Grant Final Report

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Enhancing self-management of T2DM with an Automated Reminder and Feedback System

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Abstract

Purpose: This was a prospective, randomized trial of a home-based, Automated Reminder and Feedback system to optimize self-management in type 2 diabetes mellitus (T2DM) compared to usual care.

Scope: T2DM occurs in 9% of adult Americans, 20% of those over age 65, and is more prevalent in ethnic minorities. Improved control delays development of complications, and healthy habits, if followed rigorously, are often more successful in prevention and/or control than medication. Despite this, many patients have suboptimal control, and do not eat properly or exercise regularly. Optimum control requires significant self-management.

Methods: Participants were recruited from Veterans Administration and community-based primary care clinics, and all had poorly controlled T2DM [glycated hemoglobin (A1c) levels $\geq$ 8%]. Study visits took place at baseline, 3months (randomization and installation of the system for the intervention group, IG), 9 and 15 months.

Results: Participants were successfully randomized to either the IG (N=101) or usual care (UC, N=99), and 170 completed 15 months. A1c decreased for all, 9.7$\pm$ 1.6% to 8.8 $\pm$ 1.6%, $p<0.0001$. Forty-three percent of the IG who completed the trial (N=38) used the system regularly, with an average drop of 0.5 points in A1c compared to 0.06 for infrequent users, $p<0.05$. Regular system users trended towards being older (62 vs. 59 years, $p=0.06$), had longer duration of disease (15.5 vs. 11.2 yrs, $p<0.003$), were more likely to be on insulin, and spent fewer hours in sedentary behavior at 15 months (TV time, 3.8 vs. 5.4 hrs/day, $p<0.008$).

Key Words: T2DM, self-management, SMBG

Final Report

Purpose

The original objective of the Enabling Patient-Centered Care through Health Information Technology grant initiative was to "explore the use of health information technology (IT) and related policies and practices to establish and enhance patient-centered care in ambulatory settings." As described in the request for applications (RFA), "patient-centered care is responsive to the needs and preferences of individual patients, provides patients with access to their medical information, and empowers patients to be active participants in care decisions and in the daily management of their health and illnesses."[1] Our research team focused on empowering patients to be more effective self-managers of their diabetes on a daily basis, and to help them better understand and interpret their individual medical information (e.g. measures of diabetes control), taking into account provider-recommended care plans and individual preferences (priority areas of the Institute of Medicine).[2] To this end we developed and refined an Automated Self-Management Monitor (ASMM) that assists patients in self care by prompting them to perform self-monitoring of blood glucose (SMBG) and to take their scheduled diabetes medications on time, as well as providing real-time, user-friendly feedback about the results obtained from SMBG.

The goal of the project was to demonstrate that the ASMM is an effective tool for providing feedback on efficacy of self-management skills (SMBG and taking medication) for a disease that is often asymptomatic, and to relate individual, "objective" glucose measures to overall glycemic control. The primary outcome was change in glycated hemoglobin (A1c). Specific aims and hypotheses of the study were to:

Specific Aim 1

Demonstrate that use of the ASMM improves glycemic control in persons with poorly controlled T2DM.

Hypothesis 1. Patients randomly assigned to receive the ASMM will have a greater reduction in A1c from the beginning of the intervention through 6 months of followup, compared to patients in a control group receiving usual care.

Specific Aim 2

Demonstrate that this effect could be sustained over longer term follow up.

Hypothesis 2. Patients randomly assigned to receive the ASMM will sustain their reduced A1c when compared to control patients after 12 months of follow up.

Specific Aim 3

Identify self management practices that improve in persons using the ASMM.

For this specific aim we tested a series of hypotheses comparing SMBG, diet composition and glycemic load, physical activity, weight control, and medication adherence between patients receiving the ASMM for 12 months and controls.

Scope

Background

Type 2 Diabetes Mellitus (T2DM) is one of the most prevalent chronic diseases in the US today.[3,4] It is increasingly prevalent with age, and occurs most often in the setting of other complex illnesses, such as hypertension. Despite randomized trial evidence showing that lowering average blood sugar delays the development of complications, up to half of diabetic patients have suboptimal blood glucose control. This is true even when considering the new control guidelines recommended by the American Diabetes Association (ADA) and the Veteran's Health Administration.[5,6]

Part of the difficulty patients have in attaining control is due to the complex nature of diabetes, with multiple potential factors that account for blood glucose levels at any given point in time. It is not surprising that patients struggle with interpreting self-monitoring of blood glucose (SMBG), when it is difficult for even the most expert health care provider to determine all the factors that may be impacting outcomes any point in time. If the incorrect factor is selected as the primary cause of an abnormal reading, the action taken to deal with that reading may not result in the anticipated effect. Dealing with acute blood glucose measures on a frequent basis, patients often lack an understanding of "overall" glycemic control, measured by glycated hemoglobin (A1c) levels, which are only checked on occasional visits to the health provider. Without such a global appreciation, it is not surprising that patients may feel anxious and stressed when individual readings are low or high and use these readings as the basis for health behavior choices on these highly variable measures. With frequent lack of a consistent relationship between health behaviors and glycemic levels, patients often abandon efforts to continue with special diets and physical activity as they don't "seem to make any difference." Based upon a lifetime experience of acute symptoms as indicators of illness, they often revert to using symptoms as indicators of disease control, rather than using objective blood glucose measures.[7] Unfortunately, as with many chronic conditions, symptoms are often unreliable as indicators of disease control. Generally with diabetes mellitus, feedback on overall success with glycemic control is highly dependent on infrequent glycated hemoglobin measurements (A1c) that are taken by health professionals (out of the persons' control), and removed in time and place from the behaviors affecting the reading. Misunderstanding of the relationship of A1c to SMBG measures has been documented.[8,9] All of these issues make the goal of having an "informed, activated patient" difficult to achieve, and research indicates that many patients with T2DM continue to have suboptimal self-management practices.[10]

Health care organizations have often sought to apply the Chronic Care Model to management of T2DM, a complex chronic disease requiring multiple modalities for successful management and control and which has been identified as a priority area for transforming health care by the Institute of Medicine.[2] These modalities include disease-focused management on the part of both the "prepared practice team" and health care system, and self-management by the "informed, activated patient" which interact in the context of a community and a health care system.[11]

Part of the difficulty in designing and studying self-management interventions for T2DM is the inherent complexity of the skills and knowledge required to do so. Standard care involves a complex regimen of medication and/or insulin and lifestyle changes, including increases in activity level, self-monitoring of blood glucose (SMBG), and dietary changes. Current estimates suggest that patients would have to spend 14 hours a week managing their diabetes to meet standard practice recommendations.[12]

Behavioral interventions, which have been shown to be efficacious in improving glycemic control, add additional time to a patient's regimen. The intensive, time-consuming lifestyle changes necessary in standard diabetic care may be causally related to the lack of long-term benefit. This complexity also does not easily lend itself to the standard "clinical trial" approach to demonstrate success of an intervention designed to support patient self-management. There is ample evidence suggesting that personal experience with a chronic condition such as diabetes leads patients to create a set of *experience-based beliefs* about the disease and its treatment. These beliefs can be accurate indicators of illness and health. We call these experience-based beliefs the *"common sense view"* of diabetes and treatment.[13,14] The common sense view may trump professional advice regarding T2DM self-management for several reasons. First, personal somatic sensations are readily available to the patient. This real-time input may be used preferentially to professional advice that came in a different environment at a different time. Moreover, these somatic sensations provide daily reinforcement, while professional advice is infrequent. Second, social support systems may reinforce the common sense view; for example, family members experiencing visible complications of diabetes are likely to feel worse than those who do not. Third, professional advice for self-management is oftentimes not borne out by experience. For example, blood glucose levels that rise because of short-term hormonal responses to exercise may be interpreted as evidence that exercise is bad for glucose control. Similarly, biological variability in blood glucose levels means that a single test may well be unusually high (or low) despite adhering (or not adhering) to professional recommendations.

