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

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Abstract

Type 2 diabetes is a condition that affects millions of Americans and often results in serious vascular complications. Studies have found that lowering HbA_{1c} levels in this population plays an essential role in reducing both micro and macro vascular complications. Consequently, medical management of type 2 diabetes has become more intensive; however HbA_{1c} levels remain too high in this population. This study evaluates the effect of an automated telephone intervention aimed at improving HbA_{1c} levels and self monitoring of blood glucose in adults with type 2 diabetes. One-hundred-twenty participants were randomly assigned to a treatment or a control group. The treatment group received a daily, automated telephone message regarding diabetes and was asked to report blood glucose levels. No difference in mean change in HbA_{1c} between treatment groups was seen at the end of the 90-day intervention. Participants in the treatment group demonstrated a significant improvement in frequency of daily self-monitoring of blood glucose (an increase of .66 times per day in the telephone group compared to .05 times per day in the control group, $p = <.001$). The treatment group also showed favorable trends on improvement in attitudes toward diabetes and perceived monitoring and exercise barriers. This study shows that an automated telephone intervention increases daily frequency of self-monitoring of blood glucose in adults with type 2 diabetes. This finding has important clinical implications because understanding daily fluctuations in blood glucose informs treatment decisions beyond the information provided by HbA1c levels. Future studies are needed to determine whether this effect is long-lasting, whether changes in attitudes and beliefs mediate the behavior change, and whether the behavior change precedes physiological changes.

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CHAPTER ONE

Introduction

Background and Scope of the Problem

Diabetes mellitus (DM) is a group of metabolic disorders resulting from disturbances in both insulin production and utilization resulting in hyperglycemia. It is a growing public health problem that is an epidemic in the United States. An estimated 23.6 million Americans have DM and approximately 1.5 million new cases are diagnosed each year (American Diabetes Association [ADA], n.d.). Diabetes is the nation's sixth leading cause of death by disease, contributing to more than 200,000 deaths annually (Center for Disease Control [CDC], 2005). Type 2 DM accounts for 90 to 95 % of all DM cases and virtually all cases diagnosed in people over the age of 45 (National Institute of Diabetes & Digestive & Kidney Diseases [NIDDK], 2007).

The total health care costs of a person with DM in the U.S. are over twice that of people without the condition (Moore, Zgibor & Dasanayake, 2003). A total of $116 billion in annual direct medical expenditures were attributable to DM in 2007. In addition, DM is associated with higher rates of lost work time, disability, and premature mortality resulting in an estimated loss of $58 billion to the U.S. economy in 2007 (ADA, n.d.). Experts expect the incidence of DM to increase in the U.S. along with the changing demographics of America. The prevalence of DM increases with age; people age 65 and older account for approximately 37% of the United States population with DM and the incidence is higher among certain racial and ethnic minorities (CDC, 2005).

Clinical studies have shown that uncontrolled hyperglycemia in type 2 DM results in the same long-term vascular complications as seen in type 1 DM (Wright, Burden, Paisey, Cull & Holman, 2002). The United Kingdom Prospective Diabetes Study (UKPDS), a ten-year landmark study involving 3867 patients with type 2 DM, demonstrated overwhelmingly that intensive therapy aimed at achieving even modest improvements in hemoglobin A_{1c} (HbA_{1c}) plays an essential role in reducing the risk of developing microvascular complications (e.g., retinopathy, neuropathy, and nephropathy) and trends toward reductions in myocardial infarction and stroke. (Stratton et al., 2000; UKPDS, 1998).

Hemoglobin A_{1c} is a manifestation of the binding of circulating adult hemoglobin (HbA) molecules on erythrocytes to glucose. It reflects total glucose exposure to HbA, including both fasting and post-prandial plasma glucose levels, over the past two to three months (Rohlfing, et al., 2002). Infrequent measuring of HbA_{1c} (i.e., every three 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 more frequently via self-monitoring of blood glucose (SMBG) is an important component of self-management of diabetes (ADA, 2007).

The importance of SMBG in patients with type 1 DM has long been recognized, but its importance in managing patients with type 2 DM has been questioned (Gallichan, 1997; Gulliford & Lantinovic, 2004; Harris, 2001). However, other studies have found direct relationships between HbA_{1c} and SMBG in patients with type 2 DM

(Evens, et al.,1999; Jones et al., 2003; Karter, Ackerson, & Darbinian, 2001; Nyomba, Berard, & Murphy, 2003). Citing evidence from clinical trials using insulin, the ADA position statement (2007) gives a *level of evidence A* recommendation for using SMBG as an integral part of DM management strategy and recommends that it be carried out three or more times a day for patients requiring multiple daily insulin injections. A *level of evidence A* indicates, "There is clear evidence from well-conducted, generalizable, randomized controlled trials adequately powered" (p. s5). Based on expert opinion consensus and clinical experience, the ADA position paper (2007) also recommends using SMBG to achieve glycemic goals in patients requiring insulin less frequently or those requiring oral medication or nutritional therapy without exogenous insulin.

Seminal studies such as the UKPDS (1998) have generated new knowledge regarding the importance of intensive management of type 2 DM, and important findings concerning the benefits of lowering HbA_{1c} levels have been disseminated in numerous practice guidelines. Despite this, glycemic control worsened in patients with type 2 DM (Koro, Bowlin, Bourgeois, & Fedder, 2004). After examing data from 1587 participants in two large representative national surveys (i.e., the National Health and Nutritional Examination surveys [NHANES III, 1988-1994] and [NHANES 1999-2000]) Koro and colleagues observed that, consistent with current recommendations toward earlier and more aggressive treatment in type 2 DM, more patients were being treated with a combination of oral hypglycemic agents and insulin. The authors also reported, however, that the rate of adequately controlled type 2 DM in adults, defined as

HbA_{1c} less than 7.0%, decreased significantly between the time periods 1988-1994 and 1999-2000, from 45% to 36% respectively.

In another study examining the NHANES data Harris (2001) examined the relationship between medical care, health status, and outcomes of 733 adults with type 2 DM from the NHANES III survery. The author reported that, in patients who reported good access to medical care (95% indicating they had one usual source of ambulatory medical care, 88% reporting having had two or more physician visits in the past 12 months, and 91% indicating that they had health insurance), at least 58% had HbA_{1c} values over 7.0% (Harris, 2001). The most recent data (NHANES 2003 – 2006) show approximately 50% of adults aged forty and older who have diabetes reporting HbA_{1c} values over 7.0%. Sixty percent of Non-Hispanic whites reported therapeutic HbA_{1c} levels while approximately 40% of non-Hispanic blacks and Mexican-Americans reported therapeutic HbA_{1c} levels (CDC, 2008).

Chronic Disease Management

Studies of chronic disease management have shown that intensive interventions using multidisciplinary teams including nurses and physicians improve medication adherence, patient self-care behavior, and glycemic control in patients with diabetes (O'Conner, et al., 1996; Peters & Davidson, 1998). The Diabetes Control and Complications Trial (DCCT) 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. The self-management component of intensive DM management was of critical importance and was shown to contribute to

delaying the onset and minimizing progression of the disease (DCCT Research Group, 1993).

Studies of interventions involving the telephone have been shown to improve adherence to medications and to improve blood pressure readings in patients with hypertension (Friedman et al., 1996), to improve quality of life in patients with cardiac problems (Follick et al., 1988), and to be effective in changing physical activity and dietary behaviors (Eakin, Lawler, Vandelanotte & Owen, 2007). Riegel et al. (2002) showed that a telephone intervention reduced hospitalizations and overall costs in heart failure patients compared to other disease management approaches. Extensive telephone access to healthcare practitioners was a key element found to maintain lower HbA_{1c} levels in the DCCT (American Association of Diabetes Educators [AADE], 2002).

Comprehensive self-management training and disease management programs that include telephone follow-up as a nursing intervention have been shown to be effective in achieving glycemic control in patients with type 2 DM. These programs typically include providing a number of interventions simultaneously (i.e., education, monitoring, social support, medication adjustment, telephone follow-up, etc.). Knowledge regarding the effects of the individual management strategies of these multifaceted programs is limited (Norris, Englgau, & Narayan, 2001). The telephone is an inexpensive, easy to use, familiar technology that is almost universally available in the United States. Data from a randomly selected national sample of 32,969 households in 2004 show that 94.6% of households have a telephone, with 88.6 reporting a land line [46.4% land and cell; 42.2% land only] (Tucker, Brink & Meekins, 2007). Therefore,

further evaluation of telephone interventions as an isolated strategy in improving outcomes in patients with type 2 DM is warranted.

CHAPTER TWO

Review of the Literature

A systematic literature review was undertaken to provide a comprehensive evaluation of relevant quantitative studies on the impact of isolated telephone interventions on glycemic control in adult patients with type 2 DM. The almost universal availability of the telephone and its familiarity make it an ideal method for communicating with patients with type 2 DM between clinic visits. Understanding the evidence regarding isolated telephone-based interventions on outcomes in patients with type 2 DM will inform providers caring for these patients and patients with other chronic conditions of the merits of such interventions.

Methods

Data Sources

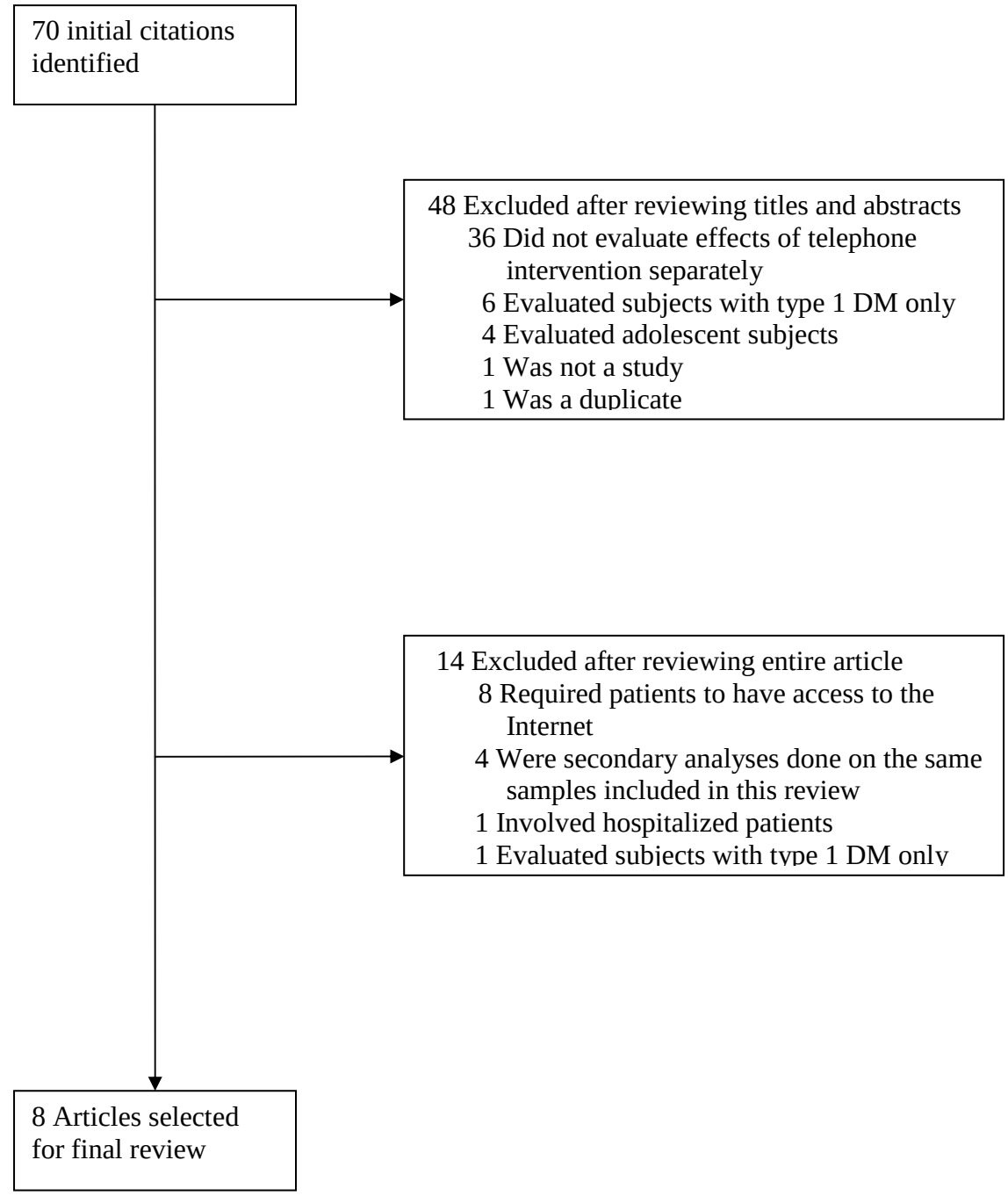
The search was conducted using EBSCOhost® research databases. The databases Academic Search Premier, ClinicalTrials.gov, Cumulative Index to Nursing and Allied Health Literature (CINAHL), The Cochrane Database of Systematic Reviews, Medline, PsychINFO, and psychARTICLES were searched using the search terms tele* and (diabetes mellitus or type 2 diabetes) and (glycemic control or HbA_{1c} or self-monitoring of blood glucose [SMBG]) and adult. The asterisk represented the system's truncation symbol that allowed variations of search terms to be searched. Limits included studies published in peer-reviewed journals in the English language and the publication years 1990 through 2008. Studies published prior to 1990 were

excluded because data supporting the relationship between tight glycemic control and chronic complications of DM were limited prior to that time (AADE, 2002).

Study Selection

Study selection criteria included original quantitative studies published in English evaluating the impact of an isolated telephone intervention on glycemic control measured by HbA_{1c}. Samples included adult patients with type 2 DM either using or not using exogenous insulin. All titles and abstracts were reviewed for relevance and those meeting the study selection criteria were retrieved along with articles in which a determination of relevance could not be made by reviewing the titles and abstracts. Reference lists of retrieved articles were screened for additional relevant studies. Seventy initial titles and abstracts were reviewed; the selection process resulted in eight published randomized controlled trials selected for this review (see Figure 1).

Figure 1. Study Selection Process.



The Cochrane Database search resulted in four documents of interest, two future protocols and two published reviews. The two protocols described processes to be used in future reviews, one involving telephone follow-up for patients with type 2 DM, and another review of mobile phone messaging involving patients with both type 1 and type 2 DM. The two reviews were of (a) interventions for improving adherence to treatment recommendations in patients with type 2 DM and (b) interventions to improve management of both type 1 and type 2 DM in outpatient settings. Only four studies in these two reviews included telephone interventions and three of these studies were excluded from this review. One study was excluded because it was computer-based; one study focused on a multifaceted intervention, and another included only children with DM. The fourth study was a duplicate study found during the initial search and was included in this review.

Studies other than randomized controlled trials (RCTs) were considered for inclusion in this review. However, no prospective cohort studies or case-control studies were retrieved after reviewing the titles and abstracts. This is not surprising since studies evaluating the effects of telephone interventions on glycemic control lend themselves to an RCT design by the nature of the research questions being asked.

Studies that required patients to either have home access to the Internet or to travel to a site where the Internet was available were excluded from the review because, although this technology is becoming more widely available in the homes of individuals, it is not as universal as the telephone. According to the United States Census Bureau, only 54.7% of households reported Internet access in 2003 (Day, Janus, & Davis, 2005).

Validity Assessment and Grading System

The overall body of evidence for the RCTs evaluated in this systematic review was rated according to the ADA (2007) grading system. The ADA grading system describes an overall level of evidence for a body of literature according to published criteria shown in Table 1. Internal validity of the studies was determined according to six domains of the Cochrane methodology (Higgins & Green, 2008) using the Cochrane Collaboration's tool for assessing risk of bias. This investigator and another researcher judged the studies separately based on what was reported in the articles in relation to the six domains. Discrepancies were discussed and consensus in judgment was achieved. A judgment of "no" indicated a high risk of bias in that domain, a judgment of "unclear" indicated an uncertain risk of bias, and a judgment of "yes" indicated a low risk of bias in that domain (see Table 2).

Table 1
ADA Grading System Used with Permission

Level of Evidence	Description
A	Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including: • Evidence from well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis • Compelling nonexperimental evidence, i.e., "all or none" rule developed by Center for Evidence Based Medicine at Oxford. Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis.
B	Supportive evidence from well-conducted cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies. Supportive evidence from a well-conducted case-control study.
C	Supportive evidence from poorly controlled or uncontrolled studies • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison to historical controls) • Evidence from case series or case reports. Conflicting evidence with the weight of evidence supporting the recommendation.
E	Expert consensus or clinical experience.

Table 2

Internal Validity of the Studies According to Cochrane Domains

Glasgow & Toobert (2000)	**Reviewers' Judgment**	**Rationale**
Sequence generation	Unclear	Participants were randomized to one of four groups, but method of randomization not described.
Allocation concealment	No	Not mentioned.
Blinding	No	Could influence some outcomes, but not HbA_{1c}.
Incomplete outcome data	Yes	Potential bias controlled for. Analysis of attrition done prior to final data analysis. While some outcome data are missing, rates are balanced across groups.
Selective outcome reporting	Yes	Free of bias.
Other sources of bias	Yes	None obvious.
Kim & Oh (2003)		
Sequence generation	Unclear	Randomization by coin toss. Final enrollees may have been assigned to achieve balance between groups.
Allocation concealment	No	No description of when coin toss occurred.
Blinding	No	Could influence some outcomes, but not HbA_{1c}.
Incomplete outcome data	No	More outcome data missing from control than intervention groups. Dropouts not compared to those retained.
Selective outcome reporting	Yes	Free of bias.
Other sources of bias	Unclear	Possible participant overlap in subject recruitment with publication in *Yonsei,2003 44*, 1-8.

Table 2 *(continued).*

Kim, Oh, & Lee (2005)	**Reviewers' Judgment**	**Rationale**
Sequence generation	Yes	Random number table
Allocation concealment	No	Not mentioned.
Blinding	No	Could influence some outcomes, but not HbA_{1c}.
Incomplete outcome data	Unclear	Five participants lost in each group. Baseline characteristics between control and intervention groups for final sample provided. No information on differences between those who stayed in study and those who did not.
Selective outcome reporting	Yes	Free of bias.
Other sources of bias	Yes	No obvious overlap with prior reports, however they do not cite their previous work.
Maljanian et al. (2005)		
Sequence generation	No	Not described.
Allocation concealment	No	Not mentioned.
Blinding	No	Not mentioned.
Incomplete outcome data	No	High rate of dropouts. Those who dropped out were less adherent and more obese.
Selective outcome reporting	Yes	Free of bias.
Other sources of bias	Unclear	Much of the paper is devoted to confirming the efficacy of the intervention, but the study design for that was longitudinal without a control.

Table 2 *(continued).*

Oh et al. (2003)	**Reviewers' Judgment**	**Rationale**
Sequence generation	Unclear	Randomization by coin toss. Final enrollees may have been assigned to achieve balance between groups.
Allocation concealment	No	Not Mentioned.
Blinding	No	Could influence some outcomes, but not HbA_{1c}.
Incomplete outcome data	Unclear	Greater attrition in control group compared to intervention group. Baseline characteristics between control and intervention groups for final sample provided. No information on differences between those who stayed in study and those who did not.
Selective outcome reporting	Yes	Free of bias.
Other sources of bias	Unclear	Possible overlap with *Journal of Advanced Nursing, 2003, 44*.
Piette et al. (2000)		
Sequence generation	Yes	Random number table.
Allocation concealment	Yes	Prior to randomization.
Blinding	Yes	Blinding for HbA_{1c}, but not self-reports.
Incomplete outcome data	Yes	Slightly fewer lost in intervention group compared to usual care, but generally dropouts and those retained were similar. Analysis was not intent-to-treat.
Selective outcome reporting	Yes	All domains listed in methods were reported. Another paper apparently reported patient-centered outcomes.
Other sources of bias	Yes	No apparent bias.

