

**IMPLEMENTATION PLANS AND SELF-MONITORING OF BLOOD
GLUCOSE IN DIABETICS**

by

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DEDICATION

In memory of my beloved grandparents, Nana and Aaji.
You are my inspiration in everything I do.

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TABLE OF CONTENTS

DEDICATION	ii
ACKNOWLEDGEMENTS	iii
LIST OF TABLES	viii
LIST OF FIGURES	x
LIST OF APPENDICES	xi
ABSTRACT	xii
CHAPTER I INTRODUCTION	1
Introduction	1
Introduction to the problem	1
Nature of the research project	7
CHAPTER II LITERATURE REVIEW	10
Introduction	10
Diabetes	10
Prior theoretical research on diabetes self-management behaviors	22
Model of action phases	36
Implementation intentions	38
Theoretical Model of Effortful Decision Making and Enactment	77
Theoretical framework for the study	82
Objectives and hypotheses	83

CHAPTER III METHODS	88
Introduction	88
Overview	88
Selection of methodological approach	89
Experimental manipulation: forming implementation plans	91
Population description and sample selection	93
Sampling and data collection	97
Study measures	102
Questionnaire Design	112
Pilot test	113
Analysis plan	114
CHAPTER IV RESULTS	118
Introduction	118
Pilot test	119
Questionnaire response	121
Description of the sample	124
ANOVA test for Aim 1	135
Structural equation modeling for Aim 2 and 3	141
Results for Aim 1	152
Results for Aim 2 and 3	153
CHAPTER V DISCUSSION	155
Introduction	155
Characteristics of the sample	155
Hypotheses concerning Aim 1: the experimental intervention	162
Hypotheses concerning Aim 2 and 3: the theoretical framework	170

CHAPTER VI CONCLUSIONS	176
Introduction	176
Conclusions and implications of the results	176
Limitations	178
Recommendations	180
APPENDICES	184
REFERENCES	220

LIST OF TABLES

Table 1.1 Recommended glycemic goals for Type 1 and Type 2 diabetic individuals	13
Table 3.1 Experimental group-control group using randomization	91
Table 3.2 Data collection timeline	98
Table 4.1 Questionnaire response rate	122
Table 4.2 Sociodemographic characteristics for experimental, first control and second control groups	126
Table 4.3 Comorbidity information for experimental, first and second control group	128
Table 4.4 Descriptive statistics for diabetes related information	129
Table 4.5 T-tests for differences between groups for diabetes related information	130
Table 4.6 Percentage distribution of responses to psychological measures	131
Table 4.7 Means and standard deviations of the psychological measures	132
Table 4.8 Cronbach's alpha for theoretical constructs	133
Table 4.9 t-tests for between group differences on psychological measures	134
Table 4.10 ANOVA to test the effect of intervention for diary	137
Table 4.11 Post-hoc Scheffe tests to determine differences between groups	137
Table 4.12 ANOVA to test the effect of intervention for first recall measure	138
Table 4.13 Post-hoc Scheffe tests to determine differences between groups	139
Table 4.14 ANOVA to test the effect of intervention for second recall measure	140
Table 4.15 Post-hoc Scheffe tests to determine differences between groups	140

Table 4.16 Correlations between psychological variables and behavioral measures 143

Table 4.17 Model fit statistics for structural equation modeling and confirmatory factor analysis 148

LIST OF FIGURES

Figure 1.1 Theoretical Model of Effortful Decision Making and Enactment	6
Figure 1.2 Theoretical framework for the study	7
Figure 2.1 The health belief model	24
Figure 2.2 The theory of reasoned action	31
Figure 2.3 The theory of planned behavior	32
Figure 3.1 Relationships that will be tested using SEM	117
Figure 4.1 Model tested in step 1: Four construct model	149
Figure 4.2 Model tested in step 4: Two construct model	150
Figure 4.3 Model tested in step 4: Final model	151

LIST OF APPENDICES

APPENDIX 1 LETTER TO PHYSICIAN	185
APPENDIX 2 COVERLETTER TO EXPERIMENTAL, FIRST CONTROL AND SECOND CONTROL GROUPS	187
APPENDIX 3 COVERLETTER TO THIRD CONTROL GROUPS	189
APPENDIX 4 INFORMED CONSENT	191
APPENDIX 5 SURVEY – EXPERIMENTAL GROUP	194
APPENDIX 6 SURVEY – FIRST CONTROL GROUP	202
APPENDIX 7 SURVEY – SECOND CONTROL GROUP	207
APPENDIX 8 RECALL MEASURES	210
APPENDIX 9 DIARY	212
APPENDIX 10 REMINDER FOR SURVEY	214
APPENDIX 11 FIRST REMINDER FOR DIARY	216
APPENDIX 12 SECOND REMINDER FOR DIARY	218

ABSTRACT

IMPLEMENTATION PLANS AND SELF-MONITORING OF BLOOD GLUCOSE IN DIABETICS

by

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Chair: Suzan N. Kucukarslan

Background: Self-management strategies are effective in diabetes management yet studies reveal a lack of patient adherence. This study examined a volitional strategy to increase rates of self-monitoring of blood glucose (SMBG) and also examined the psychological processes that underlie goal striving and goal achievement. The study aims were 1) to evaluate the impact of implementation plans on SMBG, 2) to determine the relationship between goal desire, goal intentions, implementation desire and implementation intentions and 3) to determine the relationship between implementation intentions and SMBG.

Methods: A randomized experimental-control study design over a two-week time was used. The study population was patients with diabetes with HbA_{1c} greater than 7%, requiring insulin therapy. Patients were recruited from a southeastern Michigan healthcare system. The intervention was a self-administered tool designed to assist patients to formulate their SMBG plans. The

SMBG behavior was measured using a two-week diary and a two-item recall measure of SMBG. Three control groups were used to control for testing effects. Control group 1 received all questionnaire questions minus the intervention, control group 2 received items related to sociodemographic information, the SMBG diary and recall measures, and control group 3 received the recall measures only. Hypotheses were tested using ANOVA and structural equation modeling (SEM) at a significance level of 0.05.

Results: The overall response rate for the study was 15.65% (n = 402). Analyses indicated that making implementation plans increased SMBG rates as assessed by the diary and the two recall measures. The SEM analysis demonstrated that goal desire is an antecedent to goal intentions and that implementation desire and implementation intentions mediate the pathway between goal intentions and performance of health behavior in a chronically ill diabetic population. Further, implementation intentions were found to be a significant predictor of SMBG.

Conclusion: Results from this study show that making specific plans to perform SMBG can be an effective strategy in increasing SMBG rates. Future research should examine the effectiveness of implementation plans in a variety of health behaviors that are required of chronically ill patients.

CHAPTER I

INTRODUCTION

Introduction

This chapter includes three sections. The first section discusses the prevalence of diabetes in the United States and patients' role in managing their condition. The second section is an outline of the significance of the study and the potential contributions of the research. The final section discusses the nature of the study and provides an overview of the objectives and hypotheses.

Introduction to the problem

Diabetes is increasing in epidemic proportions in the United States. According to the American Diabetes Association (ADA) the prevalence of diabetes in the United States was 4.9% in 1990 and has reached 7.8 % of the population today.^{1, 2} This is a 37% increase in 18 years. Diabetes is an important public health concern recognized as one of the focus areas in the Healthy People 2010 initiative.^{3, 4}

Diabetes results in several serious microvascular and macrovascular complications leading to blindness, kidney disease and amputations of the lower extremities.⁵ As a result of the complications, it causes significant morbidity and

disability. Persons with diabetes have twice the risk of mortality when compared to non-diabetics.⁵ Thus, diabetes and related complications result in a significant financial burden to society. In 2002, the financial impact due to both direct as well as indirect costs was estimated at \$ 132 billion.⁶

Glycemic control is essential in preventing or delaying the occurrence of diabetic complications.⁵ Several studies show that diabetes self-management leads to glycemic control in diabetic patients, which in turn leads to better health outcomes.⁷⁻⁹ Diabetes self-management includes such behaviors as weight reduction, exercise, medication adherence and self-monitoring of blood glucose.⁵

Despite the scientific support for tighter control of blood sugar, many persons with diabetes do not adequately manage their condition, thus lacking good glycemic control.¹⁰⁻¹³ This lack of glycemic control may be a result of the lack of adherence to recommended self-management behaviors among diabetics. A number of studies have investigated the adherence rates to self-management behaviors in diabetics including medication use, insulin injections, urine and blood testing.¹⁴⁻¹⁹ As expected, results from these studies illustrate that adherence is low in most of the diabetes self-management behaviors.

The prevalence, associated mortality and morbidity, the economic costs, and consequently the social and individual burden of diabetes emphasize the urgent need to help diabetic patients better manage the disease. Since adherence to self-management behaviors is an issue in diabetes,¹⁴⁻¹⁹ improving adherence to self-management behaviors is the first step towards helping patients better manage their disease.

Significance

The focus of this study was to examine the motivational and volitional factors associated with performance of self-monitoring of blood glucose (SMBG). In addition, this study also examines if a simple intervention termed as making implementation plans helps diabetics improve rates of performance of SMBG.

There has been extensive research in trying to understand the determinants of intentions or likelihood of performing health behaviors in diabetic patients using theoretical frameworks. Typically, these studies are based on commonly used theoretical frameworks such as the health belief model (HBM) or the theory of reasoned action (TRA) and the theory of planned behavior (TPB).²⁰⁻
²⁸ This research based on the HBM, TRA and TPB examines health beliefs and motivational factors which influence decision and/or adherence to health behaviors. Studies which use theoretical frameworks such as the HBM, TRA and TPB also have looked at the association between intentions and subsequent performance of the health behaviors. Goal striving and goal achievement processes have both motivational and volitional components. This study aimed to evaluate the impact of both, motivational and volitional factors on goal striving and goal achievement within a single theoretical framework based on the Theoretical Model of Effortful Decision Making and Enactment.²⁹ The Theoretical Model of Effortful Decision Making and Enactment examines two distinct constructs: goal intentions and implementation intentions and their respective antecedents – goal desires and implementation desires in the process of effortful decision making and enactment. It also examines the effects of decision

processes, goal feasibility, anticipated emotions, attitudes, subjective norms, and perceived behavioral control all of which are mediated by goal desire, goal intention, implementation desire and implementation intentions in the goal striving process. The Theoretical Model of Effortful Decision Making and Enactment is depicted in Figure 1.1.

Another stream of research related to diabetes health behaviors is intervention research, which focuses on developing and understanding interventions effective in improving adherence to self-management behaviors. Several theoretical based intervention studies have been conducted in diabetes research. For instance, interventions in changing health behavior amongst diabetics have been based around the HBM,³⁰ the TPB,³¹ the social learning theory³¹. The intervention in this study is modeled on an as yet untested theoretical construct within diabetics - that of making implementation plans. This construct fits in nicely within the theoretical framework that will examine the goal striving process. The aim is to test its effectiveness in increasing the rates of SMBG in the diabetic population. Making implementation plans consists of specifying when, where and how to perform a health behavior and is rooted in the Model of Action Phases (MAP).³²

This dissertation aimed to expand the research on decision making and enactment in diabetics by using constructs from the Theoretical Model of Effortful Decision Making and Enactment. In doing so, the emphasis was on both the motivational and volitional processes involved in decision-making and enactment. Secondly, it tested a volitional intervention based on making implementation

plans in order to see if it is an effective method for improving rates of performance of health behaviors in diabetic patients. The constructs that were the focus of this study are illustrated in Figure 1.2.

Figure 1.1 Theoretical Model of Effortful Decision Making and Enactment

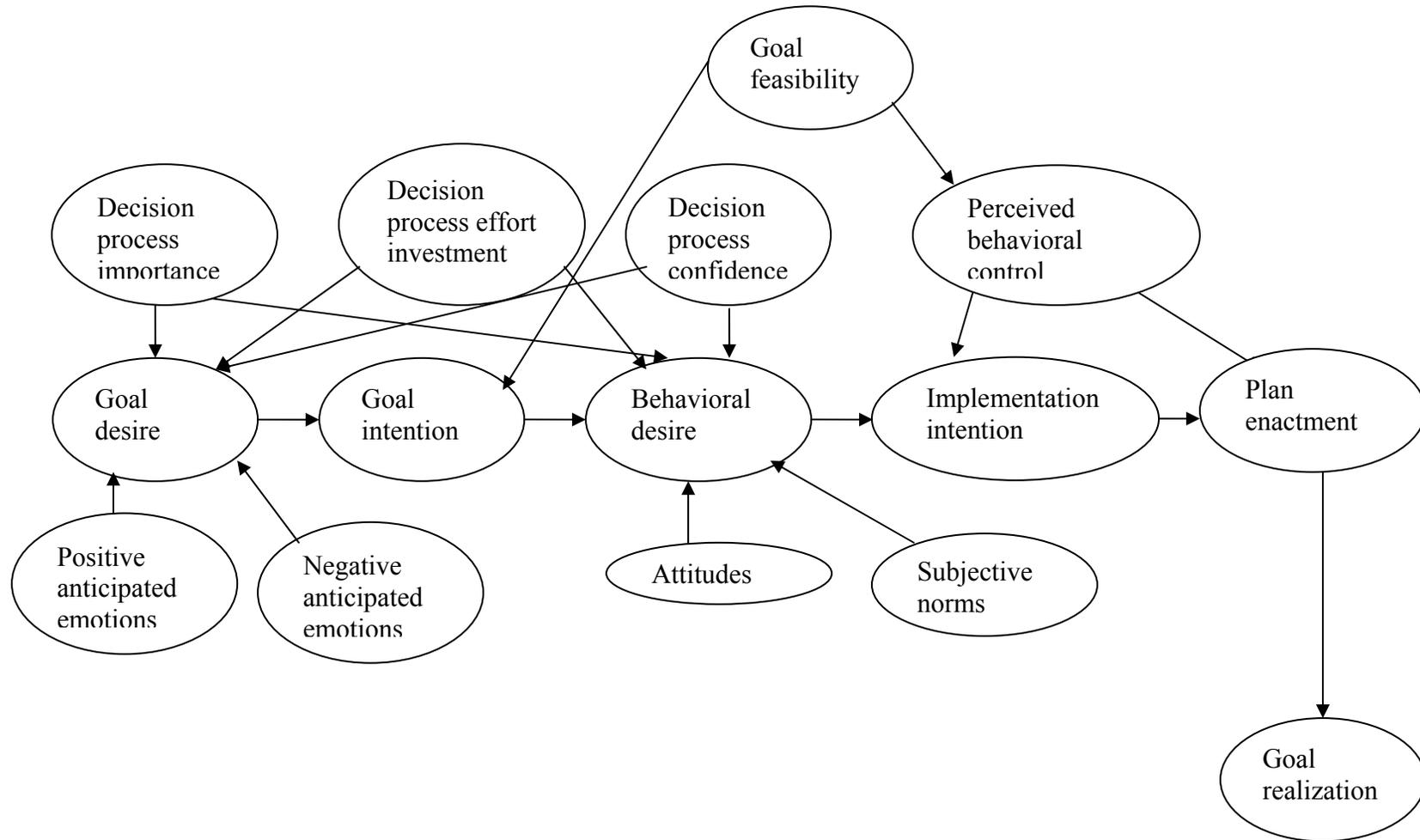
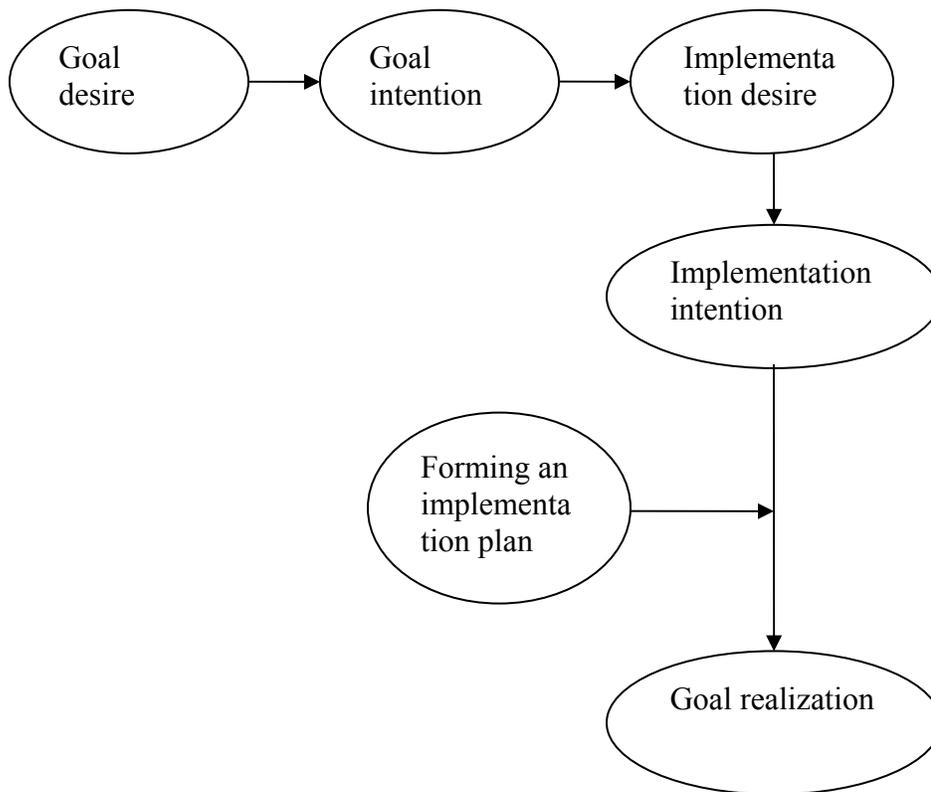


Figure 1.2 Theoretical framework for the study



Nature of the research project

The goals of this study were to determine the effectiveness of making implementation plans on the performance of SMBG in diabetics. In addition, the study also focused on determining the appropriateness of using the Theoretical Model of Effortful Decision Making and Enactment as a framework to illustrate goal striving and goal achievement in the diabetic population.

The study was an experimental longitudinal study conducted on a sample of 2569 type 1 and type 2 diabetics aged 18 years and older using a questionnaire methodology. The diabetic sample was selected from the

administrative databases of a southeastern Michigan health system and randomly assigned to one of four study groups. The experimental group completed the experimental intervention – which consisted of formulating implementation plans. The experimental as well as first control group completed the psychological measures for the theoretical framework. The experimental, first control and second control group also completed items about their sociodemographic information and the prospective diary measuring SMBG over a fourteen day period. All the groups including the third control group completed the 2-item recall measure.

Objectives and hypotheses

The primary aim of this study was to determine if making implementation plans increase rates of SMBG. Hypotheses 1-3 tested this aim. The secondary and tertiary aims examined the appropriateness of the constructs of the Theoretical Model of Effortful Decision Making and Enactment with respect to goal striving and goal achievement related to managing diabetes and specifically as it relates to SMBG. Hypotheses 4-9 tested the second and third aims of this study.

Aim 1: To determine if formulating implementation plans increases the rates of self-management behaviors.

Hypothesis 1: Participants who form implementation plans will have higher levels of SMBG as measured by the diary compared to those who do not.

Hypothesis 2: Participants who form implementation plans will have higher levels of SMBG as measured by the first recall measure compared to those who do not.

Hypothesis 3: Participants who form implementation plans will have higher levels of SMBG as measured by the second recall measure compared to those who do not.

Aim 2: To determine the relationship between goal desires, goal intentions, implementation desires and implementation intentions.

Hypothesis 4: The greater the goal desire the greater the goal intention.

Hypothesis 5: The greater the goal intention the greater the implementation desire.

Hypothesis 6: The greater the implementation desire, the greater the implementation intention.

Aim 3: To determine the relationship between implementation intentions and self-monitoring behavior

Hypothesis 7: The greater the implementation intention, the greater the performance of SMBG as measured by diary.

Hypothesis 8: The greater the implementation intention, the greater the performance of SMBG as measured by the first recall measure.

Hypothesis 9 The greater the implementation intention, the greater the performance of SMBG as measured by the second recall measure.

CHAPTER II

LITERATURE REVIEW

Introduction

This chapter includes a description of diabetes, its complications, diabetes self-management behaviors and adherence to self-management behaviors including self-monitoring of blood glucose. It also includes a description of prior theoretical research on self-management behaviors in diabetes. This chapter offers a brief background on the model of action phases and a review of implementation intentions and their application to health related behaviors and also includes a background on the Theoretical Model of Effortful Decision Making and Enactment – providing a background of the theoretical basis for the study. It concludes with a description of the theoretical framework that will be used in the study and describes the objectives and hypotheses of the study.

Diabetes

Diabetes is a widely prevalent disease and is estimated to affect 7.8% of the American population.² Diabetes is common in people of all ages, gender and ethnicities. It is the sixth leading cause of death in the United States.³³

The number of people with diabetes has continued to increase and statistics show that this number has nearly doubled from 1998 to 2004.³⁴ Unhealthy and unbalanced diet, lifestyle factors including a sedentary lifestyle and obesity have been linked to this increase in incidence and prevalence of diabetes.

Diabetes is a condition in which either the body fails to produce insulin or fails to use insulin appropriately, or both. As a result of the inability to produce or use insulin appropriately, untreated diabetes lends itself to hyperglycemia. Hyperglycemia is the condition in which the blood sugar levels are higher than the recommended range.¹

Due to the increased blood glucose levels, untreated diabetes can lead to long-term complications such as retinopathy, nephropathy and foot ulcers.³⁵ It is also a risk factor for other chronic conditions such as cardiovascular and cerebrovascular disease.³⁵

There are three categories of diabetes as defined by the American Diabetes Association (ADA) in their diagnostic and classification criteria - Type 1, Type 2 and gestational diabetes.³⁶ Type 1 diabetes, also called insulin dependent diabetes mellitus or juvenile diabetes occurs when the body fails to produce insulin. Type 1 diabetes commonly affects children and adolescents and accounts for 5% -10% of diabetes cases.³⁷ Type 2 diabetes occurs when the body fails to properly use insulin or does not respond well to the insulin.^{1, 35-36} Thus, although insulin is produced by the body, blood glucose is not converted to

energy nor is it converted for storage because of the inability of the body to respond to insulin, resulting in hyperglycemia.¹ Type 2 diabetes is more prevalent amongst adults and accounts for almost 90% - 95% of all diabetic cases.³⁷ In addition to type 1 and 2 diabetes, gestational diabetes occurs during pregnancy. Gestational diabetes will not be discussed in detail since gestational diabetic patients are excluded from the current study.

Types 1 and 2 diabetes are diagnosed by one of three methods,³⁵ endorsed by the ADA. The first method detects diabetes by the presence of symptoms of diabetes which include polyuria, polydipsia, and unexplained weight gain and a casual blood plasma glucose level of ≥ 200 mg/dl.³⁵ Casual indicates that testing is done at any time of day without any regard for when the last meal was consumed. The second method to detect diabetes is fasting plasma glucose ≥ 126 mg/dl with fasting defined as no caloric intake for at least 8 hours. The third method of detecting diabetes involves 2-hour postload glucose ≥ 200 mg/dl during an oral glucose tolerance test. This test assesses whether the glucose level ≥ 200 mg/dl, 2 hours after consuming a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.

Diabetes causes an enormous financial burden on the patient as well as the healthcare system. The ADA estimates that about \$44 billion were spent on direct medical expenditures due to diabetes and related complications.³⁸ Of the \$44 billion spent, \$8 billion were spent on diabetes and acute glycemic care, \$12 billion were spent due to the excess prevalence of related chronic complications,

such as retinopathy and nephropathy; and \$24 billion were spent on other associated general medical conditions in diabetics.³⁸

Given the statistics and numbers, it is evident that diabetes is prevalent in the population in epidemic proportions and is a major public health concern. It is thus imperative to study different aspects of this disease and of managing this disease so as to help manage the burden that it places on individual patients as well as the healthcare system.

Diabetes complications and glycemic control

Diabetes is the cause of significant morbidity and mortality as a result of associated complications. Glycemic control is essential in preventing complications entirely or in diminishing their frequency of occurrence. Thus, glycemic control or lowering of blood sugar levels is important because it reduces neuropathic complications, the risk of myocardial infarction, the risk of cardiovascular disease, and the risk of nephropathy.³⁹⁻⁴⁴

Recommended glycemic goals for non-gestational diabetic individuals are shown in Table 1.1³⁹

Table 1.1 Recommended glycemic goals for Type 1 and Type 2 diabetic individuals

Summary of recommendations by the ADA for adults with diabetes (Type 1 and Type 2)

HbA _{1C} *	<7.0%
Preprandial plasma glucose**	90-130 mg/dl
Peak postprandial plasma glucose**	<180 mg/dl

* HbA_{1C} also known as glycated hemoglobin is used to indicate a patient's blood sugar control over the last 2-3 months.

** Preprandial refers to before a meal and postprandial refers to after a meal.

The ADA describes several ways to assess if a patient is meeting his/her glycemic control goals. These include self-monitoring of glucose and performing the HbA_{1C} test to assess average blood glucose over the preceding 2-3 months.³⁹

Several studies have shown routine eye check ups, cholesterol check ups and glucose monitoring and other self-management strategies are essential and effective in managing diabetes and achieving glycemic control.⁷⁻⁹

Despite the fact that treatment strategies for diabetes abound and evidence that self-management leads to glycemic control which in turn leads to better outcomes, diabetes is shown to be poorly controlled. The National Health and Nutrition Examination Survey (NHANES) revealed that between 1999-2000, only 37% of diabetic adults were achieving the glycemic goals recommended by the ADA.¹⁰ In addition, several studies have demonstrated poor glycemic control in various settings. Up to 18% of the participants in one cross sectional survey were found to have poor glycemic control.¹¹ In another study of Type 2 diabetic patients, glycemic control was poor across the board.¹² The data for this study was also taken from NHANES.

A study on the quality of diabetes care delivered at community health centers showed that overall, appropriate quality of care was provided to patients with respect to frequency of HbA_{1C} testing.¹³ This study was conducted at the Community Health Center Network which contracts with 2 managed care organizations in California to provide health care for enrollees. As part of their quality control efforts, glycemic control, frequency of HbA_{1C} testing, proportion of

poorly controlled diabetics and HbA_{1C} values are recorded. This study reveals that despite adequate quality of care being given to diabetic patients with respect to frequency of HbA_{1C} testing, poor glycemetic control was demonstrated in 27% of patients.¹³

Diabetes self-management

A standard definition of self-management in chronic diseases or one that is specific to diabetes does not exist. One of the definitions often used is that 'it is the active role a patient must play in managing his/her condition'. It has also been defined as a set of skilled behaviors that must be performed by a chronically ill individual to manage his/her disease.⁴⁵ Thus self-management:⁴⁶

'refers to the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to affect the cognitive, behavioral, and emotional responses necessary to maintain a satisfactory quality of life. Thus a dynamic and continuous process of self-regulation is established.'

Self-regulation and self-care are terms that have often been used to describe self-management.

Self-management of chronic conditions includes a plethora of activities that must be performed by the chronically ill patient to manage his/her disease.⁴⁷

These activities include self-monitoring, adjustment, communication with providers and coping strategies that together help in achieving management of the chronic disease.⁴⁷

Self-management strategies in diabetes are effective in the prevention, detection or further progression of diabetes complications. The ADA states that several self-management strategies such as weight reduction, exercise, medication adherence and self-monitoring of blood glucose are effective in managing diabetes and in achieving glycemic control which is the most important end point in the control of diabetes.^{35, 48} Seven of these self-management strategies are key to diabetes care.⁴⁸ These seven self-management behaviors are healthy eating, being active, monitoring, taking medication, problem solving, reducing risks and healthy coping. Thus, self-management specifically with diabetics is not one health behavior but a set of health behaviors that helps the diabetic patient manage the disease.

Adherence to self-management in diabetes

Factors affecting self-management in diabetes. Self-management in diabetes as illustrated is a complex task involving a variety of behaviors. As can be expected, it is affected by a wide variety of psychosocial factors. The factors examined to date range from knowledge about the disease, to self-efficacy to work related factors.⁴⁹

Some studies which have examined barriers to diabetes self-management regimens have found several factors affect the ability of the diabetic

to adhere to their regimens. Not having glucose testing strips to perform glucose testing and bad weather preventing them from exercising were some of the barriers mentioned by type 1 diabetics.⁵⁰ Another study found that type 1 diabetic patients' expectancies which included items related to self efficacy, outcome expectations and assessing the frequency of negative thoughts related to depression were associated with adherence to glucose testing, insulin adjustment, diet and exercise.⁵¹ Further, environmental support which included family behaviors, family support, medical care satisfaction and barriers was related to adherence to adjustment of insulin and glucose testing. Patient perception of treatment effectiveness has been found to be related to adherence to exercise, glucose testing and diet.⁵²

The associations between personal and work related factors and the frequency of self-management behaviors were tested in one study using the Job Demand Control Support Model (JDCS).⁵³ The JDCS model is a multidimensional model that examines the relationship between the person and work environment and focuses on three constructs namely demand, control and support. These three constructs ultimately shape how a person perceives the work experience. Subjects in the study completed a questionnaire with measures related to social support, self-efficacy, diabetes specific coping measures and job characteristics such as autonomy and support. Low support at work was found to be related to lower frequency of dietary self-management for type 2 diabetics.⁵³ The frequency with which Type 1 diabetics follow dietary guidelines and adjust their insulin doses was associated with a diabetes

avoidance coping style. Those who have a diabetes avoidance coping style involve themselves in activities and thoughts that are not related to their diabetes thus distracting them from issues related to their disease. A major limitation of this study was that while work related variables were investigated using a theoretical framework, other variables such as social support and self-efficacy were chosen arbitrarily.

Sigurðardóttir conducted a database search from 1995 - 2002 to review studies which examined factors affecting self-management behaviors in diabetics.⁴⁹ Based on this review of studies Sigurðardóttir found that a plethora of factors affect self-management in diabetes. These include factors like self-efficacy, physical skills, emotional aspects, and knowledge.⁴⁹ This review by Sigurðardóttir highlights that a wide variety of factors affect self-management in diabetes.

Adherence rates to diabetes self-management behaviors. Studies suggest that adherence to the various self-management behaviors is poor. A retrospective study using secondary database analyses was conducted to measure adherence to antihyperglycemic medications.¹⁴ Participants were type 2 diabetics who were newly treated with oral antihyperglycemics. Results indicated that 10.5% of diabetics failed to obtain their second prescription. At the end of 12 months, 37% of the patients were no longer taking their prescribed antihyperglycemic medication. Even among those patients taking their drugs, 46.2% were not taking their prescriptions as prescribed and were thus nonadherent.

