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Randomized trial of technology-assisted self-monitoring of blood glucose by low-income seniors: improved glycemic control in type 2 diabetes mellitus

Jason C. Levine[1] · Edith Burns[2] · Jeffrey Whittle[2] · Raymond Fleming[3] · Paul Knudson[2] · Steve Flax[4] · Howard Leventhal[5]

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Abstract Self-monitoring of blood glucose (SMBG) has been recommended for people with type 2 diabetes mellitus. This trial tested an automated self-management monitor (ASMM) that reminds patients to perform SMBG, provides feedback on results of SMBG, and action tips for improved self-management. This delayed-start trial randomized participants to using the ASMM immediately (IG), or following a delay of 6 months (DG). Glycated hemoglobin (HgbA1c) level and survey data was collected at home visits every 3 months. 44 diabetic men and women, mean age 70, completed the 12-month trial. Baseline HgbA1c was 8.1 % ± 1.0, dropping to 7.3 ± 1.0 by 9 months, with a 3-month lag in the DG ($F = 3.56$, $p = 0.004$). Decrease in HgbA1c was significantly correlated to increased frequency of SMBG, $R = 0.588$, $p < 0.01$. Providing older diabetics with objective immediate contingent feedback resulted in more frequent SMBG that correlated with better glycemic control. This type of technology may provide real-time feedback not only to patient users, but to the health care system, allowing better integration of provider recommendations with patient-centered action.

✉ Jason C. Levine
Jason.levine2@utoledo.edu

[1] Department of Psychology, University of Toledo, 2801 W. Bancroft St. Mail Stop #948, Toledo, OH 43606, USA

[2] Medical College of Wisconsin, Milwaukee, WI, USA

[3] University of Wisconsin-Milwaukee, Milwaukee, WI, USA

[4] FlexTech Systems, Brookfield, WI, USA

[5] Rutgers University, New Brunswick, NJ, USA

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Introduction

Although type 2 diabetes mellitus (T2DM) is widespread (Harris et al. 1998), and complications mitigated when controlled (Centers of Disease Control and Prevention 2001; UK Prospective Diabetes Study Group 1998, The Diabetes Control and Complications Trial Research Group 1993) achieving control for many patients is difficult. Optimum control requires management of daily life style behaviors (e.g., diet, taking medication) and maintaining these long-term. The American Diabetes Association and other experts recommend self-monitoring of blood glucose (SMBG) as an integral part of diabetes care, although there are mixed results regarding effectiveness in controlling blood glucose for patients with T2DM (McAndrew et al. 2007). A recent review of SMBG studies using glycosolated hemoglobin (HgbA1c) as the primary outcome variable (McAndrew et al. 2007), found positive, non-significant, and negative effects of SMBG in different study designs. The majority of RCTs (Farmer et al. 2007) showed improvements in HgbA1c for monitoring conditions compared to controls. Two recent trials also found similar improvement in HgbA1c for patients in both monitoring and control conditions (Farmer et al. 2007; O'Kane et al. 2008).

It is difficult to determine whether the variability of results is due to chance, individual differences, and/or variation in the instructions and how participants conduct and use the results of monitoring. Examining the variability through the lens of the common sense model