This Common Sense View suggests several hurdles faced by a patient engaged in SMBG. First, s/he must perform the procedure, which is modestly uncomfortable, at prescribed times. Second, s/he must correctly interpret the result and the appropriate response. Finally, she must make that response, which may be something he prefers not to do. Breakdown may occur at each point in a person with poor glycemic control. If SMBG occurs primarily in response to somatic sensations, then the patient may conclude that the somatic sensations are accurately identifying the times when his blood glucose is out of the target range. If the patient is unclear on whether modestly elevated values are out of the desired range, s/he may not recognize them as an indication to further reduce caloric intake, increase physical activity, or seek professional guidance regarding medication adjustment.

The Common Sense View provides a theoretical framework which may explain the ambiguous evidence supporting the use of regular SMBG as an integral component of self-management of T2DM. Cross-sectional and longitudinal studies provide inconclusive support for this recommendation, while the majority of randomized trials do support a positive relationship

between SMBG and better glycemic control.[15] Obviously the act of performing SMBG in and of itself does not affect glucose levels; improvement in glycemic control due to performing SMBG likely results from how the measures affect patient behaviors. It is worth noting that SMBG has been less routinely effective in persons using oral agents. For these patients, it is less clear how the SMBG results should be used to change behavior. Such patients have typically already received advice to modify diet, reduce weight, and increase physical activities. Standard practice does not encourage patients to alter doses of oral hypoglycemic medications in response to SMBG values. Thus, the role of SMBG here should be to help the patient to understand the relationship of behaviors to glycemia, and to supporting self-management by providing ongoing feedback regarding the degree of control. If this "cognitive behavioral loop" is successfully integrated into the individual's Common Sense View, SMBG will lead to improved glycemic control.[16,17]

Settings and Participants

The study team targeted AHRQ priority populations residing in Milwaukee County, and receiving care through a Medical College of Wisconsin (MCW)-affiliated primary care clinic (either the Zablocki Veterans Administration (VA) Medical Center, or community-based primary care clinics), primarily serving low-income, inner-city, and minority and elderly patients. The intervention was specifically designed to address the Institute of Medicine Priority areas of self-management and diabetes, but the approach is also relevant to multiple other priority areas requiring patient self-management, including hypertension, obesity, and medication management. It may also function to improve care coordination by increasing patient activation to participate in their medical care, and as a future way to integrate consumer health IT with clinical health IT systems. The population recruited is described in the Methods section of this report in greater detail.

Methods

Study Design

This study was designed as a prospective, randomized trial of the ASMM, including a logic algorithm for improving self-management of T2DM (Intervention Group = IG) compared to usual care (UC) in adults with poorly controlled T2DM, defined as a glycated hemoglobin level (A1c) greater than or equal to 8%. The ASMM was composed of a personal computer and glucometer interface unit, requiring installation in the home. All participants were instructed to follow their primary care providers' (PCP) recommendations for diabetes management, and ASMM systems for the IG were programmed according to these recommendations. Participants were randomized to UC or IG three months after being enrolled into the study and were followed for 15 months after enrollment. Because the ASMM is a home-based system, all study interactions were conducted at participants' homes to maintain consistency, regardless of study group.

Participant Identification and Recruitment

A multi-step approach was taken for recruiting and enrolling participants into the study:

1. Fliers describing the study and seeking participants were posted in low-income community housing sites, and at primary care clinics affiliated with the Medical College of Wisconsin (i.e. the Zablocki VA Medical Center and Primary Care Initiative Clinics, which are clinics based in the greater Milwaukee Community).

2. Potential participants from the same outpatient clinics were identified by mining laboratory data from the participating clinics' electronic health record systems. Patients with A1c measures in the 4 weeks prior to recruitment that were greater than or equal to 8% were identified from laboratory records. Primary care providers (PCPs) were informed of the intent to invite their patients to participate, and asked to advise the research team if they felt the patient would not be appropriate for the study. Based on PCP recommendations, letters that briefly described the study and offered an opportunity to obtain additional information about it were then mailed to remaining eligible participants. Eligible participants could accept or decline participation by calling the study coordinator's phone number or by appropriately marking and mailing an enclosed pre-addressed and stamped postcard. Those who did not respond within two weeks were contact by phone and invited to participate verbally.

Patients were invited to participate in the study based on the following inclusion criteria:

1. Diagnosis of T2DM

2. Willing and able to identify the provider who primarily manages the T2DM

3. Glycated hemoglobin (A1c) greater than or equal to 8%

4. Receiving pharmacological treatment for T2DM (oral medication and/or insulin)

5. Has received a glucometer

6. Has obtained glucometer strips within the prior 24 months

7. Has a permanent place of residence

8. Speaks English

Patients were excluded from the study based on the following criteria:

1. Unwilling to perform SMBG

2. Plans to spend more than 3 months or move their primary dwelling outside Southeastern Wisconsin during the following year

3. Unwilling or unable to have electronic equipment installed in the home

4. Unwilling to have home visits

5. Unwilling to have us contact their PCP regarding medication and SMBG schedule

6. Comorbidity likely to predict life expectancy of less than 2 years including, active chemotherapy or radiation therapy for solid tumors (except hormonal therapy for prostate cancer); hospice enrollment; cirrhosis; end-stage renal disease; two or more admissions for congestive heart failure within 6 months; and lung disease requiring supplemental home oxygen

7. Laboratory abnormalities and conditions likely to affect A1c including, hemoglobin of less than 9; beta thalassemia; sickle thalassemia; hemolytic anemia; and receiving erythropoietin

If the patient was eligible and willing to participate, a research assistant (RA) scheduled a home visit during which the RA obtained written informed consent and enrolled participants in the study. Glycemic status was then verified by measurement of A1c with a fingerstick blood sample. Those with A1c levels less than 8% were screen failures and were not continued in the study. If the A1c was greater than or equal to 8%, the participant was oriented to the study, provided with a glucometer to be used during the study and strips, had SMBG technique observed and corrected, and the home assessed to ensure that the ASMM could be installed at the next visit. All participants were given an informational brochure, "Living Well with Diabetes: a guide for staying healthy," developed by the Clinical Diabetes Center at Montefiore Medical Center, and provided by Abbott (2008).

Data Sources and Collection

Data were collected from participants during home study visits by a research assistant (RA) and dietician RA. Visits occurred at baseline, 3 months (when participants were randomized to UC or IG, and the ASMM installed), 9 months, and 15 months. During each home visit the RA administered a series of questionnaires, which were available to study staff on a software program called RedCap, using templates maintained on study laptop computers. The RA recorded participants' responses in the computer templates. During the home visits the RA also downloaded glucometer readings and obtained a fingerstick blood sample to measure A1c. If the participant was in the IG, information logged in the ASMM at the 9 and 15 month visit was downloaded onto study laptops. The dietician RA met with participants at separate visits at 3, 9 and 15 months, to review and collect diet information using 3-day food diaries.

