telephone consultations enabling real-time decision support; blood glucose online diary; secure messaging system; and educational websites	The use of information tools, specific software, and the internet provides support and encourages behavior necessary to prevent clinical inertia and effectively manage diabetes by improvement of therapeutic compliance through motivational support. The development of telemedicine and mobile internet contributes to better diabetes management for the user.

[a] VC: video conferencing.

[b] HCP: health care professional.

[c] CGM: continuous glucose monitoring

[d] NHS: National Health Service

[e] MDT: multidisciplinary team.

[f] RCT: randomized controlled trial.

[g] GP: general practitioner.

[h] NP: nurse practitioner.

[i] RN: registered nurse.

[j] ICT: Information and Communication Technologies.

[k] GPS: Global Positioning System.

[l] SBAR: Situation, Background, Assessment, Recommendation.

Discussion

Search Outcome

This systematic review synthesizes the database results of relevant studies in the use of technology in and around the care home setting to support the care home community and staff responsible for the care of residents living with diabetes. Considerations for the development of design and technology included views and perceptions of the care home community on the role of technology design and the potential value of using technology for the systematic management of diabetes in older residents. Studies highlighted that there is a comprehensive role for co-design in the way that technology can be used within the care home setting for empowering care homes. Supporting technologies and monitoring devices are being used together with telephone calls, interactive Web-based management systems, educational websites, and multidisciplinary communication. This review highlights that technology solutions are being sought and used; however, uptake of the use of technology is slow to progress and training and support in the use of telehealth technology is crucial to aid HCPs.

Most studies included multifaceted interventions necessary to effectively manage diabetes. However, despite the broad inclusion criteria, limited research was found in this area. It is clear that multiple competencies are required by care home staff to individually manage cases of elderly residents living with diabetes; fundamentally, it is knowledge, skills, and the ability of care home staff to access specialist support and services that affect the quality of care for residents helping to prevent clinical inertia in diabetes management including care coordination and feedback provision to the point of care and standardized tools to structure communication [48,51,52]. To prevent complications associated with diabetes and comorbidities, personal individual care planning for residents to adapt and individualize treatment initiatives for diabetes management in nursing homes was emphasized [42].

Educational needs for care home staff are being recognized and supported [41-44,47] by using technological interventions such as VC alongside educational workshops, pilot programs, electronic learning (e-learning), and websites [41,45,48,49,52] including Web-based learning and information communication toolkits [44,45]. The significance of design and support is recognized within studies rating the suitability of blended learning as an approach to education, including a combination of hands-on skills-based training from experts to enhance evidence-based practice skills in addition to using Web-based or e-learning facilities.

Technology being used in the care home setting by visiting HCPs was also reported alongside individual care planning and individualized monitoring for glycemic control [42,43]. More frequent use of insulin pumps, continuous glucose monitoring, and smart meters with feedback systems was also found [43,47,48]. Positively reported to aid in diabetes management was the use and development of telemedicine, telehealth and telecare, TEC services, and Web platforms supported by the use of tools to communicate [30,45,47,49-52]. Two-way video links, virtual wards, and Android tablets allowed multidisciplinary team communication, integration, and care coordination [45-48] providing support for both patients and those caring for them. Environmental assistive devices, computers, trackers, monitors, and tablets are used to promote mental engagement with the outside communities and support networks including family [51], and they take a therapeutic approach with the aim to empower residents with a view to improve the overall quality of care and quality of life for residents in care homes [49,50].

Limitations

Promoting systematic reviews as best practice has its challenges; it is thorough and therefore time-consuming as well as labor-intensive, requiring collaboration between authors. Data and methodology were poorly described in some studies and nonexistent in others; homogeneity from different study designs meant that we found considerable diversity of studies, reports, and case studies, which made it difficult to assess the risk of bias. Particularly, the limitation of the methodology used in this review was the information used for the analysis procedure based on the availability and quality of data to assess the risk of bias. However, some studies were written by experts in this field who were able to guide analysis and determine these objectives. Some included studies of qualitative nature were inappropriate for this approach, and therefore, the strengths of these studies needed to be balanced against the practical limitations of being able to determine the risk of bias; no studies were excluded on the basis of quality.

Conclusions

To summarize on existing evidence and approaches found by conducting this review, there is limited published evidence of a standard practical role for technologies connecting the care home community with diabetes support, education, resources, and systems. There are many emerging forms of technology to enhance, support, and inform decisions about the management of residents' diabetes care; however, there is no standardized approach to address access to specialist support or definitive standards of care in relation to diabetes management in the care home setting.

The use of technology has the potential to initiate early intervention, enable efficient responsive care, and most importantly, link the care home community to multidisciplinary clinical teams for support and communication. Therefore, standards need to be established with regard to care and management, with guidelines put in place. This includes mandatory educational frameworks for care home staff providing access to education and training so that the staff can maintain health and social care clinical competencies across the board. Improved diabetes education for care home staff is an important approach to improved diabetes management and the delivery of quality care.

Learning from examples of existing TEC and looking at new ways that health care technologies can help to provide a proactive approach in linking care homes with community health care services will assist in managing symptoms and reducing the impact of complications and hold potential to improve patient care pathways. Initiatives using technology to help support continuity of care for older people living with diabetes in the care home setting with complex care needs should be explored further.

Care homes play a vital role in the provision of support and care for most elderly members of our society for long-term care. Future aspirations for the care home setting are for care homes to be recognized as providers of safe, high-quality, individualized, and coordinated care. To achieve this fully, care home staff need to be supported in the delivery of excellent standards of care, being involved in new and creative approaches to the delivery of care. Nevertheless, engaging care home staff with a shared interest in improving the care of older people in care homes is multifaceted. Understanding how a new initiative or model of care will influence outcomes for care home residents has the potential to increase support for a change in practice.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA P) 2015 checklist.

[PDF File (Adobe PDF File), 315KB - diabetes_v4i2e11526_app1.pdf]

Multimedia Appendix 2

Data extraction form.

[PDF File (Adobe PDF File), 113KB - diabetes_v4i2e11526_app2.pdf]

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Abbreviations

CGM: continuous glucose monitoring
e-learning: electronic learning
GP: general practitioner
GPS: Global Positioning System
HCP: health care professional
ICT: Information and Communication Technologies
MDT: multidisciplinary team
NHS: National Health Service
NP: nurse practitioner
PRISMA: Preferred Reporting Items for Systematic Review and Meta-Analysis
RCT: randomized controlled trial
RN: registered nurse
ROBIS: Risk of Bias in Systematic reviews
SBAR: Situation, Background, Assessment, Recommendation
TEC: technology-enabled care
VC: video conferencing

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130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org