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A Randomized Controlled Trial of an Automated Telephone Intervention to Improve Glycemic Control in Type 2 Diabetes

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A randomized controlled trial was conducted to evaluate the impact of an automated telephone intervention on glycemic control in patients with type 2 diabetes. One hundred twenty participants were randomly assigned to a treatment group that received a daily, automated telephone message regarding diabetes or to a control group that received usual care. The treatment group demonstrated a significant improvement in the frequency of self-monitoring of blood glucose levels compared with the control group ($P < .001$). A favorable trend in positive attitudes toward diabetes and a reduction in perceived monitoring and exercise barriers were seen in the intervention group compared with the control group. **Key words:** *chronic disease management*, *diabetes*, *health belief model*, *randomized controlled trial*, *telephone intervention*, *type 2*

BACKGROUND AND SIGNIFICANCE

Diabetes mellitus (DM) is a growing public health problem that is an epidemic in the United States. An estimated 23.6 million Americans have diabetes, and approximately 1.5 million new cases were diagnosed in 2007.[1] Diabetes is the nation's sixth leading cause of death by disease, accounting for more than 200 000 deaths in the United States annually.[2] Healthcare costs of individuals with DM in the United States are over twice those of individuals without the disease.

The prevalence of type 2 DM, which accounts for 90% to 95% of all DM cases, increases with age. Twenty percent of Americans 65 years and older are estimated to have type 2 DM. The incidence is also higher among certain racial and ethnic minorities. Experts predict the incidence of type 2 DM to increase in the United States as longevity increases and as the population becomes more racially and ethnically diverse.[2]

Serious long-term vascular complications result from uncontrolled hyperglycemia in type 2 DM.[3] Studies have shown that reduction in hemoglobin A_{1c} (HbA_{1c}) levels plays an essential role in reducing the risk of developing microvascular complications (ie, retinopathy, neuropathy, and nephropathy) and trends toward reductions in macrovascular complications (ie, myocardial infarction and stroke).[4,5]

Hemoglobin A_{1c} is a manifestation of the binding of circulating adult HbA molecules on erythrocytes to glucose. It reflects total glucose exposure to HbA, including both fasting and postprandial plasma glucose levels, for the past 2 to 3 months.[6] Infrequent measuring

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of HbA_{1c} levels (ie, every 3 months) gives an objective, accurate assessment of glycemic control over the previous weeks to months, but it does not provide "real-time" assessments of blood glucose levels. Thus, monitoring glucose levels more frequently via self-monitoring of blood glucose (SMBG) is an important component of self-management of diabetes.[1]

Seminal studies such as the United Kingdom Prospective Diabetes Study[5] have created new knowledge regarding the management of type 2 DM, and important findings concerning the benefits of lowering HbA_{1c} levels have been disseminated in numerous practice guidelines. As a result, more patients are being treated with oral hypoglycemic agents and insulin combined. However, overall glycemic control, defined as HbA_{1c} level less than 7.0%, has not improved and has worsened in patients with type 2 DM.[7] Other studies have shown that access to and utilization of medical care does not assist patients in achieving adequate glycemic control.[8]

The lack of improvement in glycemic control may be because good outcomes in chronic conditions depend to some degree on medical care, but perhaps to a larger degree on self-management of the condition by the patient. Although healthcare providers play an essential role, the majority of diabetes management takes place away from the healthcare system, while people are living their lives at home and in the community. Patients are largely responsible for their own diabetes self-management between clinic visits.

Diabetes self-management involves a number of behaviors that patients must engage in on a daily basis to maintain safe blood glucose levels. These behaviors include dietary modifications, regular exercise, and SMBG. The self-management component of intensive DM management is of critical importance in DM care and has been shown to delay the onset and minimize progression of complications of the disease.[9]

Clinical trials have shown that intensive interventions using multidisciplinary teams including nurses and physicians improve patient self-care management and glycemic control in patients with diabetes.[10,11] The Diabetes Control and Complications Trial (DCCT)[9] utilized multidisciplinary teams of nurses, physicians, and dietitians to provide frequent clinic and intensive telephone follow-up for patients with type 1 DM in the intensive treatment group. At the conclusion of the trial, when funding was no longer available for research teams, medical systems could not maintain the level of staff involvement achieved during the trial. This raises the question of the feasibility of providing intense multidisciplinary support to large numbers of patients with diabetes to help them engage in necessary self-care behaviors and to achieve glycemic targets.

The telephone is an easy-to-use, familiar technology that is almost universally available in the United States. Studies of primary interventions involving the telephone have been shown to improve adherence to medications and to improve blood pressure readings in patients with hypertension, to improve quality of life in patients with cardiac problems, and to be effective in changing physical activity and dietary behaviors.[12-14] Riegel and colleagues[15] showed that a telephone intervention reduced hospitalizations and overall costs in heart failure patients compared with other disease management approaches. Extensive telephone access to healthcare practitioners was a key element found to maintain lower HbA_{1c} levels in the DCCT.[16] However, there is a paucity of literature evaluating the impact of isolated telephone interventions on glycemic control in adults with type 2 DM, suggesting that well-designed studies to establish the effectiveness of this potentially cost-effective modality need to be undertaken.