Descriptive Data. Standard survey questions were used to collect participant demographics, alcohol and tobacco use, diabetes history, and other medical history and medication regimens. At every visit participants were weighed and had waist circumference measured using the same portable scale and weighted tape measure and wearing typical indoor clothing.

Descriptive Data: Primary Outcomes. The primary outcome measure was A1c, measured with the DCA 2000+ portable monitor (Bayer Inc., Tarrytown, NY) which provides reliable and accurate results compared to routine laboratory testing.

Descriptive Data: Secondary Outcomes. Secondary outcomes included measures of self-management behaviors:

- SMBG frequency: Each participant's glucometer was reviewed at baseline, and the number of readings over the prior two weeks was recorded to estimate pre-enrollment SMBG patterns. Participants were then provided with a Precision Xtra® glucometer (Abbott) and a supply of strips. The RA manually downloaded glucometer data at each visit, after checking calibration.

- Diet: Diet content was measured using a 3-day food diary at the 3 (representing baseline diet), 9, and 15 month visits. Participants were instructed on the procedure for completing the diaries at baseline and provided with the diary. An additional copy of the diary and written directions were mailed 2 weeks prior to each ensuing visit. Food diaries were reviewed with the dietician RA at a separate home visit at each time point. This approach helped to ensure more accurate completion of the food record and keep individual visits under 90 minutes.

- Physical activity: Physical activity was assessed using the Modified Activity Questionnaire, which asks about physical activities related to both occupational and leisure time.

- Medication adherence: Self-reported adherence was assessed using the Medication Adherence Rating Scale (MARS) adapted for diabetes. The RA reviewed diabetes medications at each visit, asking to see pill and insulin containers and noting any new medicines or changes in dose.

- Self-Efficacy: self-efficacy for self-managing diabetes was measured using a standard scale. This scale asks how confident patients feel in their ability to manage their diabetes. Because the intervention focused on self-management, formal assessment of the participants' experience with care was not conducted. At the end of the trial, participants in the IG group were also asked about their satisfaction with the ASMM and how it may have been more helpful, with a few open-ended questions.

- Quality of Life (QOL): QOL was measured with the SF-12 Health Survey.

Descriptive Data: Outcome Moderators. These are factors that could potentially influence the participants' ability to understand and respond to information provided by the ASMM system.

- Depression: Depression was measured with the CES-D 10.

- Anxiety and neuroticism: were measured using the subscale from the NEO-Personality Inventory.

- Cognitive function: Cognitive status was screened with the St. Louis University Mental Status Exam (SLUMS) and executive function with the Compustroop Task.

- Health literacy and numeracy: health literacy was measured with the REALM-R and numeracy using Schwartz Numeracy Scale.

- Active patient orientation: Participants' receptiveness to information and self care was assessed using the well established Krantz Health Opinion Survey.

- Fear of hypoglycemia: We will measure fear of hypoglycemia using the 27-item scale developed by Cox, and adapt the same scale to assess fear of hyperglycemia.

- Functional status and self-assessed health: Functional status was assessed with the Lawton's Instrumental Activities of Daily Living (IADLs) and Katz ADLs, and the 2-item Self-Assessed Health scale.

- Social Support: Social Support was assessed with the Medical Outcomes Study Social Support Survey.

- Common Sense Beliefs about Diabetes (CSB): CSB were assessed with a set of 18 items asking about such factors as perceptions of disease chronicity or acuity, role of symptoms, and factors affecting control.

Intervention

The ASMM, provided by the study, consisted of a personal computer and a specially designed glucometer interface unit. The special interface is a basic, ergonomically designed box device with a slot for inserting the glucometer, and single buttons identified by mnemonic symbols to simplify patients' use. All required system functions could be accomplished through this single interface, enabling those participants with limited exposure to or lack of confidence with computers to participate in the study. At initial setup, the ASMM was programmed to provide audio reminders to perform SMBG and take diabetic medications according to a management interval schedule guided by the participant's primary provider, and timed to fit each person's daily routine. Once programmed, the ASMM generated an audio reminder each time a blood glucose level was to be checked or medication taken, starting 30 minutes after the programmed "usual time." This was repeated at 15 minute intervals for up to one hour, or until the participant pushed the button indicating that they did check their blood sugar or that a medication was taken, or the glucometer was placed in the interface slot. If the action was not completed within this 90 minute interval, the ASMM automatically reset for the next programmed event. In cases where a participant downloaded a glucose measure within the expected timeframe, prior to receiving a reminder, no reminder was generated.

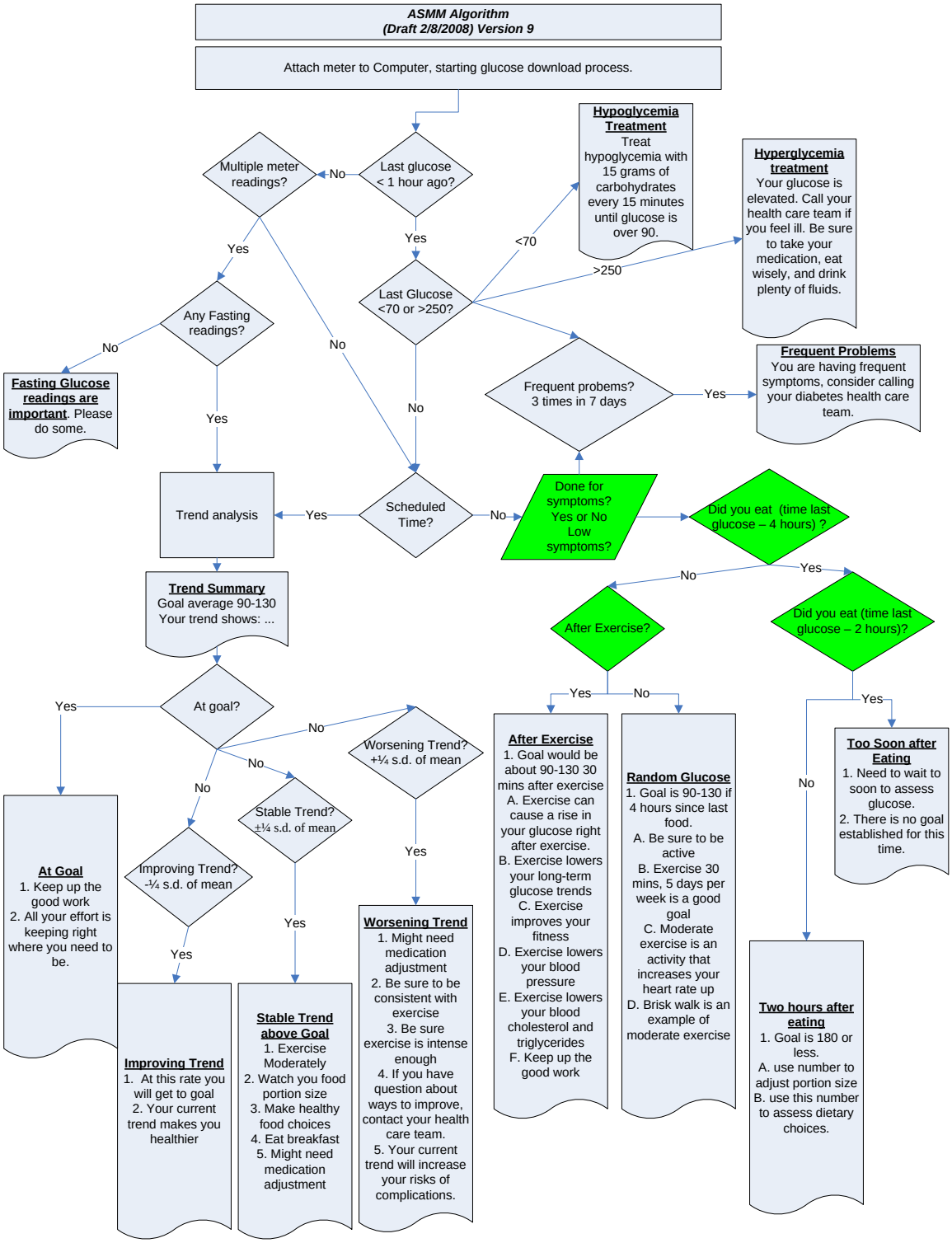
Feedback. The ASMM provides immediate and "long-term" feedback regarding SMBG, designed to educate the user on the effectiveness of their control and to encourage appropriate responses to extreme values. The feedback algorithm accounts for the fact that participants may not adhere perfectly to their proposed SMBG schedule (Figure 1). Immediate Feedback:

