Published in final edited form as:
J Diabetes Complications. 2014 ; 28(2): 171–176. doi:10.1016/j.jdiacomp.2013.11.008.

Diabetes self-management support using mHealth and enhanced informal caregiving

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Abstract

Objective—To characterize diabetes patient engagement and clinician notifications for an mHealth interactive voice response (IVR) service.

Design—Observational study.

Methods—For three to six months, VA patients with diabetes received weekly IVR calls assessing health status and self-care along with tailored education. Patients could enroll with an informal caregiver who received suggestions on self-management support. Notifications were issued to clinicians when patients reported significant problems.

Results—Patients (n=303) participated for a total of 5,684 patient-weeks, during which 84% of calls were completed. The odds of call completion decreased over time (AOR = 0.96, $p < 0.001$), and were lower among unmarried patients (AOR = 0.67, $p = 0.038$) and those who had difficulties with health literacy (AOR = 0.67, $p = 0.039$), diabetes-related distress (AOR = 0.30, $p = 0.018$), or medication nonadherence (AOR = 0.57, $p = 0.002$). Twenty-one clinician notifications were triggered per 100 patient-weeks. The odds of notification were higher during the early weeks of the program (AOR = 0.95, $p < 0.001$) and among patients who were older (AOR = 1.03, $p = 0.004$) or more physically impaired (AOR = 0.97, $p < 0.001$).

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Author contributions: JEA researched the data and wrote the manuscript. KZ and RT reviewed and edited the manuscript and contributed to the Discussion. JDP planned the study, reviewed and edited the manuscript, and contributed to the Discussion.

Conclusions—By providing information that is reliable, valid, and actionable, IVR-based mHealth services may increase access to between-visit monitoring and diabetes self-management support. The system detects abnormal glycemia and blood pressure levels that might otherwise go unreported, although thresholds for clinician notifications might require adjustment to avoid overloading clinicians. Patient engagement might be enhanced by addressing health literacy and psychological distress.

Keywords

diabetes; mHealth; primary care; care management

Introduction

Inadequate self-management of blood glucose and blood pressure in type 2 diabetes is prospectively associated with chronic hyperglycemia, microvascular complications, and heart disease.[1] Although outcomes can improve with care management,[2] comprehensive services are often unavailable due to limitations in the availability of personnel, appropriate technologies for between-visit monitoring, and reimbursement for telephone contacts.[3] Mobile health (mHealth) refers to the use of mobile devices to support medical care and public health. It appears that mHealth services, including interactive voice response (IVR) calls (in which a person responds to re-recorded prompts from a calling computer using their telephone keypad), may help address these barriers to effective care.[4,5]

Another strategy to improve outcomes is to enhance patients' social support for self-management. In-home caregivers often lack the tools needed to systematically monitor changes in patients' diabetes-related health status and support their self-care;[6] and many caregivers are at risk for burnout.[7] Moreover, many patients live alone, with up to 7 million Americans receiving “long-distance” caregiving.[8] In order to enable geographically-distant supportive individuals to be more involved and effective, we developed an mHealth service using IVR to provide patient monitoring and self-care support between clinician contacts.

In this report, we describe the implementation of this program in primary care settings. Patients with diabetes received weekly automated IVR monitoring and self-care support calls designed to assess self-monitoring of blood glucose (SMBG), medication and dietary adherence, blood glucose levels, blood pressure levels, foot inspection, and overall functioning. If the patient reported a difficulty in any of these key areas, the system provided the patient with prerecorded self-management education corresponding to the area of difficulty. In addition, the system provided automated updates on patients' status to an informal caregiver living outside the patient's home, and notified the primary care team when the patient reported clinically significant problems. To better understand program implementation, we investigated sociodemographic indices, physical functioning, depressive symptoms, diabetes related distress, and functional health literacy as predictors of variation in: (a) patient engagement and the frequency, and (b) the types of clinical feedback generated by the service.

