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Randomized Controlled Trial of mHealth Telemonitoring with Enhanced Caregiver Support for Diabetes Self-management

John D Piette[1,2], **Ananda Sen**[3,4] **and James E Aikens**[3*]

[1]*VA Ann Arbor Center for Clinical Management Research, Ann Arbor, Michigan, USA*

[2]*Department of Health Behavior and Health Education, School of Public Health, University of Michigan, Ann Arbor, Michigan, USA*

[3]*Department of Family Medicine, University of Michigan, Ann Arbor, Michigan, USA*

[4]*Department of Biostatistics, University of Michigan, Ann Arbor, Michigan, USA*

[*]**Corresponding author:** Dr. James E Aikens, Department of Family Medicine, University of Michigan, 1018 Fuller Street, Ann Arbor, MI, 48104-1213, USA, Tel: 011-734-998-7120; Fax: 011-734-998-7335; E-mail: aikensj@umich.edu

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Abstract

Objective: To determine the benefits of a mobile health (mHealth) telemonitoring and self-management support program for diabetes that includes feedback to a patient-selected support person.

Methods: Participants are patients with poorly controlled type 2 diabetes (HbA1c ≥ 7.5%) who nominate a close friend or adult relative from outside their home ("CarePartner;" CP) who is willing to support their diabetes self-management. Patients are then randomized to receive one year of usual care alone or the mHealth+CP program. In the program arm: (a) patients receive weekly automated diabetes telemonitoring calls that include self-management guidance, (b) their CPs receive emailed updates on the patient's diabetes that include guidance on supporting their self-management, and (c) their primary care teams receive faxed notifications about medically urgent issues that they report. Assessments are being performed at Baseline, Month 6, and Month 12. The primary outcomes are 12-month glycemic control and diabetes distress, and we are also exploring secondary effects upon diabetes self-management behaviors, health-related quality of life, systolic blood pressure, and relationship quality.

Conclusion: To our knowledge, this is the only mHealth intervention for any condition that involves a patients-selected support person. If it proves effective, then a new, low-cost, sustainable intervention would be available to improve diabetes outcomes, especially for patient who are medically underserved or socially isolated.

Keywords:

Diabetes; mHealth; Telemonitoring; Illness self-management

Introduction

Inadequate self-management of blood glucose and blood pressure among patients with type 2 diabetes are prospectively associated with chronic hyperglycemia, microvascular complications, and heart disease [1]. Although care management services can improve these outcomes [2], these services depend upon the availability of health professionals to provide between-visit monitoring and patient education [3]. Mobile health (mHealth) services, including interactive voice response (IVR) calls in which patients respond to automated prompts, may help address these barriers to effective care management [4,5].

Support from informal caregivers also might improve diabetes outcomes. However, these support persons usually lack formal tools for monitoring patients' health status and providing as-needed guidance [6], and they are at risk for burnout due to their caregiving burden [6,7]. Moreover, many patients live alone, with up to 7 million Americans receiving "long-distance" caregiving [8]. While some patients have a geographically-distant support person, these caregivers usually receive infrequent and insufficiently-detailed updates about the patient's diabetes health status [9].

In response to these problems, we developed the mHealth system to automatically provide weekly telemonitoring of diabetes patients. This service also provides as-needed problem-tailored education to patients, and notifies their health care teams when patients experience significant difficulties. Finally, it provides a patient-designated caregiver (the CarePartner, CP) with structured updates about the patient's status and as-needed guidance on supporting the patients' self-management. The results of a six-month patient preference trial indicate that this system provides clinical information that is reliable, valid, and actionable [10]. Most scheduled IVR calls were completed, and attrition rate was only 13%. Importantly, patients became less likely over time to report: (a) poor medication adherence, (b) abnormally high or low self-monitored glucose values, and (c) problems with either monitoring their glucose or checking their feet [11]. After intervention, improvements were seen in long term medication adherence, physical functioning, depressive symptoms, and diabetes specific distress [12]. Finally, among initially nonadherent patients who opted to involve a CarePartner support person, adherence was significantly more improved than it was among those who participated alone [13].

Based on these encouraging preliminary results, we are now conducting a randomized controlled trial (RCT). Our primary hypothesis is that, relative to usual care alone, the mHealth system (mHealth+CP) improves the primary outcomes of glycemic control and diabetes related distress. We will also evaluate its potential benefits to the secondary outcomes of diabetes self-management, health-related quality of life, systolic blood pressure, and caregiver relationships.

