

TESTING A CONCEPTUAL FRAMEWORK FOR SELF CARE IN PERSONS WITH
DIABETES: THE EFFECT OF DEPRESSION

By

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Abstract

Diabetes is a major source of morbidity, mortality, and economic expense. Not only do people with diabetes have a higher risk of developing depression, the rate of depression is much higher than in the general population (ADA, 2010). Depression is believed to influence Diabetes Self Care Management (DSCM), self efficacy, and self care agency. Therefore, the main study aim was to examine the relationships among these factors using a cross-sectional model testing design. The secondary aim was to examine item characteristics and reliability of the Diabetes Self Management Scale (DSMS). A convenience sample of 78 individuals with type 1 or type 2 diabetes mellitus who were taking insulin was recruited. Participants completed five psychometric questionnaires. Path analysis techniques were used to examine relationships among the variables. For the DSMS, item and reliability resulted in a reduced 40-item scale with an alpha of 0.947. The new scale had a strong correlation with self efficacy ($r=0.80$) which supports the validity of the scale. The results of the path analysis testing showed that depression negatively affected self efficacy ($B=-1.43$; $p<.01$; $r^2=.18$) and self care agency ($B=0.53$; $p<.01$; $r^2=.23$). The effect of depression on DSCM was completely mediated by self efficacy and self care agency. The findings may indicate that enhancing self efficacy and self-care agency might mitigate the negative impact of depression on DSCM.

Keywords: Depression, Diabetes Self-Care Management, Diabetes Self Efficacy, Diabetes Self-Care Agency, Diabetes Knowledge

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Chapter I

Introduction

Diabetes is a chronic condition that affects about 25.8 million people in the United States or 8.3% of the population. About 215,000 people younger than 20 years of age had diabetes in 2011, and 1.9 million new cases of diabetes were diagnosed in people aged 20 years or older in 2010 (CDC, 2011). People with diabetes are at high risk for life threatening complications such as heart disease, neuropathy, nephropathy, eye complications, foot complications, skin complications, gastroparesis, stroke, and depression (ADA, 2010). These diabetic-related complications negatively affect the quality and the length of life of people with diabetes and are some of the main causes of mortality and health care costs (ADA, 2010; Nicolucci, Greenfield, & Mattke, 2006). Therefore, persons with diabetes should be capable and responsible for performing diabetes self care management to achieve glycemic control and prevent complications (Sousa, Zauszniewski, Musil, McDonald, & Milligan, 2004).

Not only do people with diabetes have a higher risk of developing depression, the rate of depression in people with diabetes is much higher than in the general population (ADA, 2010). Lustman et al. (2000) found in their meta analysis study that depression is associated with hyperglycemia in persons with type 1 and type 2 diabetes. De Groot, Anderson, Freedland, Clouse, and Lustman (2001) conducted another meta analysis to further explore the association between depression and diabetic complications. The analysis showed significant relationships between depression and a variety of diabetes complications such as diabetic retinopathy, nephropathy, neuropathy, macrovascular complications, and sexual dysfunction. Also, depression was consistently associated with increased severity of diabetes complications. In

other words, the coexistence of diabetes and depression is associated with significant morbidity, mortality, and increased health care cost (Egede & Ellis, 2010).

Although depression was associated with less adherence to different aspects of diabetes self care management, the direct effect of depression on glycemic control was insubstantial (Egede, 2005). This insubstantial effect is probably due to presence of other factors that mediated the relationship between depression and glycemic control (Cherrington, Wallston, & Rothman, 2010). Thus further studies are required to verify the relationship between depression and Diabetes Self Care Management (DSCM) (Lloyd, Pambianco, & Orchard, 2010)

Study Aims

Primary Aim

The aim of this study was to examine the relationship between depression and diabetes knowledge, self care agency, self efficacy, and self care management. The conceptual model guiding the study was the Diabetes Self Care Management model (Sousa, Zauszniewski, Musil, McDonald, & Milligan, 2004).

Secondary Aim

The Secondary Aim was to evaluate the item characteristics and reliability of the Diabetes Self Management Scale (DSMS).

Significance and Problem of the Study

Healthy People 2010 emphasizes that people with diabetes need to make a variety of critical decisions on a daily basis about diabetes. In general, the majority of clinicians consider that diabetes is a self care management disease, and that patients should be capable and responsible to take care of themselves. Motivating persons with diabetes is necessary in managing the disease and reducing the risk of complications (Sousa et al., 2004).

Depression among people with diabetes is not uncommon (ADA, 2010). Li, Ford, Zhau, Ahluwaliai, Pearson, and Mokdad (2009) assessed the prevalence of undiagnosed depression in persons with diabetes and found that the unadjusted prevalence was 8.7%. About 45% of persons with diabetes who had depression were undiagnosed. The researchers concluded that undiagnosed depression is common among persons with type 1 or type 2 diabetes; so early detection of depression is needed. Li, Ford, Strine, and Mokdad (2008) found that the prevalence rate of major depression among adults with type 1 and type 2 diabetes in the U.S. was 8.3%, ranging from a low of 2.0% in Connecticut to a high of 28.8% in Alaska. Depression was highest among African Americans and persons with T2DM who were taking insulin.

Lustman et al. (2000) conducted a meta analysis study to address the effect of depression in persons with T1DM and T2DM on glycemic control. The researchers reviewed a total of 24 cross-sectional studies retrieved from Medline and PsycINFO that satisfied their inclusion criteria. These studies were published between 1975 and 1999 and reported the association of depression with glycemic control in adults with diabetes. The authors concluded that depression is associated with hyperglycemia in people with type 1 or type 2 diabetes. Severity of depressive symptom was associated with higher health care costs (Ciechanowski, Katon, & Russo 2000). However, the type of the association and the direction of the relationship between glycemic control and depression were not clear, and more research is needed to identify the mechanisms by which depression and glycemic control may be linked.

More recent studies investigated the relationship between depression and diabetes such as De Groot et al. (2001) who conducted a meta analysis study to explore the relationship between depression in diabetes and the complications of both T1DM and T2DM in terms of strength and consistency, direction, and whether the relationship differs among specific diabetes

complications. A total of 27 articles published between 1975 and 1999 that examined the relationship between depression and diabetes complications in type 1 and type 2 diabetes, were used in the meta analysis. A significant relationship between depression and a variety of diabetes complications was found, and depression was consistently associated with increased severity of diabetes complications. However, the authors indicated that there is still a need to identify the pathways that mediate this association.