Methods

Patient eligibility and recruitment

Patient participants were recruited from 16 Department of Veterans Affairs (VA) outpatient clinics in Michigan, Illinois, Indiana, and Ohio between March 2010 and December 2012. Eligibility criteria were: an ICD-9 diagnosis of type 2 diabetes; ≥1 outpatient VA primary care visits in the prior 12 months; and ≥1 current VA prescriptions for an antihyperglycemic medication. We excluded patients with diagnoses indicating cognitive impairment or severe

mental illness or who were living in a supervised residential facility. Potential participants were mailed an introductory letter and then screened by telephone. After providing written informed consent, patients received information about using the IVR system and communicating effectively with informal caregivers and clinicians. The study was approved by human subjects committees at the Ann Arbor VA Healthcare System and University of Michigan.

Baseline assessment

We assessed patient characteristics at baseline by telephone. We created dichotomous indicators to identify patients who were: of minority race/ethnicity, married, and employed; and had household income < $15K yearly and at least some college education. We computed a summed index of physician-diagnosed medical comorbidities based on a self-report checklist of common chronic conditions. From the Medical Outcome Study 12-Item Short Form (SF-12),[9] we calculated the Physical Composite Summary (PCS; higher scores reflect better physical functioning) and Mental Composite Summary (MCS; higher scores reflect better adjustment); scores range 0-100 (mean = 50, SD = ±10). From the 10-item version of the Center for Epidemiological Studies Depression Scale (CES-D)[10] we created a binary indicator for clinically significant depressive symptoms using Irwin et al.'s cutoff for older adults.[11] We applied the established cutoff of 40 to define diabetes distress using the Problem Areas in Diabetes (PAID),[12] which measures diabetes-specific psychological distress. The Morisky Medication Adherence Scale (MMAS) was used to identify patients at baseline with significant medication nonadherence, using the standard cut-off of 2.[13,14] Finally, we measured health literacy (the capacity to obtain, process, and understand basic health information and services to make appropriate health decisions) by using a single-item screener for inadequate health literacy (sensitivity: 0.80, specificity: 0.49) that was specifically developed for VA outpatients.[15,16]

Intervention program

Intervention strategies were based upon the assumption that patients, informal caregivers, and healthcare teams can use frequent information updates about the patient's health and self-care to promptly identify emerging problems and improve illness self-management.[17] The overall goals of the intervention were 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.

Patients were enrolled in two waves, with the first wave receiving IVR calls weekly for three months and the second receiving IVR calls weekly for six months. During each week that an IVR call was scheduled, the system made up to three attempts to contact each patient on up to three different patient-selected day/time combinations (i.e., up to nine attempts). The calls followed tree-structured algorithms, and lasted between 5-10 minutes during which patients responded to questions about their experiences during the past week using their telephone touchtone keypad and heard messages that gave verbal reinforcement (e.g., “That's great. For a person with diabetes like you, it is important to look at your feet every day.”) and as-needed self-management messages based on their responses. The wording of questions and messages was developed with input from experts in diabetes self-management, endocrinology, primary care, and mHealth service design. Queries for information focused on: symptoms of hypoglycemia and hyperglycemia, performance of fasting 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 had hypertension and had self-monitored their blood pressure ≥ 3 days that week, additional questions assessed: patient-reported systolic blood pressure levels of > 300 mmHg at least half the time during the prior week or < 90 mmHg on ≥ 2 days during the prior week, possession of at least a two-week supply of antihypertensive medication, adherence to antihypertensive medication, and whether the patient was following a low sodium diet. Further details on item wording and call flow are available from the authors.

Patients could opt to designate one family member or close friend to receive emailed summaries of each completed call along with structured suggestions on supporting the patient's diabetes self-management. These individuals were required to be living outside the patient's residence, because our goal was to supplement any in-home informal caregiving that was already occurring. We used the Norbeck Social Support Questionnaire (NSSQ)[18] to help patients identify the best individual for this role. To be eligible, informal caregivers needed to be ≥ 18 years old, have no history of cognitive or severe psychiatric impairment, and have access to email. Participating caregivers underwent DVD-based communication training using motivational interviewing principles.

Finally, whenever patients reported a pattern of either abnormal blood glucose or blood pressure levels, or significant medication nonadherence, the system responded automatically by faxing a clinician notification that explained the issue to patients' primary care team. Additional reported problems (e.g., symptoms of high blood glucose), were included in those notifications, but did not independently generate notifications. Based upon clinician input, the thresholds for generating notifications were selected to have a low false-positive rate, provide actionable information, and efficiently use human resources for follow-up without burdening clinicians.