Toljamo and Hentinen, assessed adherence to self-care behaviors in diabetics from Finland.¹⁵ Participants for the study were insulin treated diabetics who were recruited from a health center and hospital in Finland. Participants completed a postal questionnaire to measure their adherence rates for a variety of self-care behaviors. The aspects of self-care examined were: insulin injection, urine testing, evaluation of diet and nutrient content, exercise, foot care, fear of hypoglycemia, and adjustment of self-care activities based on tests. The results depict that differences in adherence to the various self-care behaviors exists. Adherence to insulin was high - with most participants accomplishing insulin administration as scheduled daily (84% of the patients) or almost daily (15%). Two thirds of the participants exercised daily or almost daily. Only 38% of the participants performed self-monitoring of blood glucose as recommended.

Self-monitoring of blood glucose

The term self-monitoring has been used in literature to either denote measurement such as blood glucose testing in diabetes and peak flow monitoring in asthma, an awareness of bodily symptoms or a combination of the two.⁴⁷ Self-monitoring is an integral component of self-management in diabetes.⁴⁸ Self-monitoring for the purpose of this study will be defined as the measurement of blood glucose levels by diabetic patients using a device called a glucometer.⁴⁷

The first few reports of self-monitoring of blood glucose (SMBG) came out in the late 1970's.⁵⁴⁻⁵⁵ Evidence from the Diabetes Control and Complications

Trial and the UK Prospective Diabetes study showed that tight glycaemic control in Type 1 and Type 2 diabetes patients resulted in lower rates of complications.⁴⁰⁻⁴¹ Consequently, with evidence highlighting that tight glycaemic control leads to lower rates of complications, SMBG has been hailed as one of the most important advances in the management of diabetes as a means to achieving tight glycaemic control and has been called a cornerstone of diabetes care.⁵⁴⁻⁵⁷ SMBG is used to test the effectiveness of therapy recommended for the diabetic patient as well as to make adjustments to medical regimen, dietary care, exercise regimen in order to achieve glycaemic control.⁵⁴

SMBG has been found to be associated with improved health outcomes in various studies.^{16, 58-62} There is unequivocal evidence for the effectiveness of SMBG within Type 1 diabetics.⁶¹⁻⁶² Several studies also illustrate the importance of SMBG within Type 2 diabetics.^{16, 58-60} For instance a study by Karter et al., found that type 1 and type 2 diabetic patients who adhered to their recommended levels of SMBG were found to have lower levels of HbA_{1c}.¹⁶ Adherent type 1 diabetes were found to have 1 point lower HbA_{1c} values and those with insulin treated type 2 diabetes who were adherent to the recommended levels of SMBG were found to have 0.6 points lower HbA_{1c} values, a significant difference from those who were nonadherent. Adherence was based on ADA's recommendation of at least 3 times a day for type 1 diabetics and at least daily for type 2 diabetics on insulin. The Retrospective Study 'Self-monitoring of Blood Glucose and Outcome in Patients with Type 2 Diabetes' (ROSSO), a four-year cohort study, found that SMBG was significantly related to lower diabetes related morbidity and

all-cause mortality among Type 2 diabetics.⁶⁰ Furthermore, the ADA recommends SMBG for all diabetic patients.⁵⁷ Thus in light of the ADA recommendations and evidence from studies indicating the effectiveness of SMBG in diabetics, adherence to SMBG and factors associated with adherence needs to be investigated.

Factors affecting self-monitoring of blood glucose. A review of the existing literature shows that certain psychosocial and personal factors have been investigated with respect to adherence to self-monitoring of blood glucose. For instance, one study found that an avoidance type of coping style was related to less frequent blood glucose monitoring while higher education level was related to more frequent blood glucose monitoring.⁵³ Intention to self-monitor was found to be a significant predictor of self-monitoring behavior in a study which used the theory of planned behavior.²⁶ Other variables such as knowledge and powerful others health locus of control have also found to be correlated with self-monitoring behavior.²⁷ Socio-demographic factors such as age, sex, education level, ethnicity have been found to be associated with SMBG in another study investigating factors related to adherence to SMBG.⁶³ Other factors include difficulty in communicating in English, higher out-of-pocket costs for glucometer strips, duration since diabetes diagnosis and intensity of therapy. Similarly another study found that duration of diabetes, recommendation from health care provider, and medication regimen were associated with SMBG.⁶⁴

Adherence to self-monitoring of blood glucose. Research has revealed low adherence to SMBG.^{15-19,} One study found that only about 60% of diabetics

adhere to their recommended levels of blood glucose testing.¹⁹ The study Karter et al., revealed that 34% of type 1 diabetics, about 54% of type 2 diabetics on insulin and 20% of type 2 diabetics on oral medications adhere to the recommended levels of self-monitoring of blood glucose.¹⁶ A retrospective study using database analyses found that less than one fifth of Scottish type 1 and 2 diabetics tested blood glucose every day.¹⁷ A study by Harris et al., also found that more than two thirds of diabetic patients did not perform self-monitoring of blood glucose.¹⁸

Based on these studies, there is strong evidence that diabetics do not adhere to the recommended levels of SMBG. Self-monitoring is key to achieving glycemic control especially in diabetics treated with insulin. It is thus imperative to conduct additional research in order to help improve adherence to self-monitoring amongst diabetics.

Prior theoretical research on diabetes self-management behaviors

It is important to examine and understand factors affecting self-management behaviors of diabetic patients. This will help inform and strengthen interventions designed to improve adherence to self-management behaviors in diabetic patients. It will also help health care professionals to better manage the disease and reduce the risk of disease-related complications. The following section summarizes three widely used health behavior theories and their application to diabetes self-management behaviors.

- Health belief model
- Theory of reasoned action
- Theory of planned behavior

Health belief model (HBM) focuses on variables that predict a person's likelihood of performing a behavior while the theory of reasoned action (TRA) and theory of planned behavior (TPB) focus on the determinants of intention to perform a health behavior.

This section also discusses their shortcomings and in doing so highlights the need to focus on the link between decision making and behavior (such as likelihood of performing an action or intention to perform an action) and behavior.

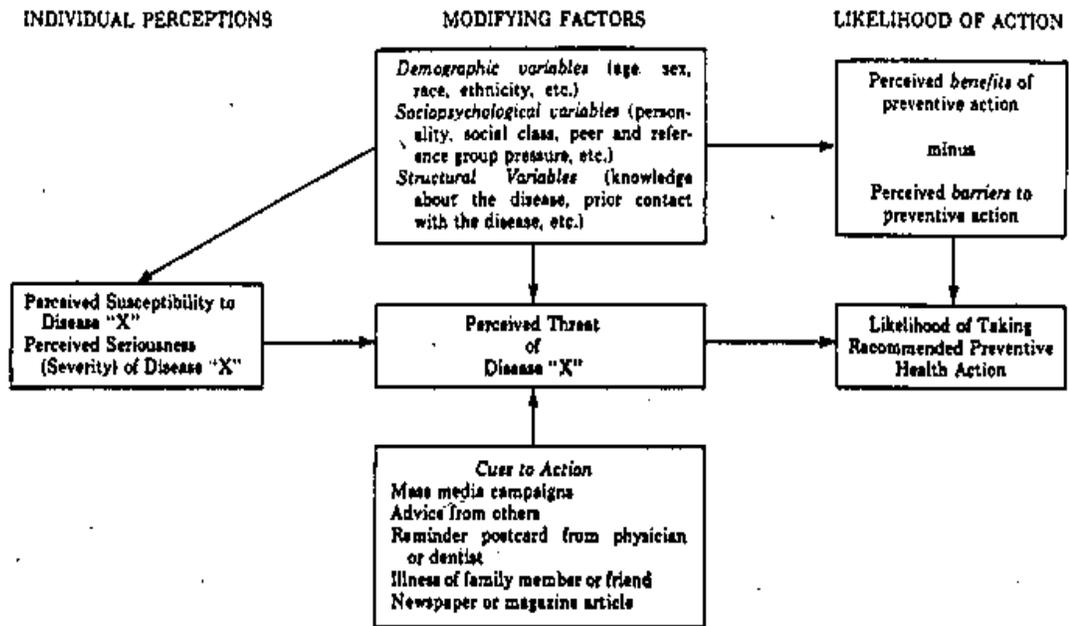
Health belief model

The HBM postulates that the constructs of perceived susceptibility and severity of the disease or condition under investigation, perceived barriers versus perceived benefits to performing the behavior that is being promoted/investigated, cues to action which are external influences such as media - are factors that influence the likelihood that a person performs the health behavior under investigation.⁶⁵ Modifications to the HBM have led to the inclusion of perceived self-efficacy which is a person's beliefs that he/she can perform a particular action.

The HBM was developed by Rosenstock to help predict uptake of preventative services such as tuberculosis screening.⁶⁵ It has since been used to help explain a variety of health behaviors including but not limited to preventative

behaviors. The HBM has consequently also been used to study adherence to self-management behaviors including diabetes related behaviors. The HBM is depicted in Figure 2.1.

Figure 2.1 The health belief model



HBM and diabetes related health behavior

Specifically with respect to diabetes, the HBM variables have been found to be significantly correlated with compliance score ($r = 0.50$).²⁰ Results were obtained by interviewing 30 insulin treated diabetes patients 6 - 12 months after attending diabetes education classes. Compliance to insulin administration, urine testing, hypoglycemia and foot care and total compliance level was

assessed. Correlation analyses were conducted to test the objectives of the study.²⁰

In another study conducted by Bond et al. specific constructs of the health belief model namely cues to action and benefits minus costs were associated with self-care behavior in young diabetics.²¹ Further, Bond et al. also found that threat of complications was associated with adherence. This study tested the ability of the HBM to predict adherence to self-management activities in 56 young people with type 1 diabetes. The participants in the study completed the diabetes health belief scale and the diabetes regimen compliance questionnaire and other measures related to the study objectives.²¹

A study by Brownlee-Duffeck et al. on 143 insulin-dependant or type 1 diabetic patients found that perceived susceptibility and costs had a negative association while benefits had a positive association with adherence.²² The subjects in the study completed the diabetes health belief questionnaire, diabetes regimen adherence questionnaire and diabetes knowledge and management skills assessment questionnaire. Results from multiple regression analysis indicate that the HBM accounted for 40% of the variance in self-reported adherence to diabetes self-management activities.²²

The health belief model was modified and extended by Aalto and Uutela to include the constructs of locus of control, self-efficacy, health value and social support in addition to the original constructs.²³ This extended model (EHBM) explained 14% of the variance in adherence to diet and 21% of the variance in adherence to self-monitoring of blood glucose using path analysis.²³ Higher

levels of benefits, locus of control and self-efficacy were associated with self-management activities.²³ The subjects for this cross sectional study were 423 type 1 diabetics who completed a mail questionnaire.

Another study by Gillibrand and Stevenson which used the EHBM suggested that among young people affected with diabetes, adherence to diabetes self care was predicted by high levels of family support.²⁴ However, the EHBM was not very powerful in predicting adherence to self care in this study, explaining only 12% of the variance in this population.²⁴ The study was a cross-sectional study on 118 young type 1 diabetics. Participants completed items related to diabetes susceptibility and seriousness, diabetes family behavior, diabetes locus of control, diabetes dependent quality of life, diabetes empowerment scale and other items relevant to the study constructs. Path analysis was used to illustrate the validity of the EHBM in the study.

Another study which also utilized the EHBM found that variables such as intention and health importance, barriers such as situational factors and emotional response were predictive of diabetes self-management behaviors.²⁵ For instance, the variable 'exercised for 30 minutes' was predicted by emotional response and intention ($r^2 = 0.33$), 'tested my blood sugar' was predicted by health importance, locus of control, costs-benefits and intention ($r^2 = 0.46$). This study was conducted on 86 type 1 diabetic college students. The college students completed the self-administered questionnaire containing the diabetes college scale which was developed based on constructs from the EHBM. Multiple regression analysis was performed to test the objectives of the study.

Shortcomings of the HBM. A review of the application of the HBM to diabetes related health behavior suggests that this model does not consistently explain significant amounts of the variation in diabetes self-management behaviors. This could stem from the fact that the health belief model has certain conceptual shortcomings. Although it focuses on beliefs about the seriousness and susceptibility to disease, it does not account for motivational factors that may encourage a person to engage in behaviors to reduce the threat or susceptibility of a disease. Thus, an important determinant of behavior - motivation is not encompassed within the framework of the health belief model. Motivation is important because it is the factor that drives a person to behave. A diabetic patient may have certain beliefs - for instance the patient may believe that exercising is good and leads to positive outcomes. However, just these beliefs do not translate into the patient actually exercising. An important component, which is the value placed by the patient on the outcomes of exercise which in addition to the expectations/beliefs that exercising leads to positive outcomes, is necessary to motivate the patient to act or to behave. Another important aspect to consider is that studies that have used the HBM as a theoretical framework have been correlational and not experimental in nature.

Another important criticism of the health belief model is that it focuses only on health beliefs whereas other beliefs might be equally important in determining behavior.⁶⁶ For instance, beliefs about one's ability to perform the health

behavior are sometimes just as important as beliefs about the health behavior itself.

The theory of reasoned action and the theory of planned behavior do not exhibit some of the conceptual shortcomings shown by the health belief model. A review of the application of the theory of reasoned action and theory of planned behavior to diabetes related health behavior follows.

Theory of reasoned action (TRA) and planned behavior (TPB)

The theory of planned behavior (TPB) postulates that intention to perform a behavior is an antecedent to actually performing the behavior.⁶⁷⁻⁶⁹ Further, determinants of intention to perform the behavior include attitudes, subjective norms and perceptions of behavioral control. It concentrates on constructs which serve as motivational factors to influence the likelihood of performing a certain behavior.²⁸

The theory of planned behavior is an extension of the theory of reasoned action which is illustrated in Figure 2.2 while the TPB is illustrated in Figure 2.3. The TRA was expanded to include perceived behavioral control leading to the development of the TPB.⁶⁹⁻⁷⁰ The TPB was developed as an extension of the TRA to help explain behaviors that were not completely under a person's volitional control. The strength of the theory of reasoned action and its extended version, the TPB, is that it is conducive for examining reasons underlying a person's motivation to act or perform a certain behavior whether or not those reasons are logical and rational. The TRA and TPB thus provide a framework

with which to discern the reasons for behaving which are relevant to individuals and the value placed on these reasons that cause them to behave the way that they do.

The value-expectancy conceptualization is traditionally used to measure the constructs for both the TRA as well as the TPB. Measurement of the constructs using value-expectancy implies that an attitude towards a behavior or object is determined by the beliefs or expectations about the perceived consequences of a behavior along with the value placed on those consequences. Thus, attitudes toward performing a health behavior such as smoking are the individual's beliefs about outcomes of smoking which could include getting lung cancer weighted by the value they place getting lung cancer. Similarly, a person's subjective norms are determined by a person's normative beliefs which are beliefs about whether important referents approve or disapprove of that individual performing a certain behavior weighted by the motivation to comply with these important referents. Perceived behavioral control is determined by control beliefs concerning the presence or absence of facilitators and barriers to performing a behavior as well as perceived power or the impact of each factor to facilitate or impede a behavior.

Fishbein and Ajzen who developed the TRA and TPB stressed on developing measures for attitude, intention and behavior which are strongly connected with each other in terms of target, context, time and action.^{56, 58 - 59} For instance, if attitude towards a health behavior is measured in a particular context, such as attitude toward smoking in the workplace, it is important that the

intention to perform the health behavior be measured in the same context. Hence, the health behavior being measured would be smoking in the workplace and not smoking in general.

Figure 2.2 The theory of reasoned action

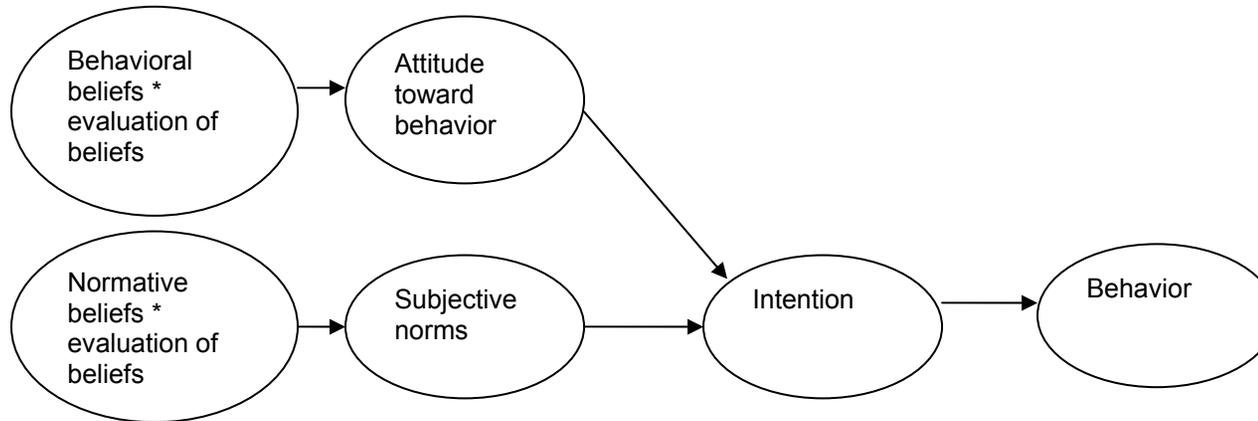
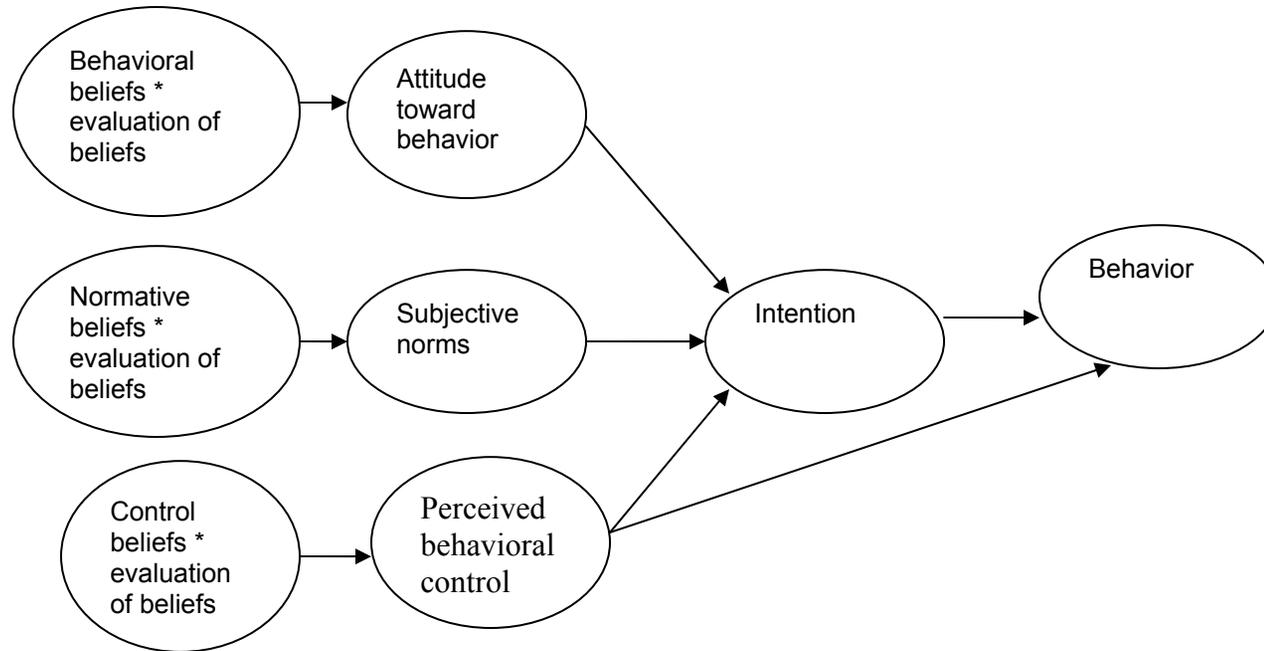


Figure 2.3 The theory of planned behavior



Studies have shown that patients' attitude, subjective norms and perceived behavioral control influence intentions to perform several health related behaviors.⁷¹⁻⁷²

TRA, TPB and diabetes related health behavior

Theory of reasoned action. The TRA concentrates on factors which serve as reasons (ex. consequences) to perform a health behavior and the value/importance of the reasons.²⁸ The TRA is appropriate framework to help predict health behaviors that are volitional. A limitation of this theory is that it fails to accurately predict those behaviors that are not volitional.

One study has evaluated the validity of the theory of reasoned action in its entirety to self-regulation in 558 insulin treated diabetic patients.²⁷ The self-regulatory behaviors tested were exercise, variation of nutrition, adjustment of insulin and regular home blood glucose monitoring. Moderately strong correlations were found between attitude and subjective norms and active self-regulation.²⁷ The correlation coefficients for intention and behavior ranged from 0.5 for adjustment of insulin and 0.67 for exercise.²⁷ This means that the amount of variance in behavior ranged from 25% for adjustment in insulin to 45% for exercising. Results indicate that 28% of the variance of actual home blood glucose monitoring behavior was explained by intention. This means that 72% of the variance in home blood glucose monitoring behavior remained unexplained. One shortcoming of the study was that it considered locus of control as an external variable - an antecedent to attitudes and social norms and thus one that

indirectly affects intention and behavior. In the extended version of the TRA – the TPB, control is not considered an antecedent to attitude but instead is a direct determinant of both, intention and behavior. Since diabetes self-management is not entirely volitional, the TPB may be better suited in understanding self-management behavior in diabetic patients.

Theory of planned behavior. Ajzen extended the theory of reasoned action to form the theory of planned behavior (TPB).²⁸ In addition to constructs from the TRA, it includes the construct of perceived behavioral control which affects both intention to perform the behavior as well as actual performance of the behavior.

The TPB has been used to predict self-management behaviors in diabetic patients. In a study of type 1 diabetics, overall the TPB could predict 47% of the variance in intention to perform self-monitoring of blood glucose and 57% of self-monitoring behavior.²⁶ Intention helped predict 37% of the variance in actual self-monitoring behavior. As in the case of the study using the TRA, 63% of the variance in behavior remained unexplained. The TPB has also been investigated for its effectiveness in predicting intention to eat healthy and engage in physical activity in individuals at risk for developing diabetes.

Shortcomings of the TRA and TPB. This section discusses some of the shortcomings of the TRA and TPB.

Intention-behavior link. In understanding the shortcomings of the TRA and the TPB it is important to focus on the intention-behavior link. The TRA and TPB presume that the motivation that helps a person to set a goal (goal intention) is

also responsible for helping the person move towards achieving the goal (goal striving/goal pursuit). However, motivation to achieve a goal does not necessarily always translate into behavior as is illustrated in studies reviewed.²⁶⁻
²⁷ This is also evident for the behavior being examined in this current study with results indicating that intention to perform SMBG predicted 28% of the variance in actual SMBG behavior in one study and 37% in another.

Ajzen defines intentions as being the motivational factor which indicates how much effort a person is willing to exert to perform a behavior.⁶⁸ Reviews of the theory of planned behavior shed some light on the intention-behavior relationship. For instance, Armitage and Conner found that intention explained about 22% of the variance in behavior (not specifically SMBG).⁷⁴ This was a meta analytic review of 161 journal articles and book chapters containing 185 empirical tests of the TPB up to 1997. Another review by Godin and Kok on the application of the TPB to health related behaviors found that intention predicted about 22.5% of the variance in health related behavior.⁷⁵ Thus reviews suggest that intentions only partly help predict behavior. While they are an important construct in trying to determine and explain behavior it is also important to look beyond intention to the intention-behavior link.

It is clear from the review that many people have trouble translating intentions into behavior. The reasons may be manifold.^{29, 76} People may have trouble getting started, encounter many distractions to performing a behavior, may be engrossed in another activity thereby missing the opportunity to perform the behavior. Oftentimes the situation to perform a behavior could be short-lived

and so people may miss the opportunity to act. Also, impediments to action (internal and/or external) may be encountered.

In addition, none of the studies that investigated health behavior using the TRA/TBP have used an experimental design.

It is evident that the intention-behavior link must be examined critically, because ultimately explanation and prediction of behavior is one of the most important goals of health behavior research. To this end, an examination of the strategies to translate intentions into behavior would prove to be of tremendous value.⁷⁷ This study aims to investigate one such volitional strategy - implementation intentions intervention with respect to diabetes related health behavior.

Model of action phases

In describing implementation intentions, it is important to discuss its theoretical background. Gollwitzer described the Rubicon model of action phases (MAP) as the four phases which help describe the performance of a goal pursuit-directed activity.³² The model of action phases states that goal pursuit activities can be thought to consist of four consecutive action phases. These four action phases start with a person's desires and end with evaluating the outcome of performing a particular action.

The first phase is the predecisional phase. During this phase, people consider and deliberate between their wishes and desires, the pros and cons of these wishes and desires in order to determine priorities amongst these wishes

and desires. The wishes and desires that are determined by the person to be highly desirable but still feasible are prioritized. This is the phase in which a person makes a goal intention thereby transforming a particular wish or desire into a desired goal. In doing so the person makes a commitment towards a particular goal and terminates further deliberation. Thus goal intentions help overcome obstacles (in terms of competing wishes and desires) during this phase. This phase is the goal setting phase.

The second action phase is postdecisional but still preactional phase. This postdecisional phase involves promotion and initiation of goal directed behaviors which are achieved via planning. Thus, this phase can be thought to be the volitional phase. However, the initiation of actions may be hindered by obstacles. For instance, one of the obstacles may be that several situations may be well suited to performing a behavior and this choice of several situations could actually hinder action initiation. The obstacle in this situation is that the person cannot determine which of the many possible situations should be chosen in order to perform the action. This point in time is when implementation intentions come into play in order to overcome these obstacles to performing goal directed behaviors. Implementation intentions are discussed in detail in the section that follows. This phase is the goal striving phase.

The third phase is the actional phase where goal directed behaviors are executed and the person focuses on achieving the goal. The phase in which the translation of intentions into actions occurs can be thought to be the volitional part of the process. This phase is the end of the goal striving phase.

The fourth phase is the postactional phase in which the outcomes are evaluated against the desired goals. As illustrated, the MAP encompasses both goal setting as well as goal striving.

Implementation intentions

Implementation intentions are volitional strategies. Implementation intentions are structured in terms of 'when situation x arises, I will perform y'.⁶⁹ Thus they link anticipated situations with goal directed activities.⁷⁸ In forming implementation intentions, the person goes through the mental process of planning when, where and how to perform goal directed activities. This planning activity results in the person committing himself/herself to responding in a certain way to an anticipated situation. Due to the linkage formed between the situation and the behavior, the control of goal directed activities is delegated to situational cues. When these cues are encountered, it is expected that they would trigger performance of the behavior. This implies that the situation specified in implementation intentions will be easily detected and would draw attention to itself even when the person is distracted with other activities. In addition to these attentional and perceptual processes, implementation intentions also function by facilitating an increased readiness to respond.

Implementation intentions differ from goal intentions. Goal intentions are structured in the form of 'I intend to achieve x' where 'x' refers to a certain desired performance or outcome. Goal intentions transform desires into a commitment to achieve a goal. Thus goal intention links a person's self to a

desired end state. Goal intentions do not necessarily imply that goal pursuit activities will be carried out successfully. Oftentimes there are obstacles in the initiation and execution of goal pursuit activities. It is at this point that implementation intentions assume importance.

The process by which implementation intentions function is twofold. First, it is expected that the mental representation of anticipated situation becomes highly activated and accessible. This heightened accessibility is thought to make the situation easier to attend to, recall and detect, even when one is distracted or busy with other things. Second, implementation intentions also link a specific behavior that will help attain the goal to an anticipated situation. In this sense, an automatization of the goal directed behavior occurs when the anticipated situation is encountered. This leads to efficient initiation of the goal directed behavior without any conscious process.

With implementation intention - a person passes control of goal directed behavior onto the environment. Thus people can switch from conscious and effortful control of their goal directed behavior to being automatically controlled by the environmental situational cues. As a result of this automatic initiation of behavior implementation intentions appear similar to habits.⁷⁹ The similarity between habits and implementation intentions lies in the fact that there is a link between a situation and performance of a behavior in the person's mind. However, the process by which habit and implementation intentions originate are different. With implementation intentions, the process of transforming goal intentions to actual performance of an action or behavior lies in one single mental

act which links environmental cues to performance of an action or behavior. With habits on the other hand, the link between a situation and behavior is the result of repetitive performance of a behavior in that particular situation.

Research on implementation intentions has shown that they are effective. Thus research shows that the act of supplementing goal intentions with implementation intentions helps people in achieving their goal and increases the rate of goal completion.

Gollwitzer and Brandstatter conducted three field studies to test the effect of implementation intentions on goal completion and immediacy of action initiation.⁸⁰ In the first study, German university students were asked to list two personal goals that they intended to complete during Christmas break. They were asked to list one goal which was easy to implement and one which was difficult to implement. Implementation intentions were assessed by asking if the participants had committed themselves to initiating goal directed activities in the presence of certain situational cues. Eighty five participants listed easy-to-implement goals and 70 listed difficult-to-implement goals - many participants listed both types of goals and thus were counted under both the easy as well as difficult to implement goal conditions. Participants completed measures related to goal qualities. Follow up was done at the end of the Christmas break to assess rate of completion of goals. For the difficult to implement goals, those who had formed implementation intentions had completed their goals 62% of the time as compared to only 22% goal completion for those who had not formed implementation intentions. This difference in rate of goal completion was

significant. For easy to implement goal intentions, the rate of completion for those who had formed implementation intentions was 84% compared to 78% for those who had not formed implementation intentions. This difference in rate of goal completion was not statistically significant. Thus, this field study showed that for difficult goals, implementation intentions increased rate of goal completion. This effect was not seen for easy to implement goals. This lack of effect may be because the easy to implement goals already had a high rate of completion. Also with easy to implement goals - as the name suggests their implementation may not be problematic to begin with and thus the formation of implementation intentions provides no added benefit to rate of goal completion.

Since the first field study was not an experimental manipulation, another field study was conducted to test whether the effect on rate of goal completion was because of implementation intentions or because goal qualities may impact rate of goal completion rather than formation of implementation intentions.⁸⁰ In the second field study, 86 German university students were recruited to participate and were all given the same goal to complete. Participants were told to write an account of how they spent their afternoon and evening on Christmas eve. Participants were told to write their accounts during the Christmas holidays and mail it in as soon as possible. Those in the implementation intervention group were told to specify when and where they were going to write their accounts. Thus, those in the intervention group specified a specific point in time (e.g. during their morning cup of coffee) and specific place (e.g. the dining table) they would start to write their accounts. In addition to specifying the time and

place, participants in the intervention group were also asked to visualize their situational cues. They were also asked to commit to initiating their action at the specified time and place by silently saying 'I intend to write the report in the situation z'. Of those who had formed implementation intentions, 71% turned in their accounts while only 32% of those who did not form implementation intentions did so in the time period specified. This difference was statistically significant, using chi-square statistics at alpha equal to 0.05. This study showed that implementation intentions facilitated action initiation when the specified opportunity to write the report arose.