Other studies addressed the relationship in more specificity to provide understanding for the pathways of effect of depression. Ciechanowski et al. (2000) conducted a descriptive cross-sectional study to explore the impact of depressive symptoms in primary care patients with diabetes on diabetes self care management, adherence to medication regimens, functioning, and health care costs. The researchers found that those in the medium and high severity tertiles of depression were significantly less adherent to dietary recommendations. Also, those in the high-severity tertile had a higher percentage of days in non-adherence to oral hypoglycemic regimens and poorer physical and mental functioning. So, health care costs for those on the high severity tertile had a higher probability of increasing. The researchers concluded that effective treatment of comorbid depression is considered an essential component of high quality care of persons with diabetes because of the major adverse effect of depression on functional impairment and self care management of illness.

Another study addressed different aspects of the relationship between depression and diabetes. Egede and Ellis (2008) studied the association between depression, diabetes knowledge, diabetes self care management, and perceived control (the extent to which patients feel a sense of control of diabetes and that their life is manageable) in an indigent sample with T2DM. They found that depression was not significantly associated with diabetes knowledge,

but significantly associated with diabetes self care management and perceived control. The authors concluded that diabetes knowledge has no influence on the relationship between depression and the outcomes of diabetes. Also, they concluded that depression impairs self care management practices by affecting the patient's perceived control; however, the mechanism of how depression leads to poor outcomes in persons with diabetes is poorly understood.

Cherrington, Wallston, and Rothman (2010) indicated that the pathway connecting depression and complications in persons with diabetes has yet to be fully explained. They conducted a cross sectional study to assess the relationship between depression, self efficacy, and glycemic control in persons with T2DM. The researchers tested the mediation effect of self efficacy on the relationship between depression and glycemic control in the whole sample and in the male and female subsamples. Cherrington et al. (2010) found that self efficacy only mediated the effect of depression on glycemic control in the whole sample and in the male subsample. The authors postulated that the difference may be due to differences in coping techniques between men and women or due to other factors. The findings, regarding presence of factors that mediated the relationship, were congruent with the findings of Egede (2005) review of the literature, who found that depression was associated with fewer adherences to different aspects of diabetes self care management including dietary recommendation, physical activity, and medication adherence, whereas the impact of depression on glucose dis-regulation was insubstantial.

Further studies were conducted to examine the effect of depression on DSCM and explore the effect on the different aspects of DSCM, for example, Lloyd, Pambianco, and Orchard (2010) who studied the correlation between depression and certain aspects of DSCM. The researchers assessed the aspects of smoking, alcohol drinking, self monitoring of blood glucose, and physical

activity as indicators of self care management. They found that depression was negatively correlated with physical activity, and not correlated to self monitoring of blood glucose. Therefore, the authors concluded that the presence of depression may lead to greater barriers to appropriate diabetes self care management, but further studies are required to verify this relationship.

In summary, depression is common among people with diabetes. In addition, depression has an impact on people with diabetes and can affect the functionality, self efficacy, and self care management. However, these effects are not completely clear because the pathways of the influences have not been explored. Further, the available literature about the relationship between depression in persons with diabetes and diabetes knowledge, self efficacy, self care agency, and self care management was not guided by a model or a theory. Egede and Ellis (2010) conducted a systematic literature review to assess the relationship between depression and diabetes. The researchers indicated that depression was related to more diabetes complications because depression was associated with persistently high HbA1c levels. Also, depressive symptoms were considered a predictor of poor adherence to self care management. These research studies suggest there is a need to address depression and self care management simultaneously. However, self care management did not fully account for the relationship between depression and a high level of HbA1c, knowing that depression also affected perceived self control.

Arguments about Temporal Sequence of Depression and Diabetes

Egede and Ellis (2010), in their previously mentioned systematic review of the literature to assess the relationship between diabetes and depression, remarked that a long time ago, a physician, called Thomas Willis, suggested that diabetes is a result of sadness and sorrow. To

examine the relationship between diabetes and depression the researchers performed a comprehensive search of the literature for studies that addressed this relationship. According to the authors, conducting a meta analysis was not possible because of the broad area that was covered and the heterogeneity of the studies.

Six recent studies that included two meta analyses were used by Egede and Ellis (2010) to investigate the casual pathway between diabetes and depression. They stated that one meta analysis study by Mezuk, Eaton, Albrecht, and Golden (2008) found that the relative risk of incidence of depression with baseline T2DM was 1.15 (95% CI 1.02 to 1.30), whereas the relative risk of incidence of T2DM with baseline depression was 1.60 (95% CI 1.37 to 1.88). That meant depression was associated with higher risk of T2DM than T2DM was to depression. Egede and Ellis indicated that these findings were supported by other studies in the literature.

Noumen, Lloyd, and Pouwer (2009) argued with Mezuk et al. (2008) findings regarding the role of type 2 diabetes as a risk factor for depression. The argument was based on that Mezuk et al. only reviewed the studies that had excluded prevalent cases of depression at the first measurement. This exclusion was done so conclusions could be drawn about the number of new cases of depression. However, this exclusion does not guarantee that participants did not suffer from depression at some point in the past. Considering history of past depression is important in similar studies because depression is a highly recurrent condition and past depression is the most important risk factor for future depression. Therefore, conclusions concerning the role of diabetes as a risk factor for new cases of depression seem premature. Noumen et al. (2009) added that researches should be careful about excluding pre-recorded cases of depression because that will influence any conclusions that can be made with regard to the role of diabetes as a risk factor for recurrent depression. The authors concluded that better designed studies are still

required in order to establish the true incidence of depression in people with diabetes and the factors associated with depression in diabetes.

Knol et al. (2007) indicated that there were two possible mechanisms underlying the association between Type 2 diabetes and depression. First, biochemical changes associated with diabetes could have accounted for the increased risk of depression. For example, hyperglycemia and hyperinsulinemia increased the activity of the hypothalamic-pituitary-adrenal axis, inducing arousal of the nervous system, which in turn may have promoted depression. Second, depression in persons with diabetes may have been viewed as the result of the burden of the disease. This was supported by the finding that when the burden of diabetes increased, the probability of mood symptoms increased as well. So, they conducted a study to investigate if disturbed glucose homeostasis or known diagnosis of diabetes was associated with depressive symptoms. The goal of this study was to determine the reason for the increased prevalence of depression in patients with Type 2 diabetes.

Knol et al. (2007) divided their study sample into four subgroups, normal fasting plasma glucose (FPG), impaired FPG, undiagnosed T2DM, and diagnosed T2DM. They found that the impaired FPG group and undiagnosed type 2 diabetes did not have an increased risk of depressive symptoms. Only those diagnosed with type 2 diabetes had an increased risk (1.7 times) of depressive symptoms. Results stayed the same even after adjustment for demographic and lifestyle variables. Knol et al. concluded that disturbed glucose homeostasis was not associated with depressive symptoms. Instead, awareness of presence of diabetes had an increased risk of depressive symptoms. So, the increased risk of depressive symptoms in diabetes might be an outcome of the burden rather than a result of high glucose levels. However, the

nature of the relationship in term of causes and consequences cannot be determined especially because the study was cross sectional one.