Weekly assessment

The system logged all attempted IVR calls. For completed calls, we created binary indictors for abnormal blood glucose symptoms, performance of fasting SMBG and foot inspection, SMBG results indicating abnormally high or low blood glucose levels, hypoglycemia self-treatment, low and high blood pressure, having less than a two-week supply of medication, adherence for both antihyperglycemic and antihypertensive (when applicable) medications, and adherence to a low-sodium diet.

Data analysis

Data were analyzed using Stata v.12.1.[19] At the patient level, we computed descriptive statistics (frequency, mean, SD) for patients' sociodemographic and clinical characteristics. We used logistic regression to identify patient characteristics associated with attrition and patients' probability of enrolling with an informal caregiver. Most remaining analyses were performed at the ‘patient-week’ level, i.e., one record for each week in which an IVR call was attempted. To examine the consistency of patients' reports within and across IVR calls, we used odds ratios and intra-class correlation (ICC) coefficients. We used logistic models to predict call completion and clinician notifications as a function of patients' sociodemographic characteristics and baseline measures of physical and psychological functioning, medication adherence, depressive symptoms, diabetes related distress, and health literacy. We also explored two-way interactions among these characteristics. We used a criterion of $p < 0.05$ to evaluate statistical significance after adjusting for clustering of calls within patients, and variables with $p > 0.15$ were dropped from final models. We expressed rates of IVR-reported problems and system-generated clinician notifications per 100 patient-weeks of participation.

Results

Participant characteristics

Of 422 eligible patients, 303 (71.8%) consented to participate (108 in the three month program and 195 in the six month program, see Table 1). The typical participant was a Caucasian male, as would be expected in the VA population. The majority were at least 60 years old, and 30% were at least 70 years old. Forty-seven percent of participants had no more than high school education, 26% had annual household incomes < $15,000, 67% were married or cohabitating, and 18% were employed (which is consistent with the high rate of retirement expected in this population). Seventy percent had ≥ 3 comorbid medical conditions, and 86% had hypertension. Levels of physical functioning at enrollment tended to be very poor (PCS mean ± SD: 32.3 ± 12.2). Although some participants reported mild depressive symptoms at baseline (CES-D: 2.50 ± 2.37; 30% elevated), MCS scores suggested that most patients were not impaired by psychological distress (50.0 ± 11.7), and the PAID indicated little evidence of diabetes-specific distress (13.2 ± 13.1; 4% elevated). Antihyperglycemic nonadherence was somewhat prevalent (MMAS mean 1.2 ± 1.0; 36% elevated), as was inadequate health literacy (52%).

Participating with an informal caregiver

Thirty-nine percent of participants (see Table 1) opted to participate with an informal caregiver. Caregiver participation was significantly more common among patients with lower income or inadequate health literacy (both p values = .007).

Attrition

Attrition (14%) was more likely among those who were enrolled into the six-month versus the three-month program (20% vs. 3%, $p < 0.001$) and among patients who did not participate with an informal caregiver (19% vs. 6%, $p = 0.003$).

Engagement in IVR calls

Patients participated for a total of 5,684 patient-weeks, and completed an IVR call during 4,760 (84%) of these (see Table 2). Based upon significant unadjusted associations, the model predicting call completion was initially adjusted for week of participation, program duration, enrollment with an informal caregiver, and being unmarried. After dropping variables with $p > 0.15$ from the adjusted model, (see Table 3, upper panel) call completion was significantly less likely among patients who had inadequate health literacy (AOR = 0.67, $p = 0.014$), elevated diabetes-related distress (AOR = 0.30, $p = 0.012$), or antihyperglycemic medication nonadherence at baseline (AOR = 0.57, $p = 0.002$).