A third field study tested the immediacy of action initiation due to the formation of implementation intentions.⁸⁰ Immediacy of action initiation refers to how quickly a particular action is undertaken. It is suggested that implementation intentions facilitate immediacy of action initiation towards achieving a certain goal and this study tested the validity of such a process. The study consisted of sixty male German students. The study subjects listened to a confederate's xenophobic views on tape and provided counterarguments to these statements. Measures corresponding to attitudes regarding integration and free recall of the confederates statements were completed by the participants. In addition some of the participants were told to form implementation intentions subsequent to seeing the statements of the confederate the first time. The study subjects in the implementation intervention group were shown the tape for the first time and told to mark the particular point at which they would present counterarguments. They were also told to commit to counterarguing at that point by saying 'I will speak up

here'. Those in the implementation intervention group thus formed a link to the particular situational cues as a point to present their counterarguments and this link was further strengthened by vocally committing to it. Those in the implementation intention intervention watched the tape 3 times. The first time, they watched the tape to familiarize themselves with the statements, the second time they watched it they had to mark points at which they would present the counterarguments and during the third run they had to actually pause the video and present counterarguments. There were two control groups in this study. The first control group also saw the tape three times. During the second run they were told to mark the points suitable for potentially counterarguing and during the third run they had to pause the video and present counterarguments. The difference between instructions to the intervention and this control group were that they were not told to form implementation intentions after the first run and also did not know that they had to actually verbalize their counterarguments during the third run. They were told about having to verbalize their counterarguments only after the second run was complete and this was done to prevent the formation of spontaneous implementation intentions by the participants. In order to control for the possible alternative explanation that implementation intentions lead to immediacy of action initiation only because the participants were aware that they had to counterargue and therefore had the opportunity to prepare the counterarguments from before, a second control group was set up. Participants in this control group were told early on that they had to present their counterarguments in writing. Only after the second run were they

told that instead of presenting their counterarguments in writing they had to present their counterarguments verbally during the third run. Immediacy of action initiation was defined as speaking up at a time that was closer to the specified marked points during the third run. Participants in the implementation intervention seized suitable opportunities to counterargue more immediately compared to those who had not formed implementation intentions. Thus those in the intervention group presented their counterarguments at times closer to their marked points to present counterarguments than did those in either of the two control groups.

Immediate action initiation due to implementation intentions was also tested by Brandstatter et al.⁸¹ They tested whether forming implementation intentions led to initiation of the action automatically once the situation was encountered even under conditions of high cognitive load. High cognitive load was described as a person being mentally preoccupied. This was done by testing in individuals with high cognitive load (schizophrenics and opiate addicts under withdrawal) as well as by manipulating cognitive load in university students.

In the study on opiate addicts, participants in the implementation intervention group were asked to write down exactly where, when and how they wanted to start writing their curriculum vitae. This writing down of where, when and how they wanted to start writing their curriculum vitae formed the implementation intention intervention. The control group made an irrelevant plan of where they would sit for lunch. The dependent variable was whether the

opiate addicts actually handed over their curriculum vitae by a certain time that evening to the researcher. Those who made specific plans about where, when and how they would write down their curriculum vitae had a significantly higher rate of goal completion.

In the study on schizophrenic patients, the focus was a go/no go task in which the participants had to press a specific key (the + key) on the keyboard when a number appeared on the computer screen but not when a letter appeared. The implementation intention intervention was delivered by telling the participants in the intervention group to tell themselves that if the number 3 appeared on the screen, then they would press the key particularly fast. Response time was the dependent variable. Those in the intervention group responded to the number 3 faster than those who were not in the implementation intervention group.

In the third study on university students, high cognitive load was induced using a dual task paradigm. The primary task was to work on meaningless consonant-vowel-consonant syllables. Participants were either required to associate freely with these syllables which formed the easy primary task or were asked to repeat them aloud and memorize them which formed the difficult primary task. In the secondary task participants had to press a button quickly when numbers appeared but not when letters appeared. Thus it was a go/no go task. Half of these participants were randomly assigned to the implementation intention intervention and the other half were assigned to the control group. Those in the implementation intention intervention were instructed to make a

resolution to respond particularly fast to a specific number. They were then instructed to say to themselves, 'I definitely want to respond to specific number as quickly as possible'. This if-then statement laid out the situation and was the implementation intention intervention. The control group only had to familiarize themselves with the specific number that they were required to respond to quickly and thus they did not form implementation intentions. As hypothesized, those in the implementation intention intervention responded quickly to the specific number despite being preoccupied with the primary task. This speeding up of response after forming implementation intentions was present even when the primary task was difficult.

The fourth study was also conducted on university students. Similar to the third study, this study employed a dual task paradigm. The primary task was a motor tracking task on the computer i.e. tracking the circle with a square. The difficulty level of the task was manipulated by reducing the size of the tracking square. The secondary task was similar to the go/no go task in study 3 except that it was presented within the circle moving across the computer screen which also served as the tracking target of the primary task. For the secondary task, as before, participants had to press a button quickly when numbers appeared but not when letters appeared. Participants were told to press the button particularly quickly if the number 3 appeared, making number 3 the critical number. Half of these participants were randomly assigned to the implementation intention intervention and the other half were assigned to the control group. Those in the implementation intention intervention were instructed to make a resolution to

respond particularly fast to number 3. They were then instructed to say to themselves, ' I definitely want to respond to number 3 as quickly as possible'. This if-then statement laid out the situation and was the implementation intention intervention. The control group only had to familiarize themselves with the number 3 that they were required to respond to quickly and thus they did not form implementation intentions. This familiarization step was to control for the effects of priming the participants in the implementation intention intervention to the number 3. Similar to study 3, those who formed implementation intentions sped up their response time to the critical number compared to those who did not form implementation intentions. This acceleration of response rate was not affected by the task difficulty of the primary task. Thus these studies illustrate that implementation intentions are also efficient even under conditions of high cognitive load thus proving that once implementation intentions are formed, they do not require a large amount of cognitive resources to initiate an action.

In order to further understand the mechanism through which implementation intentions function, Webb and Sheeran conducted a meta analysis as well as an experimental study.⁸² Their aim was to determine if deliberative processes rather than accessibility of the implementation plan could explain the effectiveness of implementation intention interventions. The specific deliberative processes that they examined were – increase in strength of goal intention and increase in self-efficacy. Results from meta analysis indicated that forming implementation intentions had a very small effect on goal intentions and self-efficacy. Based on the meta analysis, the authors concluded that it was

unlikely that the effectiveness of implementation intentions could be explained by increases in either goal intention or self-efficacy. The experimental study assessed if the accessibility of specified cues were heightened and if the link between cue and response were strengthened by implementation intentions. Seventy two undergraduate participants were randomized into either a related planning condition or an unrelated planning condition. All participants were told at the beginning of the study that the experiment would start in the laboratory and end in the cafeteria. They were also told that before continuing with the experiment in the cafeteria, they should collect a coupon from the Cognition lab. They were told where the Cognition lab was located. Participants in the related planning condition were told to plan the steps that were required to collect the coupon. They were told to write down when (time), where (the location of the coupon) and how (which route) they would employ to collect the coupon. Those in the unrelated planning condition were asked to plan the steps to spend the coupon. A filler task consisting of using 10 letters to make 10 different words was then given to all the participants. This filler task was designed to remove planning related cognitions from working memory. Next, participants completed a lexical decision task which consisted of a sequential priming paradigm. Participants were given the following sequence: a fixation dot followed by the prime word, followed by a random row of consonants of the same length as the prime and finally the target word. Participants were told to decide as whether the word presented was a verb or not by pressing keys labeled yes or no. The prime words were presented sufficiently quickly so that they remained outside the

participants conscious awareness. Amongst the target words and primes were: three words related to the critical cues specified in implementation intentions, three matched words relating to neutral cues, a word representing the target behavior – collect and a word representing a neutral behavior – confirm. Cue accessibility was measured as response to the critical cues following neutral primes. Cue-response association strength was measured as participants' response latencies to the target behavior having being primed with a critical cue. The main dependent measure was whether or not the participants picked up the coupon. After completing the lexical decision task, participants were told to remember a list of five foods and to go to the cafeteria where the experimenter would be waiting for them. This was done in order to ensure that the participants would be preoccupied with walking to and doing things in the cafeteria. Chi-square tests indicated that those in the relevant planning condition had significantly higher rates of picking up the coupon than those in the unrelated planning condition. MANOVAs indicated that participants in the related planning condition also responded significantly faster to the cue words and to the cue response association trials than those in the unrelated planning condition. In a test of mediation, cue accessibility and cue-response association strength mediated the effect of the forming the implementation intention on goal achievement.

In summary, it has been shown that implementation intentions increase rate of goal completion.⁸⁰ They do so by heightening the mental representation of a situation thereby making the situation easier to detect, recall and easier to

attend to.²⁹ They lead to immediate action initiation and are also efficient even under high cognitive loads.⁸¹

Implementation intention interventions and health-related behaviors

Implementation intentions have not been investigated with respect to health behaviors related to the management of chronic conditions. However, they have been studied in health promotion and prevention behavior such as reducing fat intake, consumption of fruits and vegetables, exercise, cancer screening examinations sun protection behavior, functional activity following surgery, vitamin C consumption and binge drinking behavior which provide relevant background for the current study. They have also been studied in relation to acute conditions such as antibiotic medication use.

An experimental intervention to analyze whether people can reduce their dietary fat intake using implementation intentions was carried out on 554 employees of an organization.⁸³ Participants gave responses to the transtheoretical model's stages of change measures which include measures related to precontemplation, contemplation, preparation, action and maintenance, as well as items measuring the TPB variables and dietary intake. The TPB variables which include attitude, subjective norm, perceived control and behavioral intention, were included to assess if it was motivational factors which were responsible for the transition from one stage to the next or whether it was the implementation intention intervention. Participants were randomized to either the implementation intention intervention or to the control group. Participants in

the implementation intention intervention were asked to plan to eat a low fat diet in the next month. They were told to make a detailed plan about how they would do it paying particular attention to the situations in which they would implement these plans. The study which used the transtheoretical model (TTM) assessed whether forming implementation intentions were responsible in helping participants transition between various stages of change.

The TTM is a model which integrates constructs from other health behavior theories and models - hence the name transtheoretical.⁸⁴ It was developed by Prochaska and DiClemente and is based on the decision making processes of people that lead to behavior change. The key constructs of the TTM are the stages of change which are precontemplation, contemplation, preparation, action and maintenance. The stages of change represent a continuum of motivational readiness to perform a behavior change. The TTM states that in order to progress from one stage to the next, people need to apply processes of change. These processes include consciousness raising, dramatic relief, environmental reevaluation, social liberation, self-reevaluation, stimulus control, helping relationships, counter conditioning, reinforcement management and self-liberation. Intervening and outcome variables for the TTM include decisional balance, self-efficacy and situational temptations and other behaviors specific to the target behavior. The TTM has been used successfully to develop health behavior interventions.

Results indicate that significantly more people transitioned from one stage to the next in the group using implementation intentions as compared to the

control group.⁸⁴ Thus implementation intentions helped participants in the precontemplation, contemplation and preparation stage to progress to the next subsequent stage of behavior change with respect to dietary fat intake.

Another study tested the effects of implementation intention on dietary fat intake on 264 British participants who were recruited from a mid-size organization.⁸⁵ The participants were randomized into the implementation intention (intervention group) and the control group. The intervention group was instructed to plan to eat a low fat diet during the next month. They were free to choose how to do it, but were instructed to formulate their plans in as much detail as possible paying particular attention to the situations in which to implement these plans. The participants completed TPB measures which included attitude, subjective norm, perceived behavioral control and behavioral intention and dietary food intake measures. TPB variables were included to check if the effects of the implementation intention intervention were independent of the motivational levels of participants based on the TPB construct intention, which stems from attitude, subjective norm and perceived behavioral control. The intervention and control group did not differ on the TPB variables. The intervention was successful because those who were instructed to form implementation intentions significantly decreased fat intake from baseline to 1 month follow up compared to the control group.

A third study tested the effects of implementation intentions on saturated fat intake in myocardial infarction patients.⁸⁶ This study consisted of 114 post MI patients who were recruited within a few days after MI into a cardiac rehabilitation

program. This two week rehabilitation program consisted of education regarding nutrition, preparation of healthy meals, selection of snacks, and exercise. A retrospective measure of patients' fat intake prior to MI was also taken (T1). Approximately two-weeks post completion of the rehab program which was approximately 8 weeks post MI, patients were randomly assigned to the control group and intervention group. Baseline measures for intention to maintain a diet with low saturated fat levels and low fat intake were obtained following this random assignment. The control group participants were reminded about what they had learnt in the rehabilitation program and they were also asked about their satisfaction, changes in health behaviors and support received from family. The intervention group was asked to complete an implementation intention intervention in addition to getting the same reminders about what they had learnt in the rehabilitation program. For the intervention, they were asked to fill out a plan that would allow them to follow a low fat diet. They filled out how many main meals they planned to eat every day, at what times of the day, the type of foods and drinks they planned on consuming. They were also told to specify how they would prepare their main meals, small amounts of food between the main meals and their snacks. The interviewers then screened the intervention with the participants. Together with the interviewer, the participant made detailed plans based on what they wrote down in the intervention. These detailed plans included the type and amount of food as well as the time and the situation. After completion of the intervention, the interviewer made comments that the plan was excellent and would help the participants behave the way they needed to in

terms of nutrition. Fat intake was measured at this time (T2) and was again measured at 8 months (T3). Saturated fat intake, total fat intake daily and overall calories from fat were not different at T1 or T2. The intervention participants showed significant differences in saturated fat intake, total fat intake daily and overall calories from fat at T3.

Keller and Abraham tested the effects of an intervention to increase daily fruit and vegetable intake that had a motivational component and an implementation intentions component on 218 students at a UK university.⁸⁷ Participants completed TPB variables, cognitions which included attitude, subjective norms, perceived behavioral control, self-efficacy measures, and anticipated regret pre and post intervention. The TPB variables were included to check if change in motivation as defined by the TPB would be sufficient to predict change in eating behavior or whether the implementation intention intervention would have an independent effect beyond the effect of the motivational variables. The participants in the experimental condition were subject to a motivational intervention component and were also asked to form implementation intentions. The implementation intentions intervention was delivered by asking the participants when and where they would buy their supply of fruit and vegetables. Space was provided for them to provide place of purchase and day of purchase. Participants were also asked to plan meals to allow them to consume recommended daily dose of fruit and vegetables. They were also asked to describe those meals under the heading 'fruits and vegetables at lunchtime' and 'fruits and vegetables at dinner'. Results indicate that the TPB and anticipated

regret together helped explain 71% of the variance in the post intervention behavior (eating significantly more fruits and vegetables). Results also indicate that those in the intervention group (motivation + implementation intention) ate significantly more fruits and vegetables. This increase in consumption of fruits and vegetables was not fully explained by change in cognitions and motivations, thereby indicating that implementation intentions in addition to the motivational component were responsible for change in behavior in the intervention group. This study highlights the importance of forming implementation intentions in addition to forming intentions.

An implementation intention intervention to promote fruit consumption was carried out on 120 students at a university.⁸⁸ Participants were randomized to the intervention and control conditions. The implementation intention intervention was delivered by instructing the students that people are more likely to eat an extra piece of fruit each day if they decide when and where they will do so. Students were then instructed to write down when and where they would eat an extra piece of fruit each day for the next two weeks. Students also completed TPB variables: attitudes, subjective, perceived control and intention to check if the experimental group and control group differed on these variables. Behavior was measured by asking the students at baseline and then at 2 week follow-up how many pieces of fruits they ate in the last week. The implementation intention intervention to increase dietary fruit consumption was effective. Thus participants in the implementation intention condition ate significantly more than participants in the control condition. Also, participants in the experimental group

ate significantly more fruits at follow up compared to baseline while fruit consumption for participants in the control condition actually declined at follow up compared to baseline.

Another study by Milne et al. explored the effectiveness of using implementation intentions to increase exercise behavior in combination with a motivational intervention.⁸⁹ The motivational intervention in this study was based on the Protection motivation theory (PMT). Protection motivation theory focuses on intention being influenced by two processes: threat appraisal and coping appraisal. The sample for the study was 248 undergraduate students. Participants were randomly assigned to one of three groups: one control group, one group receiving only the motivational intervention and a third group which received both the motivational and implementation intention intervention. Data were collected at three time points over two weeks. At time 1, participants completed questions related to demographics, and exercise behavior over the past week, month and year. In addition, at time 1, the motivational intervention was administered to two of the three groups (excluding the control group using a factual leaflet). All groups then completed PMT variables: perceived vulnerability, perceived severity, fear, response efficacy, self-efficacy and response costs and intention after the intervention was delivered at time 1. One week subsequent to time 1, exercise behavior was measured by asking participants how many times over the past week they had engaged in at least one 20 minute exercise session. All groups then completed PMT variables and exercise intention. The motivational + implementation intention intervention

group then completed the implementation intention intervention. The implementation intention intervention asked participants to write down when in day/days and where in terms of place and the time they would exercise vigorously for at least twenty minutes in the next week. One week subsequently all participants completed measures related to PMT variables, intention and exercise behavior. Exercise behavior was a self-report by the participants. The motivational intervention was responsible for causing changes in response efficacy, intention and self-efficacy. Provision of the motivational intervention had no effect on subsequent exercise behavior however the implementation intention intervention did show significant effects. At time 3, 91% of those in the implementation intention intervention group engaged in exercise, compared to 35% in the motivational intervention and 38% in the control group. Thus there was a significant difference in exercise behavior among the groups at time 3. The implementation intention intervention also increased the number of 20 minute exercise sessions engaged in by the participants in the implementation intention intervention group.

A study by Prestwich et al., found that combining a motivational intervention using decision balance sheet (DBS) and implementation intentions caused an increase in exercise frequency and total time spent exercising.⁹⁰ Participants were undergraduates and faculty at a UK university. All participants in the study were asked by the researchers to try to exercise two times more than they currently did during the week. Participants were assigned to one of four conditions: one was a control group, one was an implementation intentions

group, one was a DBS group and one was an implementation intentions + DBS group. A fitness test was performed at time 1 and subsequently four weeks after time 1 to get an objective measure of behavior. A diary also recorded the time, date, place and duration of exercise for four weeks subsequent to time 1. At time 1, participants completed measures related to demographics, past exercise behavior, intentions and perceived behavioral control prior to completing the fitness test. Those in the DBS group completed measures related to anticipated gains and losses related to exercising two or more times per week. These gains and losses were characterized as gains and losses to self and gains and losses to others and approval and disapproval from self and others. Participants who completed the implementation intention intervention were told to write down the time, place and type of extra exercise that they would engage in over the following four weeks. Participants in the DBS + implementation intention intervention completed both interventions. Results indicate that those in the combined intervention showed the greatest improvement in exercise frequency. However, those in the only implementation intention intervention also significantly increased their frequency and amount of time they exercised per week. This reveals that while the motivational intervention is important to goal realization - implementation intentions can be effective on their own.

A third study assessed the effectiveness of implementation intentions on exercise behavior.⁹¹ Participants were 112 college students. This study also examined the effect of implementation intentions on another socially relevant behavior - recycling drinking containers. However, since this behavior is not a

health related behavior, it will not be discussed in detail. This study was different compared to the previous study in that the researchers did not experimentally manipulate implementation intentions. Instead, they just measured implementation intentions to examine if those that had spontaneously formed them reported increased levels of exercise behavior. Behavioral intention, perceived behavioral control, implementation intentions and past behavior were measured at time 1. With respect to implementation intentions, participants were asked if they had made specific plans about when, where they would exercise over the next fortnight, what type of exercise they would do and how they would transport themselves to the specified place. These questions had a yes/no response options. After two weeks, participants indicated whether they had exercised regularly over the past fortnight. Exercising regularly was defined as physical activity lasting at least 20 - 30 minutes at least once or twice a week. Principal component analyses on the implementation intention questions indicated only one factor and thus all the items were summed up to form one index score for implementation intention. Results indicate that implementation intentions were strongly significantly correlated with behavior at $r = 0.669$. In the hierarchical stepwise regression, both behavioral intention and implementation intentions had a strong and significant effect on subsequent behavior. While behavioral intention was the strongest predictor of actual behavior, implementation intentions did also add to the explanation of actual behavior. Both these constructs explained about 55.7% of the actual performance of behavior.

Hill and colleagues examined if implementation intentions were effective in increasing exercise in a classroom intervention. Participants were 503 secondary school students.⁹² They were instructed by tutors regarding what one session of exercise meant. Participants were then given a questionnaire which asked them to answer questions related to the TPB variables and exercise. They were told to answer and that they answer all questions in relation to the subsequent three weeks. They were then assigned to four experimental conditions: completing an exercise word search which was the control condition, reading a motivational leaflet designed to target intention, behavioral control, attitudes and normative beliefs in relation to exercise, completing the motivational leaflet and a quiz about the leaflet content and the last condition which consisted of completing the motivational leaflet and the implementation intention intervention. The implementation intention intervention asked participants to clearly state what they wanted to do. They were told to record a new additional exercise goal for the subsequent week. They were told to state what they would do, when, and how they would achieve this and any specific aids they may need. Follow up was done at 3 weeks post intervention. Results indicated that all three interventions – leaflet alone, leaflet + quiz and leaflet + implementation intention intervention increased exercise behavior. However, implementation intentions did not increase behavior significantly more than either of the other interventions. This study illustrates that implementation intentions are among some of the effective strategies to help increase exercise behavior.

Another study aimed to examine the effects of implementation intentions on weight loss.⁹³ The participants for this study were 55 overweight or obese participants who had just attended their first Weight Watchers session. Participants in the study were randomly assigned to the experimental intervention in addition to Weight Watchers program or the control which consisted of just standard the Weight Watchers program. The standard weight watchers program consists of weekly one hour group meetings which focus on nutrition, exercise and behavioral weight control strategies. Questionnaires were completed both preintervention and 2 months post intervention by both control and experimental group participants. Other measures included weight and height in order to calculate Body Mass Index (BMI). Self-reported frequency of planning which food to eat, when to eat, which exercises to perform, what time to perform the exercise, where to exercise and how to stick to diet even when there are temptations as well as intention to lose weight were other measures. The implementation intention intervention consisted of participants making a plan for the nutrition and physical activity. In order to help the participants with the planning intervention they were told that planning when, where and what to eat and exercise has been found to be helpful in translating intentions to actions. They were then told to make an exact plan of when and where they would eat the food they had selected and when, where and how they would exercise over the next week. The intervention then asked the participants to make detailed plans regarding six food categories and included a prompt for each of the food categories. The intervention participants were then asked to make coping plans

regarding risky or tempting situations and what they would do in order to maintain their diet. Similarly, they filled out the implementation intervention for when, where and how they planned to exercise in terms of number of minutes per session, time and particular exercises. They were then asked to fill out a coping plan about what they would do if they were in a situation that would put them at risk for quitting the exercise. After participants completed plans for both diet and exercise a researcher reviewed the plans and invited participants to make more detailed plans where applicable. The researcher then congratulated the participants for making the plans and subsequently gave each participant seven more forms to fill out in order to get plans for the following eight weeks. The implementation intention intervention was effective with intervention group participants losing 4.2 kg versus control group participants' loss of 2.1 kg at two month follow up. This was a statistically significant difference. In terms of frequency of planning, intervention group participants increased their frequency of planning compared to control group participants who showed no increase. Regression analysis suggests that the differential effect of the two interventions was mediated by change of planning frequency in the intervention group.

Several studies have examined the effect of implementation intentions on cancer screening behavior. Orbell and colleagues examined whether behavioral intentions to perform breast self examinations (BSE) supplemented with implementation intentions led to an increase in performance of BSE compared to behavioral intentions not supplemented with implementation intentions.⁹⁴ Subjects for this study were 155 female students and staff at a UK university.

Subjects were divided into the experimental and control groups. Subjects completed measures related to TPB variables and the subjects in the experimental arm of the study also completed a brief implementation intervention. As with previous studies, the TPB variables were assessed to determine if the effect of the implementation intention intervention was independent of the motivational factors assessed by the TPB. The implementation intention intervention asked the participants to decide and write down what time of the day and where they would perform the BSE and to commit to doing it. The implementation intention was effective in that 64% of women in the intervention group had performed BSE at 1-month follow up compared to only 14% in the non-intervention group. Among women with the same level of behavioral intention at baseline, 100% of those in the implementation intervention group performed BSE compared to 53% in the control group. This difference of performance of BSE was significant. The study subjects in the intervention group performed their BSE at the time and place specified in their implementation intentions. This indicates that there is a strong memory effect of implementation intentions in linking a behavior with a specified time and place.

Implementation intentions have been assessed with respect to their impact on testicular self examinations (TSE).⁹⁵ Participants for this study were 76 non psychology undergraduate students between 18 - 35 years to reflect the age group that is at highest risk for the incidence of testicular cancer. The participants were allocated randomly to an experimental and control condition. At baseline, all participants completed a questionnaire which included questions

related to knowledge about testicular cancer, intention to perform TSE and past experience with TSE. Those in the experimental condition were requested to write down when and where they would complete their TSE during the next three weeks. All participants were given an illustrated leaflet containing instructions on performing TSE. Three weeks subsequent to the first contact, participants completed a self-report measure for the performance of TSE in the preceding three weeks. Intention was also measured at this time. Results indicate that those in the intervention group reported performing TSE significantly more than those in the control group despite having similar intentions to perform TSE, past experiences and knowledge about TSE.

A second study sought to examine if implementation intentions would help improve rates of TSE.⁹⁶ This study used a PMT intervention in addition to implementation intention intervention. The PMT intervention was included in order to help participants increase goal intentions to perform TSE. This was done because implementation intentions are effective only if they are preceded by the formation of goal intentions. Participants for this study were undergraduate men who were randomly assigned to one of four groups: control, PMT only, PMT + implementation intention intervention and only implementation intention intervention group. All participants completed PMT variables, demographic variables and past behavior. The PMT intervention was delivered by means of an educational leaflet prior to participants completing the PMT variables and the implementation intention intervention was presented as a supplement to the leaflet. For the implementation intention intervention, the

participants were told to write down the day, place, time and any other contextual information such as 'after shower' or 'after breakfast' where they would perform TSE in the next month. Follow up was done at one month and one year. At the one month follow up behavior was assessed by asking the participants if they had performed a TSE in the past month. At the one year follow up participants were asked if they had established a routine for performing TSE every month. At the one month follow up, 254 participants completed the behavioral measure and at the one year follow up, 173 participants completed the behavioral measure. Results indicate that the PMT intervention was successful in increasing goal intentions to perform TSE and coping appraisal. At the one month follow up, only 22% of the control group performed TSE compared to 44% of the implementation intention intervention group - a significant difference. At the one year follow up, the difference in performance remained significant, with 15% of the control versus 37% of the implementation intention intervention group reporting routine performance of TSE over the past year. This study was significant because it had a long follow up period. The long follow up period illustrated that the effects of implementation intentions did not wane over time.

Another study by Sheeran and Orbell assessed cervical screening behavior following an implementation intention intervention.⁹⁷ Participants were 114 women registered at one clinic in England who were due for a cervical cancer screening test over the next three months. These women received a standard postal reminder from their physician reminding them that they should attend cancer screening test within the next three months. They also received a

mail questionnaire assessing their attitudes, subjective norms, perceived behavioral control and intentions. Participants were randomly assigned to the experimental and control groups. Those in the experimental group were told to write down when, where and how they would make an appointment for cervical cancer screening. The target behavior was actual attendance for cervical cancer screenings within the three month period following the mail questionnaire. Those who formed implementation intentions had a significantly higher rate of attendance to cervical cancer screening tests, with 92% of those in the experimental compared to 69% in the control group attending the cancer screening tests.

A study sought to investigate the impact of implementation intentions on sun protection behavior among parents of 436 children.⁹⁸ Follow up was done at 5 months subsequent to baseline measures. The parent-children dyads were randomly assigned to experimental and control groups and were subjected to baseline and follow up questionnaires via email. The implementation intention intervention was delivered in the baseline questionnaire. Parents were told to describe the situation when they would apply SPF 20+ every 2 hours on their child. Baseline and follow up intention to always apply SPF 20+ every 2 hours when the child was outside on a sunny day was measured. Parental sunscreen use was measured at follow up for how often the parents had protected their child with SPF 20+ every 2 hours when the child was outside on a sunny day. While the implementation intentions did not significantly affect sun protection behavior overall, there was a significant interaction effect between intentions and

implementation intentions. Thus, for those parents with high intentions, the implementation intention intervention was effective. Among those with high intentions, the intervention resulted in 13.5% more parents always using SPF 20+ compared to the control group. This is consistent with prior research indicating that implementation intentions are only effective if a person is already motivated to perform the behavior.

Armitage conducted a study to test the effectiveness of a worksite intervention aimed to reduce smoking.⁹⁹ Data comes from 90 participants that were randomly assigned to control and intervention group. All measures were assessed at baseline and at follow up which was 2 months post baseline. These measures related to theory of planned behavior variables, perceived control over temptations, smoking status (quitting and a biologically validated measure of nicotine dependence). Quitting was only measured at follow up. Nicotine dependence was the measure for past behavior. Questionnaires were distributed to the participants who were requested to fill it out. In addition to the questionnaires, the experimental group participants were requested to complete implementation intention intervention. The implementation intention intervention mentioned that the investigators would like the experimental group participants to make plans to quit smoking during the next two months. Experimental group participants were told they were free to choose how to quit but that they should formulate their plan in as much detail as possible. Participants were told to pay particular attention to situations in which they could implement the plan to quit. A few blank lines followed these instructions to enable the participants to write

down their implementation intentions. Hierarchical regression analysis indicates that intention mediated the effect of past behavior on future behavior. Results also showed that amongst the intervention group 11.63% quit smoking at follow up which was significantly different from those who quit in the control group at 2.13%. Results also indicate that the effects of the intervention were over and above the motivational effects of temptation and theory of planned behavior variables.