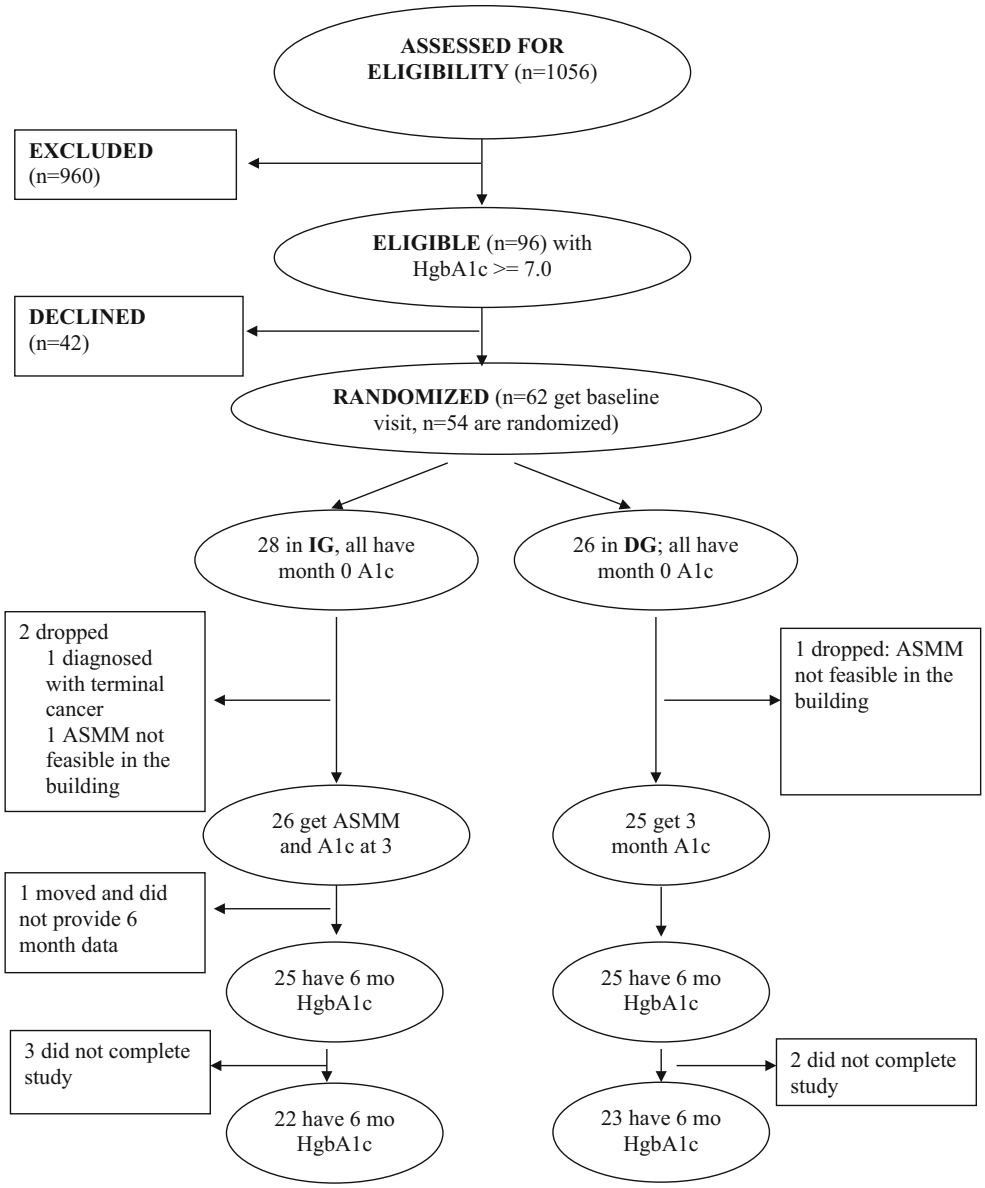

Fig. 1 Recruitment and randomization sequence

(CSM) that views self monitoring as a form of problem solving, suggests that all of these factors may be involved (Leventhal et al. 2003; McAndrew et al. 2007). The CSM suggests two factors that may be responsible for the variability in outcomes. The first is a life-long reliance on symptoms as signs of illness and treatment efficacy (Leventhal et al. 2003; Mann et al. 2009), a strategy effective for acute conditions but invalid for management of usually "asymptomatic," chronic condition such as diabetes. The second is the often unintended focus of patients on individual blood glucose readings which often have an ambiguous relationship to behavior (e.g., eating, exercise), and are not placed within the context of overall control. Thirdly, practitioners tend to focus on HgbA1c and remote goals, rather than the immediate issues surrounding the performance and evaluation of specific behaviors. CSM hypothesizes therefore, that successful self-monitoring requires attention to objective, individual readings at appropriate time points and evaluating readings appropriately in relation to specific actions (food consumed and physical activity), not physical symptoms or a remote target such as HgbA1c (Leventhal et al. 2003). If used properly, SMBG can clarify the relationship between behaviors (diet, exercise, etc.) and glucose control. Ideally the feedback should be immediately contingent to SMBG in order to shape desirable health behaviors most effectively (Miltenberger 2012).