Problems reported during IVR calls

As shown in Table 2, the most frequently reported diabetes-related problems were: experiencing symptoms of either high or low blood glucose levels (each reported during 13% of patient-weeks), self-treating hypoglycemia (12%), obtaining a blood glucose level < 90 mg/dL (9%), not inspecting feet (8%), and not performing SMBG (7%). In contrast, there were relatively few reports of having less than a two-week supply of antihyperglycemic medication (3% of patient-weeks), antihyperglycemic nonadherence (1%), and high blood glucose levels (1%). The most frequently reported hypertension-related problems were: obtaining high blood pressure readings during self-monitoring (12% of patient-weeks), not checking blood pressure (11%), and nonadherence to a low sodium diet (10%); with very few reports of low blood pressure (3%), or either low antihypertensive medication possession (1%) or nonadherence (< 1%). Finally, compared to patients who participated with an informal caregiver, those who did not participate with an informal caregiver were

only 40% as likely to report frequent high glucose levels (p = 0.021), and only 56% as likely to regularly check their blood pressure (p = 0.017).

Reported health and self-care problems were strongly interrelated within IVR calls. That is, patients who reported hypoglycemia symptoms were highly likely to concurrently report blood glucose levels < 90 mg/dL (OR = 8.24, 95% c.i.: 5.70–11.90, p < 0.001) and self-treatment of hypoglycemia (OR = 67.05, 95%, 95% c.i.: 46.2–97.3, p < 0.001). Those who reported experiencing symptoms of hyperglycemia were far more likely than other patients to concurrently report high glucose levels (OR = 13.9, 95% c.i.: 7.9–24.3, p < 0.001). Additionally, those who reported having less than a two-week supply of antihyperglycemic medication were highly likely to also report low adherence to antihyperglycemic medication (OR = 170.10, 95% c.i.: 54.3–533.0, p < 0.001). Patients also tended to be consistent in reporting the same diabetes-related problems across time, with ICCs ranging from 0.22 (obtaining a low blood glucose level, 95% c.i.: 0.16–0.30, p < 0.001) to 0.60 (performing SMBG, 95% c.i.: 0.54–0.66, p < 0.001). Supporting the validity of IVR medication nonadherence calls, the odds of IVR-reported antihyperglycemic nonadherence doubled for each 1-point increase on the 5-point baseline MMAS (OR = 2.32, 95% c.i.: 1.72–3.14, p < 0.001). Similarly, for the IVR item assessing performance of SMBG, the odds of endorsement reduced by half with each 1-point increase on a 5-point baseline item assessing difficulty performing SMBG (OR = 0.47, 95% c.i.: 0.37–0.60, p < 0.001).

Clinician notifications

A total of 1189 clinician notifications were generated, equating to 21 notifications per 100 patient-weeks of follow-up. Notifications tended to cluster within a small group of patients, such that 46% of notifications were generated by the 15% of patients who triggered at least 10 notifications each. The most common trigger was high blood pressure (55% of notifications), followed by low blood glucose (42%), low blood pressure (12%), and high blood glucose (7%). Only 1% of the notifications were triggered by nonadherence to either antihyperglycemic or antihypertensive medication.

Based upon unadjusted associations, the model predicting clinical notifications was initially adjusted for week of participation, program duration, age, comorbidity and physical impairment. After eliminating variables with P < 0.15 from the adjusted model (see Table 3, lower panel), clinician notifications were found to become significantly less likely over time (AOR = 0.95, p < 0.001). Additionally, notifications were significantly more likely among patients who either were older (AOR = 1.03, p = 0.01) and more physically impaired (AOR = 0.97, p < 0.001).

Discussion

This report describes our implementation of an mHealth service using IVR monitoring and self-management support in a large sample of older adults with type 2 diabetes. To summarize, most solicited patients participated, 39% of whom co-participated with an informal caregiver. Attrition was low, and unrelated to patients' sociodemographic characteristics, suggesting that even vulnerable patients will engage in this type of service. The vast majority of attempted weekly IVR calls were successfully completed. The rate of call completion declined somewhat over time, although it is unclear whether that was due to program dissatisfaction or some patients' perception that they had had already benefited and were experiencing diminishing returns. Call completion was also less likely among patients who were unmarried, had inadequate health literacy, or at baseline were either highly distressed about their diabetes or nonadherent to medication regimens. The program issued 21 clinician notifications per 100 patient-weeks, usually because patients reported either high blood pressure or low blood glucose levels. Notifications were more likely during the

initial weeks of the program, and tended to cluster among a relatively small group of physically impaired older patients.