THEORETICAL FRAMEWORK

When interventions intended to cause health-related behavior change are grounded in health behavioral theory, investigators' abilities to identify important assumptions that lie beneath the interventions, to provide a clear rationale for choosing an intervention, and to propose theoretically based hypotheses are enhanced. These are important factors in understanding both anticipated and unanticipated effects of interventions.[17]

This study is informed by the health belief model (HBM) of illness.[18] The HBM posits that health-related behaviors are influenced by perceptions of susceptibility and severity of illness, as well as perceptions of the benefits and barriers associated with following a prescribed healthcare regimen. If perceived barriers related to following a recommended healthcare regimen are low and perceived susceptibility to and severity of illness is high, an individual is more likely to engage in a recommended health-related behavior.[19] Individuals may have differing perceptions of benefit and risk associated with different components of diabetes self-care behaviors.

Support for the use of the HBM in diabetes research is found in the literature. Daniel and Messer[19] found that baseline health beliefs of the severity of DM predicted reduced HbA_{1c} levels at the time of a follow-up survey 18 months later in a group of patients with type 2 DM. Both high perceived severity of DM and low perceived barriers to self-care behaviors were related to therapeutic HbA_{1c} levels and reductions in HbA_{1c} levels. In a sample of patients with type 2 DM, Polly[20] found that perceived barriers to treatment were related to treatment adherence and that glycemic control was related to perceptions of disease severity. In a sample of African Americans with type 2 DM, Fitzgerald and colleagues[21] reported that adherence to dietary restrictions was related to negative perceptions of diabetes.

Subjective perceptions of illness are influenced by a number of demographic, social, and situational factors that are present in everyday life that result in individualized health beliefs that influence health-related behaviors. Therefore, interventions that impact individuals when they are away from the healthcare system and interacting with social and situational factors are needed to assist patients in achieving glycemic targets.

PURPOSE STATEMENT

The purpose of this randomized controlled study was to evaluate the effect of an easily implemented automated telephone intervention on glycemic control in patients with type 2 DM. Previous research has not adequately examined the effects of isolated telephone interventions in this population, and the research that has been conducted has not been grounded in theoretical principles that regulated health-related behavior. This study attempted to address these gaps in the literature.

The automated telephone messages delivered to patients with type 2 DM in this study were based on the HBM and were intended to influence patients' beliefs and attitudes regarding type 2 DM and self-management. Components of the telephone intervention focused on the serious nature of type 2 DM and its complications (severity), the relationship of hyperglycemia to complications (susceptibility), and benefits of self-management in controlling blood glucose levels.

The primary aim of this study was to determine the impact of a daily, automated telephone intervention on HbA_{1c} levels compared with standard care in adults with type 2 DM. The secondary aim was to determine the impact of the automated telephone intervention on SMBG frequency in adults with type 2 DM. The tertiary aim of the study was to determine the impact of the automated telephone intervention on self-reported beliefs regarding severity of diabetes, susceptibility to complications of diabetes, and the benefits of and barriers to self-management of diabetes compared with standard care in adults with type 2 DM.

METHODS

Research design

An experimental pretest-posttest design was used to test the null hypotheses, which are as follows: (*a*) no greater improvement in HbA_{1c} levels will be seen in the intervention group from baseline to the end of the 90-day intervention period compared with the standard care group, (*b*) no greater improvements in SMBG frequency from baseline to the end of the 90-day intervention period will be seen in the intervention group compared with the standard care group, and (*c*) no greater differences in positive attitudes and favorable beliefs about diabetes from baseline to the end of the 90-day intervention period will be seen in intervention patients compared with the standard care group.

Sample

A convenience sample of 120 participants was recruited for the study from 2 clinics at an urban medical center in the Midwest, a primary care clinic, and an endocrinology clinic. The clinics are located at the same site and providers work together to care for a diverse population of patients. Recruitment took place between June 2007 and June 2008. Inclusion criteria were as follows: (*a*) diagnosis of type 2 DM documented in the medical record for at least 12 months, (*b*) age greater or equal to 50 years at the time of enrollment, (*c*) HbA_{1c} levels equal to or greater than 7.0% within the past month, (*d*) ability to speak and understand the English language, (*e*) access to either a land line or cellular phone, (*f*) ability to hear and orally respond to automated telephone voice commands, (*g*) responsible for own self-care, (*h*) access to reliable glucose meter that has 3-month storage capacity, and (*i*) self-care regimen that includes SMBG at least daily. Patients were excluded if they were unable to give informed consent or were too ill to participate.

Study procedures

The study was approved by the institutional review board responsible for protection of human participants in research. Patients were recruited for the study during a scheduled clinic appointment. The investigator ensured that the informed consent process was followed.

Randomization to the intervention or control group was stratified by sex and by the use of insulin to achieve an approximate balance between men and women using and not using insulin in each group. A predetermined randomization schedule from a series of permuted blocks was employed for each stratum. Opaque randomization envelopes that contained the randomization assignment were labeled with participants' study numbers by a third party prior to initiation of the study. The investigator opened the envelope with the participant's preassigned study number to reveal the randomization assignment after the informed consent document was signed. Neither the participant nor the investigator had knowledge of the randomization assignment prior to that time.

Blinding of participants and the investigator was not possible because of the nature of the intervention. An attempt was made to avoid drawing attention to the randomization assignment when providers were present. The investigator provided no clinical care during the study. Laboratory personnel who ran the HbA_{1c} assays were unaware of the patients' study status.