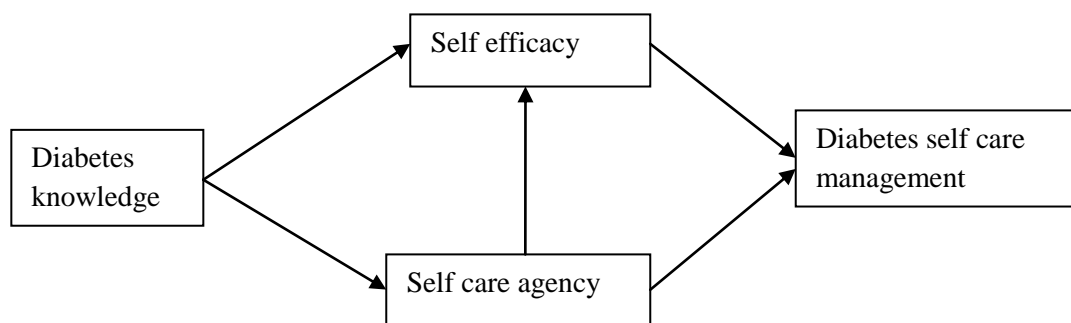
Lloyd, Pambianco, and Orchard (2010) conducted a cross sectional study to examine the relationship between depressive symptomatology, diabetes-related distress, and aspects of diabetes self care management in persons with Type 1 diabetes. They found a strong association between depressive symptomatology and diabetes-related distress, independent of other potential factors including complication status, duration of diabetes, and gender. However, they stated that causal relationships cannot be inferred because of the type of the study. From the different self care management aspects the study addressed, the researchers found only the physical activity aspect had a significant association with depression. The aspects of smoking, drinking alcohol, and frequency of self monitoring of blood glucose were not significantly associated with depression.

Lustman and Clause (2007) addressed the relationship between diabetes and depression and summarized the existing knowledge regarding determining the temporal sequencing of the two conditions. The authors stated that whether depression precedes diabetes or diabetes proceeds depression has been a “chicken versus egg” issue for long time. Studies have shown that the temporal order may go either way: diabetes to depression or depression to diabetes. Also, they indicated that the current evidence in the literature shows that the prevalence of depression is increased significantly in persons with both types of diabetes compared with those without diabetes, and depression appears to increase significantly the likelihood of developing type 2 diabetes.

Theoretical and Conceptual Framework for Hypotheses Testing

Sousa et al. (2004) and Sousa and Zauszniewski (2005) synthesized knowledge about self care and identified a framework and described the relationships between diabetes self care management, self efficacy, glycemic control, self care agency, and diabetes knowledge. The purpose of this framework was to provide all the necessary elements for a research model of diabetes self care management, and to determine utility of various personal and environmental factors in nursing practice (See figure 1).

Figure 1. The relationships between the concepts of the Research Model for Diabetes Self care Management as proposed by Sousa et al. (2004).



Definitions of Concepts in Sousa's Model

Sousa et al. (2004) proposed a conceptual framework for diabetes self care management based on concepts from Orem's Self care theory, Bandura's self efficacy theory, and a comprehensive review of empirical works. In this conceptual framework the authors defined the concepts in the framework as the following

Diabetes knowledge (DK) was defined as “The individual's knowledge of the disease and knowledge about diabetes diet [healthy eating], exercise [being active], blood glucose monitoring, and medication/insulin administration [taking medication]” (Sousa et al., p. 63).

Diabetes knowledge is an important aspect in diabetes and allows persons with diabetes to evaluate themselves and determine interventions necessary to meet their needs and delay diabetic complications. Diabetes knowledge was described as a personal resource that can be obtained through life experience, formal, and informal education.

Self care agency (SCA) was defined “as the individual's capabilities to perform self care activities to meet his or her self care needs in promoting and maintaining human structure, functioning, and development” (Sousa et al., p. 63). SCA includes foundational traits and operational traits. The foundational traits include personal capacities such as sensation, perception, memory, and orientation. The operational traits include capacities to recognize personal and environmental conditions and factors important for self care actions such as judgment and decision making.

Self Efficacy (SE) was defined as integrating “the cognitive, social, and skills capability that a person has to perform a course of action” (Sousa & Zauszniewski, p. 64). Self efficacy contains efficacy expectancy and outcome expectancy. Efficacy expectancy means beliefs in personal capability to perform the action, whereas outcome expectancy represents beliefs in the results of performing the action. However, self care agency is required because self efficacy is not sufficient alone to cause performance of the action. So, the researchers proposed the mediation effect of self efficacy on the relationship between SCA and DSCM.

Diabetes Self care Management (DSCM) was defined as “the exercise of self care- the actual performance of self care actions by individuals to manage their diabetes” (Sousa &

Zauszniewski, p. 64). DSCM is the core concept in this model. The goal of diabetes self care management is to maintain near-normal glucose levels by means of self care actions by performing actions of following diet, performing physical activities, monitoring blood glucose level, and using of medications.

Definition of Depression

Depression is a common mental disorder that presents with depressed mood, loss of interest or pleasure, feelings of guilt or low selfworth, disturbed sleep or appetite, low energy, and poor concentration. These problems can become chronic or recurrent and lead to substantial impairments in an individual's ability to take care of his or her everyday responsibilities (World Health Organization (WHO), 2012).

Description of the Relationships in the Framework

A cross sectional correlational model testing design was used in Sousa and colleagues (2004, 2005) studies to examine the proposed relationships in the Research Model for DSCM. In these studies, diabetes knowledge, self care agency, and self efficacy were considered as personal factors that affect the performance of self care actions. Self care actions were represented by diabetes self care management. Ultimately, self care actions will cause the achievement of physical health of the diabetic person.

The relationships among these concepts (diabetes knowledge, self efficacy, self care agency, and diabetes self care management) were tested to identify the types and the directions of these relations. Sousa and colleagues tested the presence of direct relations between each and every concept in the framework. Then they tested for indirect relations through examining the presence of mediating or moderating effects among the concepts. Testing the relationships was based on the propositions of Orem's theory, Bandura's theory, and empirical works. For

example, Sousa and Zauszniewski (2005) indicated that previous studies showed the presence of a direct relationship between diabetes knowledge and self efficacy. Other studies indicated that self efficacy requires SCA to cause performance of actions. So the research model for DSCM indicated the direct relation between DK and SE, and mediation effect of SCA on the relationship between SE and DSCM. Self care agency was reported as a concept that had not been tested by diabetic researchers, so assessing its influence on the other concepts was needed.