Immediately after each download the ASMM repeats the most recent reading (e.g., “1-0-8”) and the time it was obtained. For readings within target range, the ASMM states that the reading is within the target range. For readings below target range, the ASMM states the reading is below the target range. Depending on the level, and when it was obtained, the ASMM will provide advice on eating something or ingesting rapidly-absorbed supplements to raise the level and suggest a time-frame for repeating the measure, which will be reinforced by reminders. If the measure is persistently and dangerously low the ASMM advises the participant to contact their PCP. For readings above target range, the system states that it is above the desired target range, and provides advice to increase fluid intake, avoid specific foods, and increase physical activity, referring the patient to the teaching materials provided to all study subjects at baseline. For measures above a predefined safety level of 450 mg/dl, they are asked to repeat the measure in 1 hour. Persistent elevation prompts advice to contact the PCP.

Long Term Feedback. With each fasting measure, the ASMM provides feedback on the average glucose for that time of day based on the prior 25 readings, indicates the direction in which glucose levels have been trending and relates this to goal values. For example, if the average fasting glucose is 140, and a value of 118 is measured, the system would state the average, and provide feedback that the current measure is a downward trend and within goal range. Trend feedback is based on fasting measures, as these are the most significant predictors of A1c in poorly-controlled T2DM.18 The ASMM suggests that the participant contact their PCP team for advice if mean fasting blood sugars are more than 80 mg/dl over one month compared to the preceding month. For ASMM feedback related to trend, extreme values (greater than 80 mg/dl away from the mean) are excluded to avoid the undue influence of outlier values.

- Maintenance: All participants were instructed to contact the research team if their provider changed their diabetic medications or SMBG regimen so the ASMM programming could be updated. For participants in the UC, we recorded the change but took no actions.

Figure 1. Logic algorithm for interpretation of blood glucose and feedback



Results

Subjects

A total of 1,143 subjects were identified with an A1c greater than or equal to 8% and invited to participate in the study, 694 of these were from VA based primary care clinics and 449 from MCW–affiliated, community-based primary care clinics (Figure 2). Out of the identified subjects, 761 declined participation, and 155 were found to have an A1c less than or equal to 8% at their initial home visit. A total of 227 subjects were enrolled in the study for the baseline visit. Of these, twenty seven subjects elected not to continue prior to randomization at the three month visit, leaving a total of 200 subjects, 99 randomized to the UC and 101 to the IG. A total of 170 subjects completed the final 15 month visit, 81 in the UC and 89 in the IG (Figure 2). Demographic and clinical characteristics (including Targeted Enrollment) of the randomized participants are shown in Table 1.

Figure 2. Recruitment and randomization sequence

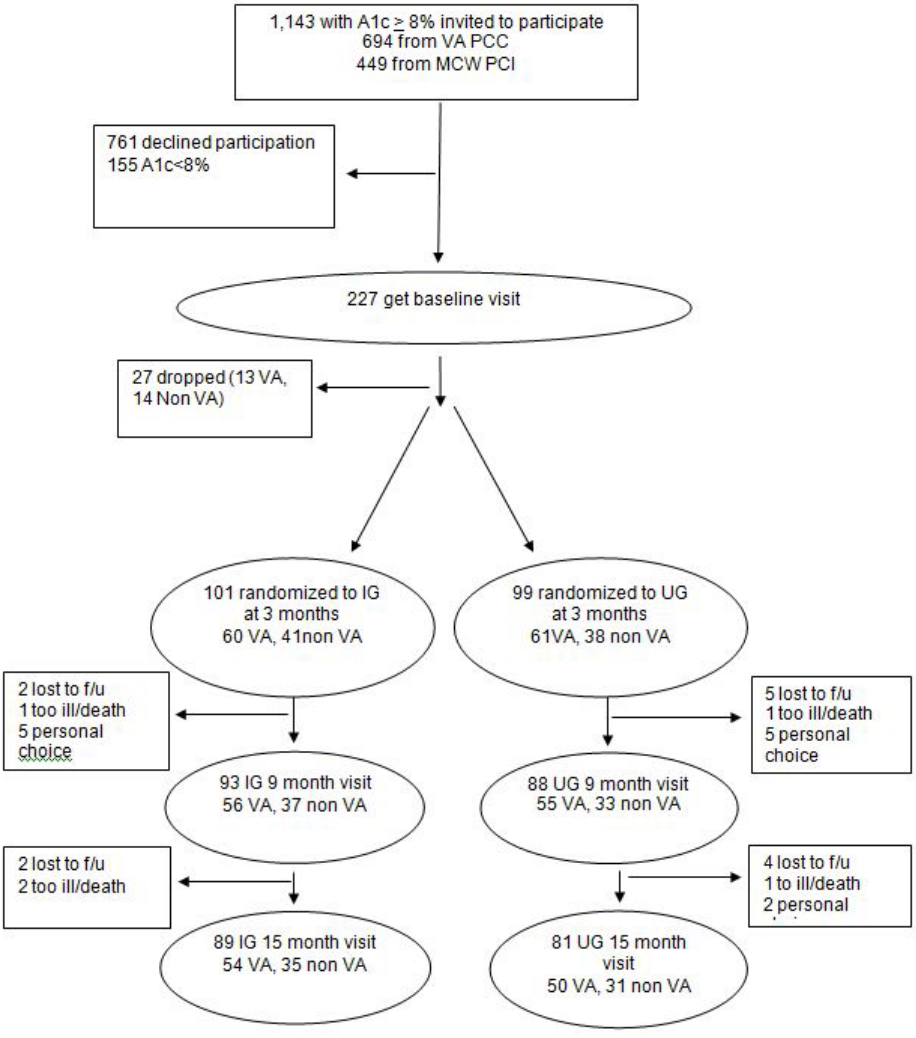


Table 1. Demographic and disease characteristics of study population randomized to UC and IG