In addition to usual care provided by the clinics, participants randomized to the telephone intervention received a daily, automated, prerecorded voice message relaying a short (less than 1 minute) message related to type 2 DM. A trained actor playing "Alice," a 60-year-old woman with type 2 DM, recorded the scripted messages in a professional recording studio. The messages changed every day during the 90-day intervention period. Messages from Alice focused on the American Association of Diabetes Educators' AADE7 Self-care Behaviors.[22] These behaviors include healthy eating, being active, monitoring (ie, SMBG), taking medication, problem solving, reducing risks, and healthy coping. The messages were also designed to influence attitudes and beliefs regarding the susceptibility and severity of type 2 DM and reduction of barriers related to performing self-care behaviors.

Participants chose the time of day they wanted to receive the automated calls and the telephone number they wanted the system to call. The system delivered up to 3 calls each day. If there was no answer or if an answering machine picked up the first call, the system called back an additional 2 times at 15-minute intervals. If the call was not received by the participant after the third attempt, the system called back the next day at the previously agreed upon time. No messages were left. Participants were asked to answer and respond to as many calls as possible throughout the study. Participants in the telephone group who received at least 90% of the automated calls during the study period were classified as "compliers."

When calls were received by participants, after listening to the brief prerecorded message, they were asked to respond to questions from Alice. The first question was, "Did you check your blood glucose yesterday?" An answer of "no" signaled a sign-off message such as "Thank-you, I will call again tomorrow." An answer of "yes" triggered the following questions: "Did you check your blood glucose before breakfast? . . . Did you check your blood glucose after breakfast? . . . Did you check your blood glucose before lunch? . . . Did you check your blood glucose after lunch? . . . Did you check your blood glucose before dinner? . . . Did you check your blood glucose after dinner? . . . Did you check your blood glucose before bed?" Each answer of "yes" triggered the following response: "Please tell me the result." Each answer of "no" triggered the system to ask the next question. Prior to the sign-off message, Alice asked 2 final questions: (*a*) "Since the last time I called, have you experienced any low glucose reactions where you needed someone's help?" and (*b*) "Since the last time I asked, have you experienced any symptoms such as sweating, weakness, dizziness, trembling, or chest pain?" An answer of "yes" to either of these questions triggered the response: "Please call your doctor's office today to report this."

The automated telephone system used in this study (Warm Health, Inc, Wayzata, Minnesota) consisted of a central computerized station with a telecommunications modem that generated the automated voice communication to multiple homes over the telephone. The only equipment needed in the monitored homes was a telephone. Warm Health, Inc, recorded participants' responses from the calls and relayed them to a secure Web site that the investigator had access to. Study participants were identified on the Web site by study number and telephone number only. Any telephone number could be used (eg, home, office, cell, friend, and any other contact number), and the participants were not asked to identify the source of the number. The system was programmed to send an e-mail alert to the investigator when a participant reported a blood glucose level equal to or greater than 400 mg/dL, equal to less than 60 mg/dL, or an answer of "yes" to either of the final questions. The investigator followed up with a telephone call to the participant and to the participant's clinic if necessary.

Control conditions

Participants randomized to the control condition received usual care provided to patients with diabetes by the clinics. Usual care consists of a clinic visit every 2 to 3 months (more often if needed); HbA_{1c} levels assessed every 90 days in patients who are above target; and diabetes education and support provided by a team of nurses, dieticians, and a pharmacist upon diagnosis and ongoing as needed.

Participants in both groups were encouraged to call the diabetes educators or the investigator if they experienced any problems or had questions during the study. All participants were offered a $25.00 stipend for participating in the study. The stipend was given to participants during the 90-day follow-up visit.

Data collection and measures procedures

Hemoglobin A_{1c} level was obtained by means of a standard venous blood draw with results determined by a standard high-performance liquid chromatography technique (Tosoh Bioscience G7 analyzer; Tosoh Bioscience, Tessenderlo, Belgium) or by a finger stick capillary blood sample with results determined by immunoassay (Bayer DCA

200 analyzer; Bayer Healthcare, Mishawaka, Indiana). These 2 methods were found to be highly correlated ($r^2 = 0.98$) in previous samples during an instrument validation process at the medical center. HbA_{1c} levels obtained within 1 month of the enrollment clinic visit were used as baseline measurements, and the follow-up measurements were taken when the participants returned for their 90-day follow-up clinic visits. Change in HbA_{1c} level was calculated by subtracting the baseline HbA_{1c} level from the 90-day HbA_{1c} level; a negative change represented an improvement. Obtaining HbA_{1c} levels every 90 days is considered standard of care for patients with type 2 DM cared for at the clinics involved in the study; therefore, neither the participants nor their secondary payers incurred additional expenses related to measurement of this outcome.

Medication changes were tracked during the study period because of the potential effect a major medication change could have on the primary outcome. Participants were categorized dichotomously according to whether or not they had at least one major medication change during the study. A *major medication change* was defined as (*a*) the addition of a new oral medication, insulin, or another injectable medication (eg, exenatide), (*b*) an increase in any dose of an oral medication, or (*c*) an increase in insulin by 4 units or more in a 24-hour period.