Table 2 *(continued).*

Piette et al. (2001)	**Reviewers' Judgment**	**Rationale**
Sequence generation	Yes	Random number table.
Allocation concealment	Yes	Sealed envelopes.
Blinding	Yes	For HbA_{1c}, but not self-reports.
Incomplete outcome data	Yes	Very few dropouts. Analysis was not intent to treat.
Selective outcome reporting	Yes	All domains listed in methods were reported.
Other sources of bias	Yes	Although the variety of explorations of HbA_{1c} subgroups may introduce bias.
Young et al. (2005)		
Sequence generation	Yes	Stratified and blocked. SAS program.
Allocation concealment	Unclear	Not fully described. Conducted by study statisticians.
Blinding	No	This could influence some outcomes, but free of bias for HbA_{1c}.
Incomplete outcome data	Yes	Data analysis intent to treat with last value carried forward.
Selective outcome reporting	Yes	Free of bias.
Other sources of bias	Yes	No apparent bias.

Data Abstraction and Study Characteristics

The data were collected and organized into a table to assist with comparisons across studies using a Review Matrix described by Garrard (2004). Data were collated according to the purpose of the study, the intervention, the design and sample, the outcome measures, the measurement instruments, and the results (see Table 3).

Table 3
Study Characteristics

Authors, year, and Research Objective	**Telephone and Control Conditions**	**Design and Sample**	**Outcome Measures and Measurement Instruments**	**Effects of Interventions**
Glasgow & Toobert (2000) Evaluate the effectiveness, adoption, and implementation of a brief behavioral dietary intervention (basic condition) and two supplemental components of DM self-management support: telephone follow-up calls (TF) and community resources enhancement (CR)	Brief structured telephone calls to provide ➢ Support, reinforcement of diabetes education, tailored dietary counseling, problem-solving ➢ 3-4 calls during 6 months (Implementation scores 80-90%) ➢ Duration of intervention 6 months ➢ Endpoint assessment 6 months Control group received general pamphlet on low fat eating	RCT ➢ Random assignment to one of four groups (basic condition, basic condition & TF, basic condition and CR, combined) ➢ Type 2 DM ➢ Average age 59 years ➢ 56% female ➢ 90% Caucasian ➢ 57% attended at least some college ➢ N=320, attrition 8.5% at 3 months, 13.4% at 6 months ➢ No report of sample size analysis	➢ GC determined by HbA_{1c} ➢ Behavioral outcomes assessed by the Kristal Fat and Fiber Behavior Scale, a reliable and validated scale ➢ Total cholesterol, weight, lipid ratio ➢ QOL measured via the Illness Intrusiveness Scale (IIS), a scale with face validity and good psychometric properties ➢ Patient satisfaction measured via an instrument adapted by the researchers (Cronbach's alpha 0.86)	➢ Small NS overall reduction in HbA_{1c} levels (0.1% to 0.2%) ➢ Sig difference favoring TF conditions on the Kristal Fat and Fiber Behavior Scale (p=0.017) ➢ NS reduction in total cholesterol and lipid ratios (p=0.10) across conditions ➢ Little change in illness-related QOL ➢ No main effects on the IIS or on patient satisfaction ➢ Adding TF did not enhance outcomes beyond basic intervention

Table 3 *(continued).*

Authors, year, and Research Objective	**Telephone and Control Conditions**	**Design and Sample**	**Outcome Measures and Measurement Instruments**	**Effects of Interventions**
Kim & Oh (2003) To investigate the effect of nurse telephone calls on HbA_{1c} levels and adherence to diabetes control recommendations	Counseling regarding ➢ Maintaining BG within near-normal range, diet, exercise, medication adjustment, SMBG ➢ Calls 2x/week for the first month, 1x/week for the second and third months (average of 16 telephone calls per participant) ➢ Duration of intervention 3 months ➢ Endpoint assessment 3 months Control group: visiting physician every three months	RCT ➢ Random assignment to telephone or control group ➢ Type 2 DM, $HbA_{1c} \geq 7\%$ ➢ Average age 60 years ➢ 70% female ➢ 100% Korean† ➢ 50% completed more than high school ➢ N=50, attrition 28% ➢ No report of sample size analysis	➢ GC determined by HbA_{1c} ➢ Diabetes adherence measured by a self-reported questionnaire developed by the researchers that included 20 items measured by a VAS. Content validity described. Cronbach's alpha for this sample 0.82	➢ Sig decrease in mean change in HbA_{1c} between groups (-1.2% vs. +0.6% $p<0.05$) ➢ Sig interaction between diet ($p=0.006$) and SMBG adherence ($p=0.024$) between groups and times ➢ NS interaction between exercise, medication-taking, low BG management and foot care adherence between groups and times

Table 3 *(continued).*

Authors, year, and Research Objective	Telephone and Control Conditions	Design and Sample	Outcome Measures and Measurement Instruments	Effects of Interventions
Kim, Oh, & Lee (2005) To evaluate the effect of a nurse-coordinated intervention to improve glycemic control, blood lipids, and patient satisfaction with care in non-obese patients with type 2 DM	Counseling regarding ➢ Maintaining BG within near-normal range, diet, exercise, medication adjustment, SMBG ➢ Calls 2x/week for the first month, 1x/week for the second and third months (average of 16 telephone calls per participant) ➢ Duration of intervention 3 months ➢ Endpoint assessment 3 months Control group: visiting physician every three months	RCT ➢ Random assignment to telephone or control group ➢ Type 2 DM, $HbA_{1c} \geq 7\%$ ➢ Average age 60.5 years ➢ 65% female ➢ 100% Korean† ➢ 55% completed more than high school ➢ N=35, attrition 29% ➢ For an effect size of 0.7 at a power of 0.8 and an α of 0.05, 33 participants needed per group	➢ GC determined by HbA_{1c},, FBG, and 2-hour post-prandial glucose levels ➢ Triglycerides and HDLC levels ➢ Patient satisfaction with care measured via a VAS with zero indicating no satisfaction and 10 indicating much satisfaction	➢ Sig decrease in mean change in HbA_{1c} (-1.2% in intervention group and +0.5% in control group, p=0.004). ➢ NS changes in FBS, 2-hour postprandial glucose, triglyceride or HDLC between groups ➢ Satisfaction with care sig higher in the intervention group (p=.023)

Table 3 *(continued).*

Authors, year, and Research Objective	Telephone and Control Conditions	Design and Sample	Outcome Measures and Measurement Instruments	Effects of Interventions
Maljanian, Grey, Staff, & Conroy (2005) To evaluate the value of an intensive telephone follow-up as an additional component of diabetes disease management program already shown to be effective in improving glycemic control, adherence with ADA standards of care, and HRQOL	Weekly phone calls to ➢ Reinforce education and self-management skills ➢ Number of calls received not reported ➢ Duration of intervention 3 months ➢ Endpoint assessment 3 and 12 months Control group received routine care consisting of visiting physician every three months	RCT ➢ Random assignment to telephone or control group *assumed* ➢ 96% type 2 DM ➢ Average age 58 years ➢ 53% female ➢ 70% Caucasian ➢ Education not reported ➢ N=507, attrition 34% ➢ No report of sample size analysis	➢ GC determined by HbA_{1c} ➢ HRQOL measured by Short Form 36 (SF36) ➢ Disease specific QOL and patient satisfaction measured by Diabetes Specific Quality of Life Questionnaire developed as part of the Diabetes Quality Improvement Project (DQIP) ➢ Depression measured by Epidemiologic Studies Depression Scale (CES-D) ➢ Adherence to self-management guidelines measured by DQIP ➢ Psychometric properties not reported, but references provided	➢ Group assignment was not a sig predictor of whether participants met ADA target of <7.0% for HbA_{1c} at 3 or 12 month follow-up ➢ No sig differences between telephone and control group on GC or any of the measures of general or specific HRQOL, symptoms of depression or patient satisfaction at either 3 or 12 months ➢ Adherence to ADA standards of care was sig better with the added telephone intervention

Table 3 *(continued).*

Authors, year, and Research Objective	Telephone and Control Conditions	Design and Sample	Outcome Measures and Measurement Instruments	Effects of Interventions
Oh, Kim, Yoon & Choi (2003) To investigate the effect of a telephone-delivered intervention on glycemic control and body mass index in Korean patients with type 2 DM	Counseling regarding ➢ Maintaining BG within near-normal range, diet, exercise, medication adjustment, SMBG ➢ Calls 2x/week for the first month, 1x/week for the second and third months (average of 16 telephone calls per participant) ➢ Duration of intervention 3 months ➢ Endpoint assessment 3 months Control group: visiting physician every three months	RCT ➢ Random assignment to telephone or control group ➢ Type 2 DM ➢ Average age 60 years ➢ 65% female ➢ 100% Korean† ➢ 54% completed more than high school ➢ N=50, attrition 24% ➢ No report of sample size analysis	➢ GC determined by HbA_{1c}, FBG, and 2-hour postprandial glucose ➢ BMI	➢ Sig decrease in mean change in HbA_{1c} (-1.2% change in HbA_{1c} in intervention group compared to a +0.3% change in HbA_{1c} in control group, p=0.000). ➢ No sig difference between groups in mean FBG or 2-hour postprandial glucose levels ➢ No sig differences between groups in BMI

Table 3 *(continued).*

Authors, year, and Research Objective	**Telephone and Control Conditions**	**Design and Sample**	**Outcome Measures and Measurement Instruments**	**Effects of Interventions**
Piette, Weinberger, Kraemer, & McPhee (2001) To evaluate automated telephone disease management (ATDM) with telephone nurse follow-up as a strategy for improving diabetes treatment process and outcomes in the Department of Veterans Affairs (VA) clinics	Biweekly automated telephone assessments to ➢ Identify patients with health and self-care problems, focus efforts of nurse educator on patients with the greatest problems, deliver targeted and tailored self-care messages ➢ Mean 13 contacts per patient, 3.8 hrs contact time ➢ Duration of Intervention 12 months ➢ Endpoint assessment 12 months Control group: no information	RCT ➢ Random assignment to telephone or control group ➢ Type 1 and Type 2 DM ➢ Average age 60.5 years ➢ 3% female ➢ 60% Caucasian ➢ 21% annual income ➢ < $10,000 per year ➢ N=272, attrition 7% ➢ No report of sample size analysis	➢ GC determined by HbA_{1c} and serum glucose levels ➢ Satisfaction with care measured using the Employee Health Care Value Survey ➢ No psychometric properties of satisfaction scale reported, but reference provided	➢ NS difference on mean HbA_{1c} (p=0.3). Patients with baseline $HbA_{1c} \geq 8\%$, adjusted mean endpoint HbA_{1c} values differed by 0.5% (p=0.04) and by 1.1% for baseline $HbA_{1c} \geq 9$ (p=0.04) ➢ Intervention patients reported more frequent SMBG and foot inspections (p=0.05), had more podiatry visits (p=0.003), diabetes visits (p=0.03), cholesterol tests (p=0.05), and reported fewer symptoms of poor GC (p=0.04)

Table 3 *(continued).*

Authors, year, and Research Objective	Telephone and Control Conditions	Design and Sample	Outcome Measures and Measurement Instruments	Effects of Interventions
Piette, Weinberger, McPhee, Mah, Kraemer, & Crapo (2000) To evaluate the effect of automated telephone assessment and self-care education calls with nurse follow-up on the management of diabetes	Bi-weekly automated telephone assessments to ➢ Patients with health and self-care problems, focus efforts of nurse educator on patients experiencing the greatest problems, deliver targeted and tailored self-care messages ➢ Mean 6 contacts per patient, 1.2 hr contact time ➢ Duration of intervention 12 months ➢ Endpoint assessment 12 months Control group: no systematic monitoring between clinic visits	RCT ➢ Random assignment to telephone or control group ➢ Type 1 and Type 2 DM ➢ Average age 54.5 years ➢ 59% female ➢ 30% Caucasian, 50% Hispanic ➢ 58% annual income < $10,000 per year ➢ N= 280, attrition 11% ➢ No report of sample size analysis	➢ GC determined by HbA_{1c}, and serum glucose levels ➢ Frequency of glucose monitoring, foot inspection and weight monitoring measured by participants ratings on a 5-point Lickert scale psychometrics not provided ➢ Perceived GC measured by participant ratings on a 5-point Lickert scale psychometrics not provided ➢ BMI ➢ Health care utilization	➢ No sig difference on mean HbA_{1c} (p=0.1) ➢ Intervention increased the proportion of patients with normal HbA_{1c} levels by 9% (p=0.04), decreased serum glucose levels by 41 mg/dL (p=0.002), and improved self-reported GC (p=0.005) ➢ Sig improvement in frequency of glucose monitoring (p=0.03), foot inspection (p=0.02), weight monitoring (p=0.001), and decrease in reported medication problems (p=0.003)

Table 3 *(continued).*

Authors, year, and Research Objective	Telephone and Control Conditions	Design and Sample	Outcome Measures and Measurement Instruments	Effects of Interventions
Young et al. (2005) To determine whether Pro-Active Call Center Treatment Support (PACCTS), using trained nonmedical telephonists supported by specially designed software and a diabetes nurse, can effectively improve glycemic control in type 2 DM	Protocol-based calls regarding ➢ Knowledge of DM, readiness for change, medication adherence, SMBG ➢ Frequency varied by ➢ Number of calls per participant not reported ➢ Duration of intervention 12 months ➢ Endpoint assessment 12 months Control group managed according to same guidelines	RCT ➢ Participants randomly selected ➢ Random assignment stratified by baseline HbA_{1c} (<7, 7-9, or >9%) ➢ Type 2 DM ➢ Average age 67 years ➢ 42% female ➢ Sample drawn from 95% white European population; 80% lowest SES category ➢ N=591, 14% attrition ➢ Sample size analysis based on mean difference between groups of > 1% reduction in HbA_{1c}, sig level 0.05, power 90%	➢ GC determined by HbA_{1c}	➢ Sig improvement in HbA_{1c} of 0.3% in the PACCTS (p=0.003). Patients with baseline HbA_{1c} of 7-9%, sig improvement in HbA_{1c} of 0.49% (p=<0.001) ➢ A 10% increase in those achieving a 1% reduction of HbA_{1c} was seen in the telephone group (p<0.001)

† presumed 100% Korean sample. Abbreviations: ADA, American Diabetes Association; BG, blood glucose; FBG, fasting blood glucose; GC, glycemic control; HDLC, high-density lipoprotein cholesterol; HRQOL, health-related quality of life; NS, nonsignificant; PCPs, primary care provider; QOL, quality of life; RCT, randomized controlled trial; RNs, registered nurses; Sig, significant; SMBG, self-monitoring blood glucose; VAS, visual analog scale

Results

Purpose

The main purpose of six of the studies reviewed was to evaluate the effect of a telephone-delivered intervention on glycemic control in patients with type 2 DM (Kim & Oh, 2003; Kim, Oh & Lee, 2005; Oh, Kim, Yoon & Choi, 2003; Piette, Weinberger, Kraemer, & McPhee, 2001; Piette, et al., 2000; Young et al., 2005). Two studies evaluated the effects of a telephone component of a broader program on glycemic control in patients with type 2 DM (Glasgow & Toobert, 2000; Maljanian, Grey, Staff, & Conroy, 2005).

Interventions

The interventions consisted primarily of outgoing calls to patients. Young et al. (2005) was the only study that reported incoming calls from patients (10% of telephone consultations). Seven of the eight interventions reviewed consisted of tailored messages based on either an initial assessment (Glasgow & Toobert, 2000) or ongoing assessments (Kim & Oh, 2003; Kim, et al., 2005, Oh et al., 2003; Piette, et al., 2001; Piette, et al., 2000; Young et al., 2005) based on participants' responses to queries. Maljanian et al. (2005) delivered scripted messages intended to reinforce education and self-management skills presented to participants at an initial education session. The authors of this study did not report an initial or ongoing assessment of participants on which the script was tailored.

Glasgow and Toobert (2000) conducted a baseline dietary assessment that resulted in a tailored dietary fat reduction goal based on participants' eating patterns and preferences. The follow-up calls provided ongoing support, reinforcement, and

problem solving aimed at attaining these goals. The interventions in the three studies conducted by Kim and Oh (2003), Kim et al. (2005), and Oh et al. (2003) provided education and reinforcement of self-care activities and provided dietary and medication adjustment recommendations based on information obtained from participants' glucose, diet, and exercise logs kept during the intervention.

The interventions in the studies by Piette, et al. (2001) and Piette, et al. (2000) consisted of automated messages aimed at determining participants' health status. Based on reports generated weekly, nurses contacted participants to address problems reported during the assessments and provided more self-care education. Primary care physicians were contacted if the acuity of the call warranted a contact. The intervention in the study conducted by Young et al. (2005) consisted of starting with a series of questions to identify gaps in knowledge and providing advice regarding lifestyle improvements. Subsequent components of the intervention consisted of assessing and supporting readiness to change, and assessment of medication adherence and glucose control. Information gathered from participants was subject to review, and referrals were made to diabetes specialist nurses who were able to adjust medications according to established guidelines.

Duration of the interventions varied from three months (Kim & Oh, 2003; Kim et al., 2005; Oh et al., 2003; Maljanian, et al., 2005) to 12 months (Glasgow & Toobert, 2000; Piette, et al., 2001; Piette, et al., 2000; Young et al., 2005). The duration of the intervention in the study conducted by Glasgow and Toobert was six months. Outcomes were measured immediately after the interventions ceased in all studies

except Maljanian et al. where outcomes were assessed immediately after the three-month intervention and again at 12 months.

Nurses were involved in all of the interventions either by directly making the calls (Glasgow & Toobert, 2000; Kim & Oh, 2003; Kim et al., 2005; Oh et al., 2003; Maljanian et al., 2005), by supervising calls made by trained telecarers (Young et al., 2005), or by conducting follow-up calls in response to participants reports from automated assessments (Piette et al., 2001; Piette, et al., 2000).

Design and Validity Assessment

All of the studies reported using a randomized controlled design. Details regarding the randomization methods and concealment allocation were lacking in some of the studies. In two studies (Kim & Oh, 2003; Oh et al., 2003), the authors reported randomization by the toss of a coin to either intervention or control groups. The authors did not explain how equal numbers in each group were obtained or whether allocation concealment was done. The study by Kim et al. (2005) described randomization using a random number table; allocation concealment was not reported. The two studies by Piette and colleagues (Piette et al., 2001; Piette et al., 2000) reported both sequence generation (i.e., randomization using a table of randomly permuted numbers) and allocation concealment (i.e., sealed envelopes prior to randomization). Young et al. (2005) was the only study that randomly selected participants from a sampling frame generated from a list of individuals with type 2 DM. The authors reported sequence generation (i.e., post-recruitment block randomization stratified by HbA_{1c}); allocation concealment was also reported, but not fully described. The two remaining studies

(Glasgow & Toobert, 2000; Maljanian et al., 2005) reported insufficient detail regarding random assignment and did not report allocation concealment.

With the exception of two studies that reported analysis of HbA_{1c} in a blinded fashion by laboratory personnel who were not aware of group allocation (Piette et al., 2001; Piette, et al., 2000), blinding was not addressed in the studies. Incomplete outcome data was addressed in all of the studies reviewed with attrition rates between 7% and 34%. Four studies were given a judgment of "yes" indicating that in the reviewers' judgment adequate measures were taken to control for this bias (Glasgow & Toobert, 2000; Piette et al., 2001; Piette et al, 2000; Young et al., 2005). Two studies were given a judgment of "unclear" because information regarding differences between individuals who stayed in the study compared to those who dropped out was not provided (Kim et al., 2005; Oh et al., 2003). One study had a high (34%) attrition rate (Maljanian et al., 2005) and another study had an imbalance in missing outcome data between groups (Kim & Oh, 2003).