Call completion appeared to be unaffected by medical comorbidity. This encouraging finding suggests that IVR-based mHealth programs may improve access to disease monitoring and self-management support among patients with complex chronic conditions and sociodemographic disparities, assuming that psychological distress and health literacy are sufficiently addressed. Rates of engagement were higher among patients enrolling with an informal caregiver. This may indicate that social support can mitigate some disparities in self-management. Among retained participants, IVR engagement rates were significantly lower among patients who reported medication nonadherence at baseline, suggesting that nonadherence behavior may generalize to participation in mHealth support. Incomplete calls were also comparatively common among patients who at baseline were highly distressed about their diabetes or had serious health literacy difficulties, both risk factors for poor diabetes self-management and outcomes.[20,21] Such patients might benefit from simplified calls and intensified psychological support. Being unmarried also predicted missed self-management support calls, which may reflect the well-known health benefits of marriage[22] as well as simply having another household member to answer the calls.

A large minority of patients opted to co-participate with an informal caregiver for self-management support. This implies that similar mHealth programs should strive to balance privacy considerations with patients' preferences to engage members of their social support network. Having a co-participating caregiver was more common among patients with inadequate health literacy and low income. This suggests the interesting possibility that patients with inadequate health literacy or low income might actively counteract these risk factors by seeking social support. Strong social ties are clearly associated with better physical health,[23] perhaps due to the availability of instrumental and emotional support or benefits to regimen adherence. Accordingly, we found that participating with an informal caregiver was associated with higher rates of call completion and weekly blood pressure monitoring, and a lower rate of high blood glucose levels.

Patients' IVR-reported health and self-care problems appeared to be reliable and valid. For example, because IVR-reported nonadherence was strongly correlated with a validated baseline measure of adherence, these IVR reports probably represent ‘true positives.’ On the other hand, if patients'IVR-reported health and self-care is highly predictable based on their baseline characteristics, frequent monitoring of that parameter may not be worthwhile relative to the monitoring of other less predictable and poorly monitored self-management issues.[24]

The mHealth program detected a significant number of patient-reported hypoglycemic episodes and hypertension patterns that might otherwise have gone unreported. Although clinicians are understandably concerned about false positives and the potentially added workload that could be generated from systems that monitor patients' status between clinician contacts, systems such as the current one may nonetheless help promptly identify issues that could be addressed to prevent serious and costly complications. Moreover, most systems (including this one) could be programmed to allow clinicians to individually specify the type and severity of problems that trigger notifications.

Our present algorithms generated notifications during 21 out of every 100 patient-weeks of participation. Although this would seem to imply that the average patient triggers only about one notification every five weeks, further analyses showed that there is a small number of patients responsible for the majority of notifications, just as a small number of patients in a health system account for the majority of utilization. In particular, notifications tended to

cluster within a small subset of physically-impaired older patients, such that almost half of notifications were generated by only 15% of participants. These patients may have different needs than the average patient, and future versions of mHealth systems should seek to identify such patients early for more intensive follow-up.[25]

Limitations

This study has several limitations. While the sample was heterogeneous in terms of participant income, education, and medical comorbidities, given the VA setting most participants were male Caucasians with multiple medical conditions. In particular, because the volume of clinician notifications was associated with patients' age and physical impairment, extrapolation may be needed to generalize the findings to younger, healthier populations. Not all solicited patients participated, but unfortunately we did not have IRB approval to record nonparticipants' characteristics. Furthermore, patients only participated for a relatively brief period of time. Because of that as well as the fact that the study lacked a control group, we cannot assume that the decrease in clinician notifications over time truly reflects a clinical benefit of the service. While we documented the volume and type of clinician notifications, we could not evaluate possible impacts upon patients' use of other health services, clinicians' workflow, cognitive load, and provision of care.