Table 1 Baseline medical characteristics and type 2 diabetes history

	Delayed group (DG) (N = 26)	Immediate group (IG) (N = 28)	*p* value
Gender: Women	19 (73 %)	14 (50 %)	
Race: White	16	17	
African American	7	9	
Hispanic	3	2	
Age in years (mean ± SD)	70.5 ± 10.5	71.5 ± 12.2	0.62
BMI (kg/M^2)			
Women	34.6 ± 1.8	34.0 ± 2.0	0.85
Men	31.0 ± 2.8	33.2 ± 2.4	0.55
Years education (mean ± SD)	10.9 ± 4.5	11.8 ± 3.4	0.40
Revised mini mental state examination	82.6 ± 2.7	83.3 ± 3.2	0.86
Number chronic conditions (mean ± SD)	8.3 ± 3.7	8.8 ± 3.2	0.64
Number Medications (mean ± SD)	7.4 ± 3.4	9.6 ± 3.8	0.03
HgbA1c (baseline)	8.1 ± 0.3 %	8.5 ± 0.3 %	0.14
HgbA1c (3 months)	7.6 ±	8.1 ±	0.10
Duration of T2DM (years)	12.3 ±	15.2 ±	0.35
# (%) Reporting complications			
Eye	15 (58)	19 (68)	
Kidney	5 (19)	4 (14)	
Circulation	4 (15)	7 (25)	
Neuropathy	7 (27)	9 (32)	
Diabetes drug treatment			
No medication	3	1	
Oral medications	10	16	
Insulin	9	7	
Insulin + Oral medication	6	2	

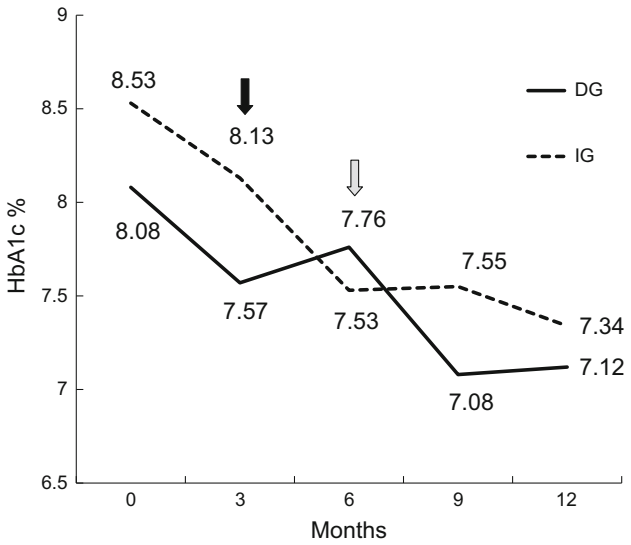

Fig. 2 Average HbA1c Percentage over Study Period. The *black arrow* indicates time of ASMM placement for the IG; the *grey arrow* time of ASMM placement for the DG. *HbA1c* glycated hemoglobin A1c, *DG* delayed group, *IG* immediate group

The systems used in prior studies to encourage appropriate use of SMBG and medication were limited in providing real time help with clear interpretations of readings, and translating the readings into suggestions for immediate action. The present paper reports the results of a prospective, randomized-start design study of an Assisted Self-Management Monitor (ASMM), designed to overcome these barriers through the application of theory; the CSM and principles of behavior modification. The ASMM provided a glucometer docking station which transferred SMBG results to a PC. The software program reminded users to perform SMBG and provided real time help with interpreting the results of glucose reading, and provided action tips. The primary outcome variables for the investigators were SMBG patterns and HgbA1c.