Characteristics	Control (N=99)	Intervention (N=101)	p-value
Age (mean ± std)	59.5 ± 11.3	59.5 ± 10.5	0.6471
Recruited from VA	61	59	0.6442
Male	78	76	0.5519
Race			0.8134
Race: Male Caucasian	54	50	
Race: Female Caucasian	10	16	
Race: Male African American	24	18	
Race: Female African American	10	7	
Race: Male Hispanic	2	1	
Race: Female Hispanic or Latino	2	1	
Race: Male Native American	0	1	
Race: Female Native American	2	2	
Race: Male Other	2	4	
Race: Female Other	0	0	
Education			0.3382
Education : High School or below	47	38	
Education : Vocational, Trade, or some College	39	45	
Education : College Graduate or higher	13	18	
Income			
Income: Less than 15,000	25	25	0.2917
Income: 15,000-29,999	20	23	
Income: 30,000-49,999	14	23	
Income: More than 50,000	20	13	
Employed	31	40	0.2205
BMI	36.0 ± 9.2	35.9 ± 7.0	0.8547
Duration of T2DM, years	12.7 ± 8.5	13.4 ± 9.5	0.8156
Medication Regimen			
Medication Regimen: Metformin	55	54	0.7666
Medication Regimen: Sulfonylurea	30	33	0.7183
Medication Regimen: Other	9	11	0.6714
Medication Regimen: Two oral medications	23	29	0.3770
Medication Regimen: Insulin	68	69	0.9551
Medication Regimen: Insulin and oral medication	38	35	0.5838

BMI = body mass index

The UC and IG were well-matched in regard to all these characteristics at the time of randomization, with no significant differences between the two groups in these parameters or secondary measures and moderators (Table 2). Approximately 30% were African American and 5% other ethnic minorities, and half reported annual incomes less than $30,000 annually, meeting the goals of the project to over-sample AHRQ priority populations. Most of the participants were obese, with an average BMI greater than 35. Average duration of diabetes was 12.7 ± 8.5 years for the control group and 13.4 ± 9.5 for the intervention group. With regards to medication use, 54.5% of subjects were on metformin, 26% were on two oral medications for their diabetes, 68.5% were on insulin, and 36.5% were on combination insulin and oral medication (Table 1). Secondary measures and moderators were also similar for the UC and IG (Table 2).

Table 2. Secondary and moderating measures at baseline

Measures	Control (N=99)	Intervention (N=101)	p-value
Any Type of Physical Activity	84 (84%)	92 (91%)	0.1745
Most Popular Types of Physical Activity (hrs/wk): Walking	4.9 ± 5.9	4.3 ± 4.0	0.9274
Most Popular Types of Physical Activity (hrs/wk): Gardening	8.3 ± 15.1	6.5 ± 13.3	0.8341
Most Popular Types of Physical Activity (hrs/wk): Bicycling	4.9 ± 5.4	3.2 ± 2.3	0.9512
Most Popular Types of Physical Activity (hrs/wk): Calisthenics Toning	4.2 ± 4.3	2.5 ± 1.9	0.5944
Most Popular Types of Physical Activity (hrs/wk): Strength Weight	3.2 ± 2.4	3.1 ± 1.9	0.8822
Sedentary Time (hrs/day): TV Hours Unemployed	5.8 ± 4.5	4.9 ± 3.5	0.4604
Sedentary Time (hrs/day): TV Hours Employed	2.8 ± 2.1	3.1 ± 2.1	0.6208
Sedentary Time (hrs/day): Weeks Confined Unemployed (N=17)	3.0 ± 3.1	11.5 ± 19.9	0.1856
Sedentary Time (hrs/day): Weeks Confined Employed (N=7)	3.2 ± 2.5	2.8 ± 1.7	1.000
MARS	28.9 ± 3.2	28.7 ± 4.3	0.5352
Self-Efficacy: Total	35.9 ± 13.3	36.0 ± 14.3	0.8449
Self-Efficacy: Ability	10.5 ± 4.4	10.3 ± 4.2	0.7280
Self-Efficacy: Worry	3.6 ± 2.8	3.4 ± 2.5	0.7569
Self-Efficacy: Satisfaction	21.9 ± 10.8	22.5 ± 11.5	0.6679
SF12: Physical	44.1 ± 6.9	43.9 ± 7.0	0.8796
SF12: Mental	42.2 ± 7.6	42.9 ± 8.3	0.4444
Cognition Checklist (CES – D10): Depression	10.1 ± 9.0	10.3 ± 7.7	0.4667
Cognition Checklist (CES – D10): Anxiety	1.6 ± 1.9	1.8 ± 1.6	0.2296
Cognition Checklist (CES – D10): SLUMS	23.7 ± 4.4	23.9 ± 4.1	0.9044
Cognition Checklist (CES – D10): Compustroop2 by error	83	82	0.7076
Health Literacy: REALM	6.2 ± 2.3	6.1 ± 2.5	0.7004
Health Literacy: Schwartz Numeracy	1.8 ± 0.9	1.7 ± 0.9	0.3665
Participatory Decision Making: Paternalistic View on Medicine	4.2 ± 3.0	4.4 ± 3.2	0.8039
Participatory Decision Making: Participatory View on Medicine	4.3 ± 1.8	4.2 ± 2.3	0.6264
Fear Hyperglycemia	19.8 ± 9.3	19.5 ± 8.7	0.7297
Fear Hypoglycemia	8.3 ± 10.4	11.7 ± 12.8	0.0628
ADLs	0.48 ± 0.88	0.41 ± 0.89	0.4445
IADLs	2.3 ± 2.5	2.2 ± 2.5	0.6789
Social Support (MOS): Positive	25.6 ± 8.6	25.6 ± 7.2	0.6622
Social Support (MOS): Negative	4.9 ± 2.9	4.8 ± 2.9	0.6974

SLUMS= St. Louis University Mental Status Exam

Veteran participants comprised 60% of the participants, and while they were older (61+9.6 vs. 56+12.3 years, $p<0.005$), they had similar ethnic and racial, educational, and employment profiles as the non-veteran participants. Veteran participants, were younger at time of T2DM diagnosis (43.6+11.7vs. 47.8+10.7 years, $p<0.02$) and were more likely to be on combination treatment with insulin and oral medications ($p<0.009$) than non-veteran participants.

Primary Outcomes

Baseline A1c was similar for both UC and IG, and was higher in those of greater age ($p=0.05$), higher BMI ($p<0.02$), and greater waist circumference ($p=0.0007$). Glycated hemoglobin decreased for all participants over the study period, 9.7+ 1.6% to 8.8 + 1.6%, $p<0.0001$. There was not a significant difference overall in the magnitude of decline for the UC vs. the IG, or for VA participants vs. community participants (Table 3). Closer examination of the IG revealed three patterns of use; 20% appeared to not use the system at all, or requested that it be removed; 37% were infrequent users, interacting with the system either on a short-term basis (1 to 2 months), or sporadically over the entire period (less than once every 2 weeks); and

the remaining 43% utilized the system on a regular basis. Of this latter group, the more the system was used, the lower that person's average glucose level. Individuals who docked on average at least once in a 2-day period had an additional decrease in glucose level of 1.4 mg/dl ($p<0.0001$) when compared to those who docked less frequently. This group of frequent users had an average drop of 0.5 points in A1c compared to 0.06 for the infrequent users, $p<0.05$ (Figure 3). Those regularly using the system during the final phase of the study (months 9 to 15), had an average decrease of 0.63 points in A1c vs. 0.12 for infrequent users, $p<0.008$ (Figure 3). Frequent system users trended towards being older (62 vs. 59 years, $p =0.06$), had longer duration of disease (15.5 vs. 11.2 yrs, $p<0.003$), and were more likely to be on insulin. At baseline they also had a greater fear of hypoglycemia, and scored higher on worry items related to diabetes self-management (Table 4).