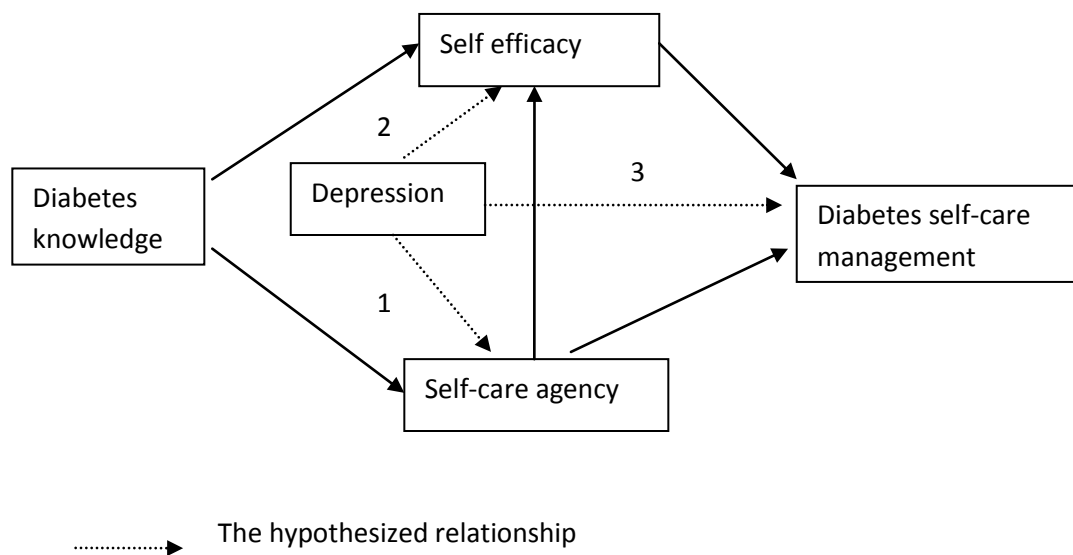
Sousa et al. (2005) found that there are direct relations between diabetes knowledge and self efficacy and diabetes knowledge and SCA. Also, there were direct relations between SCA and SE, SCA and DSCM, and SE and DSCM. An indirect relationship was found in that SCA mediated the effect of SE on DSCM. Further description of the findings is presented in the literature review in Chapter 2. Sigurdardottir (2005) also tested a model of self care in diabetes and reported that the relationships between self efficacy, diabetes knowledge, and physical skills influence metabolic control. These findings supported the Sousa et al. (2004) framework.

All tests of relationships between the concepts of the Sousa et al. (2004) model controlled for demographics. Simple linear regression, standard multiple regression, and hierarchical multiple regression were used to test the relationships between the variables proposed in the research model. Diabetes knowledge had a positive effect on self care agency and self efficacy ($\beta = 0.17$, $p < 0.05$; $R^2 = .24$, $p < .01$). Self care agency positively affected self efficacy ($\beta = .61$, $p < .001$). Self efficacy had a positive effect on diabetes self care management ($\beta = .72$, $p < .001$). Self care agency mediated the effect of diabetes knowledge on self efficacy ($b = .59$, $t(138) = 8.703$, $p = .000$). Self efficacy partially mediated the effect of self care agency on diabetes self care management ($b = .60$, $t(132) = 9.00$, $p = .000$). Diabetes self care management had negative relation with HbA1c level ($b = -.18$, $p < .05$).

Depression and the Research Model for DSCM

In previous studies depression was found to have an impact on diabetes self efficacy and diabetes self care management. Also, depression was found to have no association with diabetes knowledge. The relationship between diabetes self care agency and depression has not been explored. Self efficacy mediated the effect of depression on glycemic control. But according to Sousa et al. model, effects on glycemic control are controlled by diabetes self care management. (See figure 2 for the proposed revision for Sousa's model).

Figure 2. The proposed revision of integrating depression into the research model for DSCM.



Research Questions for Primary Aim

1. Is there a relationship between depression and diabetes Self care Agency (SCA)?
2. Does depression affect diabetes Self Efficacy (SE)?
3. Does depression affect Diabetes Self care Management (DSCM)?
4. Are there any mediation effects in these relationships?

Research Question for Secondary Aim

What are the reliability coefficient and the characteristics of the items of the Diabetes Self Management Scale (DSMS)?

Assumptions

1. DK directly and positively affects diabetes SE and SCA
2. SCA directly and positively affects SE
3. SE directly and positively affects DSCM
4. SCA directly and positively affects DSCM
5. SE mediates the effect of SCA on DSCM
6. Diabetes knowledge has no direct effect on depression

Summary

Diabetes is a condition that impacts the lives of a large population and is associated with higher mortality, morbidity, and health care costs. Diabetes self care management (DSCM) is an essential part of management of diabetes to reduce the risks of diabetic complications. The Enhance-Behavior Performance Model (EBP) addressed DSCM and indicated that diabetes knowledge precedes diabetes self care-agency (SCA) and self efficacy (SE), which also precede and affect the achievement of DSCM. On the other hand, DSCM precedes and affects the achievement glycemic control. Sousa et al. (2004) proposed a research model (see figure 1) based on the EBP model and tested the relationships between diabetes knowledge, SCA, SE, and DSCM to clarify the pathways of effects.

Diabetes is also associated with higher risk of depression. The co-morbidity of diabetes and depression is associated with even greater risk of diabetic complications and higher costs of management. Depression was found to influence DSCM; however, the pathways of effects are

not completely understood. So, this descriptive model testing-design study is to address the relationships between diabetes knowledge, SE, SCA, depression, and DSCM.

Chapter II

Review of the Literature

A step-wise method was used to search the literature and retrieve the relevant articles. In this method, the literature was searched for the key words of interest. For example, to find the related articles for the topic of diabetes knowledge and diabetes education, literature was searched using the keywords of knowledge and diabetes education. After that, the articles were ordered in term of their rank where the meta-analysis studies had the highest rank and simple qualitative descriptive studies had the lowest (see Table 2 for the ranking of the articles as used to review the literature). Articles from the highest available rank were selected to conduct the review of the literature for this paper. For example, if a meta analysis study that is related to the topic was found, the need to review articles from a lower rank was waived unless the lower rank article was more recent than the meta-analysis study, or addressed a new variable.

Table 1.
Ranking of the types of studies in descending order.

Ranking	Type of study
1	Meta analysis
2	Randomized Control Trials (RCT)
3	Single clinical trial
4	Systematic literature review
5	Simple quasi experimental
6	Systematic review of non-experimental studies
7	Simple non-experimental
8	Meta-synthesis
9	Simple qualitative study

Databases such as CINAHL, Pubmed, ProQuest, PsycINFO, and Google Scholar were searched for studies that addressed the relationship between diabetes knowledge and diabetes education, self efficacy, Self Care Agency (SCA), and Diabetes Self Care Management (DSCM). The articles were assessed through reviewing the title and reading the provided abstract. The

literature search resulted in few studies that directly addressed the relationship between diabetes knowledge and diabetes self care agency. Searching the literature using the strategy described on page 17 revealed limited studies that addressed the relationships between diabetes knowledge and diabetes education, self efficacy, self care agency, and Diabetes Self Care Management (DSCM). For example, Sousa et al. (2004) studied the previously mentioned relationships separately and combined. So, to prevent redundancy in the description of the studies, the literature review is reported in this paper in form of discussing and describing the retrieved studies individually.