Information downloaded from participants' personal glucose meters provided data on SMBG frequency. Glucose meters were downloaded during the enrollment clinic visits and again during the 90-day follow-up clinic visits. Glucose frequency was assessed for the 30-day period prior to the enrollment clinic visit and again for the 30-day period prior to the follow-up clinic visit. Daily SMBG frequency was calculated by adding the number of times participants checked their blood glucose levels during the previous 30 days and dividing that number by 30 to obtain a mean number of times per day that participants checked their blood glucose levels. Change in daily SMBG frequency was calculated by subtracting the baseline SMBG frequency per day from the 90-day SMBG frequency. A positive change represented an improvement in SMBG frequency.

Participants were asked to complete and return the Diabetes Care Profile (DCP) at the time of the enrollment clinic visit and again at the 90-day follow-up clinic visit. The DCP is a self-administered questionnaire derived from the Diabetes Education Profile,[23] which was based on the HBM. It consisted of 163 items including profile subscales that assess demographic, social, psychological, and physiological factors related to diabetes and its treatment. Respondents were able to complete the questionnaire in 30 to 40 minutes.

The questionnaire consisted of items using 5-point Likert, close-ended, and dichotomous scales. Item readability was assessed at a third-grade reading level. Studies have demonstrated moderate to excellent internal consistency reliability for the DCP in diverse samples of people with diabetes. The Cronbach α, indicating scale internal consistency, of individual DCP scales ranged from .60 to .95, with exercise barriers showing the lowest coefficient and long-term care benefits showing the highest.[23,24] Content and construct validity was also demonstrated in these studies.

In the current study, the subscale *control problems* was used to evaluate perceived *severity* of diabetes. Participants indicated how many high and low blood glucose levels they experienced in the past 90 days. The subscale *importance of self-care* was used to evaluate perceived *susceptibility* to complications of DM. Participants rated the level of importance they placed on glycemic control and self-care activities. The subscale *long-term benefits* was used to evaluate the perceived *benefits* of diabetes self-care. Participants indicated their agreement or disagreement to items related to the relationship between self-care and delaying diabetes-related complications. The subscale *barriers* was used to evaluate perceptions of exercise and monitoring barriers to diabetes self-care. Participants indicated how often they were unable to exercise or test blood glucose levels in relation to a number of potential barriers. The subscale *positive and negative attitudes toward diabetes* was used to evaluate attitudes.

Scores for the subscales were obtained by following the formula provided by the developers of the questionnaire.[25] The item scores of each subscale were summed and then divided by a count of nonmissing items. Scores ranged from 1 to 5 for each subscale. Reverse scoring was done for the *negative attitude* subscale and the *barrier* subscale by adding 1 to the maximum value of the scales and then, for each individual, subtracting from it the score they actually got. Change scores were calculated by subtracting baseline scores from follow-up scores. In terms of a positive treatment effect, changes from low scores to higher scores in all subcategories were seen as desirable.

DATA ANALYSIS

Power calculations were based on preliminary data collected on a small sample of patients likely to meet the inclusion criteria for this study. The sample experienced a mean decrease in HbA_{1c} level of −0.5 percentage points ± 1.2 percentage points over a 90-day period. Therefore, an effect size of −0.6 percentage points ± 1.2 percentage points was used for the power calculation. These calculations assumed a sample size of 60 per group, 80% power, and a 2-sided *t* test with type 1 error set at 0.05. Calculations were conducted by using nQuery Advisor software (Statistical Solution, Ltd, Saugus, Massachusetts). A mean change in HbA_{1c} level of −0.6 percentage points is considered a clinically significant improvement.

Baseline variables were compared by intervention group using χ^2 for categorical variables, independent sample *t* tests for normally distributed continuous data, and Mann-Whitney *U* tests for continuous data that were not normally distributed. An intent-to-treat analysis with last value carried forward (LVCF) was used to account for missing endpoint data. Mean differences between treatment groups on outcome variables were assessed by using independent sample *t* tests. In situations where differences in baseline variables between treatment groups were found, these differences were controlled for using analysis of covariance for continuous variables and general linear model (GLM) for categorical covariates. Data were analyzed by using SPSS, Version 11.5 for Windows (SPSS, Inc, Chicago, Illinois).

RESULTS

One hundred twenty participants aged 50 to 93 years were recruited from 1050 patients screened for enrollment. Eight hundred two patients were initially screened out by medical record review prior to their clinic visits; 8 of these patients were participating in another study. Sixteen patients did not come to their scheduled appointments, leaving 232 patients who were approached for enrollment (recruitment rate 52%). One participant in the study died shortly after being allocated to the treatment group and another participant in that group did not comply with study follow-up procedures. Two participants in the comparison group were lost to follow-up, and 2 participants did not comply with study follow-up procedures (Fig 1).