All eight studies appeared to be free of bias related to selective outcome reporting and the majority of the studies contained no obvious other sources of bias. However, two studies (Kim & Oh, 2003; Oh et al., 2003) recruited participants from the same institution during overlapping periods of time. It was unclear whether these two samples were independent of each other (see Table 2).

Samples and Settings

Samples ranged in size from 35 (Kim, et al., 2005) to 591 (Young et al., 2005). A sample size analysis was reported in two studies (Kim, et al., 2005; Young et al., 2005). Five of the studies included patients with type 2 DM only (Glasgow & Toobert,

2000; Kim & Oh, 2003; Kim et al., 2005; Oh, et al., 2003, Young et al., 2005). Ninety-six percent of the participants in the study conducted by Maljanian et al. (2005) had type 2 DM. The two studies by Piette and colleagues (2001, 2000) did not specify type of DM; however, since 90-95% of individuals with diabetes have type 2 DM, and less than 40% of the participants in their samples were taking insulin, one can surmise that the majority of the participants in these two studies had type 2 DM.

Three of the studies recruited small samples of predominately female, educated participants from an endocrinology outpatient department of a tertiary care hospital in an urban city in South Korea (Kim & Oh, 2003; Kim et al., 2005; Oh et al., 2003), which limits generalizability to similar individuals at a similar setting. These studies also excluded patients with severe cardiovascular disease or uncontrolled hypertension, which further limits generalizability. Young et al. (2005) recruited participants from a primarily Caucasian low socioeconomic inner-city location in Greater Manchester, England from a number of general practices. The fact that a number of general practices were included in the study enhances external validity, but generalizability is still limited to a similar group of Caucasian individuals who reside in a low socioeconomic urban area in England. One of the studies by Piette and colleagues recruited participants from two general medicine clinics of a county public health system in California (Piette et al., 2000). Their sample was 50% Hispanic with the majority of participants earning $10,000 or less per year (Piette et al., 2000). This study was replicated in a Veterans Affairs (VA) health care system; this sample was mostly male with a race mix of Caucasian, Black and Hispanic participants who were better off at baseline in terms of socioeconomic status, self-care, and glycemic control compared

to the county cohort (Piette, et al., 2001). Intervention effects were observed in both studies, but to a lesser extent in the VA study. The replication study showing intervention effects in the same direction as the original study and the diversity of participants and settings in these two studies enhances the external validity of these two studies. Maljanian et al. (2005) recruited participants from a hospital-based DM clinic in Connecticut. This sample was primarily middle-aged and Caucasian. Glasgow and Toobert (2000) increased the external validity of their sample by recruiting from 12 primary care small group practices that had privileges at a community hospital in Oregon. Their participants were primarily Caucasian, and over half reported having attended at least some college.

The average age across studies was similar, mean = 60 years (range 54.5 - 60.5). With the exception of the study conducted at a VA medical center (Piette et al., 2001), close to sixty percent of the participants in the studies were female, mean 57% (range 42% - 70%). Of the seven studies reporting insulin use, on average approximately 34% of participants were using insulin (range 16% - 48%).

Glycemic Control Outcomes

Glycemic control was determined by HbA_{1c} in all of the studies either by comparing the mean change in HbA_{1c} between intervention and control groups or by comparing mean endpoint HbA_{1c} between the two groups. Using ANCOVA to adjust for baseline values and use of insulin, Glasgow and Toobert (2000) analyzed 267 participants who had follow-up HbA_{1c} data at both three and six months. They found no statistically significant differences among the three treatment groups in mean change in

HbA_{1c} at either endpoint; an overall mean reduction of 0.1% to 0.2% was seen (*p* value not reported).

Using ANOVA, Kim and Oh (2003) analyzed 36 participants who had follow-up data at three months and found a statistically significant decrease in mean change in HbA_{1c} between the treatment and control groups (-1.2% in the intervention group and + 0.6% in the control group, $p < .05$). Similarly in the study reported by Kim, et al. (2005), using ANOVA, the authors analyzed 25 participants who had follow-up data at three months and found a statistically significant decrease in mean change in HbA_{1c} (-1.2% in the intervention group and + 0.5% in the control group, $p = .004$). Oh et al. (2003) reported a statistically significant mean change in HbA_{1c} in 38 participants completing their three-month study; the ANOVA showed a -1.2% change in HbA_{1c} in the intervention group compared to a + 0.3% change in HbA_{1c} in the control group ($p < .001$). The authors of these three studies did not report an adjusted analysis, but noted that there was no statistically significant difference in baseline HbA_{1c} levels between intervention and control groups.

In the study by Young et al. (2005), mean differences in HbA_{1c} in 394 intervention participants and 197 control participants at 12 months were analyzed by baseline HbA_{1c} strata. Overall, a statistically significant improvement in mean change in HbA_{1c} of 0.3% was seen in the intervention group when compared to the control group ($p = .003$). For participants with a baseline HbA_{1c} of $\geq 7\%$, the improvement increased to 0.49% ($p < .001$); participants with baseline $HbA_{1c} < 7\%$ experienced no change. No changes were found to be due to age, gender, or practice type.

When adjusting for baseline values and use of insulin, Piette et al. (2000) found no statistically significant differences between the treatment and control groups mean endpoint HbA_{1c} measured at 12 months (8.4% intervention group vs. 8.1% control group, $p = 0.1$) in their analysis of 248 participants. A statistically significant proportion of participants were found to have a normal HbA_{1c} defined as < 6.4% in the intervention group compared to the control group at the end of the study (8% normal in the control group compared to 17% normal in the intervention group, $p = .04$). Similarly, in their replication study (Piette et al., 2001), the overall adjusted endpoint mean HbA_{1c} at 12 months in 272 participants providing data was non-significant (8.1% intervention group vs. 8.2% control group, $p = 0.3$). However, when the analysis was restricted to participants with a baseline $HbA_{1c} \geq 8\%$ (n=122), adjusted mean end-point HbA_{1c} values differed by 0.5% between intervention and control groups ($p = .04$). Among participants whose baseline HbA_{1c} was $\geq 9\%$, adjusted mean end-point values differed by 1.1% ($p = .04$).

Maljanian et al. (2005) reported on 274 participants at three and 12 months. There was no statistically significant difference between intervention and control participants on adjusted analysis of mean endpoint HbA_{1c} (p value not reported). Group assignment was not a significant predictor of whether the participant met the ADA target of < 7.0% for HbA_{1c} at the three or 12-month follow-up point. The authors speculated that an overall decrease in HbA_{1c} to a mean of 6.8% may have reached a floor effect with the successful base program, and that without the base program, the telephone intervention may have had a more pronounced effect on glycemic control.

Synthesis

A moderate number of studies was initially identified, but only eight met the final inclusion criteria for this review. These eight studies were heterogeneous in terms of the populations studied, the settings, the type and intensity of the interventions, the outcomes assessed, and study quality. Overall the interventions in the studies had mixed effects on glycemic control in adult patients with type 2 DM. In the UKPDS, for each reduction in mean HbA_{1c} of 1%, a reduction in risk of 37% was realized for microvascular complications, 14% for myocardial infarction, and 21% for deaths, [$p < .001$] (Stratton et al., 2000). The studies in this review that evaluated interventions of a shorter duration (i.e., three months) showed changes in HbA_{1c} that are thought to be clinically relevant: a mean change in HbA_{1c} of -1.2% in the intervention groups compared to mean change in HbA_{1c} of + 0.6%, + 0.5%, + 0.3% respectively in the control groups (Kim & Oh, 2003; Kim et al., 2005; Oh et al., 2003). The other study that demonstrated a statistically significant difference between intervention and control groups on change in HbA_{1c} was of questionable clinical significance (- 0.3%); the intervention duration was 12 months (Young et al., 2005).

Four studies did not show positive effects on glycemic control when comparing entire cohorts of intervention versus control groups (Glasgow & Toobert, 2000; Maljanian, et al., 2005; Piette, et al., 2001; Piette et al., 2000). In one study, the primary focus was a dietary intervention aimed at improving behavioral, physiological, quality of life (QOL), and satisfaction outcomes. The intervention was moderately successful at achieving self-reported dietary improvements (Glasgow & Toobert, 2000). Maljanian and colleagues (2005) demonstrated a reduction in HbA_{1c} with an initial

hospital-based disease management model. However, no further reductions in HbA_{1c} were seen when the telephone component was added, perhaps due to a floor effect (Maljanian, et al., 2005). The two studies by Piette and colleagues did not show statistically significant differences between groups on mean HbA_{1c} at the end of their 12-month interventions. They did observe some differences when dividing groups into cohorts of participants with HbA_{1c} levels < 6.4% (Piette et al., 2000) and ≥ 8.0% (Piette et al., 2001).

Internal Validity

The overall *"grade"*, based on the ADA (2007) grading system, assigned by this author to this body of evidence evaluating the use of isolated telephone interventions on glycemic control in patients with type 2 DM is a *Level of Evidence "C"* meaning that there is "evidence from RCTs with one or more major or three or more minor methodological flaws that could invalidate the results" (p. s5). Despite fairly large sample sizes in five studies, only two reported a sample size analysis (Kim et al., 2005; Young et al., 2005), which limits the ability to determine if the studies were adequately powered *a priori* based on a theoretically determined effect size. Only two studies adequately reported allocation concealment (Piette et al., 2001; Piette et al., 2000). Lack of allocation concealment can lead to bias that undermines the theoretical benefits of random assignment. Studies have shown that lack of allocation concealment can lead to exaggerated treatment effects (Schulz & Grimes, 2002).

Control conditions were mentioned in all but one study (Piette et al., 2001), but sufficient detail regarding control conditions was lacking across studies, making it difficult to judge whether conditions other than exposure to the intervention were

responsible for observed outcomes. Only one study reported comparing changes in medication between treatment and control groups that occurred during the intervention period (Young, et al., 2005) and only three studies compared diabetes-related health care visits between intervention and control groups during the intervention period (Maljanian, et al., 2005; Piette et al., 2001; Piette et al., 2000). Theoretically, large samples and random assignment of participants to intervention and control groups should control for these potentially confounding variables, but because of their strong potential affect on outcomes, reporting on the balance of medication changes and interim diabetes-related visits between groups would have enhanced the internal validity of the studies.

Two studies did not report the actual number of telephone calls patients received during the intervention period (Maljanian, et al., 2005; Young et al., 2005). Glasgow and Toobert (2000) reported an implementation score of 80 to 90% for calls scheduled three to four per individual over six months. The remaining studies reported an average of 16 calls per participant over a three-month intervention (Kim & Oh, 2003; Kim, et al., 2005; Oh, et al., 2003), an average of six calls per participant over 12 months (Piette, et al., 2000), and an average of 13 calls per participant over 12 months (Piette et al., 2001). The variation in both the intensity and reporting of intensity of the interventions makes it difficult to draw conclusions based on this variable. It remains unclear what intensity of telephone intervention is most likely to impact glycemic control.

External Validity

The generalizability of this body of literature is limited to patients with type 2 DM who have similar characteristics to the participants who were studied and who are receiving care in similar settings. This is largely because only one study used random selection of participants. Random selection of participants is the only method that can theoretically ensure representation of the true population from which the sample was drawn.

Conclusions

The DCCT (1993) reported that the costs associated with an expert team of clinicians working with patients in the intensive therapy group were considerable and that new strategies are needed to maintain this level of intensive therapy safely for individuals at a more manageable cost. The UKPDS (1998) confirmed the findings of the DCCT in patients with type 2 DM. Previous research has shown that self-management training and disease management programs are effective in achieving glycemic control in patients with type 2 DM, but that knowledge regarding the effects of individual management strategies is limited (Norris, Englgau, & Narayan, 2001).

This review attempted to clarify the effects of isolated telephone interventions on glycemic control in type 2 DM. Limitations of this review include a narrow search strategy that may have contributed to the small number of articles reviewed. No attempt was made to review unpublished works. Glycemic control was not the primary outcome of interest in all of the studies reviewed which may have limited the power these studies had to detect changes in glycemic control. No attempt was made in this review to examine the potential mediating effect that changes in self-care behavior or

other factors may have had on glycemic control, which limits the ability to understand the affects of these factors on glycemic control.

Although current evidence does not support isolated telephone interventions to improve glycemic control in Type 2 DM, well-designed studies to establish the effectiveness of this potentially cost-effective modality can be an important step in addressing the diabetes epidemic.

CHAPTER THREE

Randomized Controlled Trial

Considering the increasing incidence of type 2 DM, its accounting for an overwhelming percentage of all DM cases and the scarcity of health care resources, the challenge for health care providers is to apply evidenced-based recommendations of cost-effective, easily implemented interventions that have the potential to assist large numbers of patients with type 2 DM improve glycemic control. Previous research has not adequately examined the effects of isolated telephone interventions in patients with type 2 DM. This study attempted to address this gap in the literature.

Problem Statement

It is well established that intensive treatment of type 2 DM is needed to achieve adequate glycemic control and to prevent complications; access to and utilization of medical care does not, by design, help patients achieve satisfactory glycemic targets. This puts patients at risk for serious long-term complications of hyperglycemia.

Theoretical Framework

Health-behavior research grounded in psychosocial principles may inform researchers as they attempt to understand this problem. Patients are largely responsible for self-management of chronic illness and are expected to follow complex prescribed health care regimens. Health-behavior theory posits that patients who experience less severe symptoms or fewer accompanying symptoms often perceive that a disease is less severe (Leventhal et al., 1980; Lange & Piette, 2005).

Both type 1 and type 2 DM are chronic diseases that require complex self-management by the patient. In type 1 DM, the pancreatic beta cells abruptly stop

secreting insulin, often due to an autoimmune response, resulting in an acute onset of illness. Patients are dependent on exogenous insulin for the rest of their lives. Type 2 DM is caused by a combination of increased insulin resistance at the cellular level, a slower decrease in insulin secretion, and abnormalities in glucose production by the liver and other hormonal deficiencies (American Association of Clinical Endocrinologists [AACE], 2007). Often the onset of illness is much slower compared to type 1 DM; symptoms may be insidious and unrecognized by patients.

Long-established treatment regimens in type 2 DM aimed primarily at restricting dietary intake, increasing physical activity, and 'taking a pill', reinforce the belief that type 2 DM is a less severe disease compared to type 1 DM (Hampson, Glasgow, & Toobert, 1990; Lange & Piette, 2006). The serious nature of uncontrolled hyperglycemia in type 2 DM may not be perceived as serious by patients who are not symptomatic or who do not recognize symptoms of hyperglycemia. Patients who do not perceive their disease to be serious may fail to see the necessity of their prescribed health care regimen. Patients who believe in the necessity of a health care regimen are more likely to follow it (Horne, 2003).

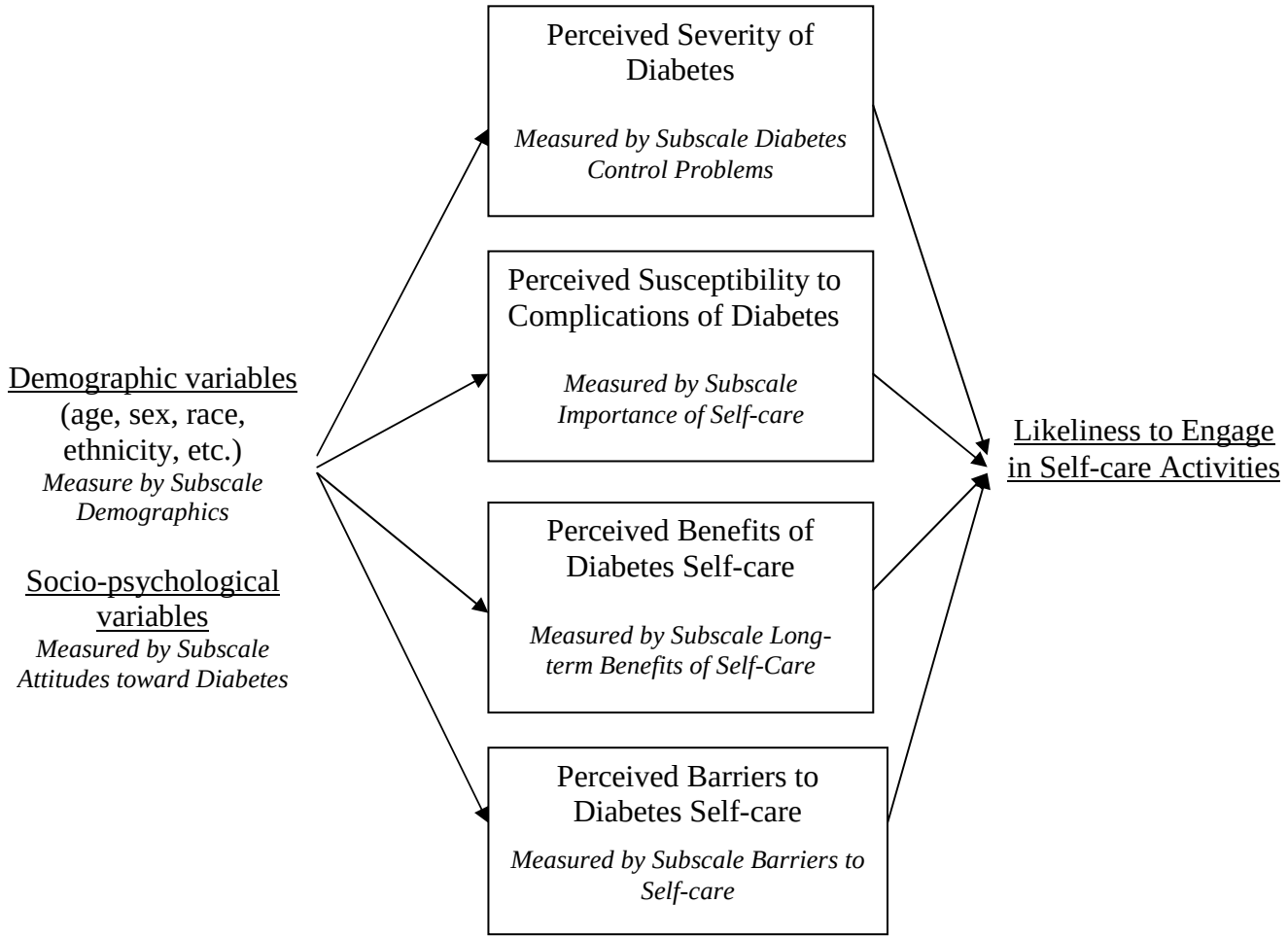
This study is informed by the health belief model of illness [HBM] (Abraham & Sheeran, 1997). The health belief model posits that health-related behaviors are influenced by perceptions of susceptibility and severity of illness, as well as perceptions of the benefits and barriers associated with following a prescribed health care regimen (see Figure 2). If perceived barriers related to following a recommended health care 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 (Daniel &

Messer, 2002). 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 (2002) found that baseline health beliefs of the severity of DM predicted reduced HbA_{1c} 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}. In a sample of patients with type 2 DM, Polly (1992) 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 et al. (1997) reported that adherence to dietary restrictions was related to negative perceptions of diabetes.

Patients spend most of their time away from the health care system where they are influenced by a number of demographic, social, and situational factors; this is where chronic disease self-management takes place. Subjective perceptions of illness are influenced by a number of these demographic, social, and situational factors. Therefore, chronic disease management interventions have evolved to reach out to individuals across the continuum of care. Clinicians are responsible not only for prescribing up to date evidence-based treatments for patients with chronic disease, but for helping them adhere to the treatment plan.