Studies That Addressed the Relationships Among Diabetes Knowledge, Self Efficacy, Self care Agency, and Diabetes Self care Management

Meta Analysis Studies

Fan and Sidani (2009) Meta-analysis

Fan and Sidani (2009) conducted a meta analysis study of randomized control trials (RCTs) to examine the differences in diabetes knowledge associated with various Diabetes Self Management Educational (DSME) programs and to calculate the effect size of the educational interventions on diabetes knowledge. Four electronic data bases were searched for relevant studies using keywords identified by the authors; these databases were MEDLINE, CINAHL, Health STAR, and EMBASE. Also, a manual search was done of journals that were expected to publish on the topic, such as Diabetes Care, Diabetes Educator, and Diabetic Medicine. The randomized control trial that examines the effect of DSME on knowledge, self management behaviour, and metabolic control were reviewed. Inclusion criteria were studies that (a) focused on adults (>18 years of age) who had T2DM, (b) included interventions that addressed educational, behavioral, or multiple components conducted in acute or primary care settings, (c)

assessed outcomes related to knowledge, self management behaviour, and metabolic control, and (d) published in English between January 1990 and December 2006.

Fan and Sidani (2009) searched the electronic databases and the journal and yielded 180 articles . A total of 130 articles were excluded as follows: 107 articles because of redundancy and/or not meeting the inclusion criteria; 17 studies because they did not provide the data needed to calculate effect size; and 6 studies because of lack detailed information about the intervention elements. A coding scheme was developed to extract data from the studies based on the operational definition provided by the authors regarding the elements and their categories (see Table 2). The outcome measures that were of interest for the authors included diabetes knowledge, self management behavior, and metabolic control. The Comprehensive Meta Analysis (version 2) program was used to estimate the effect size. The researchers did not describe how diabetes knowledge was measured in the retrieved studies.

Table 2.

The Elements of DSME interventions and their categories as provided by Fan & Sidani (2009).

Element	Categories
Type of DSME	<p>Educational: Interventions in which persons with diabetes receive information from health care provider and focusing on the provision on information to improve the knowledge.</p> <p>Behavioural: Interventions targeting improve self management behavior and focusing on active skill training</p> <p>Psychological: Interventions in which the primary goal is to address negative mood states, coping skills, and social support</p> <p>Mixed: Encompassing a combinations of the 3 types above.</p>
Teaching method	<p>Didactic: Involves conveying diabetes- related information to patients and characterized by limited discussion and intercation between providers and participants.</p> <p>Interactive: Consisted of active participant involvement in the learning process.</p> <p>Mixed:</p>

	Encompassing a combinations of the 2 types above
Strategy of delivering DSME	Written material Online/web based Video Face to face By phone Mixed
Format	Individual Group Mixed
Number of diabetic related topics	One topic More than one topic
Dose of DSME	Number of sessions Length of sessions/ total contact hours Duration of intervention delivery Delivery of booster sessions; a booster session is an additional session or phone contact following completion of the intervention.

The authors stated that out of the 50 included studies, about 56% were conducted in North America, 10% in Asia, 4% in Australia, and 34% in Europe. In general, most of the DSME interventions were from the mixed type encompassing knowledge, behavior, and psychology; offered using mix of teaching strategies; with a mix of individual and group format; delivered in multiple sessions; and covering more than one topic. Nineteen studies addressed diabetes knowledge as an outcome of DSME. Knowledge was the main outcome of DSME with a weighted overall effect size (d) of 1.29 ($p < 0.05$). The range of effect size for the 19 studies was (0.9 to 1.67). The mixed type of DSME intervention yielded the highest effect size on knowledge ($d = 1.32$; standard error (SE) = 0.2; $p < 0.05$), whereas the type of DSME had moderate effect size and was statistically insignificant ($d = 0.59$; SE = 0.36; $p > 0.05$). All different elements of DSME interventions significantly affected diabetes knowledge ($p < 0.05$), except for the DSME programs that had length of sessions of 10 to 20 total contact hours. No discussion or rationalization for these results were provided. In general, authors concluded that DSME interventions improve

diabetes knowledge of adults with T2DM persons, and different DSME intervention elements vary in their effect on diabetes knowledge.

Randomized Controlled Trials Studies

Atak, Gurkan, and Kose (2008)

A recent Randomized Control Trial (RCT) by Atak et al. (2008) studied the effect of group patient education on knowledge, self management behaviors, and self efficacy in persons with T2DM using a randomized controlled (pretest, posttest design) trial in Turkey. The sample was a convenience sample of 80 participants who were randomly assigned into either a control (n=40) or intervention group (n=40). A pre knowledge-test was given to measure participants knowledge, and to guide the educational program developed. No description of this pre test was available.

Knowledge and reported-self management behaviors were measured by a knowledge test that was developed for this study, and included 12 questions about knowledge on T2DM. The questions were based on the recommendations of 2 physicians from the Department of Endocrinology and Metabolism in University of Ankara and teaching letters of the Diabetes Education Study Group (DESG) of the European Association for the Study of Diabetes (EASD). The 12 questions to measure diabetes knowledge was pilot tested by administering the test to 10 diabetic persons. No changes were made except removal of a question about the place of living. Pilot study participants were excluded from the main study. No further description of the pilot testing results, or the reliability or validity of the measure was provided.

A 90-minute educational program using a question based patient centered approach was delivered to the participants by the researcher. The program included diabetes specific information about self management behaviors including blood glucose self monitoring, hypo and

hyperglycemia, exercise, diet, weight control, foot care, and the importance of medical care. The program was delivered to five intervention groups in different weeks to prevent contamination of the intervention. The control group received only an explanation for the correct answers following the post test.

The authors evaluated the effect of the education on diabetes knowledge by assessing mean score differences between the pre and post tests, using t-tests. Knowledge and self reported self care management were divided into the categories of hypoglycemia, diet, and diabetic, retinopathy. Self reported self management behaviors were tested by testing the mean score differences in the categories of exercise, preventing hypoglycemia, blood glucose self monitoring, weight control, regular eye checks, measuring blood pressure, and foot care. Each one of these categories included other sub-categories that were tested for mean score difference between pre and post test.

Atak et al. (2008) evaluated the knowledge regarding the sub-categories of nutrients with high caloric content, daily fat distribution, walking regularly, and regulated blood glucose to prevent diabetic retinopathy after implementing the educational program. They reported that the participant's knowledge regarding of nutrient with high caloric content and daily fat distribution were the only categories to improve after implementing the program.