Sheeran and Orbell conducted two additional studies aimed to assess the effectiveness of implementation intentions.¹⁰⁰ In the first study, they examined if vitamin C tablet intake increased over 3 weeks due to an implementation intention manipulation. Participants were 78 university students who either received the manipulation or were in the control group. All the participants completed a questionnaire at baseline which contained questions related to attitudes, subjective norms, perceived behavioral control, intentions and past behavior. For the implementation intentions manipulation - participants were told to write down where and when they would take a vitamin C tablet every day for the next 3 weeks. At follow up which was 10 days and 3 weeks post baseline, participants were asked to indicate how many vitamin C tablets they had taken in the past 10 days (for the first follow up) and in the past 11 days (for the second follow up). At the 10 day follow up, participants also completed questions assessing intention to take vitamin C tablets. At the three week follow up participants were also asked when and where they had taken the vitamin C tablet every day and if they had not taken the vitamin C tablet every day, why they

hadn't done so. Vitamin C consumption was also assessed by pill count at both the follow ups. While there was no difference in the two groups at the ten day follow up, at the three week follow up, those in the implementation intention intervention, had missed significantly fewer pills compared to the control group. This was true for both the self-report measure as well as using pill counts. Further, the time and location that the participants wrote down in the implementation intentions intervention was significantly associated with when and where they said they actually consumed their vitamin C tablets at the three week follow up. In order to rule out the possibility that the increase in vitamin C consumption was because of increased motivation in the experimental group goal intentions were compared between the groups. Results indicate that the goal intentions were similar for the experimental and control group, both before and after the manipulation.

In a follow up experiment the effects of implementation intentions on vitamin C tablet consumption was assessed.¹⁰⁰ This study was conducted on 37 undergraduate students. At baseline, participants were given a bottle containing vitamin C tablets and were told that it was entirely up to the participants to take the tablets if they so chose to. At time 2, two weeks subsequent to baseline, the number of pills consumed by participants was counted. At this time, participants were asked to try and take a vitamin C tablet every day for the next three weeks. Half the participants received an implementation intentions manipulation similar to that in the first experiment where the participants were told to write down when and where over the next three weeks they would take the vitamin C pill daily. At

this time, participants also completed TPB measures. The reason that the researchers measured vitamin C consumption in the initial two weeks is to assess pill consumption as a function of motivational factors. The subsequent three weeks assessed pill consumption as a function of participants' volitions. The volitional phase requires that participants are motivated to take the vitamin C tablets and the issue is whether or not they can enact their intentions. At time 3, which was three weeks subsequent to time 2, participants who formed implementation intentions missed fewer doses of vitamin C compared to those who did not form implementation intentions. This effect of implementation intentions remained even when only those participants who had missed taking pills during the two week baseline period were considered.

Another study sought to examine the effectiveness of an implementation intention manipulation to prevent binge drinking.¹⁰¹ The participants were 102 undergraduate students who were randomly assigned to the control and the experimental group. At time 1, both the experimental group and control group participants received information about safe drinking limits and adverse consequences of binge drinking. The experimental group also had to choose a strategy among a list of six strategies which would enable them to refuse a drink. An example of the six strategies to refuse a drink is 'no thanks, I am watching my weight'. They were further told to specify a time and place where they would implement this chosen strategy. This planning and choosing a strategy formed the implementation intention intervention. Previous drinking and actual binge drinking behavior were measured in terms of frequency and recency of drinking

six or more units on one drinking occasion over the past two weeks. Previous drinking behavior, likelihood of future binge drinking and social desirability scale were measured at time 1 and binge drinking was measured at follow up at time 2. Those in the implementation intention intervention group reported lower frequency of binge drinking at follow up as well as greater reduction in drinking frequency at follow up compared to the control. Also, a lower proportion of the experimental group compared to the control group had engaged in binge drinking since the intervention.

Implementation intentions have also been examined with respect to whether they affect functional activity after joint replacement surgery.¹⁰² Participants for the study were 64 patients who were scheduled to undergo hip or knee replacement surgery. The initial interview was conducted 2 weeks prior to the surgery and follow up was done 3 months post-surgery. During the initial interview, TPB constructs related to the 32 functional behaviors that were targeted in this study were collected. Behavioral expectation instead of behavioral intention was measured since functional activity for arthritis is not entirely volitional. In addition, independent activity, behavior prior to surgery was measured. Participants were given a booklet in which to record implementation intentions over the 13 weeks post surgery. This booklet contained a blank page for each week following surgery. Participants were told to note down what activity they would pursue during that week and to specify when they would do it. This booklet was given to the patients prior to surgery and collected at the end of the 3 month post-surgery period. Behavior was assessed at 3 month follow up

by asking the participants about when they had initiated each of the 32 activities in terms of weeks post surgery. At the end of the 3 month period, booklets had been completed by 26 patients who formed the implementation intention intervention group while the remaining 38 patients formed the control group. Those in the intervention group initiated 18 of the 32 behaviors earlier than those in the control group. The authors also found that implementation intentions completely mediated the link between goal intentions and speed of action initiation.

While evidence overwhelmingly points towards the effectiveness of implementation intentions, some of the interventions have not been successful. One such study sought to increase exercise using implementation intentions.¹⁰³ Participants in the study were 274 working adults. Half the participants completed the intervention while the other half were in the control group. In addition all participants also completed TPB measures and job stress measures using a web based questionnaire. The implementation intention intervention was delivered to the participants by stating that while many people intend on exercising, many do not ever get around to doing it. The participants were told that it has been found that if people made specific plans about when, where and how they would exercise, then they were more likely to actually do it and less likely to forget or not get around to doing it. Participants were then told to take a moment to plan when, where and how they would exercise in the next week and to write down this information. The information they wrote down was the form of exercise, the day/days they would exercise, time of day and location. The study

used a web based questionnaire. Results indicate that attitudes and perceived behavioral control but not subjective norms predicted intention to exercise and intention to exercise predicted actual exercise behavior. It was also found that as perceived behavioral control increased, occupational stress decreased. With respect to the implementation intention intervention, they found that implementation intentions did not improve exercising, and in fact those in the control group exercised more than those in the implementation intervention. Exercise behavior was assessed at 1 week. One of the reasons offered by the authors to account for their findings was that implementation intentions may not be suited to behaviors that require flexibility. The rigidity of scheduling behaviors at a certain place and a certain time may restrict the person from acting when other opportunities arise. An alternative explanation could be that the desire to achieve the goal of exercising is in conflict with other goals a person has because the participants in the study were employees with jobs and it is plausible that their goals related to their job and personal life competed with their goal to exercise.

Another study which tested whether implementation intentions could help increase consumption of fruits and vegetables by two servings in cardiac patients found that implementation intentions were ineffective.¹⁰⁴ This study was conducted on 115 patients who were randomly assigned to one of three groups and 94 of these completed follow up. The first group was a control group who were just told to eat two extra portions of fruits and vegetables every day over the next three months. The second group completed TPB variables and were also

told to eat two extra portions of fruits and vegetables each day for the next three months. The third group completed TPB variables, were told to eat two extra portions of fruits and vegetables each day over the next three months and also completed the intervention after completing the TPB variables. Those in the implementation intention intervention were told to make a decision about what they will eat and when and where they will do so over the next three months. The participants in the intervention group were also told to write down the time and place where they already eat a portion of fruit or vegetable and then make a plan for the two extra portions. Daily fruit and vegetable consumption was assessed at recruitment, and follow up was done at 7 days, 28 days and 90 days. A time by group ANCOVA was conducted to examine if the implementation intention intervention was successful, with fruit and vegetable consumption at baseline entered as a covariate. All the groups increased their fruit and vegetable consumption over time. However the intervention group was not significantly different than the other groups in consumption. The reason that the implementation intention intervention may not have been effective was that all the groups seemed to have increased their consumption. This could be because the instructions were given to all groups to eat two additional portions of fruits and vegetables over the next three months. This in itself could have led to spontaneous formation of implementation intentions in the control and TPB only group. All three groups were also telephoned at 7 days, 28 days and 90 days for their self report on consumption of fruits and vegetables and this may have led to participants reporting an increase in consumption due to demand effects. The

telephone call may also have acted as a type of an intervention which could have led to an actual increase in fruit and vegetable consumption in all the three groups.

Implementation intentions have been studied with respect to medication use as well. One study tested whether implementation intentions help improve adherence to short-term antibiotics.¹⁰⁵ Participants were grouped into four groups: one was a control, one was a group that completed TPB variables, one was a group that formed their own implementation intentions and the fourth was a group that was given the implementation intention (researcher formed implementation intention). Participants in the group that had to form their own implementation intentions were told that they were more likely to take their antibiotics if they made the decision about when and where they would take them. They were then told to decide when and where they would take their medication. They were given examples of situations that may work for the implementation intentions such as after brushing their teeth in the morning. Those in the researcher given implementation intention group, the researcher provided the participants with the implementation intention intervention for each daily dose based on what was appropriate for the participant. The instructions used with this group were similar to those used for the group that had to form their own intentions. Adherence was assessed on the day after participants were due to complete their antibiotic regimen. It was assessed by means of pill count. The implementation intention intervention did not have any effect on adherence to antibiotics. This was true for both participant-formed as well as researcher

given implementation intentions. The reason for this lack of effect could be because adherence to the antibiotic regimen was already high at 75.8% across the four groups. The implementation intention intervention may be more effective in behaviors that show low adherence or are difficult to achieve compared to the short term medication use behavior. Another reason for the lack of effect of implementation intentions could be that those in the control group and in the group that completed the TPB variables were also told by the researcher to take their antibiotics as prescribed. This could have resulted in the two groups forming spontaneous implementation intentions which could have resulted in the high rate of adherence across all four groups.

Implementation intention interventions have been shown to favorably impact the performance of several health related behaviors like BSE,⁹⁴ fruit and vegetable consumption,⁸⁷⁻⁸⁸ and fat intake⁸⁵. Their impact in many cases has been shown to be over and above the impact of motivational factors as assessed by the TPB variables.^{83, 85, 87-88, 94} This indicates that implementation intentions are effective strategies that work beyond the motivational factors that result in people making an intention to perform a behavior. Implementation intentions actually facilitate the transformation of the intention into actual performance of the behavior. However, there is not enough evidence to suggest that implementation intentions work in clinical populations since many studies have been conducted on undergraduate students. Chronically ill patients are different from the undergraduates. These differences could be in terms of their motivation to perform certain behaviors, in the day-to-day distractions, in competing life

goals. Also, undergraduate students are a captive audience when they participate in a study and their results based on this population may be biased. It is also not clear whether implementation intentions are effective for single one shot behaviors or repetitive behaviors, for simple straightforward behaviors or complex behaviors. It is thus crucial to study the process and variables that mediate the link between intention-behavior since this is the point at which implementation intentions act. This link is studied in detail in the section that follows.

Theoretical Model of Effortful Decision Making and Enactment

Since this study investigates the intention-behavior link, it is important to examine variables that mediate the relationship between intention and behavior in addition to studying strategies to help translate intention to behavior. Bagozzi et al. examined the psychological variables that mediate the relationship between the decision making process and subsequent goal striving or goal pursuit activities.²⁹ The authors came up with a Theoretical Model of Effortful Decision Making and Enactment which is depicted in Figure 2.4. The Theoretical Model Of Effortful Decision Making And Enactment describes the process by which decision making results in action and goal attainment and includes two important components of the decision process: choice or goal intention and decision enactment. The Theoretical Model Of Effortful Decision Making And Enactment is based on a synthesis of different decision making literature.

Similar to the model of action phases, the Theoretical Model Of Effortful Decision Making And Enactment also distinguishes between two types of intention - goal intention and implementation intention. Goal intention is a commitment by the decision maker to attain a chosen goal while implementation intentions are the commitment towards specific means to attain the chosen goal.

The Theoretical Model Of Effortful Decision Making And Enactment captures desires as the proximal determinant of intentions. While intention is the commitment to attain a particular end state or a goal, desires represents the intensity with which the goal is pursued in effortful decision making. Since desires are antecedents of intentions, the Theoretical Model Of Effortful Decision Making And Enactment distinguishes between goal desires and implementation desires. Goal desire is a necessary prerequisite to making a goal intention because it provides the motivational impetus to form an intention. Implementation desires are the antecedent of implementation intentions. Implementation desires reflect the intensity with which the decision maker wants to pursue specific goal directed activities. The difference between goal desires and implementation desires is that goal desires are desires to achieve end states while implementation desires are targeted towards the means to achieve the desired end state.

While the model of action phases includes goal desirability in the predecisional phase, the Theoretical Model Of Effortful Decision Making And Enactment includes goal desires. It is important to distinguish between the two concepts. A goal may be highly attractive and desirable to a person but unless

the person desires to achieve the goal, he/she will not pursue it. An example of the difference between a desirable end state and a desired end state is when a gold bracelet may be highly desirable for a woman who may admire it in the store window. However, she may not necessarily want to own the bracelet and thus has no desire for it and because she has no desire to own it, she will not engage in activities related to owning the bracelet.

Plan enactment in the Theoretical Model of Effortful Decision Making and Enactment is the degree to which the original plan made during the implementation phase was adhered. Thus it is the degree of performance of an action or behavior, including when, where and how by the decision maker. Goal realization is the final construct of the model and is the attainment of the chosen goal. Thus plan enactment focuses on the means to an end while goal realization focuses on the end itself.

The Theoretical Model Of Effortful Decision Making And Enactment also takes into consideration three decision process characteristics: namely, importance, effort investment and confidence as motivation mustering variables and determinants of the core constructs of the theoretical model. Other variables such as goal feasibility, perceived behavioral control, positive and negative anticipated emotions, attitudes and subjective norms are determinants of the constructs of the Theoretical Model Of Effortful Decision Making And Enactment.

In order to provide empirical support for the theoretical model, 169 undergraduate psychology students took part in an empirical study.²⁹ Students were told to pick goals that they intended to accomplish over the next two weeks

and exclude habitual goals. They were then asked to list all the actions that would be required of them to perform the goal. This was the implementation plan intervention. Students then completed measures related to decision process importance, effort investment and confidence. They also completed measures related to attitudes, subjective norms, perceived behavioral control, anticipated emotions, goal desire, goal feasibility, implementation desire, implementation intention in the first phase. During follow up at two and a half weeks, responses related to plan enactment and goal realization were elicited. Confirmatory factor analysis and structural equation modeling were performed to test the validity of the model. As compared to the TPB which explained 10% of variance in goal realization and the model of action phases which explained 11% of the variance, the Theoretical Model Of Effortful Decision Making And Enactment could explain 70% of the variance in goal realization.

The Theoretical Model Of Effortful Decision Making And Enactment was also tested in a study by Dholakia et al. They focused on the variables of goal desire, goal intentions, implementation desires, implementation intentions, plan enactment and goal realization.¹⁰⁶ The study added two constructs - self-efficacy as a determinant of goal desires and plan completeness as a mediator between implementation intentions and plan enactment. They termed goal desire, self-efficacy, goal intentions and implementation desires as distal goal related variables because they are at a higher level of abstraction and because they come earlier in the decision process. The proximal implementation related variables are implementation intentions, plan completeness, plan enactment and

goal realization. These were termed proximal because of their lower level of abstraction and their proximity to the actual enactment. Their study consisted of three experiments which examined implementation intentions by way of forming an implementation plan as well as remembering past actions as a self-regulatory strategy for decision enactment. The first experiment consisted of 281 undergraduate students who either chose their own goal or were assigned a goal. Those in the volitionally chosen goal condition were told to choose a goal that was important to them but not a habitual goal such as buying groceries. Those in the assigned goal condition were assigned the goal of studying for two hours continuously over the upcoming weekend. The implementation intention intervention was delivered as instructions to form detailed plans to achieve their goals. Questions regarding what specific actions they would take, when, where, how and for how long were asked to help participants make detailed plans. The implementation intention intervention was delivered in the same manner for the other two experiments. In a second experiment of 106 undergraduate students, the goal given to the experimental group was a novel task of visiting a specific website to complete an overconfidence scale. The third experiment consisted of 78 undergraduate students who like in experiment 1 either choose their own goal or were assigned a goal. Similar to experiment 1 those in the volitionally chosen goal condition were told to choose a goal that was important to them but not a habitual goal such as buying groceries. Those in the assigned goal condition were assigned the goal of studying for two hours continuously over the upcoming weekend. The third experiment sought to examine goal desires which was

measured twice, before and after the formation of implementation plans and remembering past actions. Results from these three experiments showed that both forming implementation intentions and remembering past actions are self-regulatory strategies that increase the level of goal realization. The study also found that forming an implementation plan raises the levels of implementation intentions, plan completeness, plan enactment and goal realization thereby providing evidence of the motivational impact of implementation plans for volitionally chosen goals. The authors suggest that when the goal is chosen by the person, the person has already passed through the deliberative phase or the predecisional stage from the MAP. Subsequently, forming an implementation plan would not impact distal goal related variables, because the person has already been through the process through which these are impacted. However, forming an implementation plan would affect proximal implementation related variables, namely implementation intentions and plan enactment.

Theoretical framework for the study

The theoretical framework that was used in the study is the Theoretical Model Of Effortful Decision Making And Enactment. The constructs from the Theoretical Model Of Effortful Decision Making And Enactment that the study will focus on are depicted in Figure 1.2. Thus, the study will investigate the following constructs with respect to self-management behaviors in diabetics: goal desire, goal intention, implementation desire, implementation intention, and goal realization. As depicted in the figure, participants will be asked to make

implementation plans subsequent to stating their implementation intentions. The previous section (on 'theoretical model of effortful decision making and enactment') contains detailed discussion on the constructs.

Objectives and hypotheses

The objective of this study was to determine if making implementation plans would improve rates of self-monitoring of blood glucose. In doing so, this study focused on an examination of the intention-behavior link. A critical examination of this link with respect to chronically ill patients and their self-management behaviors is missing. This study was an attempt to bridge this gap in the literature.

Making implementation plans which are an important self-regulatory strategy in the link between intention-behavior will be the main focus of this study. Implementation intentions interventions have been shown to be extremely effective in many studies related to health behavior.^{83, 85, 87-88, 94, 89-91, 95-98, 100-102} Formulating Implementation intentions appear to be a very effective tool that may help diabetic patients to adhere to their health regimen. This study differed from previous ones in two aspects: the health behavior and the patient population being examined.

Previous studies on implementation intentions have focused on preventative health behavior and health promotion behavior. Implementation intentions have not been examined with respect to self-management behaviors in chronically ill patients. Behaviors carried out by chronically ill patients are

intuitively different from the behaviors studied in terms of their underlying reasons, rationale and motivation for performance. Thus it is of prime importance to understand how implementation intentions function in self-management behaviors of chronically ill patients.

Much of previous research on implementation intentions focuses on either an undergraduate population or a general population and not on chronically ill patients. Chronically ill patients have the onus of managing their disease on a daily basis for the rest of their lives. Research reveals that chronically ill patients are often unable to adhere to their self-management regimens.^{14-15, 17-18} The self-management behaviors that must be performed by the chronically ill patient impacts many aspects of a patients' life oftentimes interfering with their daily activities. Self-management behaviors in chronically ill patients are complex behaviors because they have to compete and often interfere with other life goals. The chronically ill patient must make the self-management behavior a part of his/her routine in order to ensure successful adherence. They also need to be performed on a daily basis for a lifetime. Thus chronically ill patients are different from the subjects that have been examined previously in studies on implementation intentions and health behaviors. As mentioned before, subjects in these studies were not chronically ill patients except for one study on knee and hip replacement surgery patients. Further, in many cases they were university students. This current study added to the implementation intention literature by examining if it is applicable to chronically ill patients who have different demands,

distractions and challenges as a result of their chronic illness than subjects who have been investigated previously.

Aim 1: To determine if formulating implementation plans increases the rates of self-management behaviors.

Hypothesis 1: Participants who form implementation plans will have higher levels of SMBG as measured by the diary compared to those who don't.

Hypothesis 2: Participants who form implementation plans will have higher levels of SMBG as measured by the first recall measure compared to those who don't.

Hypothesis 3: Participants who form implementation plans will have higher levels of SMBG as measured by the second recall measure compared to those who don't.

It is also important to understand whether the theoretical framework is well suited for use in this patient population and for the behavior that is being examined. Literature reveals that patients with chronic illness have trouble adhering to their self-management behaviors. This illustrates that self-management behaviors are effortful for many of the chronically ill patients. Effortful decision making denotes that there are difficulties encountered in enacting the decision even when a choice to act has been made. In order to understand the intention-behavior link better, it is important to examine the processes that mediate the relationship between a goal intention and goal pursuit and enactment activities. The Theoretical Model Of Effortful Decision Making And Enactment seems well suited to studying the intention-behavior link in self-

management of chronically ill patients. Thus a secondary aim of this study was to investigate psychological variables based on the Theoretical Model Of Effortful Decision Making And Enactment that mediate the link between intention and behavior. In doing so, this study focused on the processes that tie goal intention to goal achievement for self-management behaviors in diabetic patients. Translating intentions into behavior is at the core of all health behavior research. Understanding the processes that link intention and behavior will be important if strides are to be made to improve adherence to health behaviors. Specifically, the study aimed to examine if the associations between the constructs of goal desires, goal intentions and implementation desires, and implementation intentions as suggested in the theoretical model hold true in the diabetic population.

Aim 2: To determine the relationship between goal desires, goal intentions, implementation desires and implementation intentions.

Hypothesis 4: The greater the goal desire, the greater the goal intention.

Hypothesis 5: The greater the goal intention, the greater the implementation desire.

Hypothesis 6: The greater the implementation desire, the greater the implementation intention.

Aim 3: To determine the relationship between implementation intentions and self-monitoring behavior.

Hypothesis 7: The greater the implementation intention, the greater the performance of SMBG as measured by diary.

Hypothesis 8: The greater the implementation intention, the greater the performance of SMBG as measured by the first recall measure.

Hypothesis 9 The greater the implementation intention, the greater the performance of SMBG as measured by the second recall measure.

CHAPTER III

METHODS

Introduction

This chapter describes the methodology that was used in the study. It includes a description of the methodological approach, the experimental manipulation and a description of the population including the inclusion and exclusion criterion. It also includes a description of the sampling and data collection methodology, the items that will be used in the questionnaire and the questionnaire design. It concludes with a description of the pilot test and a description of the analyses that were conducted.

Overview

This study aimed to understand psychological processes and strategies that help transform intention to behavior, using the Theoretical Model of Effortful Decision Making and Enactment. The population for the current study was type 1 and type 2 diabetic patients aged 18 and older with HbA_{1c} greater than 7% and requiring insulin therapy to control and manage their disease. One self-management behavior was examined in this study: self-monitoring of blood

glucose. The focus of the study was an implementation intention manipulation as a strategy to help patients transform behavioral intentions into actual behavior.

Selection of methodological approach

The study design was a four group experimental-control using randomization design as depicted in Table 3.1. This design was a modification of experimental designs suggested by Kerlinger.¹⁰⁷

This design was selected for a few reasons. The experimental group-control group design assures that the experimental manipulation was the only cause in the observed change of the dependent variable. This enables investigation of causal relationships between the variables.

The second control group ensured greater control over sensitization due to testing effects related to the completion of psychological measures. These psychological measures refer to items measuring Theoretical Model of Effortful Decision Making and Enactment variables that will be completed by the experimental and the first control group. It is possible that just by completing these measures which relate to the goal of managing their diabetes and to their intentions to perform self-monitoring of blood glucose participants could have changed their behaviors. This change in behavior would have been because the participants were sensitized to aspects related to managing their disease and performing SMBG. Thus the change in behavior would have had no relation to the implementation intention intervention but instead would have been an effect of the testing. This testing effect was controlled for with the inclusion of the

second control group. Control will be achieved by checking to see if there are any significant differences in the self-monitoring behavior as recorded in the diary and the two item recall measure related to performance of SMBG over the past seven days between the first and second control groups. If these two control groups are similar, then any change in the intervention group can be attributed solely to the experimental manipulation. If they were not similar, then it is possible that there were other extraneous variables including testing effects that could account for a difference in the SMBG.

The third control group ensured control over testing effects on the dependent variable. It was possible that just the act of keeping a prospective diary would have caused the participants in the experimental, first control and second control group to report increased frequency of SMBG. The third control group ensured that this testing effect was controlled for. This third group answered only two recall items related to performance of SMBG over the past fourteen days. If differences between the second control and third control group were seen on these two measures, this is evidence that the act of keeping the diary had an effect on the reporting of SMBG.

Randomization ensured that the experimental group and control groups did not differ at baseline.

Table 3.1 Experimental group-control group using randomization

	Time 1	Experimental manipulation	Time2 (two weeks subsequent to time 1)
[R] Experimental	Y_b + diary sent	X	diary plus 2 item recall measure
[R] First Control Group	Y_{bc1} + diary sent	~X	diary plus 2 item recall measure
[R] Second Control Group	diary sent	~X	diary plus 2 item recall measure
[R] Third Control group	2 item recall measure	~X	Not applicable

[R] denotes randomization

X denotes experimental manipulation

~X denotes no experimental manipulation,

Y_b , Y_{bc1} denotes scores for psychological measure from questionnaire for the respective groups

Diary refers to a log book which will be used to record self-monitoring behavior between Time1 and Time2

2 item recall measure refers to measure of SMBG frequency over the past 7 days

Experimental manipulation: forming implementation plans

The experimental manipulation was delivered in the questionnaire to the experimental group.

The experimental manipulation was designed to enable participants in the experimental group to form implementation plans. Participants in the experimental group were requested to complete a planning intervention with the following instructions:

An important goal for many diabetic patients on insulin is to test their blood sugar regularly. Please think about the goal of testing your blood sugar levels as recommended by your doctor over the next two weeks. With this goal in mind, we ask you to tell us in the table about when and where you will test your blood sugar daily.

Please fill out the following table with information about your plans to test your blood sugar over the next two weeks. Fill in the table for the number of blood sugar readings that you plan to take daily. For example, if you plan to test your blood sugar twice a day, fill in the table for ‘first blood sugar test of the day’ and ‘second blood sugar test of the day’.

Following these instructions, the participants were told to fill in a table about when, where and whether someone would help them perform their glucose tests. Before filling up the table with their plans, the participants were exposed to an example for filling up the table.

In order to get these participants to start thinking about their self-monitoring behavior additional questions were asked prior to the implementation intention manipulation. They were given the following instructions: **‘Finally, we would like you to make a plan for achieving your goal of managing your diabetes over the next two weeks. For each of the following questions, please tell us specifically how you plan to test your blood sugar over the next two weeks. Write your responses below in the space provided.’** This was followed by questions regarding how willing they were to manage their diabetes over the next two weeks and how many times per day they would check their blood sugar over the next two weeks. They were also asked how many times over the next two weeks they would test their blood sugar away from home, what things triggers their desire to test their blood sugar, questions regarding their glucometer and a question about whether someone will assist them in testing their blood sugar and if so, who it will be.

As the final portion of the experimental manipulation, the participants were told to close their eyes for a moment after they fill out their plans in the table and think about the plans they made. They were then be asked to answer an item

assessing how committed they are to following their plan to test their blood sugar. This item was measured on a five point scale with anchors as 'not committed at all', and 'very committed' with an endpoint of 'moderately committed'. This was aimed to help the participants commit to the plans they made.

Population description and sample selection

Inclusion and Exclusion criteria

Criteria for inclusion in the study were: 1) Diagnosed with type 1 and type 2 diabetes, 2) Age 18 and older, 3) Prescribed insulin regimen to control and manage diabetes, 4) Most recent HbA_{1C} greater than 7%, 5) Able to read and write English, 6) Those whose health care providers have recommended self-monitoring of blood glucose.

The rationale for inclusion criteria 4) was that HbA_{1C} less than 7% is the medical treatment goal for diabetics as recommended by the ADA.³⁹ This HbA_{1C} value was the last recorded value on the patient's records over a two year duration. Literature reveals that those who practice self-management behaviors such as self-monitoring have tighter blood glucose control.^{17, 18} Conversely, those that have adequate blood glucose control, practice SMBG more frequently than those who do not. Thus it was anticipated that those who have HbA_{1C} values below 7% are already practicing self-management behaviors and the experimental manipulation would not have made a significant impact on these behaviors. Inclusion criteria 5) was a requirement since the questionnaires will

be self-administered in English and thus the ability to read and understand English was crucial.

Exclusion criteria were: 1) Pregnant type 1 and type 2 diabetics. Pregnant women were excluded because it was anticipated that their diabetes and related health behaviors will be more closely monitored by health professionals and this may have had an impact on the intervention.

Identifying eligible participants. Eligible patients were identified from a southeastern Michigan healthcare system using an administrative database. Inclusion criteria 2), 3), and 4) was based on information in the database. For inclusion criteria 1) it was assumed that only diabetics will have been prescribed insulin. Thus those who are selected from the database as a result of inclusion criteria 2) are also assumed to have diabetes.

Inclusion criteria 5) and 6): Ability to read and write English was self-identified by the participants. Also, only those patients who reported that their doctor has recommended self-monitoring of blood glucose were included.

Exclusion criteria 1) was based on self-identified pregnant women.

Sample size determination

In order to determine the sample size, power analysis based on the ANOVA which was used to test the hypotheses for aim 1 of the study was conducted.¹⁰⁸ Also, sample size determination based on number of subjects required for Structural Equation Modeling (SEM) which was used to test the hypotheses for aim 2 was conducted. The higher of the two numbers based on

the two sample size determinations was set as the minimum sample size necessary for this study.

The ANOVA was used to detect differences between means of three groups. Statistical power, the probability of a type 1 error (α), and the effect size of the statistic must be specified to calculate the minimum sample size for power analysis.

Power has been defined as the probability of making the correct statistical decision ($1-\beta$). As a convention, Cohen suggests using 0.8 as the power and an α of 0.05.⁸¹

Cohen describes effect size (f) for ANOVA as the standardized difference between the population means. When the values of the means as well as the standard deviation are not known, Cohen suggests using standard criteria or index of $f=0.1$ for small effect size, $f=0.25$ for medium effect size and $f=0.4$ for large effect size. When the differences are very readily discernable by the observer without any effort, a large effect size is recommended.¹⁰⁹ The medium effect size is recommended when the effects are large enough when viewed by the observer but the changes are not as conspicuous as with the large effect size. When the effect is expected to be produce differences that are not readily discernable, a small effect size is recommended for use. For this study, an effect size of 0.4 was expected. This was based on previous research.^{83, 85, 87-88, 94}

Using the pre-determined values of power, effect size (d), significance level (α), and the number of groups, Cohen calculates the appropriate sample

size as 52 per group to test the first hypotheses.¹⁰⁸ This translated into $52*4=208$ total respondents since there were four study groups.

The rule of thumb to calculate sample size for SEM is that the ratio of sample size to parameters to be estimated should be at least 5:1 and as high as 10:1 if possible.¹¹⁰ In general a total of 100 participants per group is considered adequate. Thus the minimum number of responses required for SEM was 100 per group for the experimental and first control group since responses from only these two groups would be analyzed using SEM. Thus the minimum sample size= $100*4=400$.

Since the number obtained from sample size determination for SEM was higher than the number obtained through power analysis for ANOVA was 100 per group. Thus, the minimum sample size for the study was set to be 400 respondents.