Future directions

As mHealth monitoring and self-management support systems for patients with diabetes become more common and better integrated with electronic medical records, future studies should include a control group, incorporate objective outcome measures, and evaluate the impact of services on clinician workflow and the costs of care. It will also be important to clarify patient preferences for caregiver involvement and to assess in more detail the impact of caregiver feedback on caregiving outcomes such as relationship quality and caregiver burden. We are now conducting a large randomized controlled trial in a representative non-VA diabetes population that addresses these shortcomings. Future research might also explore ways to integrate the self-management of various comorbidity combinations into mHealth monitoring and self-management support. Finally, it would be worthwhile to evaluate the reduced respondent burden of less frequent monitoring for healthier patients against the possible risks of reduced engagement and delayed problem detection.

Conclusions

Undoubtedly a range of options will be needed to meet all diabetes patients' needs for self-management support. However, we conclude that many patients will engage readily and consistently with weekly IVR calls that yield information that is reliable, valid, and actionable. Some patients want an informal caregiver to receive advice on how to support their diabetes self-management efforts. At the same time, modifications and adjunctive strategies are probably needed for patients who are isolated, have limited health literacy, or are significantly distressed. Although this type of system generates a manageable volume of clinician notifications, the volume and types of notifications should be adjusted to clinician preferences and perhaps patient characteristics. In sum, automated diabetes monitoring and self-management support programs may help fill the gap between what some patients need, and what resource-constrained health systems can realistically provide. Future research should compare such systems to usual care, evaluate their impact on clinic workflow and economic outcomes, and explore flexibility in call frequency and targets.

Acknowledgments

JDP is a VA Senior Research Career Scientist. KZ and RT are supported by VA Career Development Awards (grant # CD2 07-206-1 to K.Z. and grant # CDA-09-206 to R.T.). Other financial support came from the Michigan

Diabetes Translational Research Center (grant # P30DK092926) and grant # R18DK088294 from the National Institute of Diabetes and Digestive and Kidney Diseases. The views expressed in this manuscript are those of the authors and do not necessarily represent the opinions of the Department of Veterans Affairs.

References

1. Alberti KGMM, Zimmet P. Definition, diagnosis and classification of diabetes mellitus and its complications. Part 1: diagnosis and classification of diabetes mellitus. Provisional report of a WHO consultation. Diabetic medicine. 1998; 15:539–53. [PubMed: 9686693]
2. Anderson RM, Funnell MM, Aikens JE, et al. Evaluating the efficacy of an empowerment-based self-management consultant intervention: results of a two-year randomized controlled trial. Therapeutic Patient Education. 2009; 1:3–11. [PubMed: 20076768]
3. Piette JD. Moving diabetes management from clinic to community: development of a prototype based on automated voice messaging. The Diabetes Educator. 1997; 23:672–80. [PubMed: 9416031]
4. Schwartz S. What works. IVR system helps diabetes center triple patient load; increases care level. Health management technology. 1998; 19:41. [PubMed: 10182551]
5. Piette JD. Interactive behavior change technology to support diabetes self-management: where do we stand? Diabetes Care. 2007; 30:2425–32. [PubMed: 17586735]
6. Rosland AM, Heisler M, Janevic MR, et al. Current and potential support for chronic disease management in the United States: The perspective of family and friends of chronically ill adults. Families, Systems, & Health. 2013; 31:119.
7. Armour T, Norris S, Jack L, Zhang X, Fisher L. The effectiveness of family interventions in people with diabetes mellitus: a systematic review. Diabetic medicine. 2005; 22:1295–305. [PubMed: 16176186]
8. Talley RC, Crews JE. Framing the public health of caregiving. Am J Public Health. 2007; 97:224–8. [PubMed: 17194871]
9. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care. 1996; 34:220–33. [PubMed: 8628042]
10. Kohout F, Berkman LF, Evans DA, Cornoni-Huntley J. Two shorter forms of the CES-D depression symptoms index. J Aging Health. 1993:179–93. [PubMed: 10125443]
11. Irwin M, Artin KH, Oxman MN. Screening for depression in the older adult: criterion validity of the 10-item Center for Epidemiological Studies Depression Scale (CES-D). Archives of Internal Medicine. 1999; 159:1701. [PubMed: 10448771]
12. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. Diabetes Care. 2005; 28:626–31. [PubMed: 15735199]
13. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Medical Care. 1986; 24:67–74. [PubMed: 3945130]
14. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. The Journal of Clinical Hypertension. 2008; 10:348–54. [PubMed: 18453793]
15. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. health. 2004; 11:12.
16. Chew LD, Grill JP, Snyder A, Bradley KA, Nugent SM, Baines AD. Validation of screening questions for limited health literacy in a large VA outpatient population. Journal of General Internal Medicine. 2008; 23:561–6. [PubMed: 18335281]
17. Piette JD, Rosland AM, Marinec NS, Striplin D, Bernstein SJ, Silveira MJ. Engagement with automated patient monitoring and self-management support calls: experience with a thousand chronically-ill patients. Medical care. 2013; 51:216–23. [PubMed: 23222527]
18. Attkisson CC, Zwick R. The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. Evaluation & Program Planning. 1982; 5:233–7. [PubMed: 10259963]
19. StataCorp. Stata Statistical Software: Release 12.1. College Station, TX: StataCorp LP; 2011.