Figure 2. Operationalized Components of Health Belief Model. Adapted from Leventhal et al., 1980.



Purpose and Aims

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 to 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 severity of diabetes, susceptibility to complications of diabetes, and the benefits and barriers of self-management of diabetes compared to standard care in adults with type 2 DM.

Methods

Research Design

An experimental pretest posttest design was used to test the null hypotheses that: (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 to 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 to 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 group compared to the standard care group.

Sample

A convenience sample of 120 participants was recruited for the study from two clinics at the University of Minnesota, 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 included: (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) $HbA_{1c} \geq 7.0\%$ within the past month, (d) ability to understand the English language, (e) access to either a land line or cellular telephone, (f) ability to hear and orally respond to automated telephone voice commands, (g) responsible for own self-care, (h) access to a reliable glucose meter that has 3-month storage capacity, (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.

Protection of Human Subjects

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

Sequence Generation and Allocation Concealment

Randomization to the intervention or control group was stratified by gender and by use of insulin to achieve an approximate balance between men and women using and not using insulin in each group. A predetermined randomization schedule generated from a computerized random number generator 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 pre-assigned study number to reveal the randomization assignment after the informed consent document (Appendix A) was signed. Neither the participant nor the investigator had knowledge of the randomization assignment prior to that time.

Blinding of Participants and Researchers

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.

Intervention Conditions

In addition to usual care provided by the clinics, participants randomized to the telephone intervention received a daily, automated, pre-recorded voice message relaying a short (less than one 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 AADE seven self-care behaviors (AADE7, n.d.). These behaviors include healthy eating, being active, monitoring (i.e., 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 (Appendix B).

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 three calls each day. If there was no answer or if an answering machine picked up the first call, the system called back an additional two 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 pre-recorded 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’ll 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 two 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, MN) 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 participant 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 (e.g., home, office, cell, friend, etc.) and the participants were not asked to identify the source of the number. The system was programmed to send an email alert to the investigator if

a participant reported a blood glucose level of ≥ 400 mg/dl, ≤ 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 control condition received usual care provided to patients with diabetes by the clinics. Usual care consists of a clinic visit every two to three 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 care coordinators or the investigator if they experienced any problems or had questions during the study. All participants were offered at $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

Assessment of glycemic control. HbA_{1c} was obtained by means of a standard venous blood draw with results determined by a standard high-performance liquid chromatography technique (Tosho Bioscience G7 analyzer) or by a finger stick capillary blood sample with results determined by immunoassay (Bayer DCA 200 analyzer). These two methods were found to be highly correlated (r^2=0.98) in previous samples during an instrument validation process at the University of Minnesota (personal communication with Jennifer Peters, 9/5/08). HbA_{1c} levels obtained within one 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. 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 affect 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 [e.g., exenatide], (b) an increase in any dose of an oral medication, or (c) an increase in insulin by four units or more in a 24-hour period.

Assessment of daily SMBG frequency. 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. Daily SMBG 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.

Assessments of severity, susceptibility, benefits and barriers. 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 (Fitzgerald et al., 1996), which was based on the health belief model of illness. It consists of 150 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 (Appendix C).

The questionnaire consists of items using 5-point Likert, close-ended, and dichotomous scales. Item readability was assessed at a third grade reading level. Several studies have demonstrated good to excellent internal consistency reliability for the DCP. Fitzgerald, et al., (1996) initially tested the instrument, in two separate studies, on 792 patients with insulin and non-insulin dependent DM. The first study administered the questionnaire to and collected physiological data on 440 community-dwelling individuals in Michigan. Cronbach's alpha, indicating scale internal consistency, of individual DCP scales ranged from 0.60 to 0.95, with exercise barriers showing the lowest coefficient and long-term care benefits showing the highest. In the second study, conducted at a university medical center in Michigan, the DCP and several previously validated scales were administered to 352 patients. Cronbach's alpha coefficients ranged from 0.66 to 0.94 in this group again with exercise barriers showing the lowest coefficient and long-term care the highest.

Fitzgerald et al. (1996) demonstrated construct validity for the DCP by showing that the subscales control problems, self-care ability, and self-care adherence were

correlated ($r \geq 0.20$) with HbA_{1c} levels ($p \leq 0.01$) in the community sample (n= 440). In a study comparing the short-form SF-36 and the DCP in patients with non-insulin dependent DM, Anderson, Fitzgerald, Wisdom, Davis, and Hiss (1997) reported that the DCP scales explained 17% of the variance in HbA_{1c} values for patients using insulin and 15% of the variance in HbA_{1c} values for patients not using insulin. The SF-36 did not show predictive value for glycemic control. Additionally the authors reported that in the DCP subscale, positive attitude was correlated with the number of reported complications ($r = - 0.32$) in patients using insulin.

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 (Michigan Diabetes & Research Training Center, n.d.). The item scores of each subscale were summed and then divided by a count of non-

missing items. Scores ranged from 1 to 5 for each subscale. The subscales monitoring barriers and exercise barriers were combined to create a *barrier* subscale with scores ranging from 1 to 10. Reverse scoring was done for the negative attitude subscale and the barrier subscale by adding one 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. A positive change was seen as desirable for all subscales.

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 decease in HbA_{1c} of - 0.5% ± 1.2% over a 90-day period. Therefore, an effect size of - 0.6% ± 1.2% was used for the power calculation. These calculations assumed a sample size of 60 per group, 80% power, and a two-sided *t*-test with type 1 error set at .05. Calculations were carried out using nQuery Advisor® software. A mean change in HbA_{1c} of - 0.6% is considered a clinically significant improvement beyond a standard clinical change.

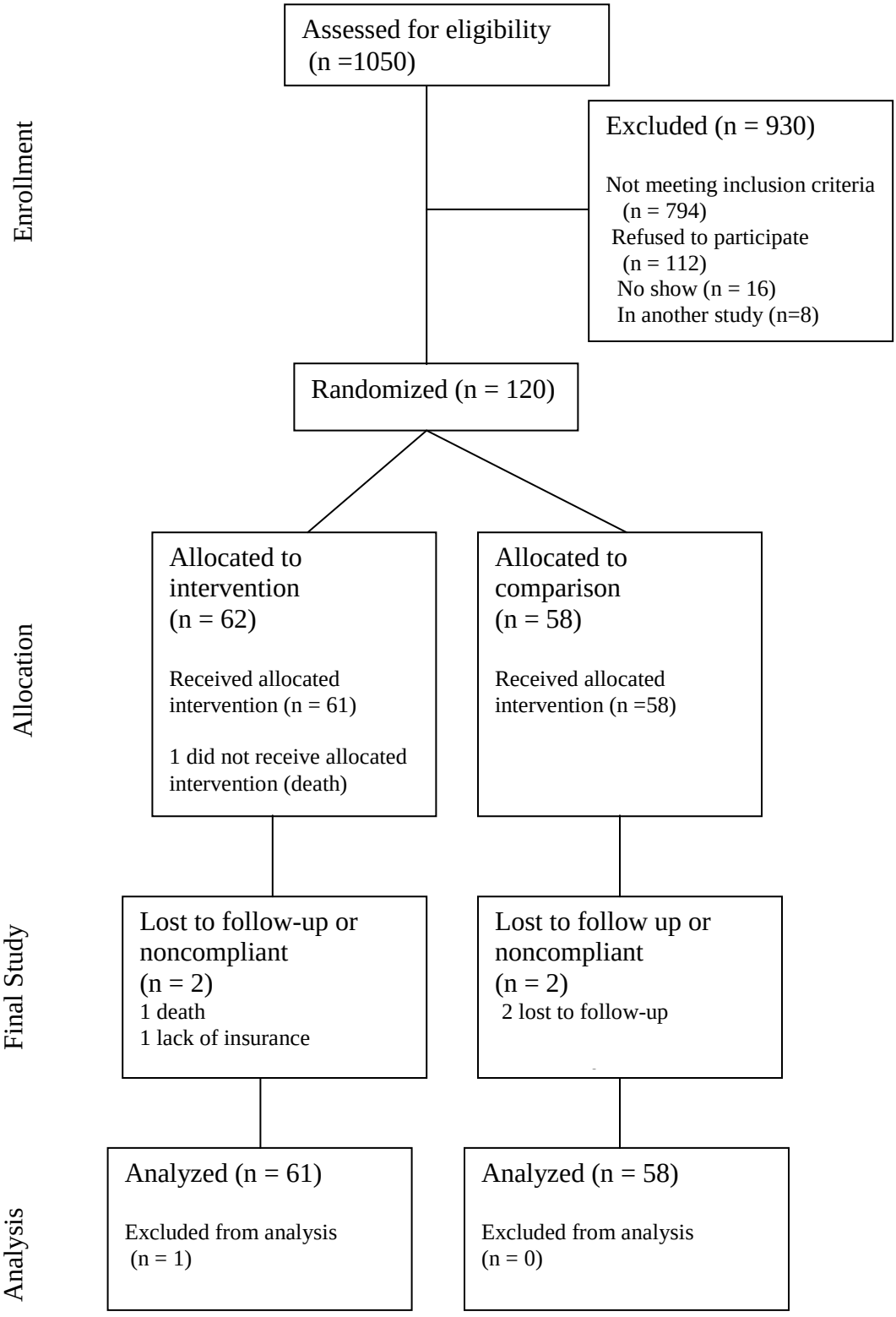
Baseline variables were compared by intervention group using χ^2 for categorical variables, independent sample *t*-tests for normally distributed continuous data, and Mann-Whitney *U* tests for continuous data that were not normally distributed. An intent-to-treat analysis with last value carried forward (LVCF) was used to account for missing endpoint data. Mean differences between treatment groups on outcome variables were assessed 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 (ANCOVA) for continuous variables and general linear model (GLM) for categorical variables. Data were analyzed using SPSS® version 11.5 for Windows™.

Results

One hundred twenty participants 50 to 93 years of age were recruited from 1050 patients screened for enrollment. Eight hundred and two patients were initially screened out by medical record review prior to their clinic visits; eight of these 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 two participants did not comply with study follow-up procedures (see Figure 3).

Figure 3. Study Flow Diagram.



Demographics

Intervention and control groups were compared at baseline on the variables gender, 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, three years older. This difference was not thought to hold any clinical significance. Difference in race category also approached statistical significance with twice as many participants in the intervention group reporting non-white race compared to the comparison group [$p = .07$] (see Table 4). Race was considered an important covariate and its effect on outcome variables was evaluated in subsequent analyses.

Baseline Outcome Variables

Intervention and comparison groups were compared at baseline on the variables HbA_{1c}, SMBG frequency, perceptions of severity of DM, perceptions of susceptibility to DM complications, positive attitudes toward diabetes, negative attitudes toward diabetes, perceptions of benefits of self-care and barriers to self care. Significant differences were found between groups on susceptibility to DM complications ($p = .02$) and beliefs regarding benefits of self-care [$p = .03$] (See Table 5). Therefore, between group endpoint analyses of susceptibility to DM complications and benefits of self-care included baseline values as covariates in the ANCOVA.

Table 4
Baseline Characteristics by Treatment Group

Variable Name	Telephone Group (n=61)	Comparison Group (n = 58)	*p.* Value
Gender	Male (33) Female (28)	Male (33) Female (25)	.76
Living Status	Live alone (13) Live with others (48)	Live alone (17) Live with others (41)	.32
Mean ± SD age	60.1 ± 7.4 years	63.0 ± 9.3 years	.06
Race	White (43) Nonwhite (18)	White (49) Nonwhite (9)	.07
Education	HS or less (13) Some college or tech (24) College grad (24)	HS or less (16) Some college or tech (21) College grad (21)	.73
Income U.S. dollars	Up to 9,999 (6) 10,000 to 19,999 (14) 20,000 to 39,999 (9) 40,000 to 59,999 (9) 60,000 and up (23)	Up to 9,999 (13) 10,000 to 19,999 (9) 20,000 to 39,999 (10) 40,000 to 59,000 (6) 60,000 and up (20)	.35
Mean ± SD Duration of DM	13.5 ± 8.4 years	12.2 ± 8.2 years	.21
Insulin	Insulin (34) Non-insulin (27)	Insulin (30) Non-insulin (28)	.66

* Significant at .05
SD = standard deviation

Table 5
Baseline Outcome Variables by Treatment Group

Variable Name	Telephone Group (n=61)	Comparison Group (n = 58)	*p.* Value
HbA_{1c}	8.71% ± 1.74 (mean rank 63.91)	8.59% ± 1.96 (mean rank 55.89)	.20
SMBG Frequency (*times per day*)	1.26 ± 1.26 (mean rank 58.78)	1.27 ± 1.15 (mean rank 61.28)	.69
Severity of DM	4.53 ± 1.09	4.32 ± 1.24	.34
Susceptibility to DM Complications	4.41 ± .652	4.13 .764	.02*
Positive attitudes toward diabetes	3.05 ± .857	3.18 ± .749	.37
Negative attitudes toward diabetes	2.56 ± .849	2.51 ± .827	.76
Benefits of Self-care	4.44 ± .979 (mean rank 66.12)	4.26 ± .803 (mean rank 53.56)	.03*
Barriers	4.19 ± 1.09	4.20 ± 1.14	.97

Values are means and standard deviations except where noted
* Significant at .05

Outcome Analysis and Hypothesis Testing

The primary outcome of interest was difference in mean change in HbA_{1c} between the telephone and comparison groups. Last value carried forward was applied to one participant in the intervention group and two participants in the comparison group. Change in HbA_{1c} was calculated by subtracting the baseline HbA_{1c} from the 90-day HbA_{1c}; a negative change represented an improvement.

Hypothesis number one. An independent samples *t*-test indicated that there were no significant differences between the telephone and control groups on mean change HbA_{1c} (p = .84) suggesting no treatment effect (see Table 6). Participants who classified themselves as either white or non-white were distributed evenly among responders and non-responders on this outcome (see Figure 4). 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}. Therefore, a GLM was computed with change in HbA_{1c} as the dependent variable and treatment group and pre HbA_{1c} *category* as independent factors in the model. Figure 5 shows that the telephone and comparison groups were comparable on mean change in HbA_{1c} in all four categories. The adjusted analysis did not change the result [p = .89] (see Table 6). 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} as the dependent variable. No significant differences were found on the main effect of treatment group or the main effect of medication change group (see Table 6).

Table 6

Mean Change in HbA_{1c} at 3 Months

	Mean Change	SE	*p.* Value		Adjusted Marginal Means	SE	*p.* Value
Unadjusted Mean Change HbA_{1c}				*Adjusted for Baseline HbA_{1c} Category*			
Telephone Group	-.834%	.236	.84	Telephone Group	-1.13	.182	.89
Control Group	-.767%	.247		Control Group	-1.10	.189	
				Adjusted for Major Medication Change			
				Telephone Group	-.834	.240	.85
				Control Group	-.768	.246	

SE = standard error

Figure 4. Change in HbA_{1c} by Race Category.

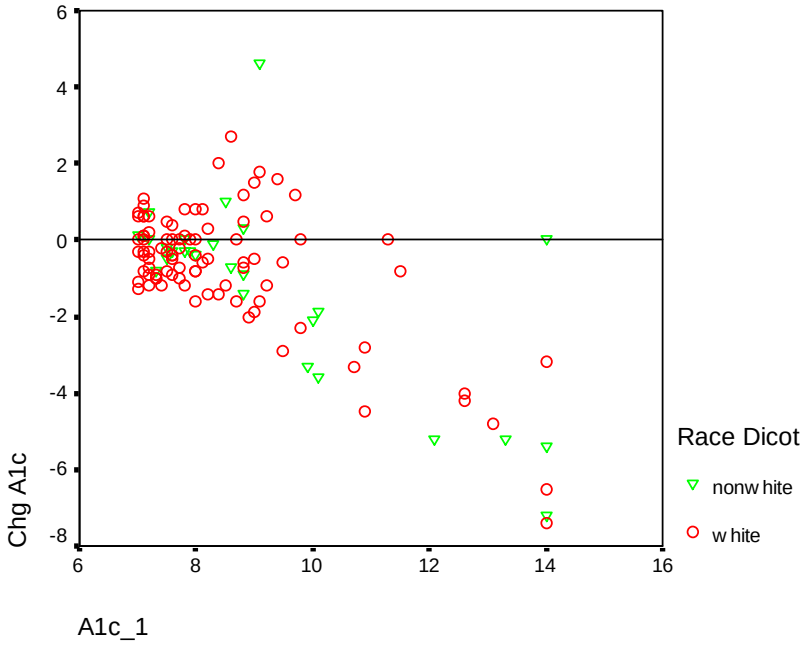
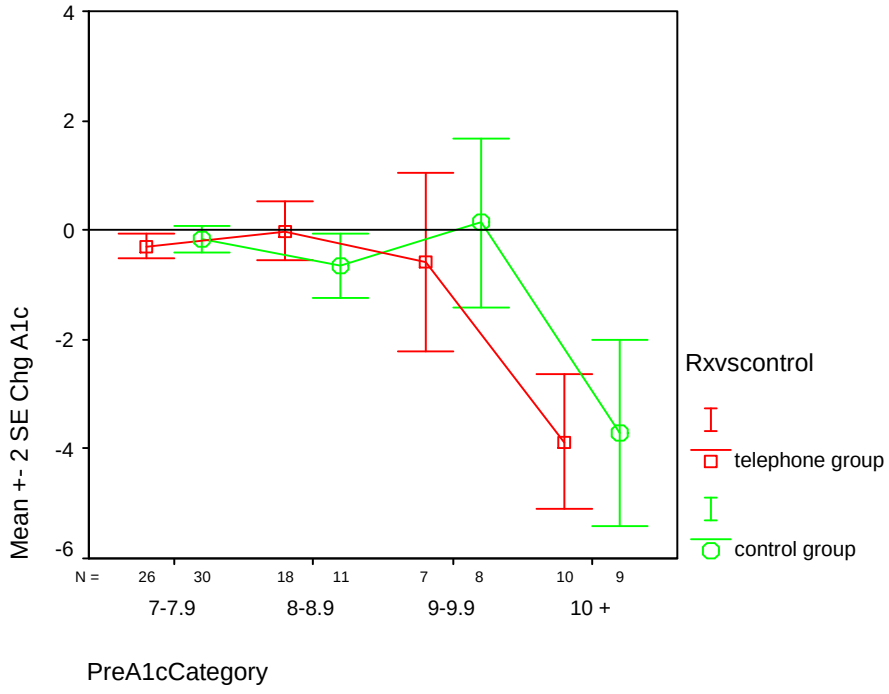
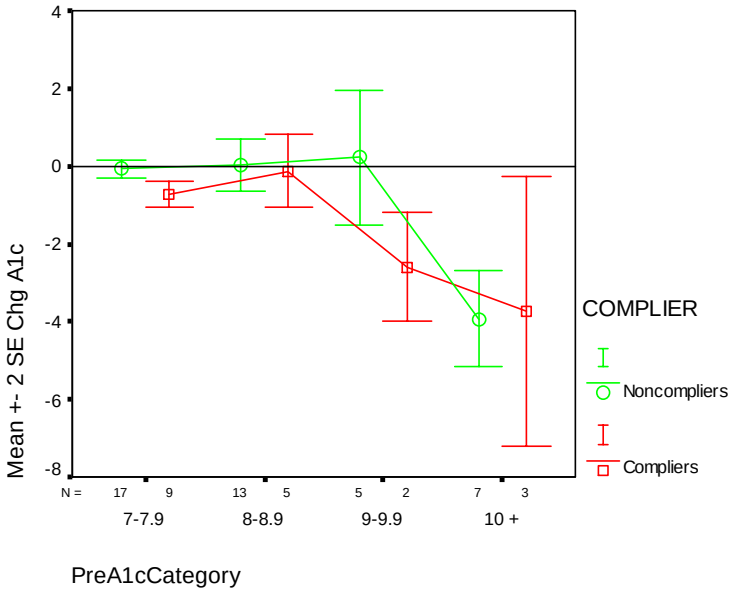


Figure 5. Change in HbA_{1c} by Baseline HbA_{1c} Category.