Ten participants in the intervention and 13 in the control group could name nutrients with high caloric content before the program, and after the implementation of the program the number increased to 20 in the intervention and decreased to 10 in the control group; and the difference was significant ($p < 0.05$). Meanwhile, 18 patients in the intervention and 11 in the control group described recommended daily fat distribution correctly before the program, and 23 in the intervention group and 12 in the control group knew the recommended daily fat allowance after

the program; and the difference was significant ($p < 0.05$). The authors concluded that patient education had a positive, but limited effect on knowledge and self reported self management behaviors.

Atak et al.(2008), in their randomized control study, examined the effect of the educational program on knowledge and self efficacy in people with T2DM. The authors found that the educational program significantly improved self efficacy; the difference in the mean scores, between the pre and post tests, for the intervention group was statistically higher than the difference in the mean scores, between the pre and post test, for the control group ($p = 0.006$). The authors did not provide the F statistics, or the power of the study.

Atak et al. (2008) also addressed the relationship between diabetes education and diabetes self care management; where diabetes knowledge was considered as an outcome measure of diabetes education and diabetes self care behavior was addressed as an outcome of DSCM. The researchers used 14 questions about self reported self management behaviors to measure self care behavior in the sample. The questions were related to exercise, preventing hypoglycemia, self monitoring of blood glucose, weight control, diabetic retinopathy, foot care, and measuring blood pressure. The questions were not explicitly described in the article and were referred to as questions based on teaching letters about diabetes and diabetes care provided by the Diabetes Education Study Group of the European Association for the Study of Diabetes. Only self reported self management behavior of exercise ($p < 0.05$) and regulating blood glucose to prevent retinopathy ($p < 0.05$) were significantly affected by the educational program. The authors reported the frequencies of the items and the p-values. For example, number of participants who reported no walking before the education was (13) and after the education was (6) in the intervention group, while these numbers were (12) and (16) in the control group

respectively. The results of central tendency and disparity were not reported. The authors indicated that these results are congruent with the literature because of lack of follow up in their educational program; and concluded that improving knowledge is not enough to maintain self care management behaviors on the long run.

George et al. (2008)

In contrast to the previously mentioned studies, George et al. (2008) in their randomized trial indicated that the brief educational intervention did not improve knowledge, probably because of the influencing effect of self efficacy on diabetes knowledge in the studied sample. The researchers studied the effect of a brief (2.5 days) psycho-educational intervention program on different outcomes such as HbA1C, hypoglycemia, blood pressure, weight, height, lipids, and psychometric profile that included diabetes knowledge and self efficacy in people with T1DM. The authors used a randomized controlled trial design, with an intervention group (n=54) and a control group (n=60). The sample was a random sample of persons with diabetes attending the researcher's specialist diabetes service in a hospital setting. Eligibility criteria included (a) T1DM for 12 months, (b) receiving multiple injection therapy for ≥ 2 months, (c) minimum age of 18 years, and (d) ability to read and write. Four participants dropped from the intervention group and 8 participants dropped from the control group. Participants were allocated in the groups using block randomization method, with 6 people in each block.

The 6 week educational program was delivered by a specifically trained diabetes specialist nurse and a specialist diabetes dietician in six groups of 8–10 participants in a 2.5-day course over a 6-week period using pre-approved educational materials. The authors did not clarify who approved the used educational materials. Sessions were interactive-based and reflection in between sessions was encouraged. Group-based problem solving exercises were

used during the sessions. Participants completed a workbook in between sessions and received feedback from peers and healthcare professionals at the following session. The control group was seen in their usual diabetes clinic, in addition to their study appointments. The control group had access to Diabetes Specialist Nurses and Specialist Diabetes Dietician, and to the Clinical Health Psychologist.

Diabetes knowledge was measured using the Diabetes Knowledge Test (DKT) scale (Fitzgerald et al., 1998). The DKT scale was integrated with the Medical Outcomes Study 36-Item Short-form Health Survey (SF-36), Illness Perception Questionnaire (IPQ), Diabetes Empowerment Scale (DES), Diabetes Treatment Satisfaction Questionnaire (DTS-Q), Hypoglycemia Fear Scale (HFS), and Diabetes Health Profile (DHP) in one questionnaire that included 220 items. The authors reported the Cronbach's alphas for the scales ranging from 0.6 to 0.94. However, no description of DKT scale or its reliability or validity was provided by George, et al. (2008).

Analysis of Covariance (ANCOVA) was used to detect differences in mean scores after adjusting for baseline scores. The authors indicated the need to have at least 90 participants to achieve 80% power for their study. The results showed that there was no significant difference in DKT means between the intervention and control group over time in the measurements done 3 months (mean difference=2.2; 95% Confidence Interval (CI)= -0.07 to 4.5; $p > 0.05$), 6 months (mean difference= 1.8; 95% CI= -0.7 to 4.2; $p > 0.05$), and 12 months (mean difference= 0.55; 95% CI= -3.2 to 4.3; $p > 0.05$) of the implementation of the program. The authors only reported the difference in means and CI. The actual means for both the intervention group and control group were not reported. The authors concluded that the lack of improvement in knowledge score suggests self efficacy skills may already have been common in this group of patients.

Comprehensive Literature Review Studies

Sigurdardottir (2005)

The conclusions of Atak et al. (2008) regarding the effect of knowledge on diabetes self care management in T2DM persons are similar to conclusions of Sigurdardottir (2005) about the effect of knowledge on diabetes self care management in T1DM persons. Sigurdardottir (2005) conducted a comprehensive literature review to explore self care and to present a model of factors that affect self care in T1DM. Different databases such as ProQuest, PsycINFO, and Medline were searched from (1995) to (2002). The literature was searched using the search terms of self care or self management, diabetes, and self efficacy. The search was limited to English and adults with T1DM. Twenty studies were found. The author did not provide any further description of the process of search but he identified all the studies he examined in an index.

Sigurdardottir (2005) did not focus on the method of reviewing and analyzing the articles, and instead, he focused on the findings to provide validation for the proposed Model for Self Care in Diabetes; no statistical findings were reported in the Sigurdardottir (2005) review. The researcher pointed to diabetes knowledge in persons with diabetes as a requirement for performing self care management. However, he reported that the studies in the review found that knowledge had little effect on self care management. Moreover, some studies addressed the influence of knowledge on self care management in only one area of DSCM such as diet, whereas other studies addressed knowledge and DSCM as outcomes of diabetes education. The author concluded depending on his review that flexible self care management depended on knowledge and lack of knowledge contributed to passiveness rather than active participation in DSCM.