Table 3. Glycated hemoglobin A1c levels over the study period

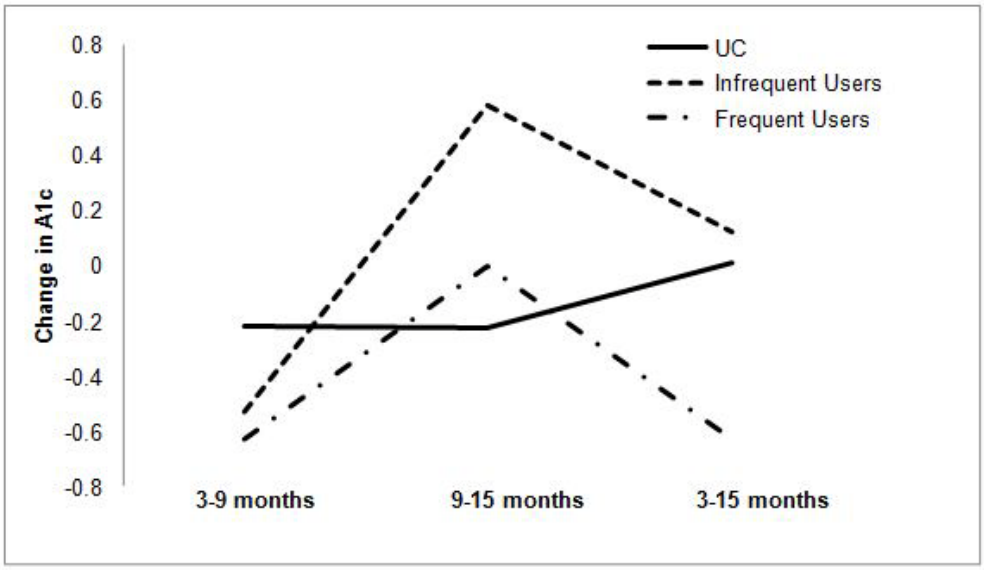
Table 3a.

Time Point	Control: N	Control: Mean ± Std	Intervention: N	Intervention: Mean ± Std	p value
Baseline	112	9.63 ± 1.5	115	9.71 ± 1.8	0.5513
Month 3	99	8.92 ± 1.4	101	8.98 ± 1.6	0.8632
Month 9	88	8.73 ± 1.4	90	8.62 ± 1.5	0.3303
Month 15	81	8.70 ± 1.6	89	8.79 ± 1.6	0.9378

Table 3b.

Time Point	VA Participants: N	VA Participants: Mean ± Std	Community Participants: N	Community Participants: Mean ± Std	p value
Baseline	134	9.62 ± 1.6	93	9.75 ± 1.7	0.5297
Month 3	119	9.06 ± 1.5	81	8.80 ± 1.4	0.2275
Month 9	109	8.70 ± 1.3	69	8.62 ± 1.7	0.3213
Month 15	91	8.78 ± 1.5	79	8.78 ± 1.6	0.9891

Figure 3. Change in A1c for frequent vs. infrequent ASMM users in the intervention group*



* Negative number indicates greater decline from prior time points, while a positive number indicates average increase in A1c levels compared to prior time points.

Table 4. Baseline measures for frequent and infrequent users between 3 months and 15 months

Measures	Infrequent Users (N=33)	Frequent Users (N=38)	p-value
Age (mean ± std)	59.3 ± 10.2	62.0 ± 8.7	0.0605
Recruited from VA	20 (61%)	23 (61%)	0.9945
Male	23 (70%)	28 (74%)	
Race			0.9063
Race: Caucasian	21 (64%)	25 (66%)	
Race: African American	10 (30%)	10 (26%)	
Race: Other	2 (6%)	3 (8%)	
Education			0.4541
Education: High School or below	12 (36%)	12 (31%)	
Education: Vocational, Trade, or some College	17 (52%)	17 (45%)	
Education: College Graduate or higher	4 (12%)	9 (24%)	
Employed	14 (42%)	15 (39%)	0.8008
BMI	36.9 ± 7.3	35.4 ± 6.9	0.5919
Duration of T2DM, years	11.2 ± 10.7	15.5 ± 8.9	**0.0026**
Cognitive Function: SLUMS	23.9 ± 4.1	24.4 ± 3.8	0.7942
Health Literacy: REALM	5.8 ± 2.7	6.4 ± 2.3	0.3628
Health Literacy: Schwartz Numeracy	1.6 ± 0.9	1.8 ± 0.8	0.3848
Medication Regimen: Metformin	19 (58%)	18 (47%)	0.3905
Medication Regimen: Sulfonylurea	19 (58%)	5 (13%)	**<0.0001**
Medication Regimen: Other	2 (6%)	6 (16%)	0.2705
Medication Regimen: Two oral medications	13 (39%)	7 (18%)	**0.0501**
Medication Regimen: Insulin	15 (45%)	30 (79%)	**0.0035**
Medication Regimen: Insulin and oral medication	8 (24%)	14 (37%)	0.2522
Fear Hyperglycemia	18.4 ± 9.8	19.4 ± 7.1	0.5218
Fear Hypoglycemia	7.5 ± 10.6	14.1 ± 11.6	**0.0066**
MARS	29.5 ± 3.8	28.6 ± 3.9	0.1826
Self-Efficacy: Total	37.2 ± 14.4	33.5 ± 12.9	0.2141
Self-Efficacy: Ability	10.4 ± 4.2	9.8 ± 3.7	0.4781
Self-Efficacy: Worry	2.7 ± 2.1	3.9 ± 2.4	**0.0272**
Self-Efficacy: Satisfaction	24.1 ± 12.8	20.4 ± 10.1	0.1316
ADLs	0.52 ± 1.2	0.26 ± 0.62	0.3134
IADLs	2.2 ± 2.8	2.2 ± 2.2	0.6727
Any Type of Physical Activity	31 (94%)	36 (95%)	0.8844
Most Popular Types of Physical Activity (average hrs/week): Walking	5.3 ± 4.2	4.1 ± 3.6	0.3994
Most Popular Types of Physical Activity (average hrs/week): Gardening	4.4 ± 5.1	10.8 ± 21.0	0.2735
Most Popular Types of Physical Activity (average hrs/week): Bicycling	3.6 ± 2.3	2.9 ± 2.9	0.2220
Most Popular Types of Physical Activity (average hrs/week): Calisthenics Toning	5.0 ± 2.8	1.9 ± 1.0	0.1527
Most Popular Types of Physical Activity (average hrs/week): Strength Weight	3.0 ± 2.8	3.5 ± 3.5	1.000
Sedentary Time (hrs/day): TV Hours	3.7 ± 2.8	4.3 ± 2.8	0.3754
Social Support (MOS): Positive	24.9 ± 7.3	25.6 ± 6.7	0.6902
Social Support (MOS): Negative	4.9 ± 2.9	4.0 ± 2.5	0.2257
Cognition Checklist (CES – D10): Depression	10.5 ± 7.5	9.5 ± 7.1	0.5464
Cognition Checklist (CES – D10): Anxiety	2.2 ± 1.8	1.4 ± 1.5	0.0751
Participatory Decision Making: Paternalistic View on Medicine	4.8 ± 2.8	4.5 ± 3.4	0.6362
Participatory Decision Making: Participatory View on Medicine	4.5 ± 2.4	4.2 ± 2.1	0.5400
SF12: Physical	43.4 ± 6.5	43.7 ± 6.6	0.8582
SF12: Mental	42.2 ± 8.7	43.9 ± 7.6	0.4164
A1C: Baseline	9.8 ± 1.8	9.3 ± 1.3	0.3068
A1C: Month 3	9.1 ± 2.0	8.9 ± 1.2	0.7996
A1C: Month 9	8.5 ± 1.5	8.4 ± 1.3	0.5911
A1C: Month 15	9.0 ± 1.9	8.4 ± 1.3	0.1126
A1C: Delta between 3-15	-0.06 ± 2.1	-0.49 ± 1.1	**0.0473**