Demographics

Intervention and comparison groups were compared at baseline on the variables sex, living status, mean age, race, education level, income, mean duration of DM, and use of insulin. No significant differences were found; however, differences in mean age approached statistical significance ($P = .06$) with the comparison group being, on average, 3 years older. This difference was not thought to hold any clinical significance. The difference in race category also approached statistical significance, with twice as many participants in the intervention group reporting nonwhite race compared with the comparison group ($P = .07$) (Table 1). Race was considered an important covariate, and its effect on

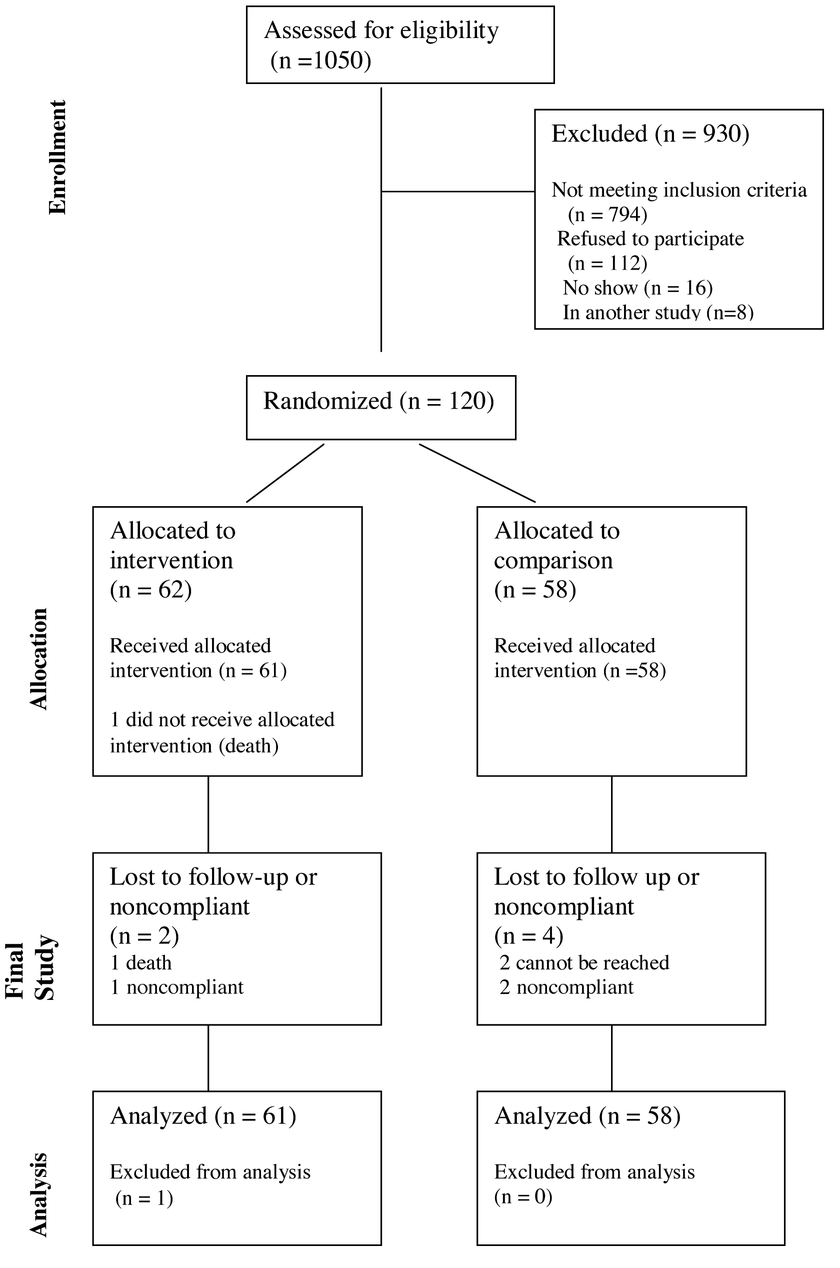

Figure 1. Study flow diagram.

outcome variables was evaluated in subsequent analyses.

Baseline outcome variables

Intervention and comparison groups were compared at baseline (Table 1). Significant differences were found between groups on susceptibility to DM complications ($P = .02$) and beliefs regarding benefits of self-care ($P = .03$). Therefore, between group end-point analyses of susceptibility to DM complications and benefits of self-care included baseline values as covariates.

Table 1. Baseline values by treatment group

Variable name	Telephone group ($n = 61$)	Comparison group ($n = 58$)	*P*
Sex			
Men	33	33	
Women	28	25	.76
Living status			
Live alone	13	17	
Live with others	48	41	.32
Age, $M \pm$ SD, y	60.1 ± 7.4	63.0 ± 9.3	.06
Race			
White	43	49	
Nonwhite	18	9	.07
Education			
High school or less	13	16	
Some college or technology	24	21	
College graduate	24	21	.73
Income US dollars			
Up to 9999	6	13	
10 000–19 999	14	9	
20 000–39 999	9	10	
40 000–59 999	9	6	
60 000 and up	23	20	.35
Duration of DM, $M \pm$ SD	13.5 ± 8.4 years	12.2 ± 8.2 years	.21
Insulin			
Insulin	34	30	
Noninsulin	27	28	.66
HbA_{1c} levels, $M \pm$ SD	8.71% ± 1.74 (mean rank 63.91)	8.59% ± 1.96 (mean rank 55.89),	.20
SMBG frequency (times per day), $M \pm$ SD	1.26 ± 1.26 (mean rank 58.78)	1.27 ± 1.15 (mean rank 61.28)	.69
Severity of DM, $M \pm$ SD	4.53 ± 1.09	4.32 ± 1.24	.34
Susceptibility to DM complications, $M \pm$ SD	4.41 ± 0.652	4.13 ± 0.764	.02[a]
Positive attitudes toward diabetes, $M \pm$ SD	3.05 ± 0.857	3.18 ± 0.749	.37
Negative attitudes toward diabetes, $M \pm$ SD	2.56 ± 0.849	2.51 ± 0.827	.76
Benefits of self-care, $M \pm$ SD	4.44 ± 0.979 (mean rank 66.12)	4.26 ± 0.803 (mean rank 53.56)	.03[a]
Barriers, $M \pm$ SD	4.19 ± 1.09	4.20 ± 1.14	.97

Abbreviations: DM, diabetes mellitus; HbA_{1c}, hemoglobin A_{1c}; SMBG, self-monitoring of blood glucose.
[a]$P < .05$.