Studies have shown that longitudinal health questionnaires have an overall response rate of up to 70%.^{111, 112} It was important to account for non response including in this study when calculating the sample size. In order to calculate sample size it was assumed that 15% of respondents will respond. The number of eligible participants that will be contacted was calculated as follows:

→ Number of eligible participants to be contacted (assuming only 15% will volunteer to participate in the study): $400*100/15 = 2666 \sim 2700$

Sampling and data collection

Patients identified from a southeastern Michigan healthcare system using an administrative database were randomized using simple random sampling into experimental and control groups. Five mailings were carried out to elicit patient responses. Refer to Table 3.2 for a timeline.

The total design method described by Dillman was used to collect the data.¹¹³ Dillman states that in order to achieve a high response rate for mail questionnaires, a variety of issues need to be addressed. These include wording of the items and the size and layout of the questionnaire. He also suggests that a pre-notification letter prior to the questionnaire being sent out, and follow up to nonrespondents increases response rates. Incentives and cover letters are also useful. This total design method suggested by Dillman, 1978 was adapted for use in this study.

Participants who returned all the study material were entered to win one of six 100 \$ raffles in order to reimburse them for their time and effort. Those who won the raffle were requested to fill a subject fee form. This subject fee form was a requirement of the University in order to reimburse the participants for participation.

Table 3.2 Data collection timeline

Letter	Time	Description	Group
	1 - 2 weeks before patient letters are mailed	Physician permission letter	All groups
1a	Time1	Patient recruitment letter + Diary + questionnaire + intervention + 2 item recall measure	Experimental group
1b	Time1	Patient recruitment letter + Diary + questionnaire + 2 item recall measure	1 st control group
1c	Time1	Patient recruitment letter + Diary + sociodemographic questionnaire + 2 item recall measure	2 nd control group
1d	Time1	Patient recruitment letter + 2 item recall measure questionnaire	3 rd control group
2	Time1 + 1 week	Reminder for questionnaire response	Nonresponders to questionnaire from Experimental, 1 st control group, 2 nd control group, 3 rd control group
3	Time1 + 2 weeks	First reminder for diary	1 st control group and 2 nd control
4	Time 1 + 2 to 3 weeks	First reminders for diary	Experimental group
5	Time 1 + 3 to 4 weeks	Second reminder for for diary	Experimental, 1 st control group and 2 nd control group

Physician Letter

A letter was mailed out to the physicians of participants identified as eligible for the study. This letter briefly described the study and asked the physicians to reply if they thought that their patient should not be enrolled into

this study. Participants who were deemed ineligible by their physician were excluded from the sample of participants to be contacted.

Questionnaire, diary and two item-recall measure

One to two weeks subsequent to sending the physician permission letter, the questionnaire and/or the diary and/or the two item recall measure was mailed to the participants.

Participants were randomized into one of four groups as follows: Eligible participants were entered into the SPSS software program and were then randomized using the randomization function into one of four groups. Participants received a packet specific to each study group based on their random selection into one of the four study groups. Participants in the experimental group received the questionnaire containing the psychological measures and sociodemographic information in addition to the experimental manipulation plus the diary which also contained the two item recall measure. Participants in the first control group received the questionnaire containing only the psychological measures and sociodemographic information plus the diary which also contained the two item recall measure. Participants in the second control group received the sociodemographic questionnaire containing only questions regarding sociodemographic information and the diary which also contained the two item recall measure. Participants in the third control group received the two item recall measure. All the participants also received the patient notification and consent letter. Participants were told to complete and

return the questionnaire if they wished to participate. Participants were also told to sign and return the patient notification and consent letter if they did not wish to participate and did not wish to be contacted again.

Participants from the experimental, first control group, second control and third control group were requested to return their questionnaires. Participants in the experimental group were told to put down the date of when they completed the questionnaire. This was to enable researchers to time the mailing of the first reminder to return diary to the experimental group.

Participants from the experimental, first control and second control group were instructed to fill in their SMBG behavior over the next two weeks in the diary.

One week subsequent to sending out the questionnaire and diary, a reminder postcard was sent to those from the experimental, first control group, second control group and third control group who did not return their questionnaires and who did not return the patient notification and consent letters indicating that they did not wish to be contacted again.

Each questionnaire and diary had a code which enabled identification of participants and allowed researchers to identify non-respondents as well as enabled mailing out the reminders. Participants had the same code assigned to the questionnaires as well as their diary to enable matching diaries to questionnaires. Participants were told about the code in the instructions to complete the questionnaire. No other identifying information such as the name of the participant was used. This helped minimize demand effects.¹¹⁴ One postage

paid envelope was sent along with the first packet to enable participants to return the questionnaire to the researchers. Another postage paid envelope was stapled to the diary to enable participants to return it after two weeks and to ensure that the participants do not return the diary along with the questionnaire.

Follow up

Approximately two to three weeks after sending out the questionnaire and diary, another mailing was carried out. For the first and second control group, this mailing was done two weeks subsequent to the mailing of the questionnaire. For the experimental group participants, this mailing was carried out 2 weeks from the date that they put down on their questionnaire. This was in order for the researchers to obtain experimental participants' self-monitoring behavior for two weeks subsequent to completing the intervention.

This mailing was only sent to those from the experimental, first control and second control group who respond to the questionnaire. For all the three groups, this mailing was the first reminder to return their diaries in the prepaid envelope stapled to their diaries.

A week subsequent to sending out the first reminders to return their diaries back, another reminder postcard was sent out to those from the three groups who returned questionnaires but did not return their diary even after the first reminder was sent out.

Study measures

Screening question

One question elicited information to enable screening eligible participants. Participants were asked if they are eligible for the study based on eligibility criterion noted in the cover letter. These eligibility criterion included inclusion criteria 3), 5) and 6) and exclusion criteria 2). This question had a yes/no response option. Those who marked 'no' to the question were not be eligible for participation

Doctor recommended levels of self-monitoring and current self-monitoring behavior

Doctor recommended levels of self-monitoring were assessed using one item. The item was: 'About how many times in a day has your doctor recommended you test your blood sugar? _____times.

Current levels of self-monitoring of blood glucose were also assessed using one item. This item was: 'I currently test my blood glucose as recommended by my doctor:'. It will be measured on a scale with five response options. The response options are: 1= 'never', 2 = 'occasionally', 3 = 'often', 4 = 'most of the time', and 5 = 'always'

Length of diabetes diagnosis

This information was collected because it was anticipated to influence self-monitoring behavior. Length of diabetes diagnosis will be collected by asking participants how long – in years and months, the participant has had diabetes.

Sociodemographic information

The sociodemographic information that was elicited was: age, gender, educational level, racial background, household income. These have been shown to affect self-monitoring of blood glucose in diabetic patients and hence were collected.¹⁶

Number of co-morbidities

Comorbidity information was collected because it was expected that it would affect self-monitoring behavior of the diabetic patients. Participants were asked to check their co-morbid conditions from among a list of the following conditions: Hypertension (High Blood Pressure), Heart Disease, Cancer, Stroke, Arthritis, Chronic Respiratory Disease such as Asthma, COPD and other (Please describe or list). These conditions were chosen based on the CDC's list of chronic diseases that cause the most significant impact on mortality in the US.³³ The participants were then categorized based on the number of comorbid conditions they self-report.

Theoretical Model Of Effortful Decision Making And Enactment measures

Most of the items used to measure the Theoretical Model Of Effortful Decision Making And Enactment were used from the study by Bagozzi et al.,²⁹ or by Dholakia et al..¹⁰⁶

Prior to questioning participants about the psychological measures related to the Theoretical Model of Effortful Decision Making and Enactment one item was administered. This item was designed to help the participants to start thinking about their personal goal of managing their diabetes. The following instructions preceded the item: 'Now we would like to get your reactions to managing your diabetes. Think about the management of your diabetes as a personal goal.' This was followed by the item: 'Please tell us to what extent managing your diabetes is a goal for you personally' which will be measured using a five point scale. The scale had the following anchors: 'not at all' and 'large extent' with a midpoint of 'moderate extent'.

Goal desire

Two items were used to measure goal desire.^{29, 106} Goal desire for the purpose of this study represented the desire of the participants to manage their diabetes. Two out of the three items used in the study by Bagozzi et al. to measure goal desire were used.²⁹ The two items were as follows:

'My desire to manage my diabetes over the next two weeks can best be described as:' using a five-point scale with the anchors being 'no desire at all'

and 'very high desire' and a midpoint of 'moderate desire'. This measure had mean values of 3.66 for control group and 5.98 for the experimental group when a seven-point scale was used in the study by Dholakia et al.⁷⁸

The second item was worded as follows: 'My overall wish to manage my diabetes over the next two weeks can be summarized as:' and have the following anchors, 'no wish at all,' and 'very strong wish' with a midpoint of 'moderate wish'. This item was also measured on a five point scale.

The third item from Bagozzi et al. study to measure goal desire was 'I feel an urge or need to attain the goals I have chosen'. This item was deleted from the pool of items used to measure goal desire in this study. In order for the intervention to be effective, it was imperative that the questionnaire was not long and tedious. Hence, the judgment was made to measure goal desire with only two items.

Goal intention

Goal intention was measured with two items. Goal intention for the purpose of this study represented the participants' intention to manage their diabetes.

The first item was: 'The strength of my actual intention to manage my diabetes over the next two weeks can best be described as', using a five point scale with response options 'no intention at all,' 'moderate intention,' and 'very strong intention'. This scale has been used by Dholakia et al.¹⁰⁶ In their study,

this item had mean values of 3.75 for the control group and 4.68 for the experimental group.

The second item stated, 'I actually intend to manage my diabetes over the next two weeks' and will have five response alternatives labeled 'not likely at all,' 'neither likely nor unlikely,' and 'very likely.' In the study by Bagozzi et al. used this item to measure implementation intention rather than goal intention as is done in this current study.²⁹ Further, Ajzen suggests using this item to measure intentions.⁶⁷⁻⁶⁹

Implementation desire

In order to measure implementation desire, two items out of the four items used to measure implementation desire in the study by Bagozzi et al., were used.²⁹ Implementation desire for the purpose of this study represented the desire of the participants to monitor their blood glucose over the next two weeks.

These items were, 'My desire to test my blood sugar over the next two weeks can best be described as:' using a five-point scale with the anchors being 'no desire at all' and 'very high desire' and a midpoint of 'moderate desire'. This measure had mean values of 4.00 for the control group and 5.39 for the experimental group when a seven-point scale was used in the study by Dholakia et al.¹⁰⁶

The second item was worded as follows: 'My overall wish to test my blood sugar over the next two weeks can be summarized as:' and have the following

anchors, 'no wish at all,' and 'very strong wish' with a midpoint of 'moderate wish'. This item was also measured on a five point scale.

The two additional items from Bagozzi et al. study were 'I feel an urge or need to perform the actions I listed' and 'I want to perform the actions I listed'.²⁹ These items were deleted from the pool of items used to measure implementation desire in this study. In order for the intervention to be effective, it is imperative that the questionnaire was not long and tedious. Hence, the judgment was made to measure implementation desire with only two items.

Implementation intention

Implementation intention for the purpose of this study represented the participants' intention to monitor their blood glucose over the next two weeks. Implementation intentions was measured with two items as used in the study by Bagozzi et al..²⁹

The first item was: 'The strength of my actual intention to test my blood sugar over the next two weeks can best be described as:', using a five point scale with response options 'no intention at all,' 'moderate intention,' and 'very strong intention'. This scale has also been used by Dholakia et al..⁷⁸ This item had mean values ranging from 3.98 to 4.98 for the control group and experimental groups using a seven-point scale.¹⁰⁶

The second item stated, 'I actually intend to test my diabetes over the next two weeks' and had five response alternatives labeled 'not likely at all,' 'neither likely nor unlikely,' and 'very likely.'

These two measures had sufficient reliability of 0.78 in the study by Bagozzi et. al..²⁹ Further, the summated mean value reported was 9.75 with a standard deviation of 1.51 with a range of 2 – 12. While the two scales used by Bagozzi et al. were a six point and five point scale, in this study, both items were measured using a five point scale.

Dependent variable: measure of behavior

Main outcome measure: Goal realization/frequency of self-monitoring of blood glucose using diary data

The dependent variable for this study was the frequency with which diabetic patients self-monitor their blood glucose. In relation to the theoretical framework, this formed the goal realization construct of the Theoretical Model of Effortful Decision Making and Enactment. Participants recorded their self-monitoring behavior over two weeks in a prospective diary.

Patients were instructed with the following:

'For each day over the next two weeks starting today, please keep a record of your blood sugar tests. In the space provided, tell us how many times you test your blood sugar. For instance, if you monitor your blood glucose levels three times today, write down 3 under the column that says 'Day 1'. Please return this diary to us after 2 weeks in the envelope stapled to this diary.'

This was followed by a table with the headings 'day 1' through 'day 14' to allow the participants to record how many times they performed SMBG over the course of 14 days.

Log books or prospective diaries have been used previously to assess self-monitoring behavior in diabetics.^{26, 115-116} The validity of this self-reported

data has also been assessed. In studies examining their validity, the diaries are compared with the glucometer readings. These diaries typically contain numerical recordings of blood glucose levels as reported by the patients.

Most studies evaluating the validity of the self-reported data look at three aspects of reporting: a) precision: whether the patient accurately reported the numerical value obtained by the glucometer. b) phantom logs: whether patients report values in the log books that are not present in the glucometer. c) omission: the underreporting of values in the log books when these values were present in the glucometers.

For the purpose of this study, the focus was whether or not the self-report on frequency of self-monitoring is a valid measure. Thus, assessing occurrence of phantom values and omission of values rather than numerical accuracy was important in order to verify the validity of this measure for the study.

Accordingly, one study assessed the accuracy of self-reported self-monitoring of blood glucose in pregnant diabetes women.¹¹⁷ This study found pregnant women with type 1 diabetes reported an average of 7.48 phantom values and those with type 2 diabetes reported an average of 3.6 phantom values and low rates of unlogged or omitted values. Compared with other diabetes types, pregnant type 2 diabetic women had the lowest rates of reporting phantom values as well as the lowest rates of omitted values.

Another study assessed the accuracy of reporting self-monitoring of blood glucose in adults with type 1 and type 2 diabetes in Canada.¹¹⁸ The study participants were part of two separate trials, one for a 12 month intensive

management for type 1 diabetes with 18 years as an average duration of diabetes. The other was for an 8 month nutrition education program for type 2 diabetics with an average duration of diabetes of 9 years. In both the studies, SMBG logbooks were part of the study protocol. The participant's logbooks were crosschecked with the glucometer readings in order to check for accuracy and reliability of the readings. This crosschecking was done for the initial and final 2 month period of each trial. For type 1 diabetic patients, 44% of the entries for the first 2 months were phantom entries. The number of phantom entries decreased significantly for this group over the duration of the study with only 5% of the entries being phantom entries during the last two months. Omitted values also decreased significantly from being 45% during the first two versus 8% during the last two months. For type 2 diabetic patients, 21% of the entries for the first 2 months and 25% of the entries for the final two months were phantom entries. Omitted values were not reported by the authors for type 2 patients.

In a study by Herndon et al., 2001, the accuracy of self-reports of blood glucose monitoring on type 2 geriatric patients was examined.¹¹⁹ A total of 472 usable diary readings were obtained from the participants. While the authors aggregated accuracy and phantom and omitted values together, and don't report separate results for each category, results indicate that fewer than 47 entries out of the 472 entries were errors. This means that phantom and omitted values represented <10% of the entries in the log books.

The studies reveal that inaccuracies in the self-report data for self-monitoring of blood glucose can range up to 20%.¹²⁰ Self reports to assess

adherence in general are not fool-proof.¹²⁰⁻¹²¹ However, diaries have been proven to be more accurate than patient interviews wherein patients are asked to answer questions recalling their self-monitoring behavior.¹²¹ Also, the control groups in this study ensured control over erroneous reporting of self-monitoring of blood glucose. For this study, the diary is an appropriate measure of self-monitoring behavior.

Secondary outcome measure: Goal realization/adherence to self-monitoring of blood glucose using a 2 item recall measure

The two-item recall measure to assess SMBG frequency was adapted from the revised Summary of Diabetes Self-Care Activities (SDSCA) by Toobert, Hampson, Glasgow, 2000.¹²² The SDSCA has been used to examine levels of self care to diabetes self-management behavior. The blood glucose testing component of the SDSCA is a two-item measure which was adapted for used in this study. These two items from the SDSCA are: 'On how many of the last SEVEN DAYS did you test your blood sugar?' and 'On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?'

These two items are measured on a seven point scale numbered 1 through 7.

The glucose testing component of the SDSCA has demonstrated inter-item correlation ranging from 0.69 - 0.75.¹²² It has also demonstrated test-retest reliability of 0.30 - 0.78.

The items in the current study were modified slightly to be applicable to this study. The first item used in this study was: 'on how many days over the past two weeks did you test your blood sugar?' where the participant were be told to enter the appropriate response in terms of number of days. The second item in this study was: 'how many days over the past two weeks did you test your blood sugar the number of times recommended by your doctor?' and the participants were told to fill in the appropriate response in terms of number of days blood sugar was tested over the past two weeks. In order to help frame the second item appropriately, it was preceded by the item: 'how many times has your doctor recommended you test your blood sugar?' with the response option of _____times.

Questionnaire Design

The questionnaire was designed to elicit measures with respect to the Theoretical Model of Effortful Decision Making and Enactment and also serve as a tool to deliver the experimental manipulation. It also enabled elicitation of sociodemographic information, information regarding co-morbidities and diabetes related information.

Description of the questionnaires

Questionnaire: Sent to the experimental and first control group. This questionnaire contained the following: the screening questions, current self-monitoring behavior, sociodemographic information, co-morbid conditions, length

of diabetes diagnosis and the Theoretical Model of Effortful Decision Making and Enactment measures. It was sent to the experimental and first control group.

Sociodemographic questionnaire: Sent to the second control group

This questionnaire contained the following: the screening questions, sociodemographic information. It was sent to the second control group.

Diary: Sent to experimental, first control and second control groups. The diary contained the dependent variable and was sent to all three groups.

Two item recall measure: Sent to experimental, first control, second control and third control group. The diary also contained the two item recall measure for the experimental, first control and second control group.

The two item recall measure was the only measure that was completed by the third control group.

Pilot test

In order to ensure clarity of the items in the questionnaire as well as the intervention and to ensure that no items in the questionnaires were ambiguous or redundant, pilot testing was conducted.

This pilot test was conducted on 10 diabetics for the first questionnaire plus experimental manipulation designed for the experimental group. The diary

plus two item recall measure was also tested on the same set of 10 diabetic patients. The pilot test participants were given 10 \$ for their time and effort.

The questionnaire designed for the experimental groups contained all the items that were used for the questionnaire for the first control and second control group. Also, the diary and the two item recall measure was the same across all the groups. Thus pilot testing the questionnaire designed for the experimental group ensure that all the items included in the questionnaires for all the groups were pilot tested as was the diary and the two item recall measure.

This pilot test also ensured that the questionnaire was well suited for the patient population.

Analysis plan

Data were coded and subsequently analyzed using SPSS and LISREL. In order to test the accuracy of coding and data entry, some of the data entered were randomly selected and compared with the hardcopy of the questionnaires.

The sociodemographic information, number of comorbidities and length of diabetes diagnosis were used to compare the experimental groups and control groups using t-tests and ANOVA for continuous variables and chi-square tests for discrete variables as applicable at alpha equal to 0.05. No difference between groups was expected since the study patients were assigned randomly.

This study attempts to investigate whether making implementation plans were indeed effective strategies to improve rates of health related behaviors in diabetic patients.

Aim 1: To determine if formulating implementation plans increases the rates of self-management behaviors.

Hypothesis 1: Participants who form implementation plans will have higher levels of SMBG as measured by the diary compared to those who don't.

Hypothesis 2: Participants who form implementation plans will have higher levels of SMBG as measured by the first recall measure compared to those who don't.

Hypothesis 3: Participants who form implementation plans will have higher levels of SMBG as measured by the second recall measure compared to those who don't.

The hypotheses for the first study aim was tested using the ANOVA at alpha equal to 0.05. This determined if the dependent variable was significantly different between the experimental, first control group and second control group.

Aim 2: To determine the relationship between goal desires, goal intentions, implementation desires and implementation intentions.

Hypothesis 4: The greater the goal desire the greater the goal intention.

Hypothesis 5: The greater the goal intention the greater the implementation desire.

Hypothesis 6: The greater the implementation desire, the greater the implementation intention.

Aim 3: To determine the relationship between implementation intentions and self-monitoring behavior

Hypothesis 7: The greater the implementation intention the greater the performance of SMBG as measured by diary.

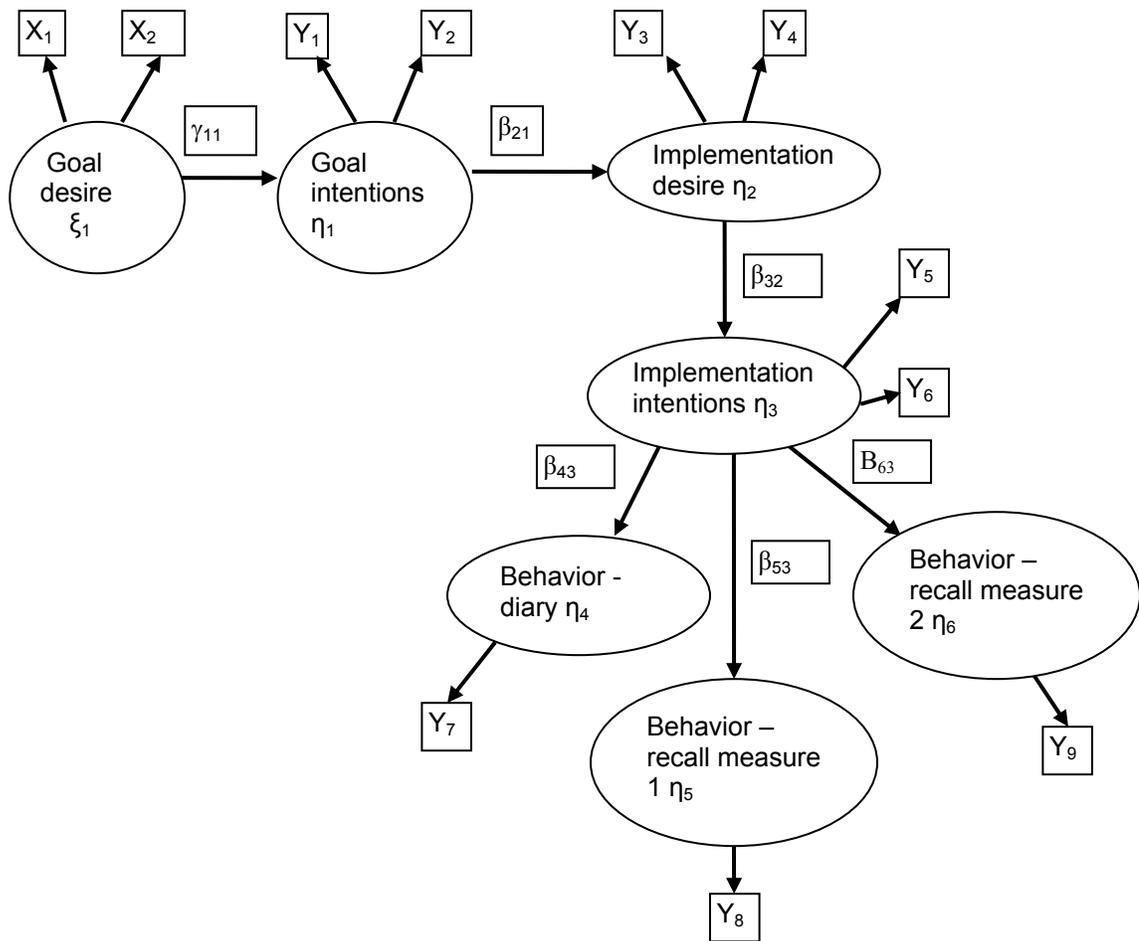
Hypothesis 8: The greater the implementation intention the greater the performance of SMBG as measured by the first recall measure.

Hypothesis 9 The greater the implementation intention the greater the performance of SMBG as measured by the second recall measure.

Structural equation modeling (SEM) was used to test the validity of the Theoretical Model Of Effortful Decision Making And Enactment in this population. Specifically hypotheses 4 - 9 were tested using SEM at an a priori significance level of 0.05. Figure 3.1 illustrates the relationships that were tested using SEM. In SEM, the goodness-of-fit of the hypothesized model was tested based on the chi-square test and other indices. The other indices were used because of the sensitivity of the chi square test to sample size. These other indices include the root mean square error of approximation (RMSEA), the non-normed fit index (NNFI), the comparative fit index (CFI), and the standardized root mean square residual (SRMR). A non-significant chi square, RMSEA and SRMR values of 0.08 or lower; NNFI and CFI value of 0.9 or greater indicate satisfactory goodness of fit.¹²³

Reliability tests were run for the multi-item Theoretical Model Of Effortful Decision Making And Enactment measures using Cronbach's alpha with a level of 0.7 or higher considered acceptable as suggested by Nunnally.¹²⁴

Figure 3.1 Relationships that will be tested using SEM



CHAPTER IV

RESULTS

Introduction

This chapter is divided into five sections: The first section describes the results of the pilot test. The second section describes the response rates for this study. In the third section general descriptive statistics for the study sample are presented. These include means, standard deviations, and frequency distributions. This section also describes group differences in terms of sociodemographic variables as well as health related information and diabetes related information. The fourth section describes results from the ANOVA test which examines the first aim of the study. This section also describes whether data fit assumptions for the ANOVA test. In addition, this section describes post-hoc Scheffe tests. The fifth section describes the SEM analyses which test the second and third aims of the study. In addition, means and standard deviations as well as reliability analyses for the psychological measures are also described in this section.

Pilot test

The pilot test was conducted on ten type 1 and type 2 diabetic patients. It was conducted in order to ensure clarity of the items, ease of reading and to elicit opinions regarding the layout of the questionnaire. Pilot test participants' opinions were also elicited regarding the layout of the table to enter SMBG plans. On the basis of the pilot test, certain parts of the questionnaire and diary were revised.

The pilot test was also used to understand if the diabetic patients were interpreting the questions as anticipated. For instance, it was important to understand if the patients were distinguishing between 'managing diabetes' and 'testing blood sugar'. In order to understand whether the questions were being interpreted appropriately, participants were asked to describe what they thought each question meant. This was done after the pilot test participants completed the questionnaire. The pilot testing also enabled an estimation of the time taken to complete the questionnaire.

Participants indicated that all the questions were clear and unambiguous. In terms of the layout of the questionnaire and table, the pilot test revealed that the layout was considered appropriate. Pilot test participants liked the layout of the questionnaire in terms of the font and spacing and did not think that it needed any changes. In addition, the pilot test participants also indicated that the layout of the table in which to write their plans for SMBG was simple and well thought out

All the participants were able to distinguish between 'managing diabetes' and 'testing blood sugar'. Pilot test participants thought that managing diabetes included a variety of behaviors such as visiting the doctor, diet control, exercise and SMBG. Testing of blood sugar on the other hand was thought to be a specific behavior that involved testing their blood sugar using glucometers at home.

Three participants were not able to distinguish between the items regarding desire and intention. They perceived the items related to desire and intention to be very similar. In spite of these results from the pilot test, the questionnaire was not modified for a couple of reasons. First, this problem was expressed by only 3 out of 10 pilot test participants. Moreover, it was not unexpected to have some pilot test participants suggest that the items were very similar since these two constructs are very conceptually closely related and thus appear very similar. In addition, the items related to these two constructs have only been used in a student population prior to this study. Students are expected to be more in tune with the subtleties and nuances of item wording as opposed to a more heterogeneous general population. In the end, the decision was made to retain all the items and SEM analyses, testing would help examine if the participants construed the items as having the same underlying construct or two different constructs as was hypothesized.

Participants took an average of 10 -11 minutes to complete the questionnaire. The pilot test participants were requested to fill out the questionnaire for the experimental group, which was the longest questionnaire in

the study. Consequently, it was anticipated that the other questionnaires would take less than ten minutes to fill out.

Participants had some additional suggestions. They thought that the first page of the questionnaire should clearly state that the questionnaire should be returned immediately. They also suggested that the first page of the diary should indicate that the diary should be kept, filled out and returned after fourteen days. This would eliminate confusion regarding when the two should be returned. This wording was included in the final version of the questionnaire and diary.

Questionnaire response

Response rate

The questionnaire was mailed randomly to a sample of type 1 and type 2 diabetic patients. This sample was drawn from the administrative database of a healthcare system in the southeast Michigan area, described in Chapter 3. Table 4.1 describes the number of diabetic patients that were contacted and the number that returned the questionnaires.

Table 4.1 Questionnaire response rate

	Experimental group	First control group	Second control group	Third control group
Mailed	675	675	675	544
Not contacted ^a	3	5	5	9
Gross potential returns (GPR)	672	670	670	535
Refused to participate	25	25	22	18
Ineligible	11	11	8	17
Questionnaires returned (SR)	111	148	104	114
Diaries returned	96	119	73	NA
Returned and usable ^b (RU)	96	119	73	114
Gross response rate	16.52%	22.09%	15.52%	21.38%
Net response rate	14.29%	17.76%	10.90%	21.38%

^a Bad mailing address

^b For experimental, 1st and 2nd control group: those who have returned both questionnaire and diary

NA Not applicable

Experimental group: Completed experimental manipulation, psychological measures, sociodemographic information, diary and recall measures

1st control group: Completed psychological measures, sociodemographic information, diary and recall measures

2nd control group: Completed sociodemographic information, diary and recall measures

3rd control group: Completed recall measures

The questionnaire and/or diary were sent to 2025 diabetic patients of which 22 were not deliverable because of bad mailing addresses.

For the purpose of this study, gross response rates were calculated as follows:

$$\text{Gross response rate} = \frac{\text{SR}}{\text{GPR}}$$

The gross response rates varied from 15.52% to 22.09%. The overall gross response rate for the study is: 18.57%

In addition, the net response rate for this study was calculated as follows:

$$\text{Net response rate} = \frac{\text{RU}}{\text{GPR}}$$

The net response rates varied from 10.90% to 21.38%. The overall net response rate for the study was: 15.65% which resulted in a total sample size of 402 respondents across four groups.

Differences between groups in response rates

Differences between the groups on either of these chi square tests would suggest a bias, which could be a result of completing the questionnaire and/or the diary. If differences in the response rates were found, it might be an indication that the results were biased. A chi-square test was conducted to determine if there were differences in the net response rates between the four groups. The tests reveal that there were no differences in terms of net response rate ($X^2=3.79$, $df=3$, $p=0.29$). Chi-square tests were also conducted on the

number of diaries (RU) returned by those in the experimental, first control and second control group who had initially returned their questionnaires (SR). Chi-square tests reveal no differences between the groups ($\chi^2=1.717$, $df=3$, $p=0.42$)

The chi-square tests indicate that there were no differences between the groups in terms of net responses or the number of patients who returned their diaries after their initial questionnaire response.