Secondary Outcomes

SMBG Frequency. The average number of glucose checks for the two weeks prior to study enrollment averaged less than once a day for all participants (Table 5). The rate increased by at least two-fold after enrollment, and remained fairly steady for the duration of the trial, though it dropped off slightly in the last six months. UC and IG on average performed fasting SMBG at the same frequency each week (Table 5).

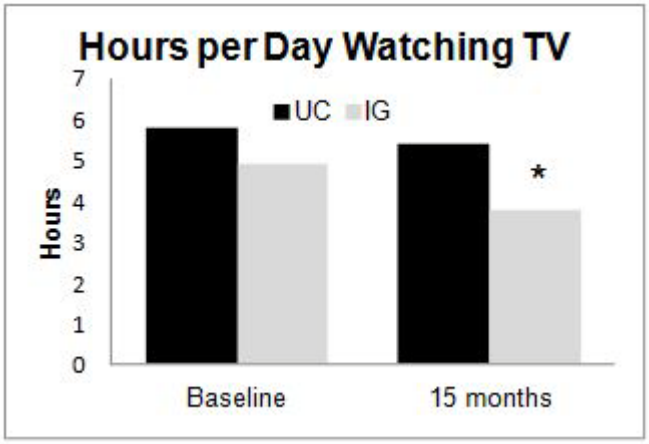
Table 5. Average frequency of SMBG as finger sticks per week

	UC	IG	p value
Pre-enrollment	4.3 ± 3.2	3.9 ± 3.2	0.7431
Baseline – 3 mo FSBS	9.5 ± 7.1	8.5 ± 7.6	0.2058
3 mo – 9 mo FSBS	8.7 ± 7.1 (N=85)	9.5 ± 6.2	0.2474
9 mo – 15 mo FSBS	7.8 ± 5.7 (N=79)	7.8 ± 5.8	0.9528

Medication Changes. We hypothesized that the VA electronic health record system, which has built-in alerts and reminders of standards for managing T2DM, might make VA providers more likely to increase doses of diabetes medicines, add more medications, and/or more often prescribe insulin. Initial analyses of medication changes over time show that community participants were indeed less likely to be prescribed new medications or have their medication dose increased compared to VA participants, 24% vs. 41%. All participants were given copies of study A1c results that might be shared with their primary providers. It was not possible to accurately determine if this was done, but it is more likely that systems factors were responsible for the prescribing differences observed. There was no difference in patterns of medication change (increase, decrease, no change) between UC and IG, or regular and non-regular system users (Fisher's Exact test $p = 0.94$, and 0.45 respectively). The fact that 45 percent of all participants had no change in medication over the 15-month course of the trial (despite high A1c measures) is an interesting observation, and may represent provider inertia.

Physical Activity. Self-reported exercise at baseline for the five most commonly engaged-in activities is noted in Table 2. Sedentary activity was estimated based on average number of hours daily spent watching TV. There were no apparent differences between the UC group and IG, or frequent and infrequent IG users at baseline (Table 2 and 4). However, at 15 months, the IG group reported fewer hours of TV watching per day, $p<0.008$ (Figure 4).The relatively small numbers of participants reporting different types of activities and lack of actual performance data made it difficult to determine if the decrease in sedentary behavior was mirrored by an increase in physical activity.

Figure 4. Change in sedentary behavior



Diet. A summary of 3-day food diaries at 3, 9, and 15 months is presented in Tables 6 to 8. There were no significant differences between the UC or IG, little or no difference between VA vs. community-based participants, and little change in diet composition reported over the course of the study. In multiple logistic regression analyses, none of the dietary components accounted for A1c levels.

Table 6. Month 3 diet

	Control (N=75)	Intervention (N=72)	p-value
Available Carbohydrates	203.8 ± 90.8	205.6 ± 89.4	0.6837
Glycemic Index Bread	85.8 ± 12.0	87.0 ± 9.7	0.4592
Glycemic Load Glucose	123.0 ± 56.7	125.9 ± 60.1	0.6098
Total Carbohydrates	223.9 ± 97.8	225.8 ± 94.8	0.6619
Total Fiber	19.3 ± 11.1	19.4 ± 9.8	0.6677
Total Fat	89.7 ± 48.3	90.7 ± 53.5	0.7889
Total Protein	95.3 ± 39.7	93.7 ± 43.9	0.5857
Percent Calorie Carbohydrate	43.4 ± 10.8	43.8 ± 11.5	0.7742
Percent Calorie Fat	37.4 ± 9.1	37.4 ± 10.8	0.8045
Percent Calorie Protein	19.0 ± 5.3	18.4 ± 5.7	0.1270
Energy	1837. 3 ± 354.0	1795.7 ± 328.3	0.7312

Table 7. Month 9 diet

	Control (N=75)	Intervention (N=72)	p-value
Available Carbohydrates	199.4 ± 71.3	191.9 ± 70.2	0.4747
Glycemic Index Bread	87.3 ± 8.3	88.2 ± 7.2	0.3961
Glycemic Load Glucose	123.0 ± 47.9	118.6 ± 45.6	0.6517
Total Carbohydrates	221.5 ± 82.6	210.1 ± 74.4	0.4372
Total Fiber	20.2 ± 8.6	17.3 ± 6.3	0.0561
Total Fat	85.1 ± 39.9	83.2 ± 44.9	0.4783
Total Protein	89.7 ± 30.9	81.1 ± 29.7	0.0961
Percent Calorie Carbohydrate	44.1 ± 8.9	44.8 ± 8.1	0.4125
Percent Calorie Fat	36.4 ± 8.9	36.9 ± 8.3	0.8937
Percent Calorie Protein	18.8 ± 5.5	17.6 ± 3.4	0.2653
Energy	1992.4 ± 652.8	1898.9 ± 731.6	0.2587
Glycemic Load Bread	175.9 ± 68.5	169.5 ± 65.2	0.6517
Glycemic Index Glucose	61.1 ± 5.8	61.7 ± 5.1	0.3972
Fructose	15.3 ± 11.3	15.3 ± 10.1	0.9151