Outcome analysis and hypothesis testing

The primary outcome of interest was difference in mean change in HbA_{1c} level between the telephone and comparison groups. LVCF was applied to 1 participant in the intervention group and 2 participants in the comparison group.

An independent samples *t* test indicated that there were no significant differences between the telephone and control groups on mean change HbA_{1c} level ($P = .84$), suggesting no treatment effect (Table 2). Participants who classified themselves as either white or nonwhite were distributed evenly among responders and nonresponders on this

Table 2. Outcomes at 3 mo

	Mean change	SD	*P*		Adjusted marginal means	SE	*P*
Unadjusted mean change HbA_{1c} levels				Adjusted for baseline HbA_{1c} category			
Telephone group	−0.834%	1.09	.84	Telephone group	−1.13%	0.182	.89
Control group	−0.767%	1.14		Control group	−1.10%	0.189	
				Adjusted for major medication change			
				Telephone group	−0.834%	0.240	.84
				Control group	−0.768%	0.264	
Unadjusted mean change SMBG frequency				Adjusted for baseline SMBG category			
Telephone group	0.657 times per day	1.07	<.001[a]	Telephone group	0.405	0.118	<.001[a]
Control group	0.047 times per day	.750		Control group	−0.171	0.120	
				Adjusted for baseline age			
				Telephone group	0.645	0.120	.001[a]
				Control group	0.060	0.123	
Unadjusted mean change severity				No adjusted analysis			
Telephone group	1.44	1.97	.10				
control group	0.86	1.86					
Unadjusted mean change exercise barriers				Adjusted for pre-exercise barrier score			
Telephone group	0.163	0.733	.09	Telephone group	0.111	0.099	.175
Control group	0.036	0.536		Control group	0.051	0.109	
Unadjusted mean change positive attitudes				No adjusted analysis			
Telephone group	0.226	0.094	.07				
Control group	0.005	0.075					

Change in HbA_{1c} levels ≥ −0.6 %	**Responders (n = 27)**	**Nonresponders (n = 34)**	***P***
Mean age	57.8 ± 5.5 y	61.9 ± 8.3 y	.03[a]

Change in SMBG frequency ≥ 0.5 times per day	**Responders (n = 31)**	**Nonresponders (n = 30)**	***P***
Mean age	58.2 ± 5.7 y	62.0 ± 8.5 y	.047[a]
Mean duration of DM	10.87 ± 7.8 y	16.27 ± 8.25 y	.011[a]
Insulin			
Insulin	13	21	
Non-insulin	18	9	.027[a]

Abbreviations: DM, diabetes mellitus; HbA_{1c}, hemoglobin A_{1c}; SD, standard deviation; SE, standard error; SMBG, self-monitoring blood glucose. HbA_{1c}% change scores represent percentage point changes.

[a]Significant at ≤ .05.

outcome. Participants in both groups who had the highest HbA_{1c} scores at baseline seemed to benefit the most in terms of a negative change in HbA_{1c} level. Therefore, a GLM was computed with change in HbA_{1c} level as the dependent variable and treatment group and pre-HbA_{1c} *category* as independent factors in the model. Categories were defined as follows: (a) category 1 HbA_{1c} 7.0% to 7.9%; (b) category 2 HbA_{1c} 8.0% to 8.9%; (c) category 3 HbA_{1c} 9.0% to 9.9%; and (d) category 4 HbA_{1c} 10% or above. The telephone and comparison groups were comparable on mean change in HbA_{1c} level in all 4 categories. The adjusted analysis did not change the result ($P = .89$) (Table 2). Therefore, the null hypothesis was supported. To determine whether a major medication change was a factor in this outcome, a GLM was calculated with medication change category and treatment group as fixed factors in the model and change in HbA_{1c} level as the dependent variable. No significant differences were found on the main effect of treatment group or the main effect of medication change group (Table 2).

Telephone response rates ranged from 6 to 90 calls (mean 64 calls) received by participants during the 90-day study period. Participant adherence to taking the calls was highest during the first 30 days of the intervention. Compliers (those who received ≥90% of the calls) experienced a greater change in HbA_{1c} level in every pre-HbA_{1c} category except in category 4. An independent samples *t* test showed a significant difference in mean change in HbA_{1c} level between compliers (-0.796 ± 1.04 percentage points) and noncompliers (0.003 ± 1.04 percentage points) ($P = .02$) in participants who had baseline HbA_{1c} levels between 7.0% and 9.9%.

The secondary outcome for the study was change in daily SMBG frequency. LVCF was applied to 6 participants (10%) in the intervention group and 8 participants (14%) in the comparison group prior to the analysis.

An independent samples *t* test indicated that there was a significant difference in mean change in SMBG frequency per day between the telephone and comparison group. The telephone group had a mean increase in SMBG frequency of 0.66 ± 1.1 times per day and the comparison group had a mean increase in SMBG frequency of 0.05 ± 0.8 times per day ($P < .001$) (Table 2). Adjusting for age and for socioeconomic status did not change the result.