Intervention dose effect. Telephone response rates ranged from six 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. Figure 6 shows that compliers (those who received ≥ 90% of the calls) experienced a greater change in HbA_{1c} in every pre HbA_{1c} category expect category four. An independent samples *t*-test showed a significant difference in mean change in HbA_{1c} between compliers (-.796% ± 1.04) and non-compliers [.003% ± 1.04], (p = .02) in participants that had baseline HbA_{1c} levels between 7.0% and 9.9%.

Figure 6. Change HbA_{1c} in Compliers by Baseline HbA_{1c} Category.



The secondary outcome for the study was change in daily SMBG frequency. Last value carried forward was applied to six participants (10%) in the intervention group and eight participants (14%) in the comparison group prior to the analysis.

Hypothesis number two. An independent samples *t*-test indicated that there was a significant difference in mean change in daily SMBG frequency between the

telephone and comparison group. The telephone group had a mean increase in SMBG frequency of 0.66 ± 1.1 time per day and the comparison group had a mean increase in SMBG frequency of .05 ± 0.8 times per day [p = <.001] (see Table 7). Participants who classified themselves as either white or non-white were equally distributed among responders and non-responders on this outcome (see Figure 7). 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. Figure 8 shows that mean change in SMBG frequency was superior in the treatment group compared to the comparison group across all four baseline categories. The adjusted analysis did not change the result (p = <.001), therefore the null hypothesis was rejected (see Table 7).

Table 7
Mean Change in Daily SMBG frequency at 3 Months

	Mean Change	SE	*p.* Value		Adjusted Marginal Means	SE	*p.* Value
Unadjusted Mean Change SMBG Frequency				*Adjusted for Baseline SMBG Category*			
Telephone Group	.657 *Times per Day*	.138	<.001 *	Telephone Group	.405	.118	<.001 *
Control Group	.047 *Times per Day*	.098		Control Group	-.171	.120	
				Adjusted for Baseline Age			
				Telephone Group	.645	.120	.001*
				Control Group	.060	.123	

SE = standard error
* Significant at .05

Figure 7. Change in Daily SMBG Frequency by Race Category.

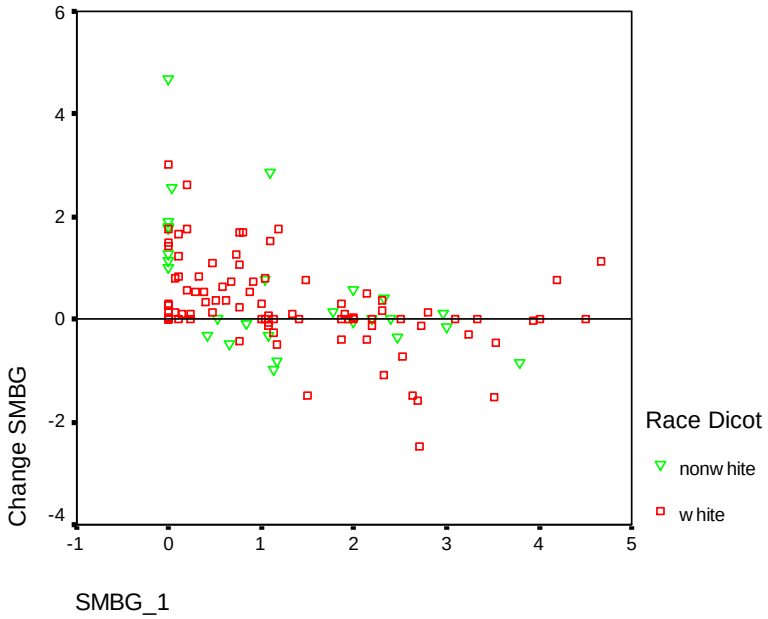
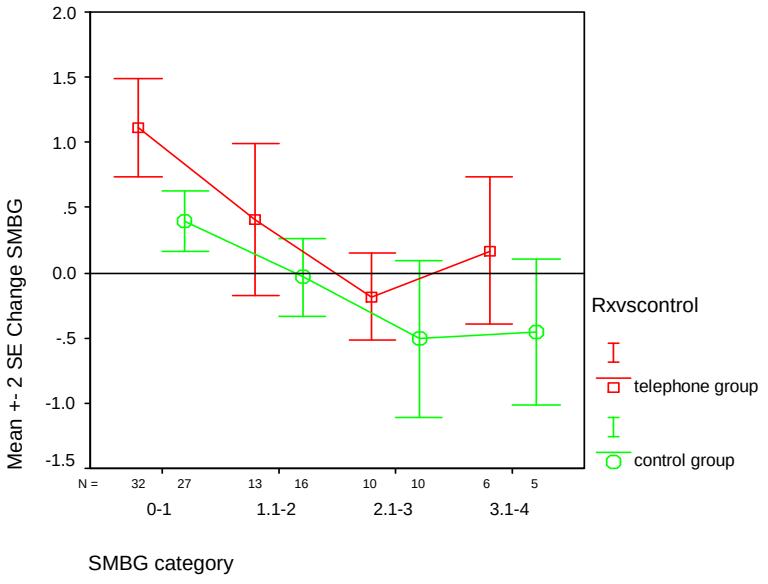


Figure 8. Change in Daily SMBG Frequency by Baseline SMBG Category.



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 ten participants in the intervention group (16%) and nine 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%).

Hypothesis number three. Independent samples t-tests evaluating differences in mean change between treatment groups on these variables showed no significant differences, supporting the null hypothesis (see Table 8). There was a trend in favor of the treatment group on changes in exercise barriers and changes in positive attitudes.

Table 8

Mean Change in Severity, Susceptibility, Benefits, Barriers, and Attitudes at 3 Months

	Mean Change	SE	*p.* Value		Adjusted Marginal Means	SE	*p.* Value
Unadjusted Mean Change Severity				*No Adjusted Analysis*			
Telephone Group	1.44	.252	.10				
Control Group	0.86	.244					
Unadjusted Mean Change Susceptibility				*Adjusted for Pre Susceptibility Score*			
Telephone Group	.050	.080	.73	Telephone Group	-.015	.077	.38
Control Group	.014	.097		Control Group	.082	.079	
Unadjusted Mean Change Benefits				*Adjusted for Pre Benefits Score*			
Telephone Group	.159	.125	.84	Telephone Group	.219	.086	.21
Control Group	.127	.112		Control Group	.064	.088	
Unadjusted Change Barriers				*No Adjusted Analysis*			
Telephone Group	.099	.104	.19				
Control Group	-.101	.114					
Unadjusted Mean Change Exercise Barriers				*Adjusted for Pre Exercise Barrier Score*			
Telephone Group	.163	.094	.09	Telephone Group	-.111	.099	.175
Control Group	- .036	.070		Control Group	.051	.109	
Unadjusted Mean Change Positive Attitudes				*No Adjusted Analysis*			
Telephone Group	.226	.094	.07				
Control Group	.005	.075					
Unadjusted Mean Change Negative Attitudes				*No Adjusted Analysis*			
Telephone Group	.103	.076	.88				
Control Group	.086	.085					

SE = standard error

Responder characteristics. For the primary outcome, responders in the telephone group were defined as participants who had a reduction in HbA_{1c} of ≥ 0.6%. 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] (see Table 9). Within this group there was a significant correlation found between mean change in HbA_{1c} and mean change in barriers to self-care beliefs (r = -.39, p = .04). Correlations were also noted between mean change in positive attitudes and mean change in barriers to self-care beliefs (r = .31, *p* = .11) and between mean change in positive attitudes and mean change in changes in susceptibility to DM complications (r = .41, *p* = .07).

Table 9
Responders vs. Non-responders HbA_{1c}

Variable Name	Responders (n = 27)	Non-responders (n = 34)	*p.* Value
Gender	Male (14) Female (13)	Male (19) Female (15)	.754
Living Status	Live alone (5) Live with others (22)	Live alone (8) Live with others (26)	.653
Mean Age	57.8 ± 5.5 years	61.9 ± 8.3 years	.03*
Race	White (18) Nonwhite (9)	White (25) Nonwhite (9)	.559
Education	HS or less (6) Some college or tech (11) College grad (10)	HS or less (7) Some college or tech (13) College grad (14)	.947
Income U.S. Dollars	Up to 9,999 (2) 10,000 to 19,999 (7) 20,000 to 39,999 (4) 40,000 to 59,999 (4) 60,000 and up (10)	Up to 9,999 (4) 10,000 to 19,999 (7) 20,000 to 39,999 (5) 40,000 to 59,000 (5) 60,000 and up (13)	.975
Mean Duration of DM	12.7 ± 7.2 years	14.2 ± 9.3 years	.501
Insulin	Insulin (13) Non-insulin (14)	Insulin (21) Non-insulin (13)	.288
Mean Baseline HbA_{1c}	9.6% ± .67	7.9% ± 2.2	<.001*

Values are means and standard deviations
* Significant at .05

Studies have shown that a change in SMBG frequency of 0.5 times per day has been associated with decreases in HbA_{1c} in patients receiving pharmaceutical therapy (Karter et al., 2006). Therefore, responders for the secondary outcome were defined as participants who had a change in daily SMBG frequency of ≥ 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] (see Table 10).

Table 10
Responders vs. Non-responders SMBG Frequency

Variable Name	Responders (n = 31)	Non-responders (n = 30)	*p.* Value
Gender	Male (16) Female (15)	Male (17) Female (13)	.692
Living Status	Live alone (5) Live with others (26)	Live alone (8) Live with others (22)	.315
Mean age	58.2 ± 5.7 years	62.0 ± 8.5 years	.047*
Race	White (22) Nonwhite (9)	White (21) Nonwhite (9)	.934
Education	HS or less (4) Some college or tech (14) College grad (13)	HS or less (9) Some college or tech (10) College grad (11)	.254
Income U.S. dollars	Up to 9,999 (2) 10,000 to 19,999 (6) 20,000 to 39,999 (4) 40,000 to 59,999 (6) 60,000 and up (13)	Up to 9,999 (4) 10,000 to 19,999 (8) 20,000 to 39,999 (5) 40,000 to 59,000 (3) 60,000 and up (10)	.656
Mean Duration of DM	10.87 ± 7.8 years	16.27 ± 8.25 years	.011*
Insulin	Insulin (13) Non-insulin (18)	Insulin (21) Non-insulin (9)	.027*
Baseline SMGB frequency	1.8 ± 1.2 times per day	.78 ± 1.1 times per day	.002*

Values are means and standard deviations
* Significant at .05

A significant correlation was found between mean change in susceptibility to complications of DM and change in SMBG frequency (r = .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).

Patient acceptance of the intervention. Patient acceptance with the intervention was tracked qualitatively by asking an open-ended question at the time of the follow-up visit. The investigator asked the following question to participants who received the automated telephone calls, "Please tell me your impression of the telephone calls you received during the study." Responses were recorded in a spreadsheet. The following themes emerged *(a) voice recognition was a problem*. For example, "I don't like talking to a machine…she can't understand me." and "She can't understand my accent." *(b) 'Alice' was a friend who will be missed.* For example, "I think I'm in love with Alice." and "I am going to miss Alice… her nagging has helped me remember to check my blood sugars." *(c) the information was good, but the calls went on for too long*. For example, "I learned a lot, but those questions went on forever." and "I think a month would have been long enough."

Discussion

The primary outcome in this study was mean change in HbA_{1c} between a group of patients with type 2 DM exposed to a daily-automated telephone call and a comparison group receiving usual care. Both groups experienced an overall negative mean change in HbA_{1c} approaching one 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.

A significant 'dose effect' was seen in participants assigned to the telephone group who answered at least 90% of the calls during the study period and who had HbA_{1c} values between 7.0 and 9.9%. No differences in positive or negative attitudes toward diabetes at baseline or follow-up were associated with this effect. 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 to patients with lower baseline HbA_{1c} values. Conversely, participants who received 90% or more of the calls during the intervention period may have been patients who were generally more adherent to their prescribed medical regimen.

Participants in the telephone group were, on average, three years younger than the comparison group. This factor was thought to be clinically irrelevant. However, on subsequent analysis, it was found that responders (participants who experienced a decrease in HbA_{1c} of 0.6% or greater) in the treatment group were significantly younger, by four years, than the non-responders. This indicates that the telephone intervention may have had a greater effect on 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 (Kim & Oh, 2003; Kim, Oh, & Lee, 2005; Oh, Kim, Yoon, & Choi, 2003; Piette, Weinberger, Kraemer, & McPhee, 2001; Young et al., 2005). Two of the studies reported greater improvements in telephone group patients who had

higher baseline HbA_{1c} levels (Piette et al., 2001; Young et al., 2005). 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 six years on average and to gain an average of five years of life and eight years of sight (Mease, 2000).

A strong treatment effect was observed in 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 (Piette et al., 2000; Piette et al., 2001). Once again, responders (participants who increased SMBG by 0.5 times per day or more) were younger by close to four years suggesting that the treatment effect was stronger in younger participants. Responders also had a shorter duration of DM by over five 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 (Adams, et al., 2003; Bruce, Davis, Cull, & Davis, 2003).

Studies have shown that increased SMBG frequency is associated with improved glycemic control (DCCT, 1995). 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 (Delamater, 2006). Information regarding daily glucose readings provides valuable information such as post-prandial glucose spikes that are not detected by infrequent HbA_{1c} levels.

Understanding daily fluctuations in blood glucose levels assists health care 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 to 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 compared to 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 (e.g., 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. Perceiving fewer barriers to self-care behavior increases the likelihood of individuals carrying out the behavior. This finding is consistent with previous research that has demonstrated an association between patient adherence to health behaviors and positive

attitudes toward these behaviors (Anderson, Fitzgerald, & Oh, 1993). 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 subjects who understand the severity of DM are more adherent to treatment and have more positive attitudes toward diabetes compared to subjects who do not understand the severity of DM (Matthews, 2007).

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 gender, 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 in the study makes it difficult to determine whether the treatment effect on 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 the treatment effects and needs further examination. Patient acceptance of the intervention was mixed based on qualitative responses. Better voice

recognition may have improved concordance with treatment. The ideal length of the intervention remains unknown.

Attrition rates on the primary outcome, change in HbA_{1c} were low because most participants returned for their 90-day follow-up visit and checking HbA_{1c} levels every 90 days is considered standard of care for individuals who have values $\geq 7.0\%$ in the clinics involved in the study. 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.

The intervention in the study simply asked participants to listen to a message and to report their daily blood glucose readings. Concordance checking was limited as was the ability to give patients real time feedback on their readings and suggestions for improving glycemic control. The capability to do this existed, but personnel were not available to keep in contact with participants in this way. Participants in the intervention group were contacted regularly during the 90-day period between clinic visits, but the lack of follow-up regarding their responses or lack of responses may have limited the effect of the intervention. Adding this dimension to the intervention in a follow-up study is recommended.

Conclusions

This study addresses a gap in understanding the effects of isolated telephone interventions on physiologic, behavioral, and psychosocial outcomes in adults with type 2 DM. No overall treatment effect was seen on change in HbA_{1c}, but a significant dose effect was observed. The automated telephone intervention in this study had a significant impact on daily frequency of SMBG, suggesting that regular contact between scheduled clinic visits enhances adherence to this self-care behavior. The intervention showed positive trends in favor of changes in perceived severity to DM, improvement in favorable attitudes toward diabetes, and reductions in perceived exercise barriers.

This study can be viewed as a pilot study evaluating the feasibility and acceptability of an automated telephone intervention on outcomes in patients with type 2 DM. 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. Adding an active control group to future studies is recommended. Further study is also needed to determine if changes in perceptions of severity of illness, attitudes toward illness, and perceptions of barriers related to self-monitoring are significant mediators to behavioral change. Future studies should measure immediate effects as well as effects at a future point in time to determine whether the intervention has a lasting effect and whether changes in HbA_{1c} follow behavioral changes.

The findings from this study can be generalized to a diverse group of individuals with type 2 DM cared for in an urban university setting in the Midwestern United States. The treatment effects observed in this study were greatest in younger participants and in participants with a shorter duration of DM, which is consistent with findings from other studies.

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Appendix A
CONSENT FORM

Impact of an Automated Telephone Intervention on HbA1c in Type 2 Diabetes

You are invited to participate in a research study evaluating the effect of a daily automated telephone call on self management of type 2 diabetes. You were selected as a possible participant for this study because you have type 2 diabetes and because you use a glucose meter at home and are receiving care at the Primary Care Clinic at the University of Minnesota, Fairview. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

If you decide to participate in this study, your participation will last three months.

This study is being conducted by Judith Graziano, RN, a PhD candidate at the University of Minnesota School of Nursing, and Dr. Brian Sick, a physician at the Primary Care Clinic at the University of Minnesota, Fairview. This research is being supervised by Cynthia Gross, PhD at the University of Minnesota School of Nursing. The automated telephone technology for this study is provided by Warm Health, Inc., a company in Wayzata, Minnesota.

Study Purpose

The purpose of the study is to determine if the automated telephone technology used in this study has an effect on the frequency with which individuals with type 2 diabetes check their blood sugars and if this makes a difference in their overall blood sugar management. The telephone technology used in the study is a newer technology, but is not considered an experimental medical treatment. In order to evaluate the effect of the automated telephone technology, half of the participants agreeing to be in the study will receive an automated telephone call for 90 days in a row. The other half of the participants will not.

Study Procedures

If you agree to participate in this study, we will ask you to do the following:
1) Complete a questionnaire consisting of questions related to your diabetes. This questionnaire is expected to take about 30-45 minutes to complete. We will ask you to complete the questionnaire at the beginning of the study and again later in the study.
2) Allow the information downloaded from your glucose meter to be used for study purposes. The nurses in the clinic will also make sure the correct date and time are programmed on your meter.
3) Show the nurses at the Primary Care Clinic how you check your blood sugar at home to make sure you are doing it correctly.
4) Use your own glucose meter at home according to your doctor's directions.

5) Schedule a return visit to the Primary Care Clinic for the next time your doctor wants to see you. 6) Allow some of your private medical information related to your diabetes will be used for study purposes.

All participants in this study will receive care for their diabetes as they normally would at the Primary Care Clinic, in addition, about half of the participants in the study will be randomly selected (like flipping a coin) to receive a daily automated telephone call for 90 days.

If you are selected to be in the telephone call group, you will be asked to give us a telephone number and to determine what time of day you would like to receive an automated telephone call at this number. It is important for you to understand that you do not have to be at this number at the time of the call. If you happen to be away from your phone, the automated system will continue to try to call you. When you receive the automated telephone call, at first you will hear a recorded voice asking you to press any key on your telephone keypad. Then the recorded voice will talk to you about management of type 2 diabetes and ask you to respond to a few questions. Simply orally respond to the questions as if you were talking to a real person. The telephone call will take less than five minutes to complete. If you report a blood sugar over 400 or less than 60, Judith Graziano will receive an email. The email will contain your study number (not your name or any other information that can identify you). Judith will notify either Susan Meyer, the diabetes educator at the Primary Care Center, or one of the registered nurses in the endocrinology clinic.

If you are selected to the standard care group, we ask that you follow your doctors' and nurses' advice regarding the care of your diabetes and to contact your doctors and nurses if you have any questions regarding your care.