Methods

Eligibility and recruitment

In order to participate, patients must: have type 2 DM (hospitalization or outpatient visit within 12 months for >2 ICD9 codes of 250.XX or therapeutic class codes C4G, C4K, or C4L in past 2 years' problem list), and be in poor glycemic control as indicated by a recent HbA1c% >7.5%. Additionally, they were required to be ≥ 21 years of age; fluent in English, able to use a telephone touchpad; and able to identify an eligible CP. We exclude patients who are either in palliative care, on a transplant waitlist, at high risk for 1-year mortality, as well as those who screen positive for significant cognitive impairment or an unstable psychiatric condition. Patients are being identified from four community clinics. We search sites' electronic health records for patients who meet the first two criteria, and recruit these patients using an introductory letter followed by telephone screening to verify their eligibility. We obtain their written informed consent in person during a research visit to their usual clinic.

Patients are asked to nominate from one to four potential CPs. They then rate each on a validated measure of social support (Norbeck Social Support Questionnaire [NSSQ]) [14] to identify the most supportive nominee for recruitment. (but within the continental US), communicate regularly with the patient (in person or by phone), have a working home or mobile telephone number, be able to access to the internet and communicate via e-mail, be free of psychiatric or cognitive impairment, be fluent in English, and be ≥ 21 years of age. After they provide verbal informed consent, eligible CPs are mailed information about the study along with a DVD-based training on supportive communication. .

Patient assessments

Clinical staff measure glycosylated hemoglobin (HbA1c, primary outcome) with the Siemens DCA Vantage Analyzer, which analyzes a drop of fingertip capillary blood. If an enrolled patient cannot return to the clinic for follow-up HbA1c testing we use a mail-in testing kit (CoreMedica Laboratories). All self-report measures are being administered over the phone by research staff. We measure diabetes related distress with the Diabetes Distress Scale (DDS), which has good evidence of validity and reliability [15]. We measure the quality of the patient's relationship with their CP by asking patients to report the frequency of communicating with their CP over the past two months, and their subjective evaluations of these discussions (feeling understood, comfort with self-disclosing, confidence in CP's ability to help, etc.) and perceptions of their CP's caregiving burden and stress level. Additionally, we are assessing patients' emotional response to their CP (e.g., appreciation, affection, indebtedness, frustration guilt, etc), and the content of discussions with their CP (DM self-management, medication use, appointment keeping, and other DM-related behavioral goals). We measure general physical and mental functioning with the Medical Outcome Study 12-Item Short Form (SF-12) [16], which is reliable and has been validated for use with diabetes patients [17]. From SF-12 data we calculate the Physical Composite Score (PCS) and Mental Composite Score (MCS) for analysis as secondary outcomes. We are measuring the frequency of diabetes self-management behaviors (healthy eating, exercise, and glucose testing) with the Summary of Diabetes Self-Care Activities (SDSCA) [18]. Evidence indicates its reliability, sensitivity to change, and convergence with other behavioral measures [18,19]. We assess medication adherence with the Brief Medication Questionnaire (BMQ) [16], which is 80-100% sensitive to repeat dose skipping and 90% sensitive to sporadic skipping [19], together with the reliable and well-validated Morisky Medication Adherence Scale (MMAS) [20,21]. We measure the supportiveness of the CP using the Norbeck Social Support Questionnaire (described above) [14]. We measure depressive symptoms with the Patient Health Questionnaire - 9 (PHQ-9) [22]. Health literacy is being assessed by the Test of Functional Health Literacy (Adults) [23]. Finally, we are using standard items to measure patients' age, gender, marital status, race/ethnicity, level of education, and yearly household income. All of these measures are administered at baseline, Month 6, and Month 12, except that sociodemographic data are collected only at Baseline.

Caregiver assessments

We are using single items to assess type and frequency of interactions with the patient and between the CP and any in-home informal caregivers. Portions of the Picot Rewards Scale [24] and Caregiver Reciprocity Scale [25] are being used to assess frustration, respect, and conflict resolution. Caregiver relationship quality and support self-efficacy are assessed among caregivers by rewording selected items from the patient measures. We measure caregiver burden using the Modified Caregiver Strain Index, which has good reliability and validity [26]. Following the methods of Langa et al., [27] we calculate caregiving opportunity costs using selected items from the Chronic Illness and Caregiving Survey [28].