Quasi Experimental Studies

Gallegos, Ovalle-Berumen, and Gomez-Meza (2006)

Gallegos, Ovalle-Berumen, and Gomez-Meza (2006) addressed the influence of education and self care agency on diabetes self care management. The researchers conducted a quasi-experimental, longitudinal study in Mexico, with adults with T2DM in ambulatory care. The purpose of their study was to examine the effect of education and counseling on metabolic control, while considering the effect of factors such as adaptation, self care agency, and environmental barriers on self care behavior and metabolic control. One of the research questions was an exploratory question about how variables such as adaptation, self care agency, and environmental barriers affect self care behavior and HbA1c levels in adults with T2DM. According to Gallegos et al. (2006), educational intervention programs were hypothesized to improve diabetes knowledge, thus, the educational programs were effective in improving self care management of diabetes. Self care management, in turn, leads to controlling glucose and lipid levels, and physical fitness. Nevertheless, the authors did not measure diabetes knowledge in the study. The researchers indicated that they measured diabetes knowledge initially in the study to determine the content of the educational program; they indicated only that some problem areas were identified based on the diabetes knowledge testing. The method of measuring diabetes knowledge was not reported. HbA1c was used to measure metabolic control, The Diabetes Self care Activities Questionnaire was used to measure self care management, and The Specialized Self care Capabilities Scale was used to measure self care agency.

A convenience sample of 57 participants was collected initially using the method of calling door to door. In the course of the study, four participants dropped out from the experimental group and 8 participants dropped out from the comparison group; the final sample

included a total of 25 participants in the experimental group and 20 in the comparison group. The intervention consisted of 6 educational sessions, each lasting 90 minutes, and an average of 20 individual counseling sessions, each lasting from 30 to 90 minutes, throughout 50 weeks. The comparison group participants continued their routine control in their health institution they usually visit. The routine control consisted of a monthly visit with the physician, and a check of glycemic level.

A multivariate analysis was conducted to examine the effect of the variables that could interact with or mediate the effects of the education on self care activities and on metabolic control. The results showed that self care agency had significant effects on the self care activities scores and on HbA1c values (Wilks' Lambda = .808; $F = 4.52$; $p < .05$). When the data were analyzed with two regression models, self care agency significantly affected self care activities ($\beta = 2.172$; $t = 3.01$; $p < 0.05$), but not HbA1c ($\beta = -0.618$; $t = -0.54$; $p > 0.05$). However, Gallegos et al. (2006) indicated that the Specialized Self care Capabilities Scale is a scale that has low reliability, and the distribution of the scores showed skewed data. The researchers concluded that the educational program, which was considered as knowledge improvement, affected self care agency in adults with T2DM.

Descriptive Studies

Sousa, Zauszniewski, Musil, McDonald, and Milligan (2004)

Sousa et al. (2004) tested a research model that they proposed and adapted from the Enhanced Behavior Performance Model (E-BPM). Sousa et al. (2004) model is the theoretical framework for the proposed project. The model states that personal and environmental factors affect diabetic person's performance of necessary self care actions to achieve better disease control. The researchers addressed the direct and indirect relationships between the concepts of

the research model that included diabetes knowledge, self efficacy, self care agency, and Diabetes Self Care Management (DSCM). The relationships addressed in the Sousa et al. study included direct and indirect relationships in form of mediation effects.

Sousa et al. presented 5 research hypotheses to test the direct and indirect relationships they proposed; these hypotheses were:

- Demographic characteristics affect diabetes knowledge.
- Self care agency mediates the effect of diabetes knowledge on self efficacy.
- Self care agency mediates the effect of diabetes knowledge on diabetes self care management.
- Self efficacy mediates the effect of diabetes knowledge and self care agency on diabetes self care management.
- Diabetes knowledge, self care agency, and self efficacy all together have positive effect on diabetes self care management.

The researchers used a cross sectional model testing design to examine the proposed relationships in the research model and to verify the accuracy of the theoretical and the empirical relationships between diabetes knowledge, self efficacy, self care agency, and DSCM.

A convenience sample of 141 adult persons with diabetes, either T1DM or T2DM, was recruited from an outpatient diabetes care center in United States. Inclusion criteria were adults age 21 years or more, minimum duration of diabetes of 6 months, insulin use by injection, and the ability to understand, speak, and write English. Those with T2DM but not managed by insulin injection, had insulin pump, were pregnant, or had known cognitive and psychomotor impairment were excluded from the sample.

Participants completed a background information questionnaire, the Diabetes Knowledge Test (DKT), Appraisal of self Care Agency Scale (ASAS), Insulin Management diabetes Self Efficacy Scale (IMDSES), and Insulin Management diabetes Self Care Scale (IMDSCS). Data were collected between December 2001 and March 2002. SPSS version 10 was used to analyze the data.

Sousa et al. indicated that data were slightly negatively skewed for all the measured variables except for self care agency which was slightly positively skewed. They indicated that because the sample was large enough, normality assumptions were not a concern. Pearson correlations were used to examine the extent of how diabetes knowledge is related to the other variables. Diabetes knowledge had significant relationships with age ($r = -.27$), type of diabetes ($r = .23$), race ($r = .42$), education ($r = .30$), duration of diabetes ($r = .24$), self care agency ($r = .22$), and self efficacy ($r = .24$) ($p < .01$). However, diabetes knowledge did not have a significant relationship with gender, social support, and DSCM.

Sousa et al. (2004) then conducted multiple regression analyses to test the effect of the demographic variables, self efficacy, self care agency, and DSCM on diabetes knowledge. The researchers found that the demographic variables of age ($b = -0.31$), education ($b = 0.17$), race ($b = 0.36$), duration of diabetes ($b = 0.25$), and self related health ($b = 0.15$) significantly affected diabetes knowledge ($p < .05$).

To examine the mediation effect of self care agency on the relationship between diabetes knowledge and self efficacy, the researchers conducted a hierarchical multiple regression analyses. In the first step, diabetes knowledge was found to significantly affect self efficacy ($b = 0.24$; $p < .05$). Also, diabetes was found to significantly affect SCA with control for self rated health ($b = 0.17$; $p < .05$). The effect of diabetes knowledge on self efficacy was tested in the third

step with control for SCA. The effect of diabetes knowledge on self efficacy became not significant ($b=0.11$; $p>.05$). Thus, the researchers concluded that SCA mediated the effect of diabetes knowledge on self efficacy. Another hierarchical multiple regression analysis was conducted to examine the mediation effect of SCA on the relationship between diabetes knowledge and DSCM. Because diabetes knowledge did not significantly affect DSCM after controlling for the age and type of diabetes ($b=.12$; $p>0.05$), SCA could not mediate the relationship between diabetes knowledge and DSCM.