Risks of Study Participation
The study has the following risks. There is a small risk that people who receive the automated telephone calls may lower their blood sugar levels and experience symptoms of low blood sugar (hypoglycemia). Symptoms of low blood sugar will be monitored by Judith Graziano, RN, the lead investigator in the study. This will be done by reviewing the transcripts from your responses to questions regarding recent blood sugar readings and how you are feeling. If you report low blood sugar levels or symptoms of hypoglycemia you will receive a follow-up call from Judith and your primary care physicians will be contacted if needed.

Benefits of Study Participation
There are no direct benefits to you for participating in this study. You may experience an improvement in your blood sugar levels as a result of this study, but this benefit is not guaranteed.

Study Costs/Compensation

There will be no costs to you as a result of your participation in this study. You will receive a $25.00 check after you complete the 3-month follow-up visit.

Research Related Injury
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality
The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a participant. Your record for the study may, however, be reviewed by departments at the University with appropriate regulatory oversight. No study-related activities will be recorded in your medial record.

If you are assigned to the automated telephone intervention group, your recorded responses will be transmitted over the internet. No employees of Warm Health, Inc., or anyone else who may gain access to this internet site will be able to connect your responses with you. To protect your privacy, only a study number will connect your recorded information to you. Neither your name nor any other personal information will be forwarded to this internet site. Only Judith Graziano, RN, the principal investigator of this study will have access to the code that links you with this study number. This link will be in a locked file in Judith's office. To this extent, confidentiality is not absolute.

Protected Health Information (PHI)
Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study
Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota, Fairview, the Primary Care Clinic or your health care providers. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions
The researchers conducting this study are Judith Graziano, RN and Brian Sick, MD, and Cynthia Gross, PhD. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at 651-206-4317 (Judith Graziano) or 612-624-9499 (Dr. Sick), or 612-624-8676 (Dr. Gross).

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), **you are encouraged to** contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview-Riverside Campus, #815 Professional Building, 2450 Riverside Avenue, Minneapolis, MN 55454.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject_____
Date_____

Signature of Investigator_____
Date_____

Appendix B

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
[Hello, this is Alice from the Primary Care Center at the University of Minnesota. Thank you for participating in this research study evaluating the effects of a daily telephone call on self-management of type 2 diabetes.] Each day I will call you at this time. During the call, I will tell you a little bit about myself and about how I manage my diabetes. I hope that by sharing what I have learned about diabetes self-management that you will gain confidence in managing your own diabetes. Each day after I share my self-management tips with you, I will ask you to tell me what your blood glucose levels were the day before. For now, please check your blood glucose levels according to your doctor's recommendations and record them in your glucose logbook. [Thanks again for your participation in this project. I'll call again tomorrow at the same time. Until then, have a great day!] diab_onramp_1.wav	[Hello, this is Alice from the Primary Care Center at the University of Minnesota. I am so glad you are willing to take a minute or two from your day to help us with this study. The goal of this study is to help the doctors and nurses at the Primary Care Center at the University of Minnesota provide the best quality of care for people with diabetes.] Tomorrow I will start to prepare you for the questions we will be asking you in a couple of days. In the mean time, please be sure to check your blood glucose levels according to your doctor's directions and to record them in your logbook. Please keep your glucose logbook near the phone, so when I ask you to tell me your glucose levels it will be handy. This information is very important to help us provide you with the best quality care. [Thanks again for participating in this project. I'll call again tomorrow at	[Hello, this is Alice from the Primary Care Center at the University of Minnesota. Today I want to introduce you to the questions I will be asking each day starting tomorrow.] First, I will ask you if you checked your blood glucose levels the day before. Please answer yes or no. Next, I will ask you if you checked your glucose level at the following times: before breakfast, before lunch, after lunch, before dinner, after dinner and before bed. After each question, please answer yes or no. If you answer no, I will go on to the next question. When you answer yes, I will then ask you to tell me the result before I ask you the next question. Please have your glucose logbook near the telephone, so you are ready to answer the questions tomorrow. Please keep in mind that not everyone checks his or her blood glucose levels at the same	[Hello, this is Alice from the Primary Care Center at the University of Minnesota. I hope you have your glucose logbook nearby.] Now I am going to ask you a series of questions about your glucose levels. Please answer the questions based on when you checked your glucose levels yesterday and what the results were. **[DATA CAPTURE]** If this time of day works for you, I will keep calling at this time. If you would like to choose a different time, please contact Judith Graziano at 651-206-4317 to let her know a time that would be more convenient for you. The information you give us about your blood glucose levels is very important in helping us provide you with the best quality of care, so keep checking them according to your doctor's instructions. [Thanks again for participating in this	[TYPICAL GREETING] [Hello, this is Alice from the Primary Care Center at the University of Minnesota. I hope you are having a great day] Today I will tell you a little bit about myself. After that, I will ask you about your glucose levels from yesterday, so please have your glucose logbook handy. I am sixty years old and I have had type 2 diabetes for 10 years. I have learned to manage my diabetes and will be sharing self-management tips with you over the next few weeks, but now I would like to ask you a few questions. Please respond to the question and then wait for the next question or response from me. **[DATA CAPTURE]** [TYPICAL ENDING] [Thanks for your time. I hope you enjoyed today's call. I'll call again tomorrow. Until then, have a great day!]	[TYPICAL GREETING] As I mentioned yesterday, I have type 2 diabetes. People with type 2 diabetes do not either make enough insulin or the cells in their bodies do not respond properly to insulin. In either case, the cells in the body cannot use glucose for energy; glucose (also called blood sugar) builds up in the blood. A high level of blood glucose is harmful to the organs of the body. I'll talk more about this over the next few days, but now I would like to ask you a few questions. **[DATA CAPTURE]** [TYPICAL ENDING]	[TYPICAL GREETING] I take insulin to keep my blood glucose under control, but not everybody does. Taking insulin used to bother me, but now I realize that over 20 million people in the United States have diabetes, and many of them take insulin. I try to maintain a positive attitude about my diabetes and this helps me take better care of myself. I realize that even though taking shots each day is a little scary, the benefits I gain from them far out weigh the risks. Now I would like to ask you a few questions. **[DATA CAPTURE**] **[**TYPICAL ENDING]

Day 8
[TYPICAL GREETING]

Yesterday I mentioned that I try to keep a positive attitude about my diabetes. You may be wondering how I do this. I have learned to view diabetes as a health condition that I can control. I am just like people who do not have diabetes; I need to watch what I eat, get regular exercise and generally take good care of myself. In addition to generally taking good care of myself, I need to keep my blood glucose levels within my target range. I'll tell you more about that tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 9
[TYPICAL GREETING]

Yesterday I mentioned that I try to keep my glucose levels within my target range. My target range is between 80 and 120. This level is similar to the blood glucose levels of people without diabetes. At this level, I have enough glucose in my system to keep my cells working, but not too much, which can cause damage to the organs in my body. It is important for you to know what your target glucose levels are. Tomorrow I will give you a telephone number you can call to find out what your target glucose levels are, but now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 10
[TYPICAL GREETING]

As I mentioned yesterday, I have a telephone numbers for you to call in case you are not aware of your target glucose levels. Two people at the number can help you. The first is Karen MacEwan, and the second is Adel West. They are nurses in the Office of Diabetes Education at the University of Minnesota. You can reach them at 612-626-1123. Karen and Adel can help you get answers to many questions you may have about diabetes management. I encourage you to call them. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 11
[TYPICAL GREETING]

A few days ago, I mentioned that I view diabetes as a health condition that I can control. One way I have found that helps me feel in control is to set realistic goals for myself (that I can actually achieve). Perhaps there is a health-related goal that you would like to achieve. A tip I would like to share with you is to break your major goals down into very small achievable parts. Tomorrow I will give you an example of how to do this. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 12
[TYPICAL GREETING]

Yesterday I mentioned that I would give you an example of how to break down large goals into smaller goals. A large goal of mine is to keep my blood glucose levels at my target range every day. An achievable small goal that will help accomplish this larger goal is to check my glucose levels according to my doctor's recommendation today. When I attain this goal, I feel more in control and have a better attitude about my diabetes. I will talk more about this tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 13
[TYPICAL GREETING]

You might be wondering how a small goal like checking my glucose levels according to my doctor's recommendation today can help me achieve the larger goal of keeping my glucose levels at my target range all of the time. The reason is, if I check my glucose levels today and record the levels in my glucose logbook, over the period of several days or weeks, I will see a pattern of when my highs and my lows are. Tomorrow I will tell you how I use this information. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 14
[TYPICAL GREETING]

Yesterday I was talking about how I use the information in my glucose logbook to help me achieve my long-term goal of keeping my blood glucose levels in their target range. Sometimes I make small adjustments in my diet or activity based on the pattern I see. When I bring my logbook with me to my doctor's visits, my doctor makes recommendations for adjusting my diet, activity or medications based on this information. I hope you plan to use your glucose logbook this same way. Now I would like to ask you a few questions.

[**DATA CAPTURE]**

[TYPICAL ENDING]

Day 15
[TYPICAL GREETING]

Yesterday I mentioned that I always bring my glucose logbook to my doctor's visits. Another important health tip is that you do not have to wait until you see your doctor if you have any concerns about your health. For example, if you notice a pattern of high glucose levels, you can call Karen or Adel at the University of Minnesota Diabetes Education Office and ask one of them for advice. The telephone number is 612-626-1123. You can also call your doctor's office and request to speak to your doctor or the nurse in the office. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 16
[TYPICAL GREETING]

I used to think that I was "bothering" the doctor when I called the office. Now I realize that the doctors and nurses really like it when we keep in touch and inform them about how we are doing. It is important that we contact our health care providers when we are not feeling well or if we have questions like, "my blood glucose is above (or below) my target range, what should I do?" I hope you feel comfortable doing this. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 17
[TYPICAL GREETING]

By learning more about diabetes self-management, I have found that I have more confidence in how I take care of my health. For example, I learned that if I can reduce my blood glucose levels so they are at a more normal range (close to my target range), I will reduce my risk of experiencing long-term complications from diabetes. I will talk about how to avoid long-term complications of diabetes later. Tomorrow I will give you tips on recognizing short-term diabetes problems. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 18
[TYPICAL GREETING]

The most common short-term complication from diabetes is hypoglycemia or low blood sugar. As we strive to achieve better glucose control, it is possible to experience an episode of hypoglycemia. It is important that you, and your family and your friends are able to recognize when you are experiencing a low. The symptoms may include:

- feeling anxious
- confusion
- cool, clammy skin
- difficulty speaking
- paleness
- irritability
- dizziness/weakness

The correct action is to take a form of simple sugar such as a half can of sugared (non-diet) soda or juice. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 19
[TYPICAL GREETING]

I mentioned the other day that I try to set realistic goals for myself. Another goal I have is to lose some weight. My doctor tells me that even a 10-pound weight loss can have a big affect on my blood glucose levels. If I lose 10 pounds, I may even be able to reduce the amount of insulin I need to take. I realize that losing 10 pounds is a big goal, so it will be easier to achieve if I break it into smaller goals. I'll talk more about that tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 20
[TYPICAL GREETING]

My smaller, more achievable weight-loss goal is to lose only 1 or 2 pounds per month. I realize that within a year I could weigh between 12 and 24 pounds less! I am doing this by exercising more and trying to eat a little less. My goal is to walk at least six days a week and to reduce portions of my food. I try to take smaller portions and to think twice before reaching for second helpings. Tomorrow I will talk more about how I am doing this and how I can still have ice cream. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 21
[TYPICAL GREETING]

I find that if I tell myself "no more ice cream", all I think about is ice cream! With my new plan of cutting down on portion sizes, I have cut my ice cream intake by quite a bit. I keep small frozen ice cream treats in the freezer and allow myself a couple per day. I try to buy the treats that are low in fat and sugar. This helps decrease my craving for sweets and helps me feel confident that I can achieve my goal. I hope this tips helps you if you would like to lose a little weight. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 22
[TYPICAL GREETING]

Sometimes I feel a little down; I may feel irritable or feel like no matter what I do to take care of myself, it does not make a difference. On those days, I have to remind myself that how I think about things or what mood I am in can affect what I actually do. I do not get concerned if I feel overwhelmed or down for a few days now and then, but the important thing is that I continue to take care of myself even when I do not feel like it. I'll talk more about this tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 23
[TYPICAL GREETING]

I talked a little bit about mood yesterday. If my blood glucose is too high or too low, it can affect my mood. Keeping my blood glucose at my target level helps me feel my best both emotionally and physically. If my blood glucose is within my target range for me and I still feel blue, I usually talk to someone about how I am feeling. I hope that you have someone to talk to so you do not feel alone with your diabetes. I will have more to say on this subject tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 24
[TYPICAL GREETING]

Feeling worried, anxious, depressed or not wanting to do the things we usually enjoy for a period longer than a few days or a week may be an indication that we need some help to feel better. This happened to me and after discussing it with my doctor and getting some help, I am feeling so much better! Remember having a chronic condition such as diabetes does not mean that we have to suffer emotionally; we can get help! I hope you are comfortable discussing your emotions with your doctors and nurses. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 25
[TYPICAL GREETING]

I'm sure you know that curing your diabetes is unlikely. However, lowering the risk of complications related to diabetes, such as heart attack, eye problems, or kidney disease can be achieved by keeping blood glucose levels in their target range. Sometimes we may feel just fine if our blood glucose levels are higher than our target levels, but our hearts, kidneys, eyes, and other organs are always thanking us for keeping our blood glucose levels in control. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 26
[TYPICAL GREETING]

One of the things I learned from the Diabetes Education Office at the University of Minnesota is that if my blood glucose level is higher than my target range, I can go for a walk to help bring it down instead of increasing my insulin or skipping a meal. I just need to recheck my blood glucose after exercising to make sure I am going in the right direction. If you are unable to walk or don't enjoy walking, you could try other ways of getting exercise. It is always a good idea to talk to your doctor before starting an exercise routine. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 27
[TYPICAL GREETING]

Although I do not always have the time or the energy to walk for long periods, I can find ways to walk a little bit throughout the day. For example, I can park farther away at the grocery store, I can climb the first flight of stairs and then take the elevator up to the floor where I am going, or I can walk around the parking lot with a friend after lunch. It's important to check your blood glucose levels more frequently when changing daily activity patterns. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 28
[TYPICAL GREETING]

I was not able to keep my blood glucose within my target range yesterday. I checked my blood glucose four times yesterday, but I was high two hours after lunch. I have been keeping careful records and can see that the mid-morning snack I usually have is not a good idea. I will make a change to a healthier snack and keep checking after lunch to see if my glucose level improves. Remember to keep in touch with your health care team if you are not sure what to do. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 29
[TYPICAL GREETING]

Much of diabetes care requires self-management, because most of the time we are not at our clinic or doctor's office. It's important to keep in mind that self-management does not mean ignoring the advice of your doctors and nurses. Rather, it means deciding to follow that advice and to keep in touch with them if their advice doesn't seem to be working or if you find something that works better. I hope you feel comfortable following the advice of your doctors and nurses and talking to them if their advice doesn't seem to be working. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 30
[TYPICAL GREETING]

Everybody needs a certain amount of glucose, or sugar, in his or her blood at all times. My self-management goal is to keep my blood glucose at my target level, usually between 80 and 120. I do this by balancing my eating plan, exercise, and medications. Good nutrition is a very important part of diabetes self-management. Well-balanced meals and healthy snacks are essential. I'll be talking about the nutrients our bodies need over the next few days. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 31
[TYPICAL GREETING]

Ideally, the types of food we eat and the timing of our meals and snacks work together with our insulin injection schedule (or other diabetes medication) and exercise to keep our blood glucose within the target range for much of the day. The good news is that the ideal meal plan for people with diabetes is no different from the healthy meal plan that nutrition experts recommend to everyone. There is no need for us to eat special foods or give up our favorite treats. With the help of a dietitian, we can create a healthy and appetizing meal plan. I'll talk more about that tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 32
[TYPICAL GREETING]

The main calories we consume come from carbohydrates, proteins and fats. Carbohydrates cause our blood glucose to rise more rapidly than proteins or fats, so we have to watch the total amount we consume at each meal. We should choose carbohydrates that provide good nutrients and fiber, but fewer calories and less fat. Good choices are vegetables, fruits, whole grains, and pasta. These are called complex carbohydrates. I try to limit carbohydrates that contain simple sugar such as cakes, cookies, sodas and ice cream. These foods make my blood sugars go very high! I'll talk about proteins and fats tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 33
[TYPICAL GREETING]

Proteins repair muscle tissue, bones, and skin and provide energy. Animal products such as meat, fish, and milk provide common sources of protein in our diet. Some vegetables and grains are also good sources of protein. Low fat forms of protein are the best for us and tend to come from sources other than animals. Fats are also needed by the body, but eating too much fat can lead to weight gain, which can further complicate our diabetes and affect our hearts. Tomorrow I'll give you the name and telephone number of a registered dietician who can help answer any food-related questions you might have. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 34
[TYPICAL GREETING]
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Our meals should include a variety of complex carbohydrates, proteins and fats in moderation. I find that if I eat these three food groups in the correct combination, my blood sugars are more likely to remain steady, avoiding highs and lows. I learned a lot about what to shop for and how to prepare healthy meals from the dietician at the University of Minnesota. I'll give you her name and telephone number in case you have questions regarding eating a healthy diet. Her name is Carol Brunzell and her number is 612-626-1123. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 35
[TYPICAL GREETING]

As I mentioned previously, one of my goals is to exercise regularly. After discussing my exercise program with my doctor, I started my exercise program very slowly. At first, I only walked five to ten minutes per day, but now I am up to 30-40 minutes per day at a brisk rate. I try to walk a minimum of five days per week. I have noticed so many benefits from regular exercise including better control of my blood sugars, my blood pressure has improved, I have lost a few pounds, and best of all, I don't need to take as much insulin. I hope you speak to your doctor abut starting an exercise program if you haven't already. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 36
[TYPICAL GREETING]

Yesterday I was talking about my exercise program. I learned some very important tips about exercise and diabetes that I would like to share with you. First, it is very important to discuss your exercise plan with your doctor and that you and your doctor agree on the plan. Initially, I had to keep in close touch with my doctor, because I had to make changes in my diet and insulin. I'll give you a couple more tips related to exercise over the next few days. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 37
[TYPICAL GREETING]

I always carry a form of simple sugar with me when I exercise. Exercise uses up the glucose in our blood more quickly than when we are inactive. Therefore, it is possible to experience episodes of low blood glucose when exercising. Consuming a simple source of sugar such as a piece of candy, fruit, or a small juice box can help bring blood glucose levels back up. Checking blood glucose levels before and after exercise and taking in extra calories if needed is the best way to avoid going too low. I'll give you another exercise tip tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 38
[TYPICAL GREETING]

Today I have a final tip regarding exercise. It is important to wear proper fitting shoes and stockings when walking or doing other forms of exercise. Stockings and proper fitting shoes help us avoid blisters that can become infected and become big problems. Always check your feet daily, especially after walking, to make sure that there are no sores or blisters. If you notice pain, redness, blistering or swelling, see your doctor right away. I hope you are finding these health tips useful. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 39
[TYPICAL GREETING]

I find that when I am angry, upset, or anxious I have days where my blood glucose is higher than my target level. Other days, I cannot figure out why my glucose levels are too high or low. One thing I have learned is that sometimes my blood glucose runs high for reasons that I do not have that much control over. It has helped me to understand that I am not a bad person and that I am not doing anything wrong when this happens. The important thing is that I keep trying to do my best. I'll talk more about emotions the next couple of days. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 40
[TYPICAL GREETING]