20. Aikens JE, Piette JD. Diabetic patients' medication underuse, illness outcomes, and beliefs about antihyperglycemic and antihypertensive treatments. Diabetes Care. 2009; 32:19–24. [PubMed: 18852334]

21. Aikens JE. Prospective associations between emotional distress and poor outcomes in type 2 diabetes. Diabetes Care. 2012; 35:2472–8. [PubMed: 23033244]

22. Robles TF, Kiecolt-Glaser JK. The physiology of marriage: Pathways to health. Physiology & behavior. 2003; 79:409–16. [PubMed: 12954435]

23. Berkman LF. Social ties and mental health. Journal of Urban health. 2001; 78:458–67. [PubMed: 11564849]

24. Piette JD, Sussman JB, Pfeiffer PN, Silveira MJ, Singh S, Lavieri MS. Maximizing the value of mobile health monitoring by avoiding redundant patient reports. Journal of medical internet research. 2013; 15

25. Piette JD, Aikens JE, Rosland AM, Sussman JB. Re-thinking the frequency of between-visit monitoring for patients with diabetes. Under review.

Table 1

Patient baseline characteristics.

		Participated with informal caregiver		
Variable	**Total sample (n=303)**	**No (n=185)**	**Yes (n=118)**	**p value**
Age, mean ± SD	66.6 ± 9.8	66.5 ± 8.9	67.8 ± 10.7	0.426
Male, %	97.0	97.8	95.8	0.308
Caucasian, %	92.9	92.7	93.5	0.860
Married, %	67.3	70.3	62.8	0.171
Yearly household income				**0.007**
< $15,000	26.1	20.5	34.8	
$15,000-$29,000	24.4	24.3	24.6	
$30,000-$54,000	28.7	31.9	23.7	
> $55,000	20.8	23.2	17.0	
Some or more college, %	53.0	50.0	57.6	0.195
Employed, %	18.2	17.2	19.8	0.571
Comorbid conditions,[i] mean ± SD	4.8 ± 2.2	4.7 ± 2.1	5.0 ± 2.2	0.360
Hypertension diagnosis, %	85.7	84.7	87.3	0.531
Inadequate health care literacy, %	52.2	44.3	64.4	**0.001**
PCS,[ii] mean ± SD	32.3 ± 12.2	32.1 ± 12.1	32.6 ± 12.4	0.746
MCS,[iii] mean ± SD	50.0 ± 11.7	49.3 ± 12.0	51.0 ± 11.2	0.230
CES-D,[iv] mean ± SD	2.50 ± 2.37	2.64 ± 2.39	2.27 ± 2.34	0.179
Elevated CES-D, %	30.2	32.2	27.1	0.345
PAID,[v] mean ± SD	13.2 ± 13.1	13.5 ± 13.4	12.8 ± 12.7	0.641
Elevated PAID, %	4.3	5.0	3.4	0.518
MMAS,[vi] mean ± SD	1.20 ± 0.96	1.17 ± 0.99	1.26 ± 0.89	0.456
Elevated MMAS, %	35.6	33.5	39.0	0.332

Notes:

[i] Based on self-reported hypertension, cardiovascular disease, hyperlipidemia, cancer, stroke, arthritis, chronic lung disease, migraine, asthma, and low back pain.