Method

This was an open, home-based, balanced and simple randomization, delayed-start control trial conducted in the United States. The protocol was approved by the Institutional Review Boards at the Medical College of Wisconsin and the Milwaukee VA Medical Center and was supported

by NIA Grants R44 AG019528-02 and AHRQ R18 HS17276-01. Abbott Laboratories provided glucometers for study participants.

Participants

The intervention targeted older individuals with limited resources, for whom effective SMBG and use of technology may be particularly difficult. Recruitment sessions were held at low-income, senior housing sites and multilevel retirement communities in the greater Milwaukee area that agreed to placement of a central computer in the building. Screening HgbA1c was performed for 1056 residents who gave informed consent after attending on-site presentations about diabetes. Inclusion criteria were: HgbA1c $\geq$7.0 %, ability to perform SMBG and use the ASMM. Exclusion criteria were: life limiting co-morbidities (e.g., end-stage kidney failure, recent diagnosis of significant cancer), hospitalization within prior 6 months, and/or significant anemia (potentially confounding HgbA1c measurement). Criteria were based on self-report and direct examination of medications. Once an eligible person agreed to participate the study coordinator used a web-based simple randomization tool to assign to the immediate or delay group.

Procedure

After enrollment and during the first home visit, a research assistant provided participants with additional information about the study, surveyed the premises to identify an optimal location for the ASMM, downloaded participants' glucometer data, and administered baseline questionnaires. The health care provider (HCP) managing participants' diabetes was contacted by mail and asked to provide target glycemic ranges and the SMBG schedule for their patient; recommendations were obtained for all participants.

At a home visit 1 month later, a research assistant (RA) provided participants with a Precision Xtra study glucometer (Abbott), reviewed and observed SMBG technique. All participants were asked to perform SMBG according to the schedule from their HCP. Follow-up visits occurred every 3 months for a total of 6 visits over 13 months. At each visit the RA reviewed and verified SMBG technique, downloaded glucometers/ASMM, and administered surveys. Participants were randomized by site to the Immediate Intervention Group (IG) or the delayed intervention group (DG). For participants randomized to the IG, the ASMM was installed at the 3rd visit (4 months after enrollment) while for the DG it was installed at the 4th visit. At the last visit we removed the ASMM. Participants were given printouts of their interim blood glucose readings to bring to their HCP.

Assisted self-management monitor

The ASMM was a 5.25″ × 5.25″ × 2″ box connected via telephone wiring to a single computer located in a locked office in each residential building. Participants could access all required system functions through this single interface, keeping the computer "hidden" from the user. Each ASMM box had three 1/4″ round buttons identified by mnemonic symbols, (e.g., glucometer, syringe). An infrared link automatically transferred information from the ASMM to the computer. To download a blood glucose reading, the participant inserted the infrared link into the glucometer, placed it in front of the ASMM, and pushed the button marked with a glucometer symbol. The computer software compared the SMBG measure to the individual's glycemic target ranges and determined the feedback.

Reminders

Prerecorded audio messages reminded participants to take medications or perform SMBG at the times recommended by their HCP. Reminder messages were triggered if they did not download a glucometer reading during a 1 h time interval around the pre-scheduled time. A sample reminder is; "You have not downloaded your morning glucose reading. Please check your blood sugar now and download it into the monitor." Messages were also triggered if they did not indicate taking a medication dose at the proper time. For each HCP-recommended SMBG schedule (e.g., twice a day, 3 days a week), the participant's choice of day and habitual times for rising and retiring were used to set the timing of the reminders.

Feedback

The ASMM provided the following types of feedback: glucose levels (1) within target ranges—system repeats numbers; (2) below lower limits (hypoglycemia)—standardized instructions on how to treat (e.g., for glucose level 60–70 mg/dl, take one glucose tablet); (3) above upper limits (e.g., increase physical activity, monitor food intake). Upper and lower "safety" limits (below 50 or above 450 mg/dl) prompted messages to recheck/intervene/contact the HCP.