Ancillary data sources

We measure outpatient services, hospitalizations, and medication use from site-specific administrative databases and patient self-report over six-month periods, from which we can estimate costs. Intervention costs include the costs of research personnel, supplies, overhead expenses and training costs. Facility based data are being used to estimate overhead costs, capital expenditures and telephone charges. Medical comorbidity will be measured from patients' problem lists using Deyo's modified Charlson Comorbidity Index [29]. Telephone contact between patients and clinicians is quantified from records and online logs. Our automated calling system provides data on the outcomes of automated call attempts, e-mails, alerts, logins, and postings.

Randomization

After baseline assessment, we randomize patient-CP pairs to intervention (mHealth+CP) or usual care, with a 1:1 allocation ratio based upon permuted blocking by clinical site.

mHealth+CP intervention arm

During each week that an IVR call is scheduled, the system makes up to three attempts to contact each patient on up to three different patient-selected day/time combinations (i.e., up to nine attempts per

week). Calls follow tree-structured algorithms and last between 5 and 10 minutes, during which patients respond to questions about the past week (using their telephone touchtone keypad) and hear messages that give self-management messages based on the patient's responses. The content of questions and feedback messages was developed with input from experts on diabetes self-management, primary care services, and mHealth service design. Queries focus on symptoms of hypoglycemia and hyperglycemia, performance of fasting self-monitoring of blood glucose (SMBG), any SMBG results <90 mg/dL, hypoglycemia self-treatment, three or more instances of SMBG in the prior week with results > 300 mg/dL, possession of at least a two-week supply of antihypergycemic medication, adherence to antihyperglycemic medication, and foot inspection. If patients report difficulty in any of these areas, the system provides them with pre-recorded self-management education specific to that issue. Even if patients do not report any problems, they can still opt to hear self-management educational messages on healthy eating, physical activity, and medication adherence. Further details on the content of IVR calls are available from the authors.

After each completed call, patients' CarePartners are automatically emailed a summary of the patients' call. If the patient reported self-management problems during the call, then the report includes an explanation, structured suggestions for how to support the patient's self-management, and an appropriate timeframe for interacting with the patient.

Whenever patients report a pattern of either abnormal blood glucose, abnormal blood pressure, or significant medication nonadherence, the system automatically faxes a notification to their primary care team. The thresholds for triggering notifications were selected with clinician input to have a low false positive rate, provide actionable information, and efficiently use human resources for follow-up without burdening clinicians. Finally, the calling system records detailed process data such as the outcome of each attempted call which research staff monitor to ensure treatment delivery and participant engagement.

Ethical approval and public registration

This study was approved by Institutional Review Board at the University of Michigan, and is registered at ClinicalTrials.gov (NCT01684709).

Data analysis

Power and sample size: For our main hypothesis, we predict a mean difference of -0.3% (95% c.i.: -0.5 – -0.1, p=0.007) in 12-month HbA1c, which is the mean impact of long-term educational and behavioral interventions for poorly-controlled DM per a 2009 Cochrane's Review [30]. Per our previously published data [31], we assume a pooled standard deviation (SD) of 1.72 and a 1-year within-subject correlation of 0.78. We also assume that mean baseline HbA1c will be 8.5% in both groups, and anticipate this to drop 0.3% in the intervention arm by Month 6 and be maintained at that reduced level at Month 12. Based upon a two-time repeated measures analysis at alpha=0.025 to adjust for two comparisons (Baseline vs. Month 6, and Baseline vs. Month 12), and assuming that controls' HbA1c will remain constant at Months 6 and 12, we estimate that 190 subjects are required per arm to provide 80% power to detect a group by time interaction. Assuming up to 40% attrition, we are enrolling up to 480 patients (and 480 CPs) total in order to achieve our necessary sample size.

Missing data: The primary analysis will use only observed data, whereas auxiliary analyses include imputed missing data. We will use logistic regression to model the likelihood of missing data, define strata in which values are missing at random, classify patients using propensities, randomly sample from observed distributions, and impute missing data.