[ii] Physical Composite Summary of the Medical Outcome Study 12-item Short Form. Higher scores indicated better functioning.

[iii] Mental Composite Summary of the Medical Outcome Study 12-item Short Form. Higher scores indicated better functioning.

[iv] Center for Epidemiological Studies Depression Scale (CES-D), 10-item version, scored per Irwin et al. Higher scores indicate worse depressive symptoms.

[v] Problem Areas in Diabetes scale. Higher scores indicate greater distress.

[vi] Morisky Medication Adherence Scale, phrased for diabetes medication. Higher scores indicate greater medication non-adherence.

Table 2

Rates[vii] of reported problems and notifications by patient-week of participation.

Variable	Total patient-weeks (n=5,684)	Patient-weeks by participating with informal caregiver		
		No (n=3,702)	Yes (n=1,982)	p value
Completed assessments (% of attempted)	83.7	81.6	87.7	**.008**
Diabetes-specific problems reported				
Symptoms of hypoglycemia	13.3	13.8	12.4	.533
SMBG < 90 mg/dL at least once[viii]	8.8	8.8	8.9	.928
Self-treatment of hypoglycemia	12.1	12.7	10.9	.456
Symptoms of hyperglycemia	12.9	14.0	10.9	.149
SMBG > 300 mg/dL at least 3 times[b]	1.4	1.8	0.7	**.021**
< 2-week supply of antihyperglycemic	2.9	2.9	3.0	.917
Low antihyperglycemic adherence[b]	1.4	1.5	1.1	.665
Not performing SMBG[ix] at least once	7.4	7.4	7.3	.978
Not checking feet daily	7.6	8.5	5.9	.261
Hypertension-specific problems (%)[x]				
SBP[xi] < 100 mmHg at least once[b]	2.6	2.4	3.0	.497
SBP > 130 mmHg at least half the time[b]	11.6	10.8	13.0	.349
< 2-week supply of antihypertensive	1.2	1.1	1.4	.603
Low antihypertensive adherence[b]	0.1	0.0	0.2	.070
Not checking SBP at least 3 days	11.2	13.0	7.8	**.017**
Not following low salt diet	9.8	10.3	8.9	.535
Clinical notifications[xii]				
Any notification	21.1	20.5	22.3	.507
Notification for ≥ 2 reasons	3.6	3.3	4.1	.459

Notes:

[vii] All rates are per 100 patient-weeks of participation, considering both attempted and completed assessments.

[viii] Triggers clinical notification.

[ix] Self-monitoring of blood glucose.

[x] Rates would be somewhat higher if calculated using only patients with hypertension and on antihypertensive as the denominator, as follows: SBP < 100 mmHg at least once: 2.9, SBP > 130 mmHg at least half the time: 13.1, < 2-week supply of antihypertensive: 1.4, low antihypertensive adherence: 0.1, Not checking SBP at least 3 days: 11.8, Not following low salt diet: 10.1.

[xi] Systolic blood pressure.

[xii] n=1189 notifications across 240 patients.

Table 3

Final logistic regression models predicting call completion and issuance of clinical notifications (n=5684 patient-weeks from 303 patients)

Variable	AOR[xiii]	95% c.i.	p value
Predictors of call completion			
Study week	0.96	0.94 - 0.97	**<.001**
Longer study duration[xiv]	0.68	0.43 − 1.09	.110
Participated with an informal caregiver	1.46	0.98 − 2.17	.061
Married	1.50	1.02 − 2.19	**.038**
Inadequate health literacy	0.67	0.45 − 0.98	**.039**
Elevated diabetes-related distress	0.30	0.11 − 0.81	**.018**
Antihyperglycemic nonadherence	0.57	0.39 − 0.82	**.002**
Predictors of clinical notifications Study week	0.95	0.93 − 0.96	**<.001**
Age (years)	1.03	1.01 − 1.04	**.004**
Physical functioning (PCS)	0.97	0.96 − 0.98	**<.001**
Elevated depressive symptoms	0.77	0.53 − 1.10	.147

Notes:

[xiii] Adjusted odds ratio.

[xiv] Three months versus six months.