Installation

The protocol for installing the ASMM was identical in both groups. Target glycemic ranges, SMBG and medication dosing schedules were preprogrammed prior to installation. Once installed, the RA ensured the participant was able to

use it correctly. At each visit, settings were changed if the HCP's recommendations had changed. The RA confirmed that the participant was still able to use the machine properly and answered any questions.

Measures

Measures included HgbA1c, demographics, medical information, SMBG frequency, diet and exercise habits. Weight and height were obtained with participants in their stocking feet and light clothing, using the same portable scale (Taylor USA, Oakbrook, IL) and standard tape measure. Patient characteristics hypothesized to influence glycemic control were assessed using standardized instruments: mood—Patient Health Questionnaire—9 (Irwin et al. 1999; Kroenke et al. 2001), cognitive status (Tschanz et al. 2002), and fear of hypoglycemia (Cox et al. 1987). Adaptations of existing scales were used to measure self efficacy for diabetes self-care (Bandura 1977; Talbot et al. 1997) and fear of hyperglycemia (Kleefstra et al. 2005). HgbA1c was measured by finger stick, using the portable DCA 2000 + monitor (Bayer, Tarreytown, NY). Measures were repeated at each follow up visit, including downloading data from the glucometer and ASMM.

Statistical analyses

Primary analysis focused on change in HgbA1c between months 3 and 6, when the IG had the ASMM in place, and the DG did not, then repeating these analyses using each participant as their own control. Outcomes were assessed with repeated measures analyses of covariance (ANCOVA), looking first at the interaction contrast between groups at three and 6 months. Results were unchanged by deleting data from three randomized participants who dropped out prior to the 6-month visit.

Frequency of SMBG was calculated using the time-stamp from downloaded ASMM data (using stored glucometer data to double-check for accuracy). Chi square analysis was used to test for differences between the DG and IG for each time period. Pearson product-moment correlations were computed between a selected number of predictor variables and pre-post change in frequency of SMBG.

Results

96 eligible residents with T2DM were invited to participate in the study. Thirty-four declined immediately, and eight more declined at the pre-baseline visit when the study was explained in detail. These 42 persons were older, had a lower HgbA1c, and were less likely to be African American. The remaining 54 persons were randomized to immediate (n = 28) or delayed (n = 26) placement of the ASMM. During the next 3 months, three participants dropped out: two resided in a building unable to house the central computer (1 IG, 1 DG) and one (IG) discovered she had cancer. During the randomized comparison period (3–6 months), one dropped from the IG because he moved. During the final 6 months, three withdrew from the IG (1 moved, 1 quit, 1 sudden death) and two from the DG (1 moved, 1 entered hospice), for a total attrition of 9 after randomization (see Fig. 1).

Mean baseline HgbA1c among the randomized 54 persons was 8.4 ± 1.26 %. The IG and DG did not differ significantly on age, gender, race, BMI, number of comorbid conditions, cognitive status, diabetes history or baseline HgbA1c (Table 1). Diabetes drug treatments for the sample included 4 persons taking no medications, 26 persons were taking only oral medications, 16 persons were only taking insulin, and 8 persons were prescribed insulin and oral medication.

Effect of ASMM on HgbA1c

HgbA1c improved in all participants between baseline and 3 months, from 8.08 to 7.57 % in the DG and 8.53–8.13 % in the IG ($F(1,42) = 4.43$, $p = 0.041$, $\eta_p^2 = 0.095$). After randomization and introduction of the ASMM (3–6 months) HgbA1c continued to decrease in the IG to 7.53 % ($F(1,20) = 4.63$, $p = 0.044$, $\eta_p^2 = 0.188$), while HgbA1c began to rise in the DG (7.57–7.76, $F(1,22) = 1.77$, $p = 0.167$, $\eta_p^2 = 0.415$) (Fig. 2).