Participants who classified themselves as either white or nonwhite were equally distributed among responders and nonresponders on this outcome. Participants in both groups who had the lowest SMBG frequency per day at baseline seemed to benefit most in terms of a positive change in SMBG frequency. Therefore, a GLM was computed with change in SMBG frequency as the dependent variable and treatment group and pre-SMBG frequency *category* as independent factors in the model. Categories were defined as follows: (a) category 1 SMBG frequency 0 to 1 times per day; (b) category 2 SMBG frequency 1.1 to 2.0 times per day; (c) category 3 SMBG frequency 2.1 to 3.0 times per day; and (d) category 4 SMBG frequency 3.1 to 4 times per day. Mean change in SMBG frequency was superior in the treatment group compared with the comparison group across all 4 baseline categories. The adjusted analysis did not change the result ($P \leq .001$); therefore, the null hypothesis was rejected (Table 2).

The tertiary aim of the study was to evaluate differences between treatment groups on self-reported severity of diabetes, susceptibility to complications of diabetes, and the benefits and barriers of diabetes self-management. For the DCP survey data, LVCF was applied to responses related to positive attitudes and negative attitudes toward diabetes in 10 participants in the intervention group (16%) and 9 participants in the comparison group (16%). It was applied to responses related to severity of DM, susceptibility to complications of DM, exercise barriers, and monitoring barriers for 12 participants in the telephone group (20%) and 10 participants in the comparison group (17%).

Independent samples *t* tests evaluating differences in mean change between treatment groups on these variables showed no significant differences, supporting the null hypothesis. There was a trend in favor of the treatment group on changes in beliefs regarding severity of DM, exercise barriers, and positive attitudes toward DM (Table 2).

For the primary outcome, responders in the telephone group were defined as participants who had a change in HbA_{1c} level equal to or greater than −0.6 percentage points. Responders were significantly younger, by a mean of 4.1 years ($P = .03$), and had a significantly higher baseline mean HbA_{1c} levels ($P < .001$) (Table 2). Within this group, there was a significant correlation found between mean change in HbA_{1c} level and mean change in barriers to self-care beliefs ($r = -0.39$, $P = .04$). Correlations were also noted between mean change in positive attitudes and mean change in barriers to self-care beliefs ($r = 0.31$, $P = .11$) and between mean change in positive attitudes and mean change in changes in susceptibility to DM complications ($r = 0.41$, $P = .07$).

Responders for the secondary outcome, change in SMBG frequency, were defined as participants who had a change in daily SMBG frequency of equal to or greater than 0.5 times per day. Responders were again significantly younger, by a mean of 3.8 years ($P = .05$). Responders in this category also had a significantly shorter mean duration of DM by 5.4 years ($P = .01$), were less likely to be using insulin ($P = .03$), and had a significantly higher baseline SMBG frequency ($P = .002$) (Table 2). A significant correlation was found between mean change in susceptibility to complications of DM and change in SMBG frequency ($r = 0.351$, $P = .01$) in the telephone group. A correlation was also noted between mean change in positive attitudes and mean change in monitoring and exercise barriers ($r = .236$, $P = .06$).

DISCUSSION

The primary outcome in this study was mean change in HbA_{1c} level between a group of patients with type 2 DM exposed to a daily-automated telephone call and a comparison group that received usual care. Both groups experienced an overall negative mean change in HbA_{1c} level approaching 1 percentage point, suggesting an overall study effect, but the groups did not differ significantly on this outcome. A potentially important confounding variable, major medication change, did not alter the outcome in the adjusted analysis. It is unknown why participants who had baseline HbA_{1c} values of 10% or greater did not experience a dose effect. These patients may have been refractory to treatment based on their high baseline HbA_{1c} values and lack of response to treatment compared with patients with lower baseline HbA_{1c} values. Conversely, participants who received 90% or more of the calls during the intervention period may have been generally more adherent to their prescribed medical regimen. Participants in the telephone group were, on average, 3 years younger than those in the comparison group. The analysis indicated that the telephone intervention may have had a greater effect on glycemic control in younger patients.

Glycemic control outcomes in participants who complied with the intervention in this study were consistent with other studies of isolated telephone interventions in patients with type 2 DM.[26–30] Two of the studies reported greater improvements in telephone group patients who had higher baseline HbA_{1c} levels.[29,30] This is a logical finding, because patients with higher baseline HbA_{1c} values have greater room for improvement. This is also an important clinical finding, because patients who maintain near-normal blood glucose levels during their lifetime are expected to remain free of kidney disease, amputations, and nerve damage for an additional 6 years on average and to gain an average of 5 years of life and 8 years of sight.[31]

A strong treatment effect was observed in the frequency of daily SMBG in this study. This treatment effect is consistent with other studies of isolated telephone interventions in patients with type 2 DM.[29,32] Once again, responders were younger by close to 4 years, suggesting that the treatment effect was stronger in younger participants. Responders also had a shorter duration of DM by over 5 years, indicating that the treatment effect was greater in patients who had diabetes for a shorter duration. These findings are consistent with previous research that shows that older age is associated with lower odds of performing SMBG.[33,34]

Studies have shown that increased SMBG frequency is associated with improved glycemic control.[35] Research has also shown that despite improved technology making SMBG easier for patients, adherence to this self-care behavior is poor both in patients using and not using insulin.[36] Information regarding daily glucose readings provides valuable information such as postprandial glucose spikes that are not detected by infrequent HbA_{1c} levels. Understanding daily fluctuations in blood glucose levels assists healthcare providers in recommending individualized treatment regimens for patients.