Preliminary data analysis: We will test baseline differences in HbA1c, DDS, age, race, gender, etc., and adjust subsequent analyses accordingly. We will check the validity of IVR data against corresponding self-report measures. Depending on the results of these checks, we will report significant discrepancies and might adjust analyses for extreme cases and/or measurement error, derive validity weights, impute modeled values or drop specific variables.

Hypothesis testing analysis: We will use a linear mixed-model analysis to model HbA1c and DDS scores as a function of group (mHealth+CP vs. control) and time (Baseline, 6 months, 12 months). We plan to interpret significant group X time interactions by plotting regression lines above and below the moderator median [32]. Adjustments will be made for potential confounders including design factors (e.g., site, presence of in-home caregiver) and baseline characteristics. We will use random intercepts to account for clustering within time and site. Likelihood ratio tests will be used to evaluate nested models. Alternative covariance structures will be evaluated using residuals and information criteria statistics. We will use the same approach to evaluate whether mHealth+CP improves the secondary outcomes of diabetes self-management, health-related quality of life, systolic blood pressure, and caregiver relationships.

Results

We began recruiting patients in March 2013. To date, we have recruited approximately 130 patient-participants (along with 130 of their CPs), which is 27% of our targeted sample. Twenty-four participants have completed their Month 12 assessment. We are scheduled to perform interim analyses in May of 2015. Given our current recruitment rate, we project that the study will be closed to new accrual by March 2016, and that data collection will be completed by March 2017.

Discussion

As described above, we are conducting an RCT in community clinics to determine the benefits of a mHealth diabetes telemonitoring and self-management program that includes a patient-selected support person. The intervention is designed to: (a) monitor patients' symptoms and self-management problems, (b) provide patients with tailored messages about diabetes self-management and medical help-seeking, (c) generate guidance on self-management support for patients' informal caregivers via structured emails, and (d) provide patients' clinicians with actionable feedback via faxed updates about selected patient-reported health and self-care problems [33].

In typical outpatient care, patients seldom receive corrective guidance until long after any poor self-management patterns have resulted in negative medical consequences. This temporal lag is a major barrier to behavior change, and can render medical interventions ineffective. Accordingly, the design of our mHealth program is grounded in the assumption that informal caregivers and healthcare teams will use problem-tailored advice to address emerging problems before they escalate, and prophylactically help the patient to improve their illness self-management behaviors. Automated data

collection is also a key strategy in our model, because it provides routine "asynchronous communication" between the patient and others that does not require their simultaneous availability. Because patients' supporters usually also juggle demands from their workplace, young children, and other sources [34], this flexibility should enhance the intervention's translatability, uptake, and maintenance.

Potential limitations

One noteworthy study limitation might be our inability to isolate the unique additive effect of having a CarePartner above and beyond the well-documented effects of telemonitoring alone. While an "mHealth alone" condition (without a Care Partner) would have provided this comparison, we have already studied this variation and concluded that having a CP probably improves telemonitoring outcomes [10-13]. Therefore, our main objective was to test the clinical effectiveness of the aggregated mHealth+CP package rather than determine the efficacy of its subcomponents.

A second potential limitation is that most of the variables are being measured by self-report which is prone to recall and social desirability report biases. However, we have previously established that the intervention provides information that is reliable and valid [35]. Moreover, most of the self-report instruments being used have strong psychometric characteristics, and three of our outcomes (blood glucose, blood pressure, and health care costs) are being assessed objectively. While attrition is often a concern in clinical research, we do not expect substantial dropout. We believe that attrition is being minimized by the general patient-centeredness of the calling system and its scripts. Patient engagement is probably also enhanced by scheduling the calls at each patient's preferred times and making up to nine calling attempts per week if needed.

Anticipated implications

To our knowledge, this is the only mHealth intervention that involves a patient-selected support person. Although we project only small to moderate effect magnitudes, the intervention is probably inexpensive to implement, given that the majority of its costs are attributable to development and testing. Therefore, if this approach proves effective, then an innovative and sustainable new intervention could potentially be made widely available. Its benefits might include not only improved self-management and medication adherence, but also long term improvements in glycemic control, functional impairment and psychological distress. In sum, this research could ultimately lead to major public health benefits, especially for vulnerable and isolated patients.

Conflicts of Interest

The author(s) declare that they have no competing interests.

Authors' Contributions

All authors contributed to the design of the study and participated in preparing the grant application, JEA and JDP drafted the manuscript, and AS designed the statistical analysis and edited the grant application.

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