Description of the sample

This section will describe the sociodemographic characteristics of the sample. It will also report health related information. This section only focuses on the respondents from the experimental, first and second control group since sociodemographic and health related information for the third control group was not elicited. Diabetes related information is also reported in this section. This information pertains to only the experimental and the first control group, since this information was not collected from the second control group or the third control group.

Socio-demographic information

Table 4.2 describes the socio-demographic characteristics of the participants of this study. The average age of the respondents was about 62 years with respondents ranging in age from 25 - 92 years. In addition, a majority (60%) of the respondents were female. The total number of comorbid conditions ranged from 0 - 7 with a mean of 1.51 (SD=1.587) comorbid conditions.

Both African Americans and Caucasians were equally represented in the population. African Americans constituted 45.3% of the sample while Caucasians formed about 47.1% of the sample population. Hispanics made up 2.5% of the population while Asians/Pacific Islanders and Native Americans made up 1.8% of the sample respectively. About 1.4% of the respondents indicated their race as 'other'.

In terms of education, 34.8% of the respondents indicated having some college education and 26.4% indicated that they were high school graduates. Further, 17% indicated they had a bachelor's degree and 13.7% said they had a professional/graduate degree. The median household income for the respondents was between \$35,001 and \$55,000.

Differences between groups on sociodemographic information

Differences between the groups in terms of sociodemographic information were assessed using chi-square tests for categorical variables and ANOVA for continuous variables. This testing was carried out to ensure that the groups were similar in terms of sociodemographic characteristics. Tests indicate that the three groups were similar in terms of sociodemographic characteristics. These tests are depicted in Table 4.2.

Comparison between study sample and Detroit population

Differences in between study sample and Detroit population was assessed for gender and race using chi-square tests. The chi-square tests revealed that

there were no differences between the sample and Detroit population for gender but in terms of the racial composition, the sample differed from the Detroit population.

Table 4.2 Sociodemographic characteristics for experimental, first control and second control groups

	n (%)	X² (df)	Sig.
Education (n=276)			
grade school	6 (2.2)	3.708 (10)	0.960
some high school	16 (5.7)		
high school graduate	74 (26.7)		
some college	96 (34.7)		
bachelor degree	47 (17.0)		
professional degree/graduate degree	38 (13.7)		
Race (n=276)			
African American	125 (45.2)	12.536 (10)	0.251
Asian or Pacific Islander	5 (1.8)		
Caucasian	131 (47.3)		
Native American	5 (1.8)		
Hispanic	7 (2.5)		
Other	4 (1.4)		
Gender (n=275)			
Female	110 (40)	2.624 (2)	0.269
Male	165 (60)		
Household Income (n=259)			
Less than \$10,000	18 (6.9)	12.996 (12)	0.369
\$10,000 - \$18,500	45 (17.4)		
\$18,501 - \$35,000	45 (17.4)		
\$35,001 - \$55,000	57 (22.0)		
\$55,001 - \$88,000	50 (19.3)		
\$88,001 - \$100,000	16 (6.2)		
More than \$100,000	28 (10.8)		
	Mean (SD)		
Age (n=239)	61.79 (11.93)	0.765	0.467
Total number of comorbidities (n=252)	2.10 (1.51)	0.936	0.394

Health related information

Comorbidity information was elicited from the experimental, first control and second control group. Approximately 70% of these respondents indicated that they were suffering from hypertension. Further, about 38% self reported arthritis as a comorbidity and 21% indicated that they also had heart disease in addition to diabetes. Cancer was a comorbid condition for 10.3% of the respondents in the three groups, chronic respiratory disease for 13.8% of the respondents and stroke for 5.3% of the respondents. In addition, 24.8% of the respondents in the experimental, first and second control groups indicated that they had some other comorbid condition not listed on the questionnaire. Information about comorbid conditions is presented in Table 4.3.

Differences between groups for comorbidities

In order to compare the three groups in terms of comorbidities, an ANOVA was conducted on the total number of comorbidities self-reported by the respondents. The ANOVA was non-significant indicating that the respondents from the three groups were similar in terms of the total number of comorbid conditions.

Table 4.3 Comorbidity information for experimental, first and second control group

Comorbidity (n=282)	n (%)
Hypertension	197 (69.9)
Heart Disease	58 (20.6)
Cancer	29 (10.3)
Stroke	15 (5.3)
Arthritis	106 (37.6)
Chronic Respiratory Disease	39 (13.8)
Number of 'other' comorbidities	
1	33 (47.1)
2	24 (34.3)
3	11 (15.7)
4	2 (2.9)

* Percentages will not add up to a 100 since respondents could indicate more than one comorbidity.

Diabetes related information

Diabetes related information was elicited from the experimental and first control group respondents. The descriptive statistics for the four items in the questionnaire which elicited diabetes related information is depicted in Table 4.4 by group and a combined total of the two groups.

Table 4.4 Descriptive statistics for diabetes related information

Item	n	Mean (SD)
About how many times in a day has your doctor recommended you test your blood sugar?	204	2.89 (1.20)
I currently test my blood sugar as recommended by my doctor*	207	3.89 (1.11)
Please tell us to what extent managing your diabetes is a goal for you personally? **	206	4.55 (0.73)
How long have you had diabetes? ***	204	15.66 (12.45)

* 1=Never, 2=Occasionally, 3=Often, 4=Most of the times, 5=Always

**1=Not at all 3=Moderate extent 5=Large extent

*** years

Differences between groups on diabetes related information

The responses to diabetes related information were also examined for differences between the two groups. The examination of differences revealed that those in the experimental and first control groups did not differ in terms of the number of times in a day that their doctor had recommended testing of blood sugar, the number of times they currently tested their blood sugar as recommended by their doctor. The two groups also were not significantly different in terms of the extent to which managing diabetes was a personal goal and in terms of how long they had diabetes. Results from these t-tests are presented in Table 4.5.

Table 4.5 T-tests for differences between groups for diabetes related information

Item	n	F	Sig.
About how many times in a day has your doctor recommended you test your blood sugar?	204	1.537	0.216
I currently test my blood sugar as recommended by my doctor*	207	0.734	0.393
Please tell us to what extent managing your diabetes is a goal for you personally? **	206	0.658	0.418
How long have you had diabetes? ***	204	0.960	0.328

* 1=Never, 2=Occasionally, 3=Often, 4=Most of the times, 5=Always

**1=Not at all 3=Moderate extent 5=Large extent

*** years

Descriptive statistics of psychological measures

In order to get an understanding of the normality of the psychological measures, frequency distributions were examined. The possible responses to these measures ranged from 1 to 5. The frequency distribution for the eight measures is given below in Table 4.6. The means and standard deviations of the psychological measures are given in Table 4.7.

Table 4.6 Percentage distribution of responses to psychological measures

Item	1	2	3	4	5
My desire to manage my diabetes over the next two weeks can best be described as ^a	0.0	0.5	9.7	22.7	67.1
My overall wish to manage my diabetes over the next two weeks can be summarized as ^b	0.0	0.5	8.2	21.3	70.0
The strength of my actual intention to manage my diabetes over the next two weeks can best be described as ^c	0.0	2.3	9.2	24.2	64.3
I actually intend to manage my diabetes over the next two weeks ^d	0.0	2.4	2.9	19.4	75.3
My desire to test my blood sugar over the next two weeks can best be described as ^e	0.5	3.9	7.2	16.9	71.5
My overall wish to test my blood over during the next two weeks can be summarized as ^f	0.0	3.9	6.3	15.9	73.9
The strength of my actual intention to test my blood sugar over the next two weeks can best be described as ^g	0.0	2.9	5.8	16.4	74.9
I actually intend to test my blood sugar over the next two weeks ^h	0.0	1.9	4.3	11.1	82.7

^a 1=No desire at all, 3=Moderate desire, 5=Very high desire

^b 1=No wish at all, 3=Moderate wish, 5=Very high wish

^c 1=No intention at all, 3=Moderate intention, 5=Very high intention

^d 1=Not likely at all, 3=Neither likely nor unlikely, 5=Very likely

^e 1=No desire at all, 3=Moderate desire, 5=Very high desire

^f 1=No wish at all, 3=Moderate wish, 5=Very high wish

^g 1=No intention at all, 3=Moderate intention, 5=Very high intention

^h 1=Not likely at all, 3=Neither likely nor unlikely, 5=Very likely

Table 4.7 Means and standard deviations of the psychological measures

Item	Mean (SD)
My desire to manage my diabetes over the next two weeks can best be described as ^a	4.57 (0.686)
My overall wish to manage my diabetes over the next two weeks can be summarized as ^b	4.61 (0.658)
The strength of my actual intention to manage my diabetes over the next two weeks can best be described as ^c	4.50 (0.762)
I actually intend to manage my diabetes over the next two weeks ^d	4.67 (0.652)
My desire to test my blood sugar over the next two weeks can best be described as ^e	4.55 (0.828)
My overall wish to test my blood over during the next two weeks can be summarized as ^f	4.60 (0.775)
The strength of my actual intention to test my blood sugar over the next two weeks can best be described as ^g	4.63 (0.724)
I actually intend to test my blood sugar over the next two weeks ^h	4.75 (0.627)

^a 1=No desire at all, 3=Moderate desire, 5=Very high desire

^b 1=No wish at all, 3=Moderate wish, 5=Very high wish

^c 1=No intention at all, 3=Moderate intention, 5=Very high intention

^d 1=Not likely at all, 3=Neither likely nor unlikely, 5=Very likely

^e 1=No desire at all, 3=Moderate desire, 5=Very high desire

^f 1=No wish at all, 3=Moderate wish, 5=Very high wish

^g 1=No intention at all, 3=Moderate intention, 5=Very high intention

^h 1=Not likely at all, 3=Neither likely nor unlikely, 5=Very likely

An examination of the frequencies and means indicates that the respondents tended to respond to the psychological measures with a '4' or '5' score. In order to further understand the normality of the measures, skewness

was calculated. A value of -1 to +1 indicates a normal distribution.¹²⁵ The skewness ranged from -1.378 to -2.710 indicating that all the measures had a greater number of positive values. This was evident from the means of the psychological measures as well which ranged from 4.50 to 4.75.

Reliability information for the four constructs of the theoretical framework is presented in Table 4.8. Reliability is presented in terms of Cronbach's alpha which provides information about the internal consistency of items.¹²⁶ It is recommended for use only if the items are believed to represent only one factor. The Cronbach's alpha for the four constructs were greater than 0.80. This is considered acceptable in the social sciences.¹²⁷ In addition, Table 4.8 also contains the Pearson's correlation coefficient since each of the four constructs is measured by only 2 items. In such cases, the Pearson's correlation coefficient is relevant.

Table 4.8 Cronbach's alpha for theoretical constructs

Construct	n	Number of items	Cronbach's alpha	Pearson's r
Goal desire	207	2	0.878	0.782*
Goal intention	206	2	0.851	0.749*
Implementation desire	207	2	0.945	0.898*
Implementation intention	207	2	0.884	0.801*

* $\alpha=0.01$

Differences between groups on psychological measures

In order to examine if the means of the psychological measures of desire and intention to manage diabetes as well as test blood sugar differed between the experimental and first control group. T-tests indicate that the means were not significantly different between the two groups as illustrated in Table 4.9.

Table 4.9 t-tests for between group differences on psychological measures

Item	F	Sig.
My desire to manage my diabetes over the next two weeks can best be described as ^a	0.118	0.731
My overall wish to manage my diabetes over the next two weeks can be summarized as ^b	0.001	0.971
The strength of my actual intention to manage my diabetes over the next two weeks can best be described as ^c	0.018	0.894
I actually intend to manage my diabetes over the next two weeks ^d	0.093	0.760
My desire to test my blood sugar over the next two weeks can best be described as ^e	0.080	0.778
My overall wish to test my blood over during the next two weeks can be summarized as ^f	0.038	0.845
The strength of my actual intention to test my blood sugar over the next two weeks can best be described as ^g	0.029	0.866
I actually intend to test my blood sugar over the next two weeks ^h	0.316	0.575

^a 1=No desire at all, 3=Moderate desire, 5=Very high desire

^b 1=No wish at all, 3=Moderate wish, 5=Very high wish

^c 1=No intention at all, 3=Moderate intention, 5=Very high intention

^d 1=Not likely at all, 3=Neither likely nor unlikely, 5=Very likely

^e 1=No desire at all, 3=Moderate desire, 5=Very high desire

^f 1=No wish at all, 3=Moderate wish, 5=Very high wish

^g 1=No intention at all, 3=Moderate intention, 5=Very high intention

^h 1=Not likely at all, 3=Neither likely nor unlikely, 5=Very likely

ANOVA test for Aim 1

Tests for assumptions about ANOVA

Testing was done in order to assess if the data met assumptions for ANOVA. ANOVA is based on four assumptions: randomness, independence, homogeneity of variance and normality.¹²⁵

The data were assumed to be random and independent since the study design was an experimental design based on a random sample of eligible participants and random allocation to the study groups. Selected eligible participants were randomly assigned to one of four study groups. To test for homogeneity of variance the Levene statistic was computed.¹²⁵ A non-significant Levene statistic indicates that the variance is equal. For all the behavioral measures that would be subject to the ANOVA test, the Levene's test was non significant indicating that the assumption for the homogeneity of variance was met. The test to assess for normality of distribution of scores of the dependent variables is to examine the skewness. The skewness test indicates how much the distribution departs from normality. A value of -1 to +1 indicates a normal distribution. A skewness value of 0.971 (SE=0.145) for the total SMBG score over 14 days indicated normal distribution. However for the recall items, the skewness values indicated that they violated the assumption of normality. For the first recall measure the skewness value was 4.404 (SE=0.127) and for the second recall measure the skewness value was 2.556 (SE=0.127). Histograms and boxplots were examined to assess whether the distribution of the recall measures was bimodal. An examination of the graphs showed that the

distribution was unimodal indicating that the ANOVA was still robust enough to compare mean differences.^{125, 128}

ANOVA tests

Table 4.10 depicts the ANOVA test for the first behavioral measure – frequency of SMBG using a diary. The dependent measure for this ANOVA was the sum of the number of times over the past fourteen days that the participants performed SMBG. This test was run for the experimental, first control and second control groups since the third control group did not complete a diary and hence this measure was not available for that group. The ANOVA was significant indicating that there were differences between the three groups in terms of how many times in total they performed SMBG over the past fourteen days. In order to assess which groups were different for this measure, post-hoc Scheffe tests were carried out.

The post hoc Scheffe t-test for this measure indicates that the experimental group was significantly different compared to both, the first and the second control groups. In addition, the Scheffe t-test also indicates that the first and second control groups were not different from each other as evidenced by a non-significant t-test. The Scheffe tests are presented in Table 4.11.

Table 4.10 ANOVA to test the effect of intervention for diary

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	3112.409	2	1556.204	4.965	.008
Within Groups	87445.080	279	313.423		
Total	90557.489	281			

Table 4.11 Post-hoc Scheffe tests to determine differences between groups

Dependent Variable	(I) Group	(J) Group	Mean Difference			95% Confidence Interval	
			(I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
Sum total of diary	1 ^a	2 ^b	6.419 [*]	2.455	.034	.38	12.46
		3 ^c	7.766 [*]	2.766	.021	.96	14.57
	2 ^b	1 ^a	-6.419 [*]	2.455	.034	-12.46	-.38
		3 ^c	1.347	2.661	.880	-5.20	7.89
	3 ^c	1 ^a	-7.766 [*]	2.766	.021	-14.57	-.96
		2 ^b	-1.347	2.661	.880	-7.89	5.20

*. The mean difference is significant at the 0.05 level.

^a Experimental group

^b First control group

^c Second control group

Table 4.12 depicts results from the ANOVA which tested differences between all four groups for the first recall measure. The ANOVA test for this behavioral measure was significant. This indicates that the four groups differed on the behavioral measure related to how many days over the fourteen days they tested their blood sugar. Post-hoc Scheffe tests were subsequently undertaken

for this behavioral measure as depicted in Table 4.13. The post-hoc Scheffe tests for the first recall measures reveal that mean differences between the experimental and third control group as well as the first control and third control group were significant. None of the other groups exhibited statistically significant differences.

Table 4.12 ANOVA to test the effect of intervention for first recall measure

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	144.630	3	48.210	5.876	.001
Within Groups	2822.138	344	8.204		
Total	2966.767	347			

Table 4.13 Post-hoc Scheffe tests to determine differences between groups

Dependent Variable	(I) Group	(J) Group	Mean Difference			95% Confidence Interval	
			(I-J)	Std. Error	Sig.	Lower Bound	Upper Bound
First recall measure	1 ^a	2 ^b	.210	.419	.969	-.97	1.39
		3 ^c	1.040	.470	.181	-.28	2.36
		4 ^d	1.560*	.425	.004	.37	2.75
	2 ^b	1 ^a	-.210	.419	.969	-1.39	.97
		3 ^c	.830	.455	.346	-.45	2.11
		4 ^d	1.351*	.409	.013	.20	2.50
	3 ^c	1 ^a	-1.040	.470	.181	-2.36	.28
		2 ^b	-.830	.455	.346	-2.11	.45
		4 ^d	.521	.461	.735	-.77	1.82
	4 ^d	1 ^a	-1.560*	.425	.004	-2.75	-.37
		2 ^b	-1.351*	.409	.013	-2.50	-.20
		3 ^c	-.521	.461	.735	-1.82	.77

*. The mean difference is significant at the 0.05 level.

^a Experimental group

^b First control group

^c Second control group

^d Third control group

Table 4.14 shows the results obtained from testing the differences between the four groups on the second recall measure using an ANOVA. This ANOVA was significant indicating that the respondents from the four groups were not similar in terms of their response to how many times over the past two weeks they performed SMBG as recommended by their doctor. Post-hoc Scheffe tests

were conducted to examine which groups differed on this measure. Table 4.15 depicts results from the post-hoc Scheffe tests. Experimental group was statistically significant from the third control group. The other groups were not different in terms of the mean difference for the second recall measure.

Table 4.14 ANOVA to test the effect of intervention for second recall measure

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	225.760	3	75.253	3.585	.014
Within Groups	7221.909	344	20.994		
Total	7447.670	347			

Table 4.15 Post-hoc Scheffe tests to determine differences between groups

Dependent Variable	(I) Group	(J) Group	Mean Difference			95% Confidence Interval		
			(I-J)	Std. Error	Sig.	Lower Bound	Upper Bound	
Second recall measure	1 ^a	2 ^b	1.4458	.6702	.201	-.437	3.329	
		3 ^c	2.0181	.7512	.067	-.092	4.129	
		4 ^d	1.9768*	.6799	.039	.067	3.887	
		2 ^b	1 ^a	-1.4458	.6702	.201	-3.329	.437
			3 ^c	.5724	.7286	.892	-1.475	2.619
			4 ^d	.5311	.6549	.883	-1.309	2.371
		3 ^c	1 ^a	-2.0181	.7512	.067	-4.129	.092
			2 ^b	-.5724	.7286	.892	-2.619	1.475
			4 ^d	-.0413	.7375	1.000	-2.113	2.031
		4 ^d	1 ^a	-1.9768*	.6799	.039	-3.887	-.067
			2 ^b	-.5311	.6549	.883	-2.371	1.309
			3 ^c	.0413	.7375	1.000	-2.031	2.113

*. The mean difference is significant at the 0.05 level.

^a Experimental group

^b First control group

^c Second control group

^d Third control group

Structural equation modeling for Aim 2 and 3

Structural equation modeling (SEM) techniques were used to assess hypotheses 4 - 9. This analysis was run on data collected from the experimental group and the first control group since only these two groups completed the psychological measures as well as the behavioral measures. The correlations between the psychological variables and behavior are presented in Table 4.16.

Several parameters test the goodness of model fit in SEM.¹²³ A non-significant chi square test indicates a model of good fit. However, because the chi square test is sensitive to sample size other indices are also used to test the goodness of fit. A value of 0.08 or lower for the root mean square error of approximation (RMSEA) and the standardized root mean square residual (SRMR) indicates a good model. Two other measures of goodness of fit used in evaluating the model are the non-normed fit index (NNFI) and the comparative fit index (CFI) where a value of 0.9 or greater indicate a good model fit.¹²³

Table 4.16 Correlations between psychological variables and behavioral measures

Factor	GD1	GD2	GI1	GI2	ID1	ID2	II1	II2	Beh1	Beh2	Beh3
Goal desire1 (GD1)	1										
Goal desire2 (GD2)	0.782**	1									
Goal intention1 (GI1)	0.745**	0.808**	1								
Goal intention2 (GI2)	0.684**	0.668**	0.751**	1							
Implementation desire1 (ID1)	0.579**	0.459**	0.625**	0.545**	1						
Implementation desire2 (ID2)	0.622**	0.537**	0.659**	0.591**	.895**	1					
Implementation intention1 (II1)	0.622**	0.560**	0.731**	0.643**	0.795**	0.837**	1				
Implementation intention2 (II2)	0.468**	0.408**	0.529**	0.552**	0.691**	0.739**	0.796**	1			
Diary (Beh1)	0.147*	0.080	0.157*	0.130	.092	0.129	0.163*	0.130	1		
Recall measure1 (Beh2)	0.080	0.067	0.087	0.082	0.061	0.050	0.044	0.053	-0.060	1	
Recall measure2 (Beh3)	0.083	0.073	0.155*	0.123	0.150*	0.127	0.165**	0.135	0.198**	0.215	1

* $p \leq 0.05$

** $p \leq 0.01$

Listwise $n=193$

Analyses using structural equation modeling was carried out in the following steps:

Step 1: In order to test hypotheses 4 - 9 and consequently the theoretical framework hypothesized in the study, structural equation modeling was carried out. The model fit statistics are depicted in Table 4.17. The parameters other than the chi-square test indicate that this model has a good fit. The amount of variance of goal intentions, implementation intentions, implementation desire and the three measures of self-monitoring behavior are presented in Figure 4.1 as are other parameters.

Step 2: To test for mediation, all the paths between goal desire to implementation desire, implementation intention and the three behavioral measures were freed. Similarly the paths between goal intentions to implementation intentions and the three behavioral measures were freed up as were the paths between implementation desire and the three behavioral measures. While the parameters including the chi-square test for this model showed that this model fit better than the original model tested in step 1, an examination of the t-tests of the freed gamma's and betas reveals that none of these freed paths were significant except for the path between goal intention and implementation intention. Hence, even though the model fit statistics for this model were a slight improvement over the model fit statistics for the model specified in step 1, this model does not represent a significant improvement over

the original model described in step 1 (Table 4.17). In order to examine statistically if any of the 12 paths were significant a chi-square difference test was run. This was done by examining the chi-square difference between step 1 and step 2. This chi-square difference test resulted in a $X^2 (12)=33.38$ which was significant. It therefore appears that one must reject the hypothesis that all 12 paths were nonsignificant. In other words, 1 or more paths were significant. In order to find out if the only significant path in this step was the path between goal intentions and implementation intention another SEM model was run. In this model all the mediating paths except for the one between goal intentions and implementation intentions were freed up to give a $X^2 (27)=65.96$. If the goal intention – implementation path was the only significant path in step 2, then the chi-square difference test between step 1 and this new model with $X^2 (27)=65.96$ would be nonsignificant. As expected, the chi-square difference test reveals a $X^2 (11)=18.64$ which was nonsignificant at a $\alpha=0.05$ indicating that none of the other paths were significant. Thus based on the two chi-square difference tests, the only significant path is the one from goal intention to implementation intention.

Step 3: A confirmatory factor analytic model was run in order to examine if there were indeed four constructs underlying the items in the questionnaire. This was done in order to examine the measurement model since the correlation matrix revealed that the 2 items measuring goal desire were very highly correlated with the two items measuring goal intention. Further, the items for implementation desire1, implementation desire2, implementation intention1 and implementation

intention2 were very highly correlated among themselves, indicating that the four construct model as hypothesized may not be the best fit for the data. The correlations among the factors were high as well. Correlation between goal desire and goal intention was 0.947 and between implementation desire and implementation intention was 0.891. The model fit statistics for the confirmatory factor analysis are presented in Table 4.17. The confirmatory factor analysis revealed that the factor loadings of the items on the four constructs was 0.81 - 0.93 indicating that the items loaded highly onto their respective factors. However the analysis indicated that the construct of goal desire was highly correlated with goal intention. Similarly implementation desire was highly correlated with implementation intentions. This may be indicative of a two construct model rather than a four construct model that was originally hypothesized. Thus, in order to test whether the two construct model was a better fit, another structural equation modeling was carried out in step 4.

Step 4: In order to examine if the two construct model better fits the data another SEM was carried out. In this step, the model specified had two constructs – one for goal related feelings and another for implementation intention related feelings. Results from this modeling indicate that this model did not have a better fit compared to the four factor model. The relevant statistics are depicted in Table 4.17 and the model specified is depicted in Figure 4.2.

Step 5: Since step 2 revealed that the path between goal intention and implementation intention was significant, a final four construct model was specified. This model was similar to the model in step 1 except for one additional path from goal intention to implementation intention. The relevant statistics for this model are depicted in Table 4.17 and the model is specified as the final model in Figure 4.3. The model fit statistics indicate a good fit. In addition, most of the paths between the constructs were significant. The only path that did not reach significance was the path between implementation intention and the second behavioral measure.

Table 4.17 Model fit statistics for structural equation modeling and confirmatory factor analysis

Model	n	Chi-square	df	Sig.	NNFI	CFI	SRMR	RMSEA
Step 1: Test of theoretical framework	193	84.60	38	0.00	0.97	0.98	0.039	0.075
Step 2: Test for mediation	193	51.22	26	0.0022	0.98	0.99	0.026	0.066
Step 3: Confirmat ory factor analysis	193	45.39	14	0.000	0.97	0.99	0.034	0.104
Step 4: Test of two construct model	193	126.95	40	0.00	0.95	0.96	0.041	0.10
Step 5: Final model	193	64.04	37	0.0088	0.98	0.99	0.033	0.057