Yesterday I talked about how our emotions can cause our blood glucose levels to rise. One of the emotions that can cause this is stress. I try to avoid stressful conditions whenever I can. For example, driving in traffic bothers me, so I try to avoid high traffic situations by planning my errands at times when there are fewer cars on the rode. I also get very nervous when I am running late, so I always leave early to avoid this type of stressful situation. Tomorrow I'll talk about planning for unavoidable stressful situations. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 41
[TYPICAL GREETING]

Some stressful situations are inevitable. For example, we all have to stand in long lines at times. When planning for situations like this, it may help to bring a friend along. You and your friend can keep each other distracted, so that standing in the line doesn't seem so bad. If you hate being late like I do, be sure to plan extra time and if you get to your destination early, have a book or newspaper along that will keep you occupied while you wait for the event to start. I'll have more to say about this tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 42
[TYPICAL GREETING]

I hope you have thought of some ways to help relieve the stress you have in your life. Sometimes stressful emotions are increased by feeling as if you are alone with your diabetes, like there is no one else with the same problem. It is important to have someone you can talk with. Sometimes family and friends don't quite understand how you are feeling because they don't' have diabetes. Tomorrow I'll tell you about a group that I belong to that helps me feel that I am not alone. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 43
[TYPICAL GREETING]

I recently started going to my clinic's patient group called Diabetes Topics. At these meetings, I learn about diabetes from health experts. I can ask questions, and I get to meet others who are living with diabetes. This group meets once a month. I usually go, but if I have other plans or just don't feel like going out, I am under no obligation to attend. Tomorrow I'll give you the telephone number of the Minnesota Chapter of the American Diabetes Association. Call this number if you would like to find out about groups near you. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 44
[TYPICAL GREETING]

Yesterday I talked about patient groups that meet to assist people to learn more about diabetes. I hope you take some time to find out what's available in your area. Ask your doctor or nurse, or you can also ask your Minnesota chapter of the American Diabetes Association. The number is 763-593-5333. If you use the internet, you can also visit the American Diabetes Association's website at www.diabetes.org. My local library helped me learn how to use the Internet. It's free, and I have been able to read all kinds of information about diabetes. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 45 [TYPICAL GREETING]

For the past few days, I have discussed resources that are available for people with diabetes. As you learn more and more about diabetes management, you will know how to make the right self-management choices and where to go for help. The best way to learn about diabetes is by going to a diabetes education session. Trained nurses teach you about the disease and help you understand what you can do to prevent problems. I'll tell you more about this tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 46
[TYPICAL GREETING]

Yesterday I was talking about diabetes education classes. At these classes, you can sit back and listen or ask questions. The nurses are great and love to help people like us. If you prefer a one-on-one meeting with the nurse, you can do that too. If it has been some time since you have received diabetes education, refresher courses are available. Please contact Karen MacEwan or Adel West at the University of Minnesota to set up a diabetes education course or refresher course. Their telephone number is 612-626-1123. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 47
[TYPICAL GREETING]

I hope you have thought about getting some diabetes education at the University of Minnesota. I promise that you will learn a lot! I have a doctor's appointment coming up very soon. This is a special visit to talk about my diabetes. I always get a little nervous about these visits, but I know that in the end, it will help me take better care of myself. Tomorrow I'll talk about how to prepare for a doctor's visit. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

[Day 48
TYPICAL GREETING]
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To prepare for my visit to the doctor, I will make sure to get all of my mediations together. I usually put all the medication bottles in a bag and bring them with me. That way the doctors and nurses at the clinic can see exactly what I have been taking. I will also remember to bring my blood glucose logbook with me, even if it is not complete. Some days I'm not as good at recording my blood glucose levels as other days, but my doctor says that any record that I keep is helpful. I'll share more tips about preparing for the doctor visit tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 49
[TYPICAL GREETING]

When I visit the doctor, I need to make sure that all of my blood tests are up-to-date. The nurse said that I might need to get a blood test that will show how well controlled my blood glucose has been during the past three months. They also want to check my cholesterol. I'm going to call the clinic to see if I can get these blood tests done ahead of time, so that I can talk with my doctor about the results during my visit. I am going to make a list of the things I have questions about and make sure I get all of my questions answered during my visit. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 50
[TYPICAL GREETING]

My recent doctor visit went very well. I have several tips to share that I learned during this visit. My doctor told me how important it is to take good care of my feet. Those of us with diabetes are at special risk for problems with our feet. Diabetes causes numbness first in the areas that are the farthest away from our head. That is why the doctor worries about my feet so much; they will usually be the first place that the numbness shows up. I'll tell you more about this tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 51
[TYPICAL GREETING]
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After doing a simple test, my doctor noticed that I had a little bit of numbness in my toes. Now she wants me to see a podiatrist to ensure that my shoes fit properly and that there are no other foot abnormalities. She told me that it is very important that I look at my feet everyday to make sure there are no problems. Because my toes are numb, I am at risk for cutting myself and not even knowing it. Before I know it, I could have an infection that could lead to my toes being amputated! I hope you make it a point to check your feet every day too. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 52
[TYPICAL GREETING]

Another thing that my doctor told me was that diabetes could affect my kidneys I had a screening test done on a small sample of urine to see if I was at risk for developing kidney disease. My doctor called me today to tell me that it was abnormal. I was not happy to hear that, but was happy to hear that there are things I can do about it. I do not want to end up on dialysis, which means a machine would have to clean my blood three times a week. Tomorrow, I'll give you some tips on how we can reduce our risk of kidney disease. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 53
[TYPICAL GREETING]

Yesterday I promised to talk about reducing the risk of developing diabetes-related kidney problems. The most important thing that we can do to avoid this problem is to keep our blood glucose levels within the target range suggested by our doctors and nurses. This reduces the amount of blood glucose the kidneys are exposed to and helps keep them healthy. I'll talk more on this subject tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 54
[TYPICAL GREETING]

Controlling our blood pressure can also help prevent kidney disease. It is important that we get our blood pressure checked often and, if it is elevated, that we get it treated. I like to go to my local fire station to get my blood pressure checked between office visits. I usually write down the results in my glucose logbook. That way my doctor can see what my blood pressure is when I am away from the clinic. Tomorrow I'll tell you about a medication that I started to take because of my abnormal urine test that also treats my high blood pressure. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 55
[TYPICAL GREETING]

Now that I have an abnormal urine test I have started taking a medication called an ACE inhibitor. The good thing is that the ACE inhibitor not only helps protect my kidneys but it is also a blood pressure medicine, so it treats my high blood pressure too. I will do what ever I can to avoid kidney disease and dialysis. I hope you are getting your blood pressure checked regularly and that you are taking your medications according to your doctor's recommendations. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 56
[TYPICAL GREETING]

Another thing my doctor told me is that I am at risk of heart disease because my cholesterol is high. Cholesterol builds up on the inside of the arteries and can put me at risk for having a heart attack. She told me that my LDL, the bad cholesterol, is high. An easy way to remember that the LDL is the bad cholesterol is to pretend that the L stands for Lousy. Since I have diabetes, my goal LDL is less than 100.
I'll talk more about this tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 57
[TYPICAL GREETING]

Yesterday I was talking about my LDL or Lousy cholesterol. Mine was 145 and, since I have diabetes, it should be less than 100. My doctor starting me on a cholesterol medication called a STATIN to reduce my risk of heart disease. I may not notice the effect right away but I hope it will prevent me from having a heart attack in the future. Tomorrow I'll talk a little bit more about all of the medications I take. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 58
[TYPICAL GREETING]

Yesterday I was telling you about the new medication I am taking called a STATIN to help lower my bad (LDL) cholesterol. The other important but easy thing I can do to help my heart is to start taking a baby aspirin everyday. It's a good idea to check with your doctor before you start taking a baby aspirin. Although I am now on three extra medications in addition to my diabetes medicines, I feel better knowing that I am doing everything I can to prevent kidney disease and heart disease. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 59
[TYPICAL GREETING]

I have a few more things to share with you that came up at my doctor's visit. There are some other things for which having diabetes puts me at risk. I am at risk for eye disease, which can cause me to go blind. If I go to see the eye doctor every year he can tell me if I am showing the early signs of eye disease and fix my eyes before I go blind. If I wait too long to see the eye doctor, he may not be able to help me. I hope you see your eye doctor regularly too. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 60
[TYPICAL GREETING]

The last thing I learned at my recent doctor's visit is that I am at increased risk for more severe infections than somebody without diabetes is. I can help protect myself by getting the flu vaccine and the pneumonia vaccine. I need the flu vaccine every Fall. I need to have the pneumonia vaccine at least once in my life. Since I am less than 65 years old, my doctor says that I will need to get it once more in five years. I hope you talk to your doctor to make sure your vaccinations are up to date. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 61
[TYPICAL GREETING]

Did you know that poor glucose control could increase our risk developing gum disease, which can lead to tooth loss? Besides keeping my blood glucose levels within my target range, there are other things I can do to help prevent gum disease. According to the American Diabetes Association web site, to fight gum disease we need to brush our teeth at least twice a day, floss our teeth every day, look for signs of gum disease and visit our dentist at least twice a year. I'll talk about signs of gum disease tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 62
[TYPICAL GREETING]

According to the American Dental Association, the signs of gum disease are gums that bleed easily, red, swollen or tender gums, gums that have pulled away from the teeth, persistent bad breath or bad taste in the mouth, loose teeth, or changes in the way the teeth bite together. Sometimes gum disease is present without any signs or symptoms, which is another reason we should check in with our dentist every six months. I hope you plan to visit your dentist every six months. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 63
[TYPICAL GREETING]

After hearing me talk about going to visit the foot doctor, the eye doctor, the dentist, and my regular doctor, it must sound like all I do is visit doctors. Sometimes I get frustrated with this too, but then I remember that most people need to visit the eye doctor once a year, the dentist twice a year, and their personal doctor for check ups, so I'm not that different. It's worth my piece of mind to know that I'm doing everything I can to take good care of myself. I hope you feel the same way. Now I would like to ask you a few questions.

[**DATA CAPTURE]**

[TYPICAL ENDING]

Day 64
[TYPICAL GREETING]

Taking good care of ourselves when we have diabetes can be expensive. Sometimes people may find it difficult to follow their doctor's instructions because of financial difficulties. Resources may be available to help in these cases. If you have financial concerns regarding your diabetes, please call Karen or Adel at 612-626-1123. I hope you give them a call if you have concerns about the price of medications, the cost of glucose test strips, or other costs associated with your diabetes care. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 65
[TYPICAL GREETING]

I had a bit of a scare yesterday. I was out running around and ran into some delays, and didn't get around to eating lunch when I normally do. I started feeling kind of dizzy and confused. Luckily, I was with a friend of mine who realized I was probably having a low, and she got me some juice to drink. I drank a half a glass of juice and started feeling better soon after. I had not checked my blood glucose since I had gotten up that morning. I hope you are eating regularly and checking your blood glucose levels frequently so you can avoid the problem I had. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 66
[TYPICAL GREETING]

Today I would like to talk about the benefits of not smoking. I have not smoked in 10 years, and I do not intend to start again. It was not as hard to quit as everybody thinks it is, but it took me a while to make up my mind to quit. I had some slips, but I am very happy I decided to quit. Other than the benefits of not having the terrible smoky smell and the stained teeth, I know that I am also protecting my heart and lungs by not smoking. I'm even protecting my teeth because smoking contributes to gum disease! I'll talk more about the benefits of not smoking tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 67
[TYPICAL GREETING]

Yesterday I mentioned that I quit smoking and never intend to smoke again. Did you know that after we quit smoking the risk of our developing serious illnesses such as heart attack, stroke, and lung cancer decreases? According to the American Lung Associate web site, the chance of having a heart attack decreases within 24 hours of our last cigarette. The longer we stay away from smoking, the greater the reduction in the risk is. Tomorrow I'll give you the telephone numbers of a great resource to help you quit smoking. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 68
[TYPICAL GREETING]

I realize that even though I was successful at quitting smoking for good, not everyone is. There is a lot of help for people who want to stop smoking. The University of Minnesota offers a QUITPLAN Smoking Cessation Clinic at no cost or very low cost. According to their web site, smokers who use this plan are seven time more likely to quit than those who try to quite on their own. I urge you to contact them if you are having difficulty quitting tobacco. The telephone numbers are 612-333-0770 or 612-302-8200 Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 69
[TYPICAL GREETING]

I mentioned a couple of days ago that I am taking many medications. I have never liked taking medicine, and if I have to take it, I want to take as few pills as possible. Unfortunately, diabetes is a complex disease with many problems. This means that there are many medicines that need to be taken to help control my blood glucose and the problems that result from having diabetes. I'll talk more about this tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 70
[TYPICAL GREETING]

Yesterday I was talking about medications. I recently found out that I can visit with the pharmacist in my clinic to have her review my list of medications. She can see if there are combination medicines that will take the place of two of the medications I am already taking. She can also check to see if a long acting medicine can replace any medications I take more than once a day. I am going to meet with her later today. I'll tell you about how this visit worked for me tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 71
[TYPICAL GREETING]

Yesterday I mentioned the visit I had with the pharmacist at my clinic. She told me that there is a combination pill for my kidney medicine, the ACE inhibitor, and another blood pressure medicine I am taking. I am going to ask my doctor if I can change to a combination pill so I don't have to take so many pills every day. The pharmacist gave me another suggestion that I will tell you about tomorrow. I will also give you the telephone number of the pharmacist if you would like to give her a call. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 72
[TYPICAL GREETING]

Yesterday I was talking about tips I got from our clinic pharmacist. She suggested that I take the long-acting form of metformin instead of taking it twice a day. I enjoyed the visit with the pharmacist because I may be able to change from taking four pills a day to taking two pills a day without changing my risk of developing problems. Before I make any changes, I will make sure that my doctor approves the changes. If you have any questions about your medications, I hope you call the University of Minnesota Specialty pharmacy at 612-672-5260 or 800-595-7140 (toll free). Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 73
[TYPICAL GREETING]

Sometimes my fingers get so sore when I check my blood glucose regularly. I mentioned this to Karen MacEwan at the Diabetes Education Office at the University of Minnesota, and she told me a way that I could test that was less painful. Instead of sticking myself right in the fingertip where all of my nerves are concentrated, she told me that I should try testing on the side of my fingertip. This really is less painful. In addition, it gives me plenty of places to test, two spots on each finger. I alternate where I test too, so I don't stick myself in the same place each time. I hope you try this. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 74
[TYPICAL GREETING]

Yesterday I was talking about blood glucose testing at home. I have heard that some people test blood from their arms or their thighs, so I asked Karen about that too. She said that it's possible to get different readings if we are using different sites. The finger is the most accurate site to check blood glucose, and shows changes more quickly than other sites. I've also heard about a glucose watch, but I've heard it isn't as accurate as finger sticks. I hope that you are following the procedures that you were taught by the nurses at the Primary Care Center when checking your blood glucose levels. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 75
[TYPICAL GREETING]

I was talking about glucose testing yesterday. Remember that if you are sick, you need to test more often. That is because If you get a cold or flu, are running a fever, are vomiting or have diarrhea, it is very easy to cause dehydration, especially for those of us with diabetes. This can lead to very high blood glucose levels that are dangerous. Sometimes people even end up in a coma. I'll talk more about planning for sick days tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 76
[TYPICAL GREETING]

Yesterday I mentioned that those of us with diabetes should plan a little in case we get sick. The best time to plan is before we get sick. It seems like it's inevitable that I get at least one cold a year, or even worse, the flu. That's why each fall, I make sure to get a flu shot so I'm less likely to get the flu, or at least it might not be such a bad case if I do. My doctor also told me that it's a good idea to get a vaccine to help prevent pneumonia. I had one a few years ago, but after I turn 65, I'll need another. I'll talk more about sick days tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 77
[TYPICAL GREETING]

When planning for sick days, it's important to talk to your doctor before you get sick. I talked to my doctor about what medicines I should take in case I get sick. I thought that if I wasn't eating, that I should not take my diabetes medicine, but my doctor told me I still need to take it. It is important that you check with your doctor to find out what you should do, since every one is different. I'll talk more about sick days tomorrow. Now I would like to ask you a few questions.

[**DATA CAPTURE]**

[TYPICAL ENDING]

Day 78
[TYPICAL GREETING]

Another thing I recently learned is that some medicines people commonly take when they are not feeling well and that are available without a prescription can raise blood glucose levels. Many of these cough and cold remedies contain sugar. I talked to my pharmacist about this, and she told me that sugar-free versions of many cough and cold medicines are available, but they are more expensive. I'll share another tip about cough and cold medicines tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 79
[TYPICAL GREETING]

Yesterday I was talking about cold medicines. During my conversation with my pharmacist, she told me that instead of buying expensive sugar-free cough medicines, I could just take the regular cough medicine, but allow for this in my carbohydrate (carb) counting. I have a few more sick day tips that I'll share tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 80
[TYPICAL GREETING]

Yesterday I was talking about cold medicines that people sometimes take when they are sick. My pharmacist told me that if I take a lot of aspirin for my fever, this can actually lower my blood glucose levels. Some decongestants and antibiotics can raise my blood glucose levels. It is important that we check with our doctors or pharmacists before we decide to take cold remedies or when we have antibiotics prescribed for us. We need to be aware of what we should watch for. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 81
[TYPICAL GREETING]

Besides being aware of my medicines, I always try to keep some food and drinks on hand that I can eat when I am not feeling well. Having some canned soups on hand, some soda crackers, some ginger ale (both with sugar and sugar free) or tea can be a real lifesaver. The last thing I want to do when I am sick is run out to the grocery store for supplies. I have another tip regarding sick day essentials that I will share with you tomorrow. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 82
[TYPICAL GREETING]

Yesterday I was talking about keeping some foods and drinks available for sick days. If you live with other people, you might want to keep a stash somewhere so you don't find your cupboard empty. If you are ill, try to eat something with about 15 grams of carbohydrates every hour, such as a slice of toast, six soda crackers, ½ cup of applesauce, or a cup of chicken noodle soup. If you are having trouble keeping food down, try taking small sips of ginger ale or tea. Please remember to keep checking your blood glucose levels; try to do this every 3-4 hours as things can change very quickly when you are sick. Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 83
[TYPICAL GREETING]

It is important to know when you need to call your doctor. Anytime you are not sure what to do, it's best to call. In addition, some general guidelines about calling the doctor when you are sick are 1. If you are running a fever or are not getting better after a couple of days, call your doctor.
2. If you are vomiting or have diarrhea for more than 6 hours, call your doctor.
3. If your blood glucose is running 240 or above, even after your medications, or before eating, or if it is staying up there for 24 hours, call your doctor.
4. Any time you have trouble breathing or chest pain, be sure you call right away.
Now I would like to ask you a few questions.

[DATA CAPTURE]
[TYPICAL ENDING]

Day 84
[TYPICAL GREETING]

It is important to not only understand the symptoms of hypoglycemia, or low blood glucose, such as weakness, feeling cold and clammy, trouble concentrating, confusion, etc., but also to be able to recognize the symptoms of hyperglycemia or high blood glucose levels. The most common symptoms of high glucose levels are increased urination and increased thirst. It is important that we keep aware of how we are feeling in addition to the information our glucose meters give us. I hope you will seek help if you are not feeling well even if your blood glucose levels are at your target range. Now I would like to ask you a few questions.

[**DATA CAPTURE]**

[TYPICAL ENDING]

Day 85
[TYPICAL GREETING]

The American Diabetes Association website has a list of many common myths about diabetes. I hope that during these telephone calls over the past weeks, I have dispelled some of these myths. I will mention a couple of these during our last few phone calls this week, but if you get a chance, go to the American Diabetes Association web site where you can get a wealth of information. The web address is www.diabetes.org

Now I would like to ask you a few questions.