The HBM served as the theoretical framework for this research. This study did not set out to test propositions in the theory, but rather it used the theory as a guide in developing a theoretically based intervention. The assumption that underlies the intervention is that if perceptions of severity, susceptibility, attitudes, and beliefs can be modified, then changes in behavior, and ultimately improved glycemic control, can be realized. Using the DCP to measure these perceptions operationalized the concepts in the model. Participants in the telephone group improved compared with those in the control group on all of these domains, but the results were not significant. However, some interesting trends were noted.

Change in perceived severity of diabetes was greater in the telephone group than in the control group. This indicates that participants exposed to the intervention were recognizing that feeling stress, being sick, having an infection, or getting too little exercise contribute to glycemic control problems. Trends in favor of the treatment group were also seen in improvements in positive attitudes toward diabetes, indicating that participants had improved feelings of life satisfaction self-efficacy (eg, confidence in being able to achieve one's goals), and in favorable changes to perceived exercise barriers. Improvements in positive attitudes were positively correlated with changes in perceptions related to SMBG and exercise barriers. This finding is consistent with previous research that has demonstrated an association between patient adherence to health behaviors and positive attitudes toward these behaviors.[37] In the current study, positive changes in attitudes toward diabetes were also positively associated with changes in susceptibility to complications of DM and change in SMBG frequency. These findings are consistent with research that has shown that participants who understand the severity of DM are more adherent to treatment and have more positive attitudes toward diabetes than participants who do not understand the severity of DM.[38]

LIMITATIONS

This study has several limitations. First, the study was conducted at one university medical center, which limits generalizability to individuals with type 2 DM who are cared for in a similar setting. Convenience sampling was used, which decreases the probability that the sample was representative of all eligible participants in the clinics from which the sample was drawn. Overall, the study sample was diverse in terms of sex, age, race, education, and income level.

Blinding of the investigator, participants, and caregivers was not possible, which may have introduced treatment and or investigator bias. Lack of an active control for participants receiving usual care in the study makes it difficult to determine whether the treatment effect on the frequency of SMBG monitoring was due to the content of the calls, simply receiving a daily telephone call, or being asked to report blood glucose values. Adherence to receiving the automated telephone calls was tracked, but no attempt was made to influence adherence to the calls during the study. Concordance with treatment is an important factor in understanding treatment effects and needs further examination. Two important factors in understanding the treatment effect are patient satisfaction and the potential influence of comorbidity on self-care behavior, which were not examined in this study.

Attrition rates on the primary outcome, change in HbA_{1c} levels, were low because most participants returned for their 90-day follow-up visit. Attrition rates were higher on the secondary outcome, change in daily SMBG frequency, because participants failed to bring their meters to follow-up appointments for a variety of reasons including simply forgetting the meter, not being able to find the meter, and leaving the meter on an airplane. An assumption can be made that some participants who failed to bring their meters to the follow-up visits may have had lower adherence to SMBG and, therefore, did not want the meter downloaded at that time. Attrition on this endpoint was evenly distributed between treatment groups, reducing the risk of this systematic bias being introduced to one group only. Attrition rates on the tertiary endpoint were also evenly distributed among treatment groups. The primary reason for attrition on this endpoint was failure to return the survey after the final follow-up visit. Participants who were not able to complete the questionnaire during the final visit were given the $25.00 stipend and a stamped addressed envelope in which to return the survey. Follow-up phone calls were made to encourage participants to follow through on this endpoint. The length of the questionnaire may have been a factor in attrition related to this outcome.

The DCP questionnaire used to measure constructs from the HBM was lengthy, which may have contributed to responder fatigue and response bias. Even though the questionnaire was based on the HBM, the items asked to measure severity and susceptibility had limited face validity. The incorporation of other scales with stronger face validity would more clearly measure these constructs and add to the validity of the findings.

Finally, the intervention in the study simply asked participants to listen to a message and to report their daily blood glucose readings. The ability to give patients real-time feedback on their readings and suggestions for improving glycemic control during the study was limited. This may have limited the effect of the intervention on the primary outcome. Adding this dimension to the intervention in a follow-up study is recommended.

CONCLUSIONS

This study attempted to address a gap in the literature that exits in understanding the effects of theoretically based, isolated, automated telephone interventions on physiological, behavioral, and psychosocial outcomes in adults with type 2 DM. No overall treatment effect was seen on change in HbA_{1c} level, but a significant dose effect was observed. The automated telephone intervention in this study had a significant impact on the daily frequency of SMBG, suggesting that regular contact between scheduled clinic visits enhances adherence to this self-care behavior. The findings from this study can be generalized to a diverse group of individuals with type 2 DM cared for in an urban setting in the Midwestern United States. Further studies that include concordance monitoring and real-time feedback to patients regarding the results of their blood glucose levels between regularly scheduled clinic visits are needed. These studies should also examine the effect of comorbidity on self-care behavior. The intervention also showed favorable trends in changes in perceived severity to DM, attitudes toward DM, and reductions in perceived exercise barriers. Further study is needed to determine whether these factors are significant mediators to behavioral changes.

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