Following introduction of the ASMM to the DG at 6 months, mean HgbA1c reversed and continued to improve until the end of the study. Over 13 months, HgbA1c dropped significantly, from 8.53 to 7.34 % in the IG and from 8.08 to 7.12 % in the DG (overall 1.2 percentage point decline in HbgA1c, ($F(4,39) = 5.072$, $p = 0.007$, $\eta_p^2 = 0.542$).

SMBG patterns

At baseline the 54 participants were using 17 different glucometer models. Thirty-four of these contained no stored readings. Ten were incorrectly calibrated (dates, times and time-span of readings impossible to determine), and two participants could not find their glucometers. Eight had properly calibrated glucometers with stored data. For these few, average number of SMBG readings/week prior to study enrollment was 7. All participants were given and began using the same the Precision Xtra (Abbot) glucometer at baseline. Mean SMBG frequency during the pre-randomization period was similar between the groups (10.6 ± 7.4 times/week and 10.7 ± 7.1 times/week,

t = 0.036, $p = 0.97$, Table 1). From 3 to 6 months, the DG was significantly less likely to perform SMBG, missing over 22 % of scheduled measures compared to 6 % missed measures for the IG ($\chi^2(1) = 977.53$, $p < 0.001$). Three months after introduction of the ASMM (6 months into study for the IG and 9 months for the DG) there were significant increases in frequency of monitoring in both groups ($p < 0.001$), with no difference between groups. SMBG frequency rose from 10.7 ± 7.1 to 16.0 ± 7.7 times/week for the IG, and from 10.6 ± 7.4 to 17.6 ± 6.8 times/week for the DG. This frequency was sustained through the end of the study period.

Predictors of change in HgbA1c or SMBG frequency

Change in frequency of SMBG was significantly correlated with change in HbgA1c, R = 0.588, $p < 0.01$. We also examined whether any other baseline characteristics were associated with change in HgbA1c or SMBG frequency. During the comparison period (3–6 months), there was a marginally-significant relationship between BMI and change in HgbA1c, $p = 0.056$; i.e. those with a higher BMI at 3 months had greater improvement in HgbA1c. None of the other factors, including gender, age, race, T2DM features, baseline cognitive function or depression were correlated with change in HgbA1c or change in SMBG frequency. Medication doses didn't change over the course of the study for 80 % of the participants. Change in HgbA1c was similar for the 9 individuals whose doses of diabetes medications were increased, and the 5 individuals whose doses of diabetes medications were decreased.

Discussion

Use of a technology-based assisted self-management monitor resulted in increased frequency of SMBG and improved HgbA1c using a delayed-control design. Both groups showed significant improvement in HgbA1c, increased frequency of SMBG and significant correlation between SMBG frequency and HgbA1c improvement after introduction of the ASMM. Although the ASMM provided reminders for medication adherence and feedback on glycemic results, the strong correlation between increased frequency of SMBG and HgbA1c suggests that participants were using the "objective" glucose readings as indicators of glycemic control and received confirmation of the efficacy of their T2DM management strategies through immediate contingent feedback. This relationship may be one reason why improvement in glycemic control was associated with SMBG in other randomized, controlled trials (O'Kane et al. 2008; Welschen et al. 2005).

Variables that have been associated with glycemic control in prior studies were measured and analyzed in the current trial. Higher initial HgbA1c and shorter duration of diabetes have been associated with more rapid improvement in glycemic control (Guerci et al. 2003; Kwon et al. 2004; Rutten et al. 1990), and thus were included in the current analysis. Both were unrelated to change in HgbA1c. Increased physical activity may improve glycemic control by increasing insulin sensitivity, utilizing larger amounts of glucose as an energy source, and possibly contributing to weight loss. Changes in dietary behavior may have occurred, as our participants may have monitored their diet more closely and changed the composition of what they ate (anecdotal feedback). Furthermore, activity levels may have actually increased, with our simple frequency measures lacking enough sensitivity to detect significant change. Lastly, patients may also have improved their adherence to medications due to reminders from the system, thus resulting in improved diabetes control.