[DATA CAPTURE]

[TYPICAL ENDING]

Day 86
[TYPICAL GREETING]

A common myth about diabetes noted on the American Diabetes Association web site is that people with diabetes need to eat special diabetic foods. I'm sure you are aware by now that this is not true. The American Diabetes Association website states that, "A healthy meal plan for people with diabetes is the same as that for everyone – low in fat (especially saturated and trans fat), moderate in salt and sugar, with meals based on whole grain foods, vegetables and fruit. Diabetic and 'dietetic' versions of sugar-containing foods offer no special benefit. They still raise blood glucose levels, are usually more expensive and can also have a laxative effect if they contain sugar alcohols."

Now I would like to ask you a few questions.
[**DATA CAPTURE**]
[TYPICAL ENDING]

Day 87
[TYPICAL GREETING]

Another common myth noted on the American Diabetes Associate web site is that insulin causes hardening of the arteries or atherosclerosis. The answer to this myth is that insulin does not contribute to atherosclerosis or high blood pressure. People who take insulin may gain weight more easily, but large research studies have shown that the benefits of taking insulin far outweigh the risks of taking it. Now I would like to ask you a few questions.

[**DATA CAPTURE**]

[TYPICAL ENDING]

Day 88
[TYPICAL GREETING]

You are probably preparing for your three-month diabetes check-up if you have not already had it. During that visit, we will ask you to complete some surveys and will also download the information from your glucose meter. Please follow the tips I gave you on preparing for your doctor's visit. Either bring your medications with you, or a list of your medications. Please make a list of questions you have for your doctors and nurses. Request a diabetes education refresher course if you have not have not received diabetes education recently.
Now I would like to ask you a few questions.

[**DATA CAPTURE**]

[TYPICAL ENDING]

Day 89
[TYPICAL GREETING]

Tomorrow will be my last telephone call to you. I hope you have enjoyed these calls and have gained confidence in managing your diabetes. Diabetes care has changed so much over the years. The advice your health care team gives you is based on scientific research and good clinical judgment. It is best to follow the advice of your health care team, which consists of your doctors, nurses, dieticians and pharmacists. The number to call for your diabetes education needs is 612-626-1123. Please do not hesitate to call this number to get the information you need to take the best possible care of yourself. Now I would like to ask you a few questions.

[**DATA CAPTURE**]

[RAMP OFF ENDING]

Day 90
[TYPICAL GREETING]

Today, I am calling to say goodbye and to thank you for participating in this research study. Your participation will help the doctors and nurses at the Primary Care Center provide you with the best quality care. Please remember that you are the most important person in your health care team. I hope you use the self-management tips I have shared with you over the past weeks and keep checking your glucose levels according to your doctor's recommendations.

Now, for the final time, I am going to ask you a few questions.

[**DATA CAPTURE**]

[RAMP OFF ENDING]

Appendix C

ID# _____

Today's Date _____

Diabetes Care Profile

Michigan Diabetes
Research and Training Center
DCP2.0

Section I - Demographics

Please answer each of the following questions by filling in the blanks with the correct answers or by choosing the single best answer.

Note: For this survey, a Health Care Provider refers to a doctor, nurse practitioner, or physician assistant.

Q1. Age: __ __ years old

Q2. Birth date: __ __ /__ __ /__ __
(Month / Day / Year)

Q3. Zip Code: __ __ __ __ __

Q4. Sex: ☐1 Male ☐2 Female

Q5. What year were you first told you had diabetes? (Please enter the year) __ __ __ __

Q6. What is your marital status? (check one box)

- ☐1 Never married
- ☐2 Married
- ☐3 Separated/Divorced
- ☐4 Widowed

Q7. What is your ethnic origin/race? (check one box)

- ☐1 White
- ☐2 Black
- ☐3 Hispanic
- ☐4 Native American
- ☐5 Asian or Pacific Islander
- ☐6 Arabic
- ☐7 Other _____

Q8. Where do you live most of the year? (check one box)

- ☐1 Your home, apartment or condo
- ☐2 Senior citizen apartment/condo
- ☐3 Home of a relative/friend
- ☐4 Retirement home
- ☐5 Adult foster care
- ☐6 Nursing home
- ☐7 Other _____

Q9. How many people live with you? (check one box)

- ☐0 I live alone
- ☐1 1 person
- ☐2 2 people
- ☐3 3 people
- ☐4 4 people
- ☐5 5 or more

Q10. How much schooling have you had? (Years of formal schooling completed) (check one box)

- ☐1 8 grades or less
- ☐2 Some high school
- ☐3 High school graduate or GED
- ☐4 Some college or technical school
- ☐5 College graduate (bachelor's degree)
- ☐6 Graduate degree

Q11. Which of the following best describes your current employment status? (check one box)

- ☐ 1 Working full-time, 35 hours or more a week
- ☐ 2 Working part-time, less than 35 hours a week
- ☐ 3 Unemployed or laid off and looking for work
- ☐ 4 Unemployed and not looking for work
- ☐ 5 Homemaker
- ☐ 6 In school
- ☐ 7 Retired
- ☐ 8 Disabled, not able to work
- ☐ 9 Something else? (Please specify): _____

Q12. How would you describe the insurance plan(s) you have had in the past 12 months?
(check all that apply)

- ☐ 1 An individual plan – the member pays for the plan premium
- ☐ 2 A group plan through an employer, union, etc. – the employer pays all or part of the plan premium
- ☐ 3 U.S. Governmental Health Plan (e.g., Military, CHAMPUS, VA)
- ☐ 4 Medicaid
- ☐ 5 Medicare
- ☐ 6 I have not had an insurance plan in the past 12 months

Q13. What type(s) of insurance plans have you had in the past 12 months? (check all that apply)

- ☐ 1 Indemnity or fee-for-service plan (i.e., you choose which health care provider you see for care without financial penalty)
- ☐ 2 Health Maintenance Organization (HMO) (i.e., you must have a primary care provider who must refer you to specialty care if needed)
- ☐ 3 Preferred Provider Organization (PPO) (i.e., you have lower co-payments when you see a preferred provider within the network, but you can see a provider out-of-network for a higher co-payment)
- ☐ 4 Point of Service (POS) (i.e., you must have a primary care provider; you have the option to self-refer to an in-network specialist, or you can see an out-of-network specialist with a higher co-payment)
- ☐ 5 Other (please specify): _____
- ☐ 6 I have not had an insurance plan in the past 12 months.

Q14. Do you test your blood sugar? (check one box)

☐1 No ☐2 Yes → Q14a. How many days a week do you test your blood sugar?
sugar?

_____ (days / week)

↓

Q14b. On days that you test, how many times do you test
your blood sugar?

_____ (times / day)

↓

Q14c. Do you keep a record of your blood sugar test
results? (check one box)

☐1 No ☐2 Yes

Section II – Health Status

Q1. In general, would you say your health is: (check one box)

☐1	☐2	☐3	☐4	☐5
Excellent	Very Good	Good	Fair	Poor

Q2. These questions ask about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time **during the past 4 weeks**: (circle one answer for each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
A. Have you felt **calm and peaceful**?	1	2	3	4	5	6
B. Did you have a **lot of energy**?	1	2	3	4	5	6
C. Have you felt **downhearted and blue**?	1	2	3	4	5	6

Section III – Education / Advice Received

Q1. Has your health care provider or nurse ever told you to take special care of your feet?
(check one box)

☐1 No ☐2 Yes ☐3 Not Sure

Q2. Has your health care provider or nurse ever told you to follow an exercise program?
(check one box)

☐1 No ☐2 Yes ☐3 Not Sure

Q3. Has your health care provider or nurse ever told you to follow a meal plan or diet?
(check one box)

☐1 No ☐2 Yes ☐3 Not Sure

Q4. Have you ever received diabetes education? (for example: attended a series of classes or series of meetings with a diabetes educator) (check one box)

☐1 No ☐2 Yes ☐3 Not Sure

Section IV - Understanding

Q1. How do you rate your understanding of: (circle one answer for each line)	**Poor**				**Excellent**
a) overall diabetes care	1	2	3	4	5
b) coping with stress	1	2	3	4	5
c) diet for blood sugar control	1	2	3	4	5
d) the role of exercise in diabetes care	1	2	3	4	5
e) medications you are taking	1	2	3	4	5
f) how to use the results of blood sugar monitoring	1	2	3	4	5
g) how diet, exercise, and medicines affect blood sugar levels	1	2	3	4	5
h) prevention and treatment of high blood sugar	1	2	3	4	5
i) prevention and treatment of low blood sugar	1	2	3	4	5
j) prevention of long-term complications of diabetes	1	2	3	4	5
k) foot care	1	2	3	4	5
l) benefits of improving blood sugar control	1	2	3	4	5
m) pregnancy and diabetes	1	2	3	4	5

Section V – Support

Q1. I **want** a lot of help and support from my family or friends in:
(circle one answer for each line)

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	Does Not Apply
a) following my meal plan.	1	2	3	4	5	N/A
b) taking my medicine.	1	2	3	4	5	N/A
c) taking care of my feet.	1	2	3	4	5	N/A
d) getting enough physical activity.	1	2	3	4	5	N/A
e) testing my sugar.	1	2	3	4	5	N/A
f) handling my feelings about diabetes.	1	2	3	4	5	N/A

Q2.My family or friends help and support me a lot to:
(circle one answer for each line)

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree	Does Not Apply
a) follow my meal plan.	1	2	3	4	5	N/A
b) take my medicine.	1	2	3	4	5	N/A
c) take care of my feet.	1	2	3	4	5	N/A
d) get enough physical activity.	1	2	3	4	5	N/A
e) test my sugar.	1	2	3	4	5	N/A
f) handle my feelings about diabetes.	1	2	3	4	5	N/A

Q3.My family or friends: (circle one answer for each line)

	Strongly Disagree	**Somewhat Disagree**	**Neutral**	**Somewhat** Agree	**Strongly Agree**
a) accept me and my diabetes.	1	2	3	4	5
b) feel uncomfortable about me because of my diabetes.	1	2	3	4	5
c) encourage or reassure me about my diabetes.	1	2	3	4	5
d) discourage or upset me about my diabetes.	1	2	3	4	5
e) listen to me when I want to talk about my diabetes.	1	2	3	4	5
f) nag me about diabetes.	1	2	3	4	5

Q4. Who helps you the **most** in caring for your diabetes? (check only one box)

☐$_1$ Spouse
☐$_2$ Other family members
☐$_3$ Friends
☐$_4$ Paid helper
☐$_5$ Doctor
☐$_6$ Nurse
☐$_7$ Case manager
☐$_8$ Other health care professional
☐$_9$ No one

Section VI - Control Problems Scale

For the following questions, please check the appropriate response.

Q1.How many **times** in the last **month** have you had a **low blood sugar** (glucose) reaction with symptoms such as sweating, weakness, anxiety, trembling, hunger or headache?

- ☐ 1 0 times
- ☐ 2 1-3 times
- ☐ 3 4-6 times
- ☐ 4 7-12 times
- ☐ 5 More than 12 times
- ☐ 6 Don't know

Q2.How many **times** in the last **year** have you had **severe low blood sugar** reactions such as passing out or needing help to treat the reaction?

- ☐ 1 0 times
- ☐ 2 1-3 times
- ☐ 3 4-6 times
- ☐ 4 7-12 times
- ☐ 5 More than 12 times
- ☐ 6 Don't know

Q3.How many **days** in the last **month** have you had **high blood sugar** with symptoms such as thirst, dry mouth and skin, increased sugar in the urine, less appetite, nausea, or fatigue?

- ☐ 1 0 days
- ☐ 2 1-3 days
- ☐ 3 4-6 days
- ☐ 4 7-12 days
- ☐ 5 More than 12 days
- ☐ 6 Don’t know

Q4.How many **days** in the last **month** have you had **ketones** in your urine?

- ☐ 1 0 days
- ☐ 2 1-3 days
- ☐ 3 4-6 days
- ☐ 4 7-12 days
- ☐ 5 More than 12 days
- ☐ 6 Don’t test

Q5. During the past year, how often did your blood sugar become **too high** because: (circle one answer for each line)	**Never**		**Sometimes**		**Often**	**Don't Know**
a) you were sick or had an infection?	1	2	3	4	5	DK
b) you were upset or angry?	1	2	3	4	5	DK
c) you took the wrong amount of medicine?	1	2	3	4	5	DK
d) you ate the wrong types of food?	1	2	3	4	5	DK
e) you ate too much food?	1	2	3	4	5	DK
f) you had less physical activity than usual?	1	2	3	4	5	DK
g) you were feeling stressed?	1	2	3	4	5	DK

Q6. During the past year, how often did your blood sugar become **too low** because: (circle one answer for each line)	**Never**		**Sometimes**		**Often**	**Don't Know**
a) you were sick or had an infection?	1	2	3	4	5	DK
b) you were upset or angry?	1	2	3	4	5	DK
c) you took the wrong amount of medicine?	1	2	3	4	5	DK
d) you ate the wrong types of food?	1	2	3	4	5	DK
e) you ate too little food?	1	2	3	4	5	DK
f) you had more physical activity than usual?	1	2	3	4	5	DK
g) you waited too long to eat or skipped a meal?	1	2	3	4	5	DK
h) you were feeling stressed?	1	2	3	4	5	DK

Section VII - Social and Personal Factors Scale

For the following questions, please circle the appropriate response.

	Never		Sometimes		Often	Don't Know
Q1. How often has your diabetes kept you from doing your normal daily activities during the past **year** (e.g., couldn't: go to work, work around the house, go to school, visit friends)?	1	2	3	4	5	DK

Q2. My diabetes and its treatment keep me from: (circle one answer for each line)	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a) having enough money.	1	2	3	4	5
b) meeting school, work, household, and other responsibilities.	1	2	3	4	5
c) going out or traveling as much as I want.	1	2	3	4	5
d) being as active as I want.	1	2	3	4	5
e) eating foods that I like.	1	2	3	4	5
f) eating as much as I want.	1	2	3	4	5
g) having good relationships with people.	1	2	3	4	5
h) keeping a schedule I like (e.g., eating or sleeping late).	1	2	3	4	5
i) spending time with my friends.	1	2	3	4	5
j) having enough time alone.	1	2	3	4	5

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Q3.	Paying for my diabetes treatment and supplies is a problem.	1	2	3	4	5

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Q4.	Having diabetes makes my life difficult.	1	2	3	4	5

Section VIII - Attitudes Toward Diabetes Scales

(Positive Attitude, Negative Attitude, Care Ability, Importance of Care, and Self-Care Adherence)

For the following questions, please circle the appropriate response.
(circle one answer for each line)

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Q1.	I am afraid of my diabetes.	1	2	3	4	5
Q2.	I find it hard to believe that I really have diabetes.	1	2	3	4	5
Q3.	I feel unhappy and depressed because of my diabetes.	1	2	3	4	5
Q4.	I feel satisfied with my life.	1	2	3	4	5
Q5.	I feel I'm not as good as others because of my diabetes.	1	2	3	4	5
Q6.	I can do just about anything I set out to do.	1	2	3	4	5
Q7.	I find it hard to do all the things I have to do for my diabetes.	1	2	3	4	5
Q8.	Diabetes doesn't affect my life at all.	1	2	3	4	5
Q9.	I am pretty well off, all things considered.	1	2	3	4	5
Q10.	Things are going very well for me right now.	1	2	3	4	5

Q11.	I am **able** to: (circle one answer for each line)	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
	a) keep my blood sugar in good control.	1	2	3	4	5
	b) keep my weight under control.	1	2	3	4	5
	c) do the things I need to do for my diabetes (diet, medicine, exercise, etc.).	1	2	3	4	5
	d) handle my feelings (fear, worry, anger) about my diabetes.	1	2	3	4	5

Q12.	I think it is **important** for me to: (circle one answer for each line)	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
	a) keep my blood sugar in good control.	1	2	3	4	5
	b) keep my weight under control.	1	2	3	4	5
	c) do the things I need to do for my diabetes (diet, medicine, exercise, etc.).	1	2	3	4	5
	d) handle my feelings (fear, worry, anger) about my diabetes.	1	2	3	4	5

		Never		Sometimes		Always	Don't Know
Q13.	I keep my blood sugar in good control.	1	2	3	4	5	DK

		Never		*Sometimes*		**Always**
Q14.	I keep my weight under control.	1	2	3	4	5
Q15.	I do the things I need to do for my diabetes (diet, medicine, exercise, etc.).	1	2	3	4	5
Q16.	I feel dissatisfied with life because of my diabetes.	1	2	3	4	5
Q17.	I handle the feelings (fear, worry, anger) about my diabetes fairly well.	1	2	3	4	5

Section X - Long-Term Care Benefits Scale

For the following questions, please circle the appropriate response.
(circle one answer for each line)

Q1. Taking the best possible care of diabetes will delay or prevent:	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
a) eye problems	1	2	3	4	5
b) kidney problems	1	2	3	4	5
c) foot problems	1	2	3	4	5
d) hardening of the arteries	1	2	3	4	5
e) heart disease	1	2	3	4	5

Section XI - Exercise Barriers Scale

For the following questions, please circle the appropriate response.
(circle one answer for each line)

Q1. How often do you have trouble getting enough exercise because:	**Rarely**		**Sometimes**		**Often**
a) it takes too much effort?	1	2	3	4	5
b) you don't believe it is useful?	1	2	3	4	5
c) you don't like to do it?	1	2	3	4	5
d) you have a health problem?	1	2	3	4	5
e) it makes your diabetes more difficult to control?	1	2	3	4	5

Section XII - Monitoring Barriers and Understanding Management Practice Scales

Q1. How many days a week have you been told to test:

a) urine sugar? _____ (days per week) ☐ 9 Not told to test

b) blood sugar? _____ (days per week) ☐ 9 Not told to test

If you **do not** test for sugar, skip Question No. 2.

For the following questions, please circle the appropriate response.
(circle one answer for each line)

Q2. When you **don't** test for sugar as often as you have been told, how often is it because:	**Rarely**		Sometimes		Often
a) you forgot?	1	2	3	4	5
b) you don't believe it is useful?	1	2	3	4	5
c) the time or place wasn't right?	1	2	3	4	5
d) you don't like to do it?	1	2	3	4	5
e) you ran out of test materials?	1	2	3	4	5
f) it costs too much?	1	2	3	4	5
g) it's too much trouble?	1	2	3	4	5
h) it's hard to read the test results?	1	2	3	4	5
i) you can't do it by yourself?	1	2	3	4	5
j) your levels don't change very often?	1	2	3	4	5
k) it hurts to prick your finger?	1	2	3	4	5

Q3. Have you ever received diabetes education? ☐ 1 No ☐ 2 Yes

If No, skip Question No. 4

For the following questions, please circle the appropriate response.
(circle one answer for each line)

Q4. How do you rate your understanding of:	Poor		**Good**		**Excellent**
a) diet and blood sugar control	1	2	3	4	5
b) weight management	1	2	3	4	5
c) exercise	1	2	3	4	5
d) use of insulin/pills	1	2	3	4	5
e) sugar testing	1	2	3	4	5
f) foot care	1	2	3	4	5
g) complications of diabetes	1	2	3	4	5
h) eye care	1	2	3	4	5
i) combining diabetes medication with other medications	1	2	3	4	5
j) alcohol use and diabetes	1	2	3	4	5

Addition to Section I (Demographics) - Income Question

Q15. Which of the categories best describes your total annual combined household income from all sources? (check one box)

☐01 Less than $5,000

☐02 $5,000 to $9,999

☐03 $10,000 to $14,999

☐04 $15,000 to $19,999

☐05 $20,000 to $29,999

☐06 $30,000 to $39,999

☐07 $40,000 to $49,999

☐08 $50,000 to $59,999

☐09 $60,000 to $69,999

☐10 $70,000 and over

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