Table 8. Month 15 diet

	Control (N=67)	Intervention (N=65)	p-value
Available Carbohydrates	191.4 ± 67.3	206.8 ± 109.9	0.3972
Glycemic Index Bread	85.5 ± 8.2	86.2 ± 8.3	0.8306
Glycemic Load Glucose	115.3 ± 43.5	125.8 ± 67.1	0.3555
Total Carbohydrates	210.9 ± 72.5	227.0 ± 113.1	0.3723
Total Fiber	18.8 ± 8.3	19.1 ± 7.9	0.6262
Total Fat	87.6 ± 37.3	84.8 ± 38.5	0.6921
Total Protein	89.1 ± 33.3	85.8 ± 32.5	0.5849
Percent Calorie Carbohydrate	42.7 ± 8.6	44.5 ± 8.9	0.1465
Percent Calorie Fat	38.4 ± 7.5	36.7 ± 8.5	0.1206
Percent Calorie Protein	18.5 ± 3.9	18.1 ± 5.8	0.1637
Energy	1969.9 ± 677.3	1997.8 ± 777.2	0.7604
Glycemic Load Bread	164.7 ± 62.1	179.7 ± 95.9	0.3531
Glycemic Index Glucose	59.8 ± 5.7	60.3 ± 5.8	0.8306
Fructose	16.8 ± 11.2	18.6 ± 18.5	0.8806

Common Sense Beliefs. Common sense beliefs (CSB) about diabetes were assessed at baseline and a preliminary factor analysis completed on the 18 items; these items segregate into five main factors, addressing beliefs about 1) causes of T2DM (e.g., behaviors vs. genes), 2) ability to control the disease, 3) beliefs about symptoms, 4) beliefs about consequences, and 5) beliefs about timeline of the disease. The Medication Adherence Rating Scale (MARS) segregated into three factors: 1) forgetting to take medications, 2) avoiding taking medications, and 3) taking medications when symptomatic. At baseline, the sum of CSB and the sum of the MARS were significantly related to A1c levels; for example, those rating T2DM as a more acute condition that is controlled/quiescent when asymptomatic, or not related to health behaviors, had higher A1c levels; and, similarly, those who reported not taking medications when they were asymptomatic, had higher baseline A1c measures.

Conclusions

In this trial the only factors which appeared to be associated with change in A1c in multivariate regression models were age and regular use of the ASMM intervention: none of the other secondary measures or moderators (i.e. physical activity, diet composition, medication dose, self-efficacy, functional status, health literacy, numeracy, cognitive status, participatory decision making, social support, depression, or anxiety) predicted A1c level. We hypothesize that more frequent users responded to the feedback by making adjustments to their self-management behaviors, but the standard measures used may not have had enough sensitivity to detect significant changes in this relatively small group of individuals. Although CSB and MARS were associated with baseline glycemic levels, the number of participants may have been too small by the end of the study to detect significant effects over time. The findings suggest the need to consider patient models of illness when designing such interventions in order to achieve greater overall efficacy than other moderating factors.

Limitations and Challenges

The biggest limitation of this study, and one that likely held the greatest implications for the primary outcome, was that the majority of participants randomized to the IG did not use the

system, and, therefore, did not receive feedback based on their SMBG results. A small group of participants, 20%, refused the system outright, although they continued in the study. Another 37% accepted the system but used it only a few times or sporadically. The primary reasons given for lack of use were related to technological problems. If the system stopped working as anticipated, participants simply continued with their usual self-management without contacting the study team, and problems were only discovered at the next home visit. Another issue was the stationary nature of the system limiting use to the home setting only – those testing at work or away from home were unable to access the ASMM for downloading and, therefore, would not receive feedback, which was only given in "real time." Eighty percent of the IG group reported at the exit interview that they would have found the system more useful if it had mobile capacity. In addition, those using the system more regularly would have liked greater variability in the feedback. These types of issues would be addressed by migrating the current ASMM to a mobile phone application with Internet access, so that data could be automatically transmitted to a Web-based repository, and reviewed and refined by both users and clinicians. Despite the limited income of participants in the study, over 80% reported owning a cellullar phone. Although many of these devices were not smart phones, this technology is developing and spreading at a rapid pace. The costs of these systems is likely to decrease with increasing market penetration and competition, making their use accessible to a wider population.

Other challenges early in the study related to a 40% rate of screen failures at the initial home visit. This is reflective of the overall complex nature of the disease. Even the "stable, long-term" indicators of disease control, A1c, showed fluctuation within a relatively short period of time, as there was a minimum of 20 days time between the initial clinic lab measure and first possible contact with a potential participant. This resulted in a longer–than-anticipated recruitment period. Other participant-related challenges were not unexpected in this group of poorly controlled diabetics, who reported a high rate of complications and other illness issues and hospitalizations, which sometimes interfered with completion of study activities (32% of all the participants had at least one serious or unexpected adverse event during the 15 months; none of these were related to study activities).

The team also experienced challenges with the hardware systems. A significant barrier was that the internal computer clocks would incorrectly reset after the occurrence of Daylight Savings Time. This would impact timing of reminders and feedback. In most instances the timing was off by only several minutes, though in some instances it was off by more than 12 hours. If the home computer systems had Internet access, this issue may not have arisen.

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List of Publications and Products

Products

Fuzzy Logic Algorithm, AHRQ Quarterly Report, 11/30/2007. https://arrs.ahrq.gov/ARRS/attachments.jsp?responseid=3017

Thesis

Claar Dru. Injuries and Quality of Life in Poorly-Controlled T2DM: prospective observation During a self-management intervention compared to usual care. M4 Honors Research Thesis submitted to MCW, Milwaukee, WI, 11/1/11.

Conference Papers

Burns EA. Considerations in design of health IT for home use. Presented at AHRQ Annual Conference, 2008, Sept 7-10, Bethesda (MD).

Burns EA, Whittle J, Knudson P, Tarima S, Wessel B, Dye (Visotcky) A, Flax S, Pleuss J, Strub C, Wiesczorek K, Leventhal H. Use of an Assisted Self-Management Monitor for Increasing Type 2 Diabetes Control: Variability in Depression Self-Reporting Predicts Improvement in Glycated Hemoglobin. Presented at Society of Behavioral Medicine Annual Meeting, 2009 Apr 22-25, Montreal (Quebec, Canada).

Manuscripts

The following manuscripts are ready for submission; once accepted, copies will be sent to journalpublishing@ahrq.hhs.gov.

1. Burns EA, Whittle J, Knudson P, Tarima S, Visotcky A, Wessel B, Pleuss J, Flax S. Randomized Trial of an Automated Reminder and Feedback System for Improving Poorly-Controlled T2DM.

2. Kaur K, Knudson P, Tarima S, Whittle J, Visotcky A, Wessel B, Burns E. Patterns of Blood Glucose over 15 Months in Poorly Controlled T2DM.

3. Carnahan J, Pleuss J, Moosereiner A, Knudson P, Tarima S, Whittle J, Wessel B, Burns E. Dietary Composition of Adults with Poorly-Controlled T2DM.

4. Claar D, Visotcky A, Tarima S, Visotcky A, Whittle J, Knudson P, Wessel B, Burns E. Injuries and Quality of Life in Poorly-Controlled T2DM.