Before designing the ASMM, the investigators considered the growing need for more explicit use of theory in diabetes intervention research. Previous studies examining the role of SMBG have fallen short in coupling monitoring with behavioral theories providing detailed analyses of the process of self-management. The review of SMBG trials by (McAndrew et al. 2007, pg. 107) highlighted the "lack of implementation of components of the behavioral monitoring system and self-regulation and behavior theory." The authors explicitly noted "inadequacy of assessment of moderators and mediators" which makes it difficult to understand the complexity of bio-psycho-social components in the self-regulation process. The common sense model used to develop the ASMM is explicit in recognizing that SMBG is but one of several factors that can change behaviors to impact a long term outcome such as HgbA1c. The goals in this framework were to: (1) increase frequency of SMBG, and (2) interpret readings as targets for action (e.g., ingest high glycemic index foods, exercise). To better achieve these goals, the intervention was designed using Leventhal's CSM of self-regulation (Leventhal et al. 2003) and principles of behavior modification, targeting immediacy and contingency—two factors that influence the effectiveness of reinforcement and learning (Miltenberger 2012). Employing a theory-driven approach to the design of this intervention, the technology-assisted device proved effective for a traditionally difficult to treat population of low-income seniors. Future studies should aim to replicate the present findings, with a focus on explicitly encouraging the use of objective SMBG measures rather than symptoms as indicators of blood glucose levels, and using these measures to develop action plans

that incorporate patient-centered behaviors into daily routines (McAndrew et al. 2007).

The present results are in contrast to reports of no differences in glycemic control with intensive monitoring versus usual care in patients who were well-controlled at baseline (HgbA1c <7.5 %) (Farmer et al. 2007), and whose professional competencies would encourage alternative strategies for behavioral changes that could result in lower HgbA1c over time. A letter to the editor from a retired diabetic administrator regarding the Farmer et al. study agreed that frequent SMBG might not be necessary for glycemic control (Keele 2007). The letter described performing more frequent use of SMBG after initial diagnosis, but then only occasionally, to "check up" now that "I know what works." This use of SMBG describes the goals of the ASMM to teach self-management skills to patients who may not intuitively grasp these concepts and rely on subjective indicators.

Similarly, the ESMON study (O'Kane et al. 2008) randomized newly diagnosed patients with T2DM to no monitoring versus SMBG 8 times weekly. All participants were managed with the same rigorous medication protocol dictated by HgbA1c level and received identical structured core education programming, which most likely explains equal improvement in both groups. In the present study, the ASMM may have been effective because it provided objective feedback on dealing with glucose measurements in "real time." It also is more representative of actual practice, where treatment regimens may be highly variable and lack environmental contingencies for effective self-management.

The study has several limitations. We are not able to define the exact mechanism that led to improvement in glycemic control. Focusing attention on objective measures (glucose levels) or providing medication reminders, may have resulted in more effective self-management behaviors (e.g., taking medicine, exercise). Future studies will need more detailed measures of intermediate variables, such as exercise and diet to determine if there were changes in life-style behaviors (King et al. 2007). We are currently conducting a straight-forward comparison of ASMM versus care in a larger, randomized trial, including detailed assessment of components of the Common Sense Model of T2DM and life-style factors in order to compare changes related to the intervention.

Diabetes is a biobehavioral disorder that requires patients assume volitional control of a biological process that is normally regulated automatically in healthy individuals. It is expected that patients assume an active role by engaging in specific actions to manage their diabetes care, with hope that the more control a patient takes, the better outcome they will have (improvement in A1c). The present study suggests that self-management of blood glucose is enhanced by the use of behavior theory and technology.

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Disclosures The author(s) report no financial or other relationship relevant to the subject of this article.

Compliance with ethical standards

Conflict of interest Jason C. Levine, Edith Burns, Jeffrey Whittle, Raymond Fleming, Paul Knudson, Steve Flax and Howard Leventhal declare that they have no conflict of interest.

Human and animal rights and Informed consent All procedures followed were in accordance with ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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