Figure 4.1 Model tested in step 1: Four construct model

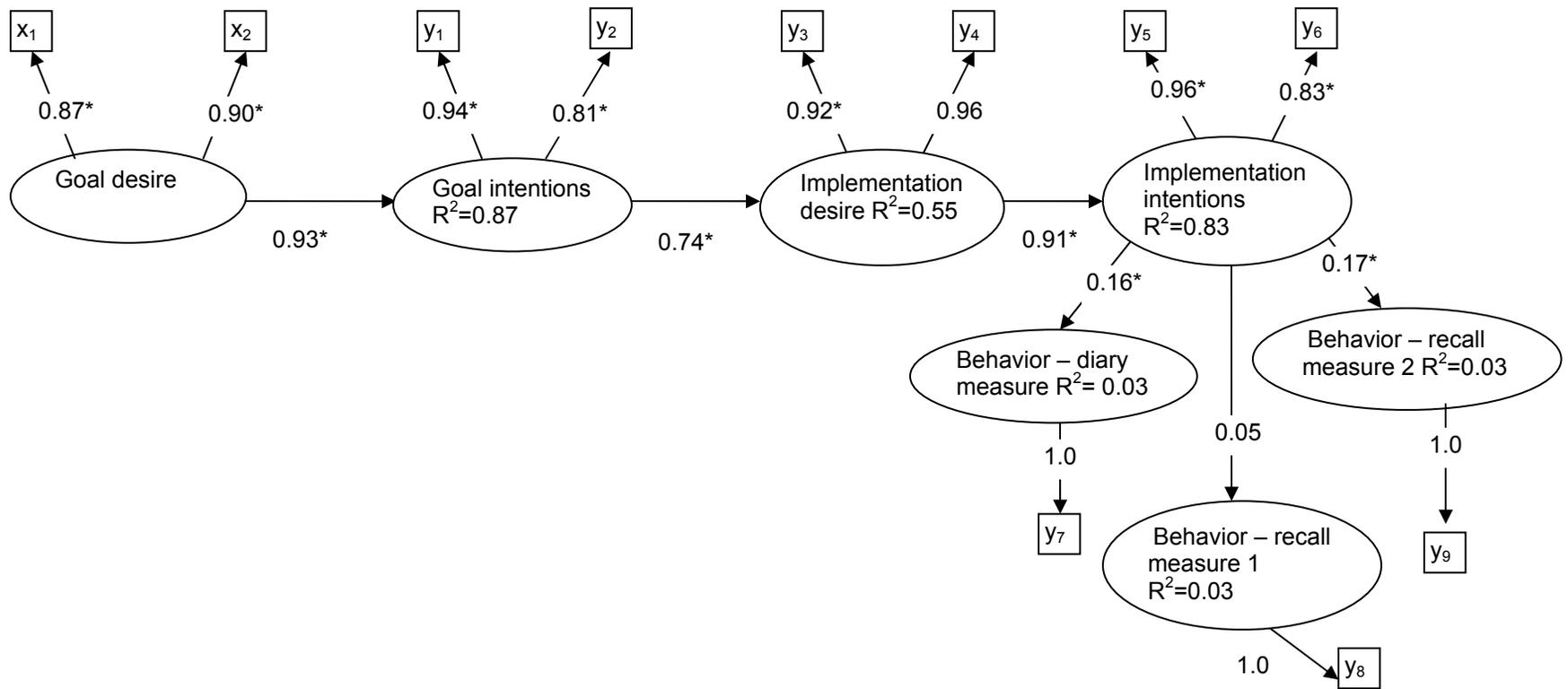


Figure 4.2 Model tested in step 4: Two construct model

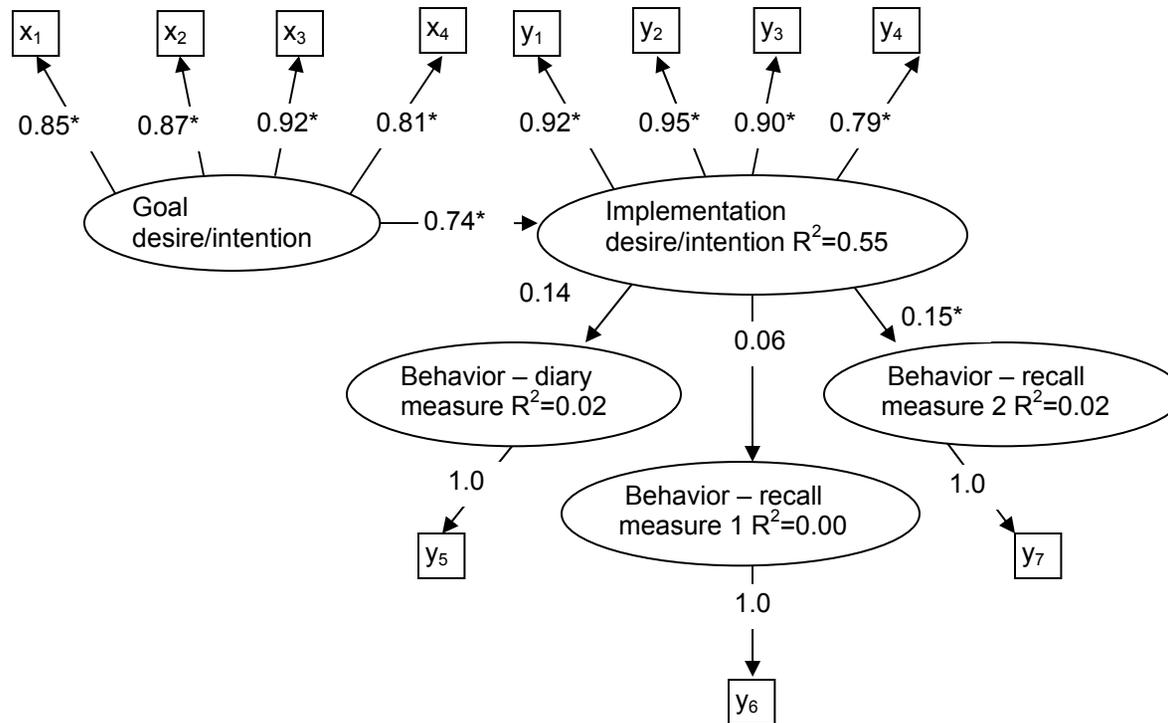
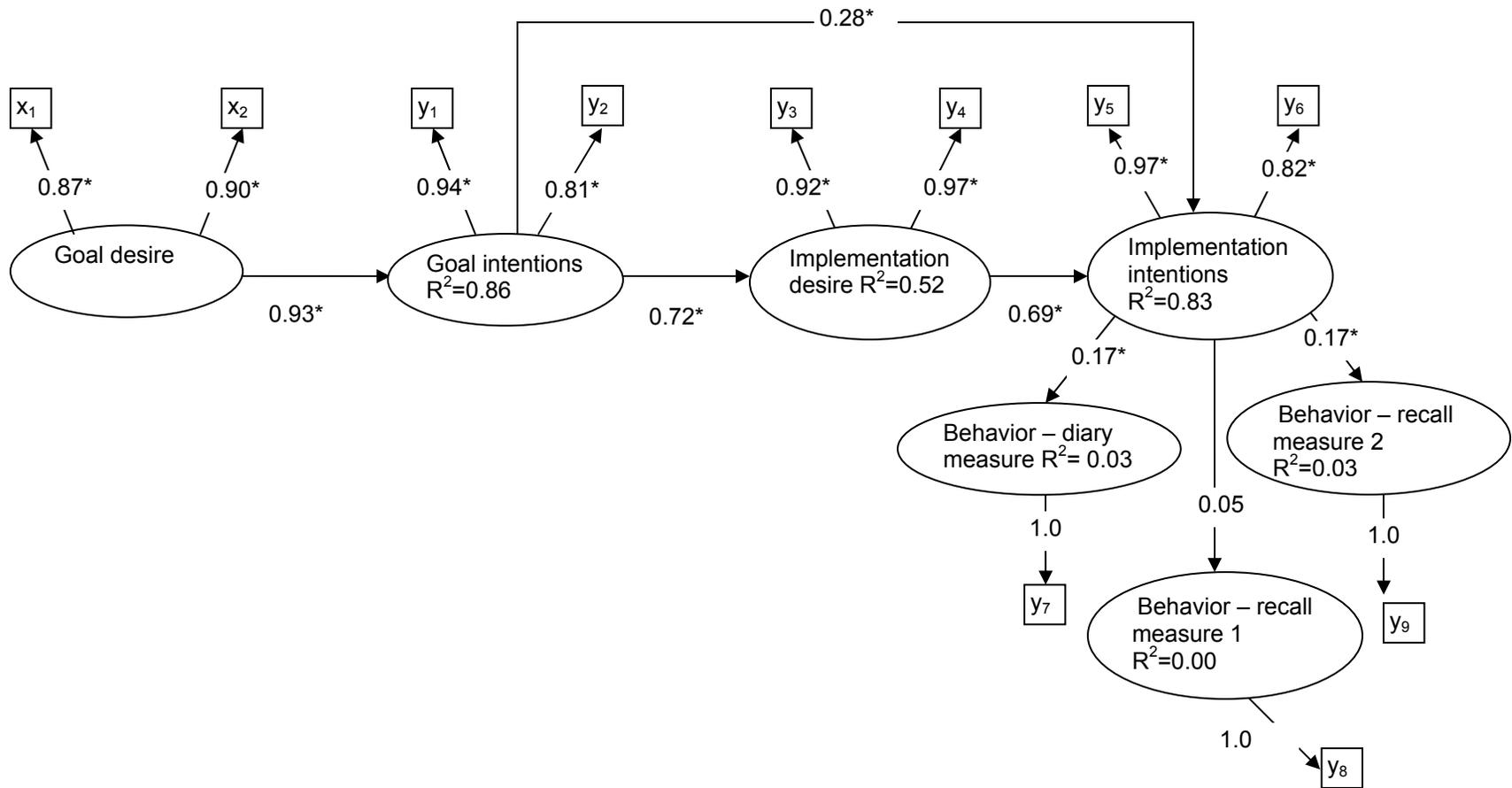


Figure 4.3 Model tested in step 4: Final model



Results for Aim 1

The first aim of the study was to determine if the implementation intention intervention increased frequency of performing self-monitoring of blood glucose. Tables 4.8 - 4.13 present the results showing the frequency of performing SMBG for the different groups.

Results for this aim come from three different behavioral measures. For the first one, measured using a prospective diary, those exposed to the implementation intention manipulation performed SMBG more frequently than those not exposed to the implementation intention intervention. The mean difference in terms of number of times participants reported performing SMBG between the experimental group and the first control group was 6.42 number of times. This was a significant difference. Similarly, the mean difference in terms of number of times participants reported performing SMBG between the experimental and the second control group significantly different at 7.77 times. The mean number of times the experimental group performed SMBG was 40.56 number of times, for the first control group was 34.14 and for the second control group was 32.79 number of times. There were no significant differences between the first and second control group in terms of frequency of performing SMBG. The experimental group was exposed to the implementation intention intervention while the first and second control groups were not.

For the first recall measure, the experimental and third control group differed as did the first control and third control groups. This recall measure examined the number of days over the past fourteen days that the participants performed

SMBG. The mean difference between the experimental and third control group in terms of number of days performing SMBG was 1.56 days while the difference between the first and third control group was 1.35 days. For the second recall measure the experimental group differed from the third control group. This measure was a self report of the number of days that the participants performed SMBG as recommended by their doctor. The difference between the experimental and third control group was 1.98 days. These between group differences in the two recall measures suggest that the experimental intervention may have been effective. Chapter 5 will discuss these results in detail in terms of the interpretation of between group differences.

Results for Aim 2 and 3

The second and third aim of this study was to test the appropriateness of using the theoretical framework to this population. Figures 4.1 – 4.3 represent the analyses to test the hypotheses for these two aims.

The SEM analyses indicate that the theoretical framework was appropriate for use in this chronically ill diabetic population. The SEM analyses were conducted in a four-step process. Initially, the four-construct model as hypothesized was tested. Results indicate that the data fit the model well as evidenced by model fit statistics. The second step consisted of testing for mediation. In this step – all the paths between the constructs were freed up. This was done in order to examine if any other paths, other than those hypothesized in the theoretical framework were significant. Results from this

analysis indicates that one path – between goal intention and implementation intention was significant. In the third step, confirmatory factor analyses were conducted to confirm a four-factor structure underlying the psychological items. Results confirm a four-factor structure. In the fourth step, a two-construct model was tested in order to see if a two-construct model fit the data better than the four construct model. Results indicate that the four-construct model is a better fit for the data. In the fifth step – a final four-construct model was specified as in step 1, with one additional path between goal intention and implementation intention. This model was the final model for this study and results indicate good model fit statistics for this model. For the final model, all the paths were significant except for the path between the implementation intention and the first recall measure. In addition, significant amounts of variation of goal intention, implementation desire and implementation intention is explained by the model.

CHAPTER V

DISCUSSION

Introduction

The first section discusses the characteristics of the sample. This includes the questionnaire response rate, followed by a discussion of sociodemographic differences and differences in health related information between the study sample and a nationally representative questionnaire of diabetics. This section also includes a discussion of psychological measures.

The next three sections discuss the implications of the hypothesis testing. The second section will discuss the hypotheses which examine the effects of the experimental manipulation. The third section will examine the hypothesis that test the theoretical framework of the study focusing on the psychological measures. This section also examines the hypothesis that test the effect of the psychological variables on the behavioral measures.

Characteristics of the sample

Questionnaire response rate

The overall response rate for the study was 15.65%. This is significantly lower than another study of diabetic patients, which also used log books to measure

behavior.²⁶ However the study referenced here also included a follow up telephone call as a means to measure behavior in addition to the use of log books. Thus the response rate reported in the study was the total response rate – a combination of the response rate for log books and from telephone calls. In the referenced study, using a telephone call led to an increase in the study response rates.

In the literature, cross sectional health surveys have documented response rates as low as 42%.¹²⁹ In comparison, it is not surprising that this longitudinal study which typically have higher drop out rates than cross-sectional studies had an overall response rate of 15.65%.

The net response rates for the four groups ranged from 10.90% - 21.38%. Since the primary aim of this current intervention study was to examine if the experimental manipulation was successful, the low response rates in this study are not expected to bias the results. This is because, for an experimental study, one which has not been carried out in the diabetic population to date, internal validity rather than external generalizability is of prime concern. Future research needs to be done in order to verify the external validity of the results in a general diabetic population to ensure that the results are generalizable.

Non-response bias

In the current study, the respondents were sent a pre-paid envelope in order to return the questionnaires and/or diary. These pre-paid envelopes were self-addressed with a University of Michigan faculty address. When the

participants returned their questionnaires and/or diaries, the pre-paid envelopes were first routed to a central mail processing facility at the University of Michigan where they were sorted and then were forwarded on to the faculty's mailbox. In sorting the mail, the central mail processing facility gathered all the pre-paid envelopes over a period of a few days – typically through one week and then forwarded a bulk package of envelopes on to the faculty's mailbox. This process did not allow comparison between early responders and late responders since there was no way to tell which of the envelopes in the bulk package came in earlier than others. An examination of non-response bias would have enabled researchers on this study to examine if the results could have been biased due to non-response bias, however the mail sorting procedure did not permit this.

Socio-demographic information

The study sample for the current study consists of 402 diabetic patients. This sample was compared to a study which used the NHANES III (1988 – 1994) and NHANES 1999 – 2000 surveys.¹⁰ The NHANES surveys are nationally representative surveys and the diabetic sample in the NHANES consisted of patients who self-report having diabetes. The current study sample was compared with the NHANES 1999 – 2000 to examine any sociodemographic differences. Compared with the NHANES sample, the study sample was slightly older (59 versus 62 years) and had a lower percentage of women (50% versus 40%). In terms of race, the NHANES sample had 60% non-Hispanic whites compared to 47% in the study sample who self-reported themselves as

Caucasians. In terms of education level, 30% of the NHANES sample reported having some college level education compared to 35% in the study sample. The NHANES sample reported a mean of 12.5 years since diabetes diagnosis compared to the study sample which indicated that they had diabetes for a mean of 15.7 years. In the NHANES sample 51% reported hypertension as a comorbidity compared to 70% in the study sample. Further, 25% in the NHANES sample reported a comorbidity of cardiovascular disease compared to 58% in the study sample who reported heart disease as a comorbidity.

It appears that compared to a nationally representative sample of diabetics, the study sample was older, consisted of more males, had fewer Caucasians and was slightly more educated. The study sample also reported having diabetes for a longer time and had a higher frequency of comorbidities indicating that the NHANES sample may be healthier than the study sample.

Diabetes related information

Respondents reported that the number of times their health care providers had recommended they check their blood sugar was approximately 2.89 times a day with a standard deviation of 1.2 times. This appears to be consistent with ADA's recommendation of at least 3 times a day for type 1 diabetics and at least once a day for type 2 diabetics.⁵⁷

Information regarding whether the respondent had type 1 or type 2 diabetes was not collected. It was therefore not possible to determine with accuracy whether participants' health care providers were recommending SMBG

according to ADA's recommendation for type 1 versus type 2 diabetics. However, the mean of 2.89 times per day with a standard deviation of 1.2 times indicates that SMBG recommendations by health care providers may be within the ADA recommended norms.

Randomization check

In order to ensure that the participants were randomly allocated to the four groups, sociodemographic differences between the groups were examined. ANOVA and chi-square tests indicate that the experimental, first control and second control groups were similar in terms of socio-demographic characteristics. This indicates that the randomization procedure was successful.

Participants in the third control group did not have to complete any other measures other than the two behavioral recall items and so their socio-demographic characteristics could not be compared. It was assumed that since the participants were randomly allocated to the three other groups, allocation to the third control group was also random.

Psychological measures

In general, study participants reported a high level of desire and a high level of intention to manage their diabetes. They also reported high levels of desire and intention to test their blood sugar. Accordingly, the average means for the psychological measures were all higher than 4.5 with a possible range of 1 – 5 and a higher score indicating higher levels of desire and intention.

Previous research suggests that intention to perform health behaviors to manage their disease is high among diabetic patients.^{26, 130} Intention to test blood sugar was found to be high among diabetics,²⁶ as was the intention to take hypoglycemic medications.¹³⁰ Based on literature, it is not unexpected to observe high levels of intention to manage diabetes or to test blood sugar as observed in literature. As a concept, 'desire to manage disease' has not been investigated in diabetics. As a result, it was not possible to make any comparison in terms of the levels of desire in this study to research done previously.

It is important to note that the high levels of goal desire and goal intention are important from the perspective of formation of implementation plans to achieve goals. In the context of the MAP, this means that the diabetic patients have gone through the predecisional process and have made the decision to manage their diabetes. Implementation intentions by definition are formed only to facilitate goal achievement and are subordinate to goal intentions.⁷⁹ The current study did not include a motivational component with the aim to increase levels of intention in the study participants. As a consequence, in order to examine the effectiveness of forming implementation plans it was important for study participants to have already gone through the predecisional process and already have goal intentions of managing their disease prior to starting the study. If participants would have reported low levels of goal intentions, the experimental manipulation could have possibly been rendered ineffective. This apparent ineffectiveness would not necessarily have been because the experimental

manipulation itself was ineffective. Instead, it could have possibly been a result of the lack goal intentions to manage diabetes since goal intentions are a prerequisite for implementation intention interventions to be effective. Hence, the high levels of goal desire and goal intention is promising and suggests that there is a chance of success for the experimental intervention.

Once the decision or the goal of managing diabetes has been made – the diabetic person must engage in goal striving to achieve this goal. The high levels of implementation desire and implementation intentions in this study also mean that the participants have chosen specific means to achieve their goal of managing diabetes by testing their blood sugar. Consistent with Bagozzi et al., 2003, implementation desires and implementation intentions in this study indicate a readiness to adopt a specific means to achieve a goal.²⁹ In this study high levels of implementation desire and implementation intentions indicates a high motivation and readiness to perform SMBG as a specific means to achieving the goal of managing diabetes.

Distinction between implementation intentions and implementation plans

Gollwitzer defines implementation intentions as being structured as 'I intend to perform x in situation y',⁷⁸ thereby defining the linking of a goal directed behavior with a situation as implementation intentions. In this study there is a distinction between implementation intentions and the process of linking the goal directed behavior with a situation. Implementation intention in this study is defined as the level of readiness and motivation to perform a specific goal

directed behavior (SMBG) consistent with Bagozzi et al. Thus, in the context of this study, implementation intention is conceptualized as 'I intend to perform SMBG'.

The process, which links this specific action – namely performance of SMBG, to a specific situation, has been defined as forming the implementation plan. It is this process of planning when, where, and how to perform SMBG which forms the experimental manipulation in the current study. Thus, forming an implementation plan rather than the measurement of implementation intentions is structured in terms of 'I intend to perform x in situation y'. In the literature, this linking process is typically defined as the implementation intention intervention while in this study it is termed 'making implementation plans'.

Hypotheses concerning Aim 1: the experimental intervention

Literature on implementation intentions interventions reveals that these intention interventions lead to increased performance of several health behaviors.^{83, 85, 87-88, 94, 89-91, 95-98, 100-102} Based on this literature which overwhelmingly points to the effectiveness of implementation intention interventions, hypotheses were developed. These hypotheses stated that those exposed to the implementation intention intervention would have higher rates of SMBG. The three hypotheses examined the rates of SMBG as determined by three different measures. Thus, the hypotheses examined the effect of the intervention on behavior as measured by the diary (hypothesis 1), first recall measure (hypothesis 2) and second recall measure (hypothesis 3).

This aim is of interest for a number of reasons. First, implementation intentions appear to be an extremely effective intervention in changing behavior. This is apparent across numerous studies on health prevention and promotion behaviors.^{83, 85, 87-88, 94, 89-91, 95-98, 101-102} The effect of implementation intentions have also been examined with respect to medication taking behavior.^{100, 105} Implementation intentions were found to improve adherence to vitamin C consumption¹⁰⁰ but were found to be ineffective with respect to adherence to short-term antibiotics¹⁰⁵. It is evident that the behaviors that have been examined are typically preventive health behaviors such as eating fruit,⁸⁷⁻⁸⁸ or reducing dietary fat intake,^{83, 85} adherence to vitamins¹⁰⁰ or short term behaviors such as adherence to antibiotics¹⁰⁵. Health behaviors in chronically ill patients are expected to have different underlying reasons and rationale for being carried out as compared to preventive health behaviors or short term health behaviors. The first aim is expected to reveal if implementation intentions are an effective strategy for health behavior change when the health behavior in question is a complex behavior related to chronic illness.

Second, implementation intention interventions have been studied amongst students, the general population and even patients - for instance those on antibiotics or those who have had joint replacement surgery. They have not been studied amongst the chronically ill population. It is of critical importance to examine the effectiveness of any tool that can help in changing behavior amongst chronically ill patients. This is because chronically ill patients have the onus of managing their disease and this is often achieved through adopting or

changing health related behaviors. Thus it is important to study the effect of implementation intentions – a potential health behavior change tool - in a population in which it has not been tested to date and in which carrying out specific health behaviors is particularly important.

Third, a study which used the theoretical framework of the theory of planned behavior found that intention could predict 44% of the variance in self-monitoring of blood glucose.²⁶ Participants in the study indicated high levels of intention to perform self-monitoring of blood glucose, however it is evident that they had some trouble translating those intentions to behavior. Results related to the first aim will examine if making implementation plans are an effective tool to help those amongst the chronically ill translate their intentions into actual performance of health behaviors.

The results from the analysis support the first aim. Results from the first hypothesis unequivocally point to the effectiveness of forming the implementation plans. We found that those who formed implementation plans had higher rates of performance of SMBG compared to those who did not make the plans. With respect to the second and third hypothesis, the results are not as straightforward – however these results too indicate that the intervention was effective. A discussion of how these results apply to each of the three hypotheses is presented in the following section.

In terms of interpretation of the results of the first, second and third hypothesis it is important to reiterate what differences in terms of the behavioral measures between the various study groups indicate. Since the only difference

between the experimental and first control group is the completion of the intervention, any statistical difference between the two will indicate that the intervention is the cause of the difference. The experimental group differs from the second control group in terms of the experimental intervention as well as completion of psychological measures. Thus any difference between the two would indicate that the combination of experimental intervention as well as completion of psychological measures was the cause. Similarly differences between the experimental and third control group can be attributed to a combination of the experimental intervention, psychological measure, sociodemographic variables and completion of the diary. Differences between the first and second control group would be attributed to completion of psychological measures and differences between the first and third control group indicate that the combination of psychological measures, sociodemographic information and completion of diary were the cause for differences.

Hypotheses 1, 2 and 3: Effectiveness of making implementation plans

The first hypothesis was concerned with testing the effectiveness of making plans on the performance of SMBG as measured by a diary. Results indicate statistically significant differences between the experimental and control groups. Results from the first hypothesis also indicate that the two control groups were not different in terms of performance of SMBG. This means that the experimental group (which completed the intervention, psychological measures, sociodemographic information, diary and the recall measures) reported higher

levels of performance of SMBG as measured by the diary compared to the first control group participants (who completed psychological measures, sociodemographic information, diary and the recall measure). Also, the experimental group was significantly different compared to the second control group (which completed sociodemographic information, the diary and the recall measures) and the two control groups were not different from each other. These results provide strong evidence that the experimental intervention did work, since the experimental group reported significantly higher performance of SMBG as measured by a diary compared to the two control groups. The control groups controlled for the testing effects that completing psychological measures, diary and recall measures could have potentially had on the reporting of SMBG performance as measured by a diary. Since the experimental group was statistically significant compared to both the control groups, it is evident that the difference can be attributed to the experimental intervention.

With respect to the second and third hypothesis, the results were not as straightforward as with the first hypothesis. For the second hypothesis, which tested differences in the first recall measure, the experimental group was statistically significantly different from the third control group. This means that the experimental group (which completed the intervention, psychological measures, sociodemographic information, diary and the recall measures) reported higher levels of performance of SMBG over the past fourteen days compared to the third control group (which only completed the recall measures). In addition, for this hypothesis, the first control group participants (who completed

psychological measures, sociodemographic information, diary and the recall measure) were also statistically different from the third control group (Table 4.10 and Table 4.11). The experimental and first control group was not statistically significantly different from each other. Also, the second control group (which completed sociodemographic information, the diary and the recall measures) was not significantly different from either the experimental or the first and third control groups.

For this hypothesis, ideally in order to label the experimental intervention a success, we would have expected the experimental group to have been significantly different from all the control groups. In addition, we also would have expected that the three control groups were not significantly different from one another.

The pattern of differences found between the groups indicates that the experimental intervention did work since the experimental group was different compared to the third control group. However this difference can also be attributed to a combination of the experimental intervention with the completion of psychological measures, sociodemographic information and the diary. In order to investigate whether it was the experimental intervention that caused the differences or a combination of the various factors aforementioned, it is also important to investigate the differences among the other groups. This will indicate if testing effects may have partly influenced the results. Cook, Campbell and Shadish, 2002 refer to testing effect as the effect that exposure to taking a test can have on subsequent scores to the test.¹³¹ In the current study, testing

effects refers to the effect that completing psychological measures and/or the diary had on the measurement of behavior.

For the second hypothesis the first control group was statistically significantly different compared to the third control group. This indicates that the combination of completing the psychological measures, sociodemographic information and the diary had an effect on the behavioral measure which led to differences between the first and third control group. However, it is also important to note that the first control group did not differ from the second control group. This indicates that completion of psychological measures did not lead to an increase in reported levels of SMBG for the first recall measure. This also means that any differences in the experimental and third control as well as the first control and third control could not have been because of the completion of psychological measures. In addition, the second control group did not differ from the third control group. Since these two groups did not differ, it is safe to conclude that the completion of sociodemographic information as well as the diary could not have caused any differences between the groups in terms of the first recall measure. Through process of elimination, completion of psychological measures, sociodemographic variables and diary have been ruled out as the cause of increase in SMBG as measured by the first recall measure. This means that the only explanation for the difference between the experimental group and the third control group is that the experimental intervention was effective.

It is also important to note that while the experimental group did not differ from either the first or second control group, the mean differences in the first

recall measure between the groups were all in the expected direction. For instance the mean of the experimental group was higher than the first control group, even though this difference did not approach significance. The effect size (Cohen's d) for this measure based on the difference between the experimental and third control group was 0.53.

With respect to the third hypothesis, the ANOVA was significant indicating that self-reports of performing SMBG as recommended were different between the groups. The experimental group was significantly different compared to the third control group. The first control group and second control groups were not significantly different compared to either the experimental group or the third control group. Differences between the experimental and second control group approached significance ($p=0.067$).

These results can be interpreted similar to the interpretation of the results for the second hypothesis. Since the experimental and third control group were statistically different, these differences could be because of the experimental intervention, psychological measures, sociodemographic information, the diary or a combination of these factors. In order to understand which of these could have accounted for the differences, a closer look into the differences between the other groups is also necessary. Since none of the other control groups differ from each other or from the experimental group – it can be concluded that the second recall measure was not affected by the completion of psychological measures, sociodemographic information or the diary. This indicates that the difference between the experimental and third control group is a result of the

experimental intervention. The effect size (Cohen's *d*) for this measure based on the difference between the experimental and third control group is 0.44.

The results for the second and third hypothesis are interesting in terms of mean differences between some of the groups. For these groups, while differences may not have been statistically significant, they could in reality be clinically meaningful. For instance, for the second behavioral measure, the mean difference between the experimental group versus the second control group in performing SMBG as recommended was 2 days (Table 4.13). This difference could be clinically meaningful. This is especially true for patients who are recommended frequent SMBG to ensure tighter glycemic control.

Hypotheses concerning Aim 2 and 3: the theoretical framework

The hypotheses related to the second and third aim were developed based on Bagozzi, et al., 2003 Theoretical Model of Effortful Decision Making and Enactment.²⁹ This theoretical model describes the process by which effortful goals are made, enacted and achieved. The hypotheses related to these two aims investigate the appropriateness of using this theoretical framework in goal striving and goal achievement related to managing diabetes. Specifically, the hypotheses focus on performance of self-monitoring of blood glucose as the means to achieve management of diabetes.

Hypotheses 4, 5 and 6 investigated the psychological processes that influence goal striving in relation to managing a chronic condition. The three hypotheses test the causal linkages between the theoretical constructs as

defined by the theoretical model. The fourth hypothesis stated that the greater the goal desire the greater the goal intention. The fifth hypothesis examined the influence of goal intention on implementation desire. The sixth hypothesis was concerned with the influence of implementation desire on implementation intentions.

Hypotheses 7, 8 and 9 investigate the relationship of the psychological constructs and the achievement of a specific health behavior – performance of SMBG. The seventh hypothesis stated the greater the implementation intention the greater the performance of SMBG as measured by a diary. The eighth hypothesis stated that the greater the implementation intention, the greater the performance of SMBG as measured by the first recall measure. The ninth hypothesis stated that the greater the implementation intention, the greater the performance of SMBG as measured by the second recall.

Hypotheses related to this aim are of importance for a variety of reasons. First, literature reveals low rates of adherence to self-monitoring of blood glucose.^{16, 17, 19} Rates as low as 20% have been reported.¹⁷ This indicates that for many diabetic patients adherence to self-monitoring of blood glucose is a problematic and effortful behavior. The theoretical model of effortful decision making and enactment is well suited to understanding the processes that influence the performance of important but effortful health behaviors in diabetic patients. Understanding the psychological processes that mediate decision making and enactment would help inform interventions aimed at improving rates of performance of effortful behaviors in diabetic patients. The focus of this aim is

on the effortful process of managing diabetes and specifically on performing self-monitoring of blood glucose as the means to do so. This second aim investigates the psychological processes that mediate the relationship between forming a goal and achieving the goal using specific goal directed behaviors among diabetic patients.

Second, this aim furthers the scope of decision making research. It does so by investigating the processes that link decisions to their enactment and finally to their achievement in a population where such processes have not been investigated. To date, intentions and likelihood of performing actions have been investigated with respect to self-management behaviors in diabetic patients.^{26, 130} In addition, adherence to self-management behaviors has also been investigated.^{16, 17, 19} Thus in literature related to diabetes self-management behaviors, goal formation and goal striving coexist but never under a single theoretical framework. This aim attempts to further decision making research by investigating a unified theory of goal making and goal enactment in chronic conditions. A discussion of the results from hypotheses 4 – 9 follows.

Hypotheses 4, 5 and 6: Theoretical framework

The fourth hypothesis was concerned with testing the effect of goal desire on goal intention. As hypothesized, 86% of the variation in goal intention was explained by goal desire and goal intention was significantly influenced by goal desire as evidenced by the path between goal intention-goal desire $\gamma=0.93$ ($p<0.05$). Similarly with regards to the fifth hypothesis, a significant variation in

implementation desires (52%) was explained by goal intentions with the path from goal intention to implementation desire $\beta=0.72$ ($p<0.05$). Tests for mediation indicate that in addition to the path between implementation desire to implementation intention, the path between goal intention to implementation intention was also significant. Thus, with regards to the sixth hypothesis, 83% of the amount of variation in implementation intentions was explained by implementation desire and goal intention. The path between the implementation desire and implementation intentions was 0.69 ($p<0.05$) while the path between goal intention and implementation intentions was 0.28 ($p<0.05$).

Analyses indicated it was plausible that the participants may not have been able to clearly distinguish between desire and intention. This was evidenced by high correlations between items measuring goal desire and goal intention as well as between items measuring implementation desire and implementation intentions. In addition many pilot test participants also indicated that they thought the items related to desire and intention were similar. All research on the Theoretical Model of Effortful Decision Making and Enactment has been conducted on student populations.^{29, 106} Student populations may be very attuned to the various psychological constructs being investigated in a study. This may not be true for more heterogeneous populations such as the chronically ill diabetic patients. Thus, in order to assess whether participants did indeed distinguish between desire and intention, a two construct model was specified and tested using SEM. This two construct model (step 2) collapsed goal desire and goal intention into one theoretical construct and implementation

desire and implementation intentions into the second theoretical construct. However model fit statistics for this model indicate that they were no better than the four construct model specified in step 1. This indicates that the participants were in fact able to distinguish between desire and intention when thinking of the process of decision making and enactment related to management of diabetes and performance of SMBG. As a consequence the final model of decision making and goal striving based on SEM analyses for diabetes self-management and specifically SMBG is a four construct model.

It was important to note that all the paths between the four constructs studied in hypotheses 4 – 6 were significant. In addition, the paths linking the items to constructs were all significant as well. The significance of the paths between the items and the constructs reveals that the items are a good measure for their respective underlying constructs. This indicates that theory is a good depiction of the psychological processes that mediate decision making and striving in diabetes health behaviors – specifically SMBG. In summary, the antecedent for goal intentions is goal desire, for implementation desire is goal intentions, for implementation intentions is implementation desire and goal intentions

Hypotheses 7, 8 and 9: Behavioral measures

The seventh hypothesis tested the effect of implementation intentions on SMBG behavior as measured by a diary. Based on the final four construct model, the amount of variation explained in this behavioral measure was not

significant at 3%. However, the path between implementation intention and behavior was significant $\beta=0.17$ ($p<0.05$). Similarly, for the eight and ninth hypotheses, the amount of variation of behavior explained was not large – 0% and 3% respectively. However, the path between implementation intention and the second recall measure was statistically significant $\beta=0.17$ ($p<0.05$).

While the theoretical framework does not explain a significant amount of variation in the behavioral measures, the paths between implementation intention and 2 measures of behavior are significant. This indicates a causal link between implementation intentions and behavior – implementation intentions lead to behavior.

CHAPTER VI

CONCLUSIONS

Introduction

This section discusses the conclusions and implications based on the results from the first three aims. It also discusses the limitations of the study and some recommendations for clinicians, researchers and diabetic patients.

Conclusions and implications of the results

Results indicate that specifying the location and time of performing SMBG is an effective strategy in increasing SMBG rates in diabetic patients. This means that a simple planning strategy can be responsible for causing an increase in the performance of an important self-management behavior in diabetic patients. To the best of our knowledge, no study to date has tested the effectiveness of this intervention in the chronically ill population. Results from this study provide the first evidence of the usefulness of a simple yet effective tool in helping chronically ill patients to better manage their disease by increasing performance of key health behaviors. Future work should examine the effectiveness of this tool in other health behaviors that are required to be performed by diabetics and also health behaviors that need to be performed in other chronic diseases.

It is important to note that this study did not specifically examine adherence. Instead, it looked at differences in rates of performance of SMBG between the various groups for the three behavioral measures. That being said, the second recall measure can be considered an adherence measure since it examined the number of days over two weeks that the participant performed SMBG as recommended by their healthcare provider. Adherence by definition is the extent to which a person's behavior coincides with medical or health advice.¹³² Accordingly, the second recall measure is a measure of adherence to SMBG.

It should also be noted that although this study examined rates of SMBG, the implication is that if rates of SMBG are higher due to the experimental intervention, the experimental manipulation can be used in future studies as well as in future interventions to help improve adherence to SMBG.

Results from testing the theoretical framework for the study prove that both motivational as well as volitional processes underlie goal formation and goal striving in health behaviors related to diabetes patients. Results also indicate that implementation intentions in addition to goal intentions are an antecedent to performance of self-monitoring of blood glucose – thus, implementation intentions precede goal achievement in diabetic patients. In other words the act of specifying the means to achieve the goal precedes the actual performance of the goal in diabetic patients. In the literature, the TPB is often used as a theoretical framework to help researchers examine psychological variables influencing the intention to perform and actual performance of a health

behavior.²⁶ The antecedents of goal intentions and the subsequent influence of goal intentions on health behavior is typically the focus of research that involves the TPB. This study highlights that while examining antecedents to goal intentions and understanding the influence of goal intentions on subsequent performance of the health behavior is important, it is equally important to understand the process that mediates the pathway between goal intentions on health behavior because several intervening variables – both volitional and motivational processes are involved in decision making, goal striving and goal achievement as it relates to health behaviors.

While the paths between implementation intentions and the behavioral measures were significant, the amount of variation of the behavior explained was not. This was true of all three behavioral measures. This indicates that while there is evidence of causality between implementation intentions and SMBG, the current study may not have fully captured all the antecedents of SMBG behavior resulting in the inability of the theoretical framework to fully capture variation in SMBG behavior.

Limitations

The response rates to this longitudinal questionnaire were low. The results from this study are therefore not generalizable to either the diabetics in southeast Michigan area or to the entire diabetic population in the U.S. In addition, it is important to note that the diabetics in this study were those on insulin and those with HbA_{1c} >7.0%. The inclusion criteria further limit the

generalizability of this study to those with poorly controlled diabetes who were also and perhaps as a result of the lack of glycemic control – on an insulin regimen. While these limitations are not inconsequential, the focus of this study was to examine if the intervention was effective rather than to examine the generalizability of the results to a larger diabetic population. Future research needs to examine the effectiveness of this tool in a broader diabetes population.

The behavioral measures were all self-reports. Self-reports are known to overestimate adherence¹³³ and thus it can be expected that the rates of SMBG reported by the participants were higher than what happened in reality. Since these self-reports were not obtained using patient face-to-face interviews but with the help of diaries and questionnaires, the extent of overestimation of SMBG performance in this study may be limited¹³⁴ but not completely nullified. Also, since there were three control groups – it is expected that this effect is controlled for. It may be interesting to conduct studies in the future by using different behavioral measures or using a combination of behavioral measures. One such method may be to examine the records from glucometers of study participants in order to get an accurate rate of SMBG performance. Another method can involve investigation of claims records to assess the number of glucometer strips purchased over a specific time period by the patient.

The current study did not collect information regarding whether the patient was a type 1 or a type 2 diabetic. This did not allow any between group comparisons in order to assess if study results differed between the two diabetes subtypes. Future research should consider collecting this information.

Another limitation to this study is that this study included diabetics regardless of their duration of diabetes diagnoses. This meant that those who were newly diagnosed were included as were those diagnosed several years ago, even some who were diagnosed decades ago. It is possible that the experimental intervention may work differently for those newly diagnosed versus those who have had diabetes for a longer time period. It should be noted that this study did collect information regarding how long the participants had diabetes, and subgroup analyses could potentially have been conducted by categorizing participants based on their duration of diabetes. However, the number of participants in the subgroups was not adequate to conduct any type of statistical tests. In the future, it would be interesting to test whether the results of this study differ based on the duration of diabetes diagnoses.

Recommendations

Based on the study findings regarding the effectiveness of making implementation plans, health professionals can help diabetic patients to increase performance of self-monitoring behavior. This can be done by developing and designing disease management interventions in which patients are told to link specific situations to targeted health behaviors. As is evidenced from the results of this study, these interventions can be sent out as questionnaires. However, the low response rate suggests that reaching patients using other means is warranted. Future research can also help determine the most optimal method of

delivering such interventions, be it a one-on-one intervention with a patient, a telephone call or a simple written format such as this study.

With regards to researchers in the health services and public health domains, this study expands the scope and promise of implementation intentions research. It provides scientific basis that this volitional intervention works in a chronically ill population. The current research can be expanded upon for use in other health behaviors related to diabetics as well as to health behaviors in other chronic conditions. This study also provides insight into the psychological processes that connect the motivational and volitional phases of goal striving in diabetes self-management. Very often, health care researchers especially in the context of chronic illnesses have examined the associations between intention and health behavior. Understanding the processes that drive behavior after the formation of an intention are also very important in the effort to mold and change health behaviors. The motivational and volitional phases of goal striving have not been investigated extensively to date under a unified theoretical framework in research related to health behavior. This study provides evidence that both - motivational and volitional factors - mediate goal striving and goal achievement processes in the diabetic population. In doing so, it provides insight into the goal striving and goal achievement processes in diabetic patients and specifically in effortful behaviors like SMBG where adherence has often been cited as a problem. Based on the results of this study, future research can investigate the effectiveness of health behavior interventions which have motivational as well as volitional components in the chronically ill population. This can be achieved by

manipulating the levels of the psychological constructs that were examined in study. This type of research would be analogous to research which uses motivational interventions to increase levels of goal intentions and reports subsequent performance of behavior. The difference would be the focus on increasing the levels of constructs such as goal desire, implementation desire and implementation intentions rather than the focus on only the goal intentions part of the goal striving process. For instance, by increasing the desirability of the behavior, researchers may be able to increase the rates of performance of the behavior. In conclusion, this research provides scientific proof that goal intention doesn't merely translate to behavior – there are several psychological steps along the way that transform intention to behavior. These steps not only have a motivational component but also have a volitional component. One of the volitional components – implementation intentions can help ward off distractions and can more efficiently and effectively lead to performance of behavior by linking situational cues to the automatic initiation of behavior. This study indicates that this volitional process – termed formulating implementation plans works in the diabetic population.

For the chronically ill diabetic patient the implications of this study are that the results may be able to help them to improve their adherence to health provider recommendations. They can be informed by their providers that making these simple plans is an effective way to get to their goal of managing the disease. Those who have trouble with adherence can potentially benefit from this simple exercise. Those who have established a schedule of performing

SMBG and may not have problems with adherence can also benefit in situations when their schedules are disrupted. For instance, those who expect to go away on vacation can be told to make these implementation plans to help them keep up with their SMBG behavior while they are vacationing.

This study is a significant step forward in decision making literature as it relates to health behavior. This is because as mentioned previously, the focus is typically on goal intentions and subsequent health behavior. This study highlights other important psychological variables that are important in the performance of health behaviors as it relates to a chronically ill population. In summary, making implementation plans is an effective way to help diabetics increase rates of monitoring of SMBG. Further, psychological processes starting with goal desires – goal intentions – implementation desire and implementation intentions mediate the pathway to goal achievement.

APPENDICES

APPENDIX 1
PHYSICIAN LETTER

Date: August 20, 2008

Dr. [Name]
Henry Ford Medical Group

Dear Dr. [Name]:

We are researchers from the Henry Ford Health System and the University of Michigan and we are conducting a study on self-monitoring of blood glucose in diabetic patients. The study aims to examine if a planning intervention of when, where and how to self-monitor blood glucose helps increase adherence to self-monitoring. All contact with the patients will be via mail surveys. Patients will be selected from among diabetics who receive their care within the Henry Ford Health System. There will be no change to medication or to any patient care services.

We have identified some of your patients as eligible for inclusion in the study (see attached patient list). We are planning to mail each of these patients a copy of the attached letter inviting them to participate in the survey. Could you please take a few minutes to review your patient list? If for any reason you feel that we should not contact a patient please indicate by writing "no" in the contact column next to the patient's name and **mail** it back to **Attn: Suzan Kucukarslan, College of Pharmacy, 428 Church Street, Ann Arbor, MI, 48109 by August 27, 2008**. If we do not hear from you by August 27, 2008 we will assume it is appropriate to contact the patients on your list.

Thank you in advance for your cooperation in this important effort. Please feel free to contact me at (734) 763-7619 or at skucuka1@hfhs.org or skucukar@umich.edu for additional information.

Sincerely,

Suzan Kucukarslan, PhD
Department of Pharmacy Services
Henry Ford Hospital

Assistant Professor
College of Pharmacy
University of Michigan

Patient's Name	MRN	DOB	Contact

APPENDIX 2

COVERLETTER TO EXPERIMENTAL, FIRST CONTROL AND

SECOND CONTROL GROUPS

Date:

Dear Member,

We are looking for people with diabetes for a study. The study will be carried out at the Henry Ford Health System and the University of Michigan. This study is about managing diabetes. This study involves answering questions on surveys. It does not involve any changes in medication or trips to the doctors' office.

You are requested to please fill out the enclosed survey and log. The survey and log are part of the study conducted by University of Michigan and Henry Ford Health Systems. If you fill it out, you will help us to understand how to help patients manage their diabetes. This will help advance scientific knowledge.

The survey should take you only about 20 minutes to complete. It will take a minute or less to fill in the log, each day.

You **are eligible** to participate if:

1. You use insulin injections to help control your diabetes.
2. You are able to read and write in English.
3. You are not pregnant.
4. Your doctor has recommended that you test your blood sugar at home.

If you **are eligible**, please complete all the questions in the survey and return it to us in the postage paid envelope. If you **are not eligible** to participate, please complete only the first question and return your survey in the postage paid envelope.

Please **do not return** the **log** to us just now. Please fill in the log over the next two weeks. **After two weeks**, please return the **log** to us in the attached envelope.

You may notice that there is a number on the survey and log. This will help us to match your survey to your log. This will also help us to send you a reminder to return your log after two weeks. In addition, this will help us to mark off your name after we receive your survey and log. You are assured of complete privacy. Results from this study will only be released as summaries. No individual names will be made public. Your answers to this study will not be shared with anyone. If you have any questions or comments about this study please call Anagha Nadkarni, the PhD. student working on this study. She will be more than happy to talk with you at 734-763-7619.

Thank you very much for your help with this project. Your answers will provide invaluable information about how to help patients manage their diabetes. We really appreciate you taking the time to fill out the survey.

Sincerely,

Suzan Kucukarslan, PhD
Department of Pharmacy Services
Henry Ford Hospital

Assistant Professor
College of Pharmacy
University of Michigan

APPENDIX 3
COVERLETTER TO THIRD CONTROL GROUP

Date:

Dear Member,

We are looking for people with diabetes for a study. The study will be carried out at the Henry Ford Health System and the University of Michigan. This study is about managing diabetes. This study involves answering questions on surveys. It does not involve any changes in medication or trips to the doctors' office.

You are requested to please fill out the enclosed survey. The survey is part of the study conducted by University of Michigan and Henry Ford Health Systems. If you fill it out, you will help us to understand how to help patients manage their diabetes. This will help advance scientific knowledge.

This survey should take you no more than five minutes to complete.

You **are eligible** to participate if:

1. You use insulin injections to help control your diabetes.
2. You are able to read and write in English.
3. You are not pregnant.
4. Your doctor has recommended that you test your blood sugar at home.

If you **are eligible**, please complete all the questions in the survey and return it to us. If you **are not eligible**, please complete only the first question and return the survey to us.

You may notice that there is a number on the survey. This will also help us to send you a reminder to return your survey. In addition, this will help us to mark off your name after we receive your survey.

You are assured of complete privacy. Results from this study will only be released as summaries. No individual names will be made public. In addition, your answers to this study will not be shared with anyone.

If you have any questions or comments about this study please call Anagha Nadkarni, the PhD. student working on this study. She will be more than happy to talk with you at 734-763-7619.

Thank you very much for your help with this study. Your answers will provide helpful information about blood sugar testing. We thank you for taking the time to fill out the survey.

Sincerely,

Suzan Kucukarslan, PhD
Department of Pharmacy Services
Henry Ford Hospital

Assistant Professor
College of Pharmacy
University of Michigan

APPENDIX 4
INFORMED CONSENT

Title of Research Project: Implementation intentions and self-monitoring of blood glucose in diabetic patients.

Investigators: Suzan Kucukarslan, PhD., Anagha Nadkarni, MS.

Date:

Dear Member,

We are looking for people with diabetes for a study. The study will be carried out at the Henry Ford Health System and the University of Michigan.

This study is about managing diabetes. Physicians of potential participants were informed that the study researchers would be contacting their patients to participate in the study. If you wish to participate, please fill out the survey. The survey has questions about diabetes. You may be asked to keep a log of blood sugar tests. This study involves answering questions on surveys. It does not involve any changes in medication or trips to the doctors' office.

The survey can be completed in twenty minutes or less. It will take a minute or less to fill in the log, each day for two weeks.

This study is going to help us to understand if planning helps patients manage their diabetes. While you may not benefit, the results will help others some day. This study is also part of the PhD. requirements for Ms. Anagha Nadkarni. Ms. Nadkarni is a graduate student at the University of Michigan, College of Pharmacy.

If you complete and return all the study materials sent to you, you will be entered in a raffle. You could win \$100. We will be giving away \$100 to six people.

You may have a small risk by telling us your information. This risk is small because all the information that will be collected from you will remain in a safe place at the University of Michigan, College of Pharmacy. Your name will not be made public. It will also not be used in any activities resulting from this study.

The results of the study will not be shared with anyone. This includes your doctor, nurse, insurance and employer. Your records will be kept confidential to the extent provided by federal, state, and local law. However, the Institutional Review Board, or university and government officials responsible for monitoring this study may check these records.

Your participation is totally voluntary. Completing and returning either the survey or the log implies your consent to participate. You do not have to take part in the study. If you choose not to take part in the study, you will get the same medical care from Henry Ford Hospital and Medical Centers. There will be no penalties. You will not lose any benefits that you would have received anyway.

If you have any other questions, please call Anagha Nadkarni at (734)763-7619 or Suzan Kucukarslan at (313) 916-1230. If you have questions about your rights as a research subject, you may contact the Henry Ford Health System IRB Coordinator at (313) 916-2024. You can also contact the University of Michigan IRB at (734) 936-0933.

Please keep this letter for your records if you **wish** to participate. If you do **not** want to be contacted again for this study, please print your name and sign below and then return this letter to us within a week.

Sincerely,

Suzan Kucukarslan, PhD
Department of Pharmacy Services
Henry Ford Hospital

Assistant Professor
College of Pharmacy
University of Michigan

Name

_____ does not want to take part in the survey.

Signature

APPENDIX 5
QUESTIONNAIRE – EXPERIMENTAL GROUP

**PLEASE RETURN THIS SURVEY IN THE PREPAID ENVELOPE
IMMEDIATELY AFTER FILLING IT OUT**

DATE: _____

1. 'I am eligible for this study:' (Check \surd one response)
Yes _____ No _____

If you checked **no**, please **stop** and return the survey in the postage paid envelope. If you checked **yes**, please **proceed** to answer the next question.

Section I: Diabetes related questions.

2. About how many times in a day has your doctor recommended you test your blood sugar? _____ times

3. 'I currently test my blood sugar as recommended by my doctor:'
(Circle the number that best fits your response)

1	2	3	4	5
Never	Occasionally	Often	Most of the time	Always

4. Can you tell us how long have you had diabetes?
_____ Years _____ Months

Now we would like to get your reactions to managing your diabetes. Think about the management of your diabetes as a personal goal.
(Circle the number 1 to 5 that best fits your response)

5. Please tell us to what extent managing your diabetes is a goal for you personally?

1	2	3	4	5
Not at at all		Moderate extent		Large extent

Now, please tell us the actual strength of your desire and intentions to achieve this personal goal on the following questions:

6. 'My desire to manage my diabetes over the next two weeks can best be described as:'

1	2	3	4	5
No desire at all		Moderate desire		Very high desire

7. 'My overall wish to manage my diabetes over the next two weeks can be summarized as:'

1	2	3	4	5
No wish at all		Moderate wish		Very strong wish

8. 'The strength of my actual intention to manage my diabetes over the next two weeks can best be described as:'

1	2	3	4	5
No intention at all		Moderate intention		Very strong intention

9. 'I actually intend to manage my diabetes over the next two weeks:'

1	2	3	4	5
Not likely at all		Neither likely nor unlikely		Very likely

Next, we would like to get your reactions to how you might achieve your personal goal of managing your diabetes. Think about testing your blood sugar as a way to achieve your goal. Please circle the number that best describes your reactions about testing your blood sugar.

10. 'My desire to test my blood sugar over the next two weeks can best be described as:'

1	2	3	4	5
No desire at all		Moderate desire		Very high desire

11. 'My overall wish to test my blood over during the next two weeks can be summarized as:'

1	2	3	4	5
No wish at all		Moderate wish		Very strong wish

12. 'The strength of my actual intention to test my blood sugar over the next two weeks can best be described as:'

1	2	3	4	5
No intention at all		Moderate intention		Very strong intention

13. 'I actually intend to test my blood sugar over the next two weeks:'

1	2	3	4	5
Not likely at all		Neither likely nor unlikely		Very likely

Section II: Finally, we would like you to make a plan for achieving your goal of managing your diabetes over the next two weeks. For each of the following questions, please tell us specifically how you plan to test your blood sugar over the next two weeks. Write your responses below in the space provided.

14. Please tell us how willing you are to manage your diabetes over the next two weeks?

1	2	3	4	5
Not willing at all		Moderately willing		Very willing

15. About how many times per day will you test your blood sugar?
_____ times a day

16. About how many times in the next two weeks do you expect to test your blood sugar away from home? _____ days

17. What are some of the things such as eating sweets, that trigger your desire to test your blood sugar level at any time?

18. Which brand of glucometer do you own? _____

19. About how old is your glucometer? _____ Years _____ Months

20. Will someone help you when you test your blood sugar level or will you do this alone? (Check \surd one box best fitting your situation)

- I always do this by myself
- Occasionally someone helps me
- Usually someone helps me

21. If someone helps you, who is it? (for example, close friend, spouse, sister etc.)

An important goal for many diabetic patients on insulin is to test their blood sugar regularly. Please think about the goal of testing your blood sugar levels as recommended by your doctor over the next two weeks. With this goal in mind, we ask that you to tell us, when and where you will test your blood sugar daily.

Please fill out the following table with information about your plans to test your blood sugar over the next two weeks. Fill in the table for the number of blood sugar tests that you plan to take daily. For example, if you plan to test your blood sugar twice a day, fill in the table for 'first blood sugar test of the day' and 'second blood sugar test of the day'.

EXAMPLE OF HOW TO FILL IN THE TABLE

	List below how many blood sugar tests you will take daily	List below when you will test your blood sugar (approximate time of day)	Where (location) will you test your blood sugar (for example living room, kitchen, bathroom etc.)	Do you do this test:	
				Alone	Someone helps me
	First blood sugar test of the day	About 7.30 in the morning.	In the kitchen	Alone	
	First blood sugar test of the day				
	Second blood sugar test of the day				
	Third blood sugar test of the day				
	Fourth blood sugar test of the day				

22. If you plan to test your blood sugar away from home, will you need to carry your glucometer with you? (Check \surd one response)

Yes _____ No _____

***** PLEASE CLOSE YOUR EYES FOR A MOMENT AND THINK ABOUT THE PLANS YOU JUST MADE. *****

23. Now that you gave us an overview of your plan to test your blood sugar over the next two weeks, please tell us how committed you are to this plan:

'I am:'

1	2	3	4	5
Not at all committed	Somewhat committed	Moderately committed	Very committed	Totally committed

Section III: Demographic information

24. When were you born? _____ Year

25. What is the highest level of education that you have completed?

(Check \surd one box)

- Grade school
- Some high school
- High school graduate
- Some college
- Bachelor degree
- Professional degree/Graduate degree

26. What is your racial background? (Check \surd one box)

- African American
- Asian or Pacific Islander
- Caucasian
- Native-American
- Hispanic
- Other

27. What is your gender? (Check \surd one response)

_____ Male _____ Female

28. Which of the following conditions have you also been diagnosed with (Check all boxes that apply)

- Hypertension (High Blood Pressure)
 - Heart Disease
 - Cancer
 - Stroke
 - Arthritis
 - Chronic Respiratory Disease such as Asthma, COPD
 - Other. Please describe or list: _____
-

29. What is your annual household income? (Check one box)

- Less than \$10,000
- Between \$10,000 and \$18,500
- Between \$18,501 and \$35,000
- Between \$35,001 and \$ 55,000
- Between \$55,001 and \$88,000
- Between \$88,001 and \$100,000
- More than \$100,000

APPENDIX 6
QUESTIONNAIRE – FIRST CONTROL GROUP

**PLEASE RETURN THIS SURVEY IN THE PREPAID ENVELOPE
IMMEDIATELY AFTER FILLING IT OUT**

1. 'I am **eligible** for this study:' (Check \surd one response)
Yes _____ No _____

If you checked **no**, please **stop** and return the survey in the postage paid envelope. If you checked **yes**, please **proceed** to answer the next question.

Section I: Diabetes related questions.

2. About how many times in a day has your doctor recommended you test your blood sugar? _____times

3. 'I **currently test my blood sugar as recommended by my doctor:**'
(Circle the number that best fits your response)

1	2	3	4	5
Never	Occasionally	Often	Most of the time	Always

4. Can you tell us **how long** have you had diabetes?
_____Years _____Months

Now we would like to get your reactions to managing your diabetes. Think about the management of your diabetes as a **personal goal**.
(Circle the number 1 to 5 that best fits your response)

5. Please tell us to what extent managing your diabetes is a goal for you personally?

1	2	3	4	5
Not at at all		Moderate extent		Large extent

Now, please tell us the actual strength of your desire and intentions to achieve this personal goal on the following questions:

6. 'My **desire to manage** my diabetes over the next two weeks can best be described as:'

1	2	3	4	5
No desire at all		Moderate desire		Very high desire

7. 'My overall wish to manage my diabetes over the next two weeks can be summarized as:'

1	2	3	4	5
No wish at all		Moderate wish		Very strong wish

8. 'The strength of my actual intention to manage my diabetes over the next two weeks can best be described as':

1	2	3	4	5
No intention at all		Moderate intention		Very strong intention

9. 'I actually intend to manage my diabetes over the next two weeks:'

1	2	3	4	5
Not likely at all		Neither likely nor unlikely		Very likely

Next, we would like to get your reactions to how you might achieve your personal goal of managing your diabetes. Think about testing your blood sugar as a way to achieve your goal. Please circle the number that best describes your reactions about testing your blood sugar.

10. 'My desire to test my blood sugar over the next two weeks can best be described as:'

1	2	3	4	5
No desire at all		Moderate desire		Very high desire

11. 'My overall wish to test my blood over during the next two weeks can be summarized as:'

1	2	3	4	5
No wish at all		Moderate wish		Very strong wish

12. 'The strength of my actual intention to test my blood sugar over the next two weeks can best be described as:'

1	2	3	4	5
No intention at all		Moderate intention		Very strong intention

13. 'I actually intend to test my blood sugar over the next two weeks:'

1 2 3 4 5
Not likely Neither likely Very likely
at all nor unlikely

Section II: Demographic information

14. When were you born? _____ Year

15. What is the highest level of education that you have completed?

(Check \checkmark one box)

- Grade school
- Some high school
- High school graduate
- Some college
- Bachelor degree
- Professional degree/Graduate degree

16. What is your racial background? (Check \checkmark one box)

- African American
- Asian or Pacific Islander
- Caucasian
- Native-American
- Hispanic
- Other

17. What is your gender? (Check \checkmark one response)

_____ Male _____ Female

18. Which of the following conditions have you also been diagnosed with (Check \checkmark all boxes that apply)

- Hypertension (High Blood Pressure)
- Heart Disease
- Cancer
- Stroke
- Arthritis
- Chronic Respiratory Disease such as Asthma, COPD
- Other. Please describe or list: _____

19. What is your annual household income? (Check one box)

- Less than \$10,000
- Between \$10,000 and \$18,500
- Between \$18,501 and \$35,000
- Between \$35,001 and \$ 55,000
- Between \$55,001 and \$88,000
- Between \$88,001 and \$100,000
- More than \$100,000

APPENDIX 7
QUESTIONNAIRE – SECOND CONTROL GROUP

PLEASE RETURN THIS SURVEY IN THE PREPAID ENVELOPE
IMMEDIATELY AFTER FILLING IT OUT

1. 'I am **eligible** for this study:' (Check \checkmark one response)
Yes _____ No _____

If you checked **no**, please **stop** and return the survey in the postage paid envelope. If you checked **yes**, please **proceed** to answer the next question.

Section I: Demographic information

2. When were you born? _____ Year

3. What is the highest level of education that you have completed?
(Check \checkmark one box)

- Grade school
- Some high school
- High school graduate
- Some college
- Bachelor degree
- Professional degree/Graduate degree

4. What is your racial background? (Check \checkmark one box)

- African American
- Asian or Pacific Islander
- Caucasian
- Native-American
- Hispanic
- Other

5. What is your gender? (Check \checkmark one response)

_____ Male _____ Female

6. Which of the following conditions have you also been diagnosed with (Check \checkmark all boxes that apply)

- Hypertension (High Blood Pressure)
 - Heart Disease
 - Cancer
 - Stroke
 - Arthritis
 - Chronic Respiratory Disease such as Asthma, COPD
 - Other. Please describe or list: _____
-

7. What is your annual household income? (Check \checkmark one box)

- Less than \$10,000
- Between \$10,000 and \$18,500
- Between \$18,501 and \$35,000
- Between \$35,001 and \$ 55,000
- Between \$55,001 and \$88,000
- Between \$88,001 and \$100,000
- More than \$100,000

APPENDIX 8
RECALL MEASURES

**PLEASE RETURN THIS SURVEY IN THE PREPAID ENVELOPE
IMMEDIATELY AFTER FILLING IT OUT**

1. 'I am **eligible** for this study:' (Check \surd one response)
Yes _____ No _____

If you checked **no**, please **stop** and return the survey in the postage paid envelope. If you checked **yes**, please **proceed** to answer the next question.

Section I: Diabetes related information

2. On how many **days over the past two weeks** did you test your blood sugar? _____ days
3. How many **times a day** has your doctor recommended you test your blood sugar? _____ times
4. On how many **days over the past two weeks** did you test your blood sugar **as recommended by your doctor?** _____ days

APPENDIX 9

DIARY

PLEASE RETURN THIS LOG IN ATTACHED ENVELOPE AFTER 2 WEEKS

BLOOD SUGAR TESTING LOG

For each day over the next two weeks starting today, please keep a record of your blood sugar tests. In the space provided, tell us how many times you test your blood sugar. For instance, if you test your blood sugar levels three times today, write down 3 under the column that says 'Day 1. Please return this log to us after 2 weeks in the envelope attached to this log.

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Number of times you tested your blood sugar level														

**** On the day that you return this log, please fill in your answers to the questions below:****

1. On how many days over the past two weeks did you test your blood sugar? _____ days
2. How many times a day has your doctor recommended you test your blood sugar?
_____ times
3. On how many days over the past two weeks did you test your blood sugar as recommended by your doctor? _____ days

APPENDIX 10
REMINDER FOR QUESTIONNAIRE

A FRIENDLY REMINDER

Last week we sent you a survey requesting you to complete it. We haven't heard from you yet. We wish to inform you that you can still complete and return the survey to us. If you still have the survey and wish to participate, please complete it. After you fill it out, please return it in the return envelope. The postage will be paid for by the university. If you need another copy mailed to you, please contact Anagha Nadkarni at 734-763-7619 or anaghan@umich.edu.

Your input is very important to us. We hope that you will be able to assist us.

Sincerely,

Sincerely,

Suzan Kucukarslan, PhD
Department of Pharmacy Services
Henry Ford Hospital

Assistant Professor
College of Pharmacy
University of Michigan

APPENDIX 11
FIRST REMINDER FOR DIARY

A FRIENDLY REMINDER!

Two weeks back we sent you a log. We asked you to keep the log with you and fill it out over the span of two weeks. This is a reminder to please return your log to us. Please place it in the return envelope which is attached to the log. The postage will be paid for by the university. If you need another envelope mailed to you, please contact Anagha Nadkarni at 734-763-7619 or anaghan@umich.edu.

Your input is very important to us. We hope that you will assist us.

Sincerely,

Suzan Kucukarslan, PhD
Department of Pharmacy Services
Henry Ford Hospital

Assistant Professor
College of Pharmacy
University of Michigan

APPENDIX 12
SECOND REMINDER FOR DIARY

A FRIENDLY REMINDER!

A few weeks back we sent you a log. We asked you to keep the log with you and fill it out over the span of two weeks. This is a reminder to please return your log to us. Please place it in the return envelope which is attached to the log. The postage will be paid for by the university. If you need another envelope mailed to you, please contact Anagha Nadkarni at 734-763-7619 or anaghan@umich.edu.

Your input is very important to us. We hope that you will assist us.

Sincerely,

Suzan Kucukarslan, PhD
Department of Pharmacy Services
Henry Ford Hospital

Assistant Professor
College of Pharmacy
University of Michigan

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