The mediation effect of self efficacy on the relationship between diabetes knowledge and SCA on DSCM was tested. Hierarchical multiple regression analyses were conducted. Because diabetes knowledge did not significantly affect DSCM in the previous regression, self efficacy could not have the mediation effect. Finally, the effect of diabetes knowledge, self efficacy, and SCA, accounting for the effect of social support and controlling for age and type of diabetes, on DSCM was tested. The linear combination of the effect of all these variables together on DSCM accounted for significant proportion of the variance (adjusted $R^2=.63$; $p<.05$). Diabetes knowledge was found not to have a significant effect on DSCM ($b=-.08$; $p>.05$). Meanwhile, SCA and self efficacy significantly affected DSCM ($b=.15$ and $b=.60$ respectively; $p<.05$).

Sousa et al. (2004) indicated that the effect of age on diabetes knowledge, where younger diabetic persons had higher level of diabetes knowledge, is hard to explain because younger individuals usually have less experience. The authors attributed this finding to the probable effect of higher ability to retain knowledge in younger individuals. No results regarding the effect of the difference in age on diabetes knowledge were presented. Also, individuals with higher education had higher diabetes knowledge. The mediating effect of SCA on the relationship between diabetes knowledge and self efficacy was described as congruent with Orem's theory,

which indicates that personal experience will not affect behavior if the patient does not exercise personal agency. These findings emphasized that the plans and the implementations to improve diabetes knowledge are essential to improve SCA, which would in turn improve self efficacy, and ultimately enhance self care management.

Sousa et al. (2004) found that diabetes knowledge had no direct effect on DSCM, which contradicted the literature findings. The authors indicated that the effect of diabetes knowledge might be indirect and through SCA and/ or through self efficacy. The authors indicated that studies that found a direct relationship between diabetes education and DSCM were focusing on certain aspects of DSCM and not DSCM as a whole. The researchers concluded that diabetes knowledge improves self efficacy and SCA, which in turn improve DSCM.

Heisler, Piette, Spencer, Kieffer, and Vijan (2005)

The findings of Sousa et al, (2004) study regarding the relationships between diabetes knowledge, self efficacy, self care agency, and self care management were congruent with the findings of Heisler et al. (2005). Heisler et al. (2005) used a cross sectional design to assess the relationship between knowledge of one's actual and target health outcomes of persons with diabetes with their self efficacy and their self care management. The researchers indicated that the effect of diabetic person's knowledge of his/her own level of HbA1C on self care management and self efficacy is still not clear. Therefore, the researchers assessed the prevalence of knowing one's most recent HbA1c value, and tested whether knowing one's HbA1c is associated with better diabetes self efficacy and self care management. A sample of adults with T2DM receiving care in southeast Michigan health care facilities was surveyed by mail between May 2001 and October 2002. The inclusion criteria were 30 or more years old, had a prescription for a glucose control medication or supplies, one hospitalization or two outpatient visits with a

diabetes-related ICD-9 code, had seen their primary care provider (PCP) in the prior 6 months, and were scheduled to see the same PCP again in the next 6 months. A total of 1280 eligible patients were identified to fit the inclusion criteria through checking electronic records. Seventy four patients were excluded because they did not have type 2 diabetes, had severe dementia, or were deceased. A total of 663 participants completed the survey (56% response rate).

Participants were asked to identify the level of their HbA1C for the last 6 months. they could choose one of six response categories, which were less than 7, between 7 and 8, between 8 and 9, between 9 and 10, more than 10, and don't know. Also, the participants were asked to describe the level as "excellent," "good," "fair" or "poor" control. To assess whether the participants provided an accurate assessment of their HbA1C, the actual HbA1c level values were obtained. The researchers classified respondents as having an accurate assessment of their HbA1c value if the respondents evaluated their diabetes control as poor and had HbA1c values >8.5, reported "fair" and had HbA1c between 7.5 and 8.5, or reported "good" or "excellent" and had HbA1c <7.5. In addition, the survey included a question about how well the participant understands how to manage his diabetes. A 1–5 Likert type scale was used to assess the understanding. Diabetes self efficacy was measured using a validated four-item scale and higher scores reflected higher self efficacy in managing diabetes. Scores could range from 0 to 100. Self care management was measured using another validated questionnaire that asked about how many of the past 7 days (days 0–7) the participants performed the following as their doctor had recommended: take diabetes medications, follow a diabetic eating plan, and monitor blood glucose. The researchers indicated that higher values on these 3 tests means higher level of the related variable. No further description of the diabetes self efficacy scale and the self care management questionnaire, or their validation method was reported. Other questions such as the

age, gender, age, level of formal education, income, thoroughness of provider communication, and race were included to provide description of the sample and the results.

Multivariate linear and logistic regression analyses were conducted to assess whether knowledge of last HbA1c was associated with an accurate assessment of level of diabetes control, diabetes care understanding, self efficacy, and self care management. Heisler et al. (2005) indicated that the sample was socioeconomically and ethnically diverse. Sixty six percent of participants reported that they did not know their last HbA1c value, and only 25% of them accurately reported their most recent HbA1c value. Higher number of years of formal education and higher level of thoroughness of provider communication were associated with accurate knowledge of recent HbA1c values. Knowing HbA1c level was associated with higher scores on the measure of patients' reported diabetes care understanding ($\beta = 0.17$; $P \leq 0.001$). However, knowledge of HbA1c was not associated with better diabetes self efficacy or diabetes self care management. The authors reported that beta coefficients ranged from -0.032 to -0.006, and the P values ranged from (.50 to .90). The authors only reported that the self care management was composed of 3 domains. No description of the domain was available. Also, no tables of the regressions tests for the effect of knowing the HbA1C level on self efficacy and self care management were present.

Heisler et al. (2005) indicated that these findings were congruent with the literature and concluded that that factors beyond knowledge of disease-specific information are necessary to improve patients' self efficacy and their diabetes self care management. That is, greater patient knowledge alone does not correlate with improved glycemic control. To enhance patients' diabetes self efficacy and self care management, health care providers need to promote patients'

capacity to define the problems they are facing, make informed decisions about their diabetes management, and set realistic goals and strategies to meet those goals.

Articles Reviewing Relationships of SE, SCA, and DSCM with Depression

Literature Review Studies

Egede (2005)

Egede (2005) conducted a literature review for the studies that addressed the effect of depression on Diabetes Self care Management (DSCM). The author did not identify the inclusion and exclusion criteria for the retrieved articles nor did he identify the sources of them. Three studies were addressed in this review that studied the relationship of interest. Two of these studies were cross sectional and the third one was a secondary data analysis of a randomized control trial. The cross sectional studies showed that depression was associated with less adherence to medications, dietary recommendations, and physical activities. The third study showed that the impact of depression on self care management was higher than its impact on glycemic disregulation. So Egede (2005) concluded that in general, studies consistently showed that depression was associated with poor diabetes self care management behavior. The author did not provide any description of statistical tests.

Egede (2005) also addressed the findings of the Lustman (2000) meta analysis study that examined the effect of depression on metabolic control, complications, and functioning in type 1 and type 2 diabetes. Lustman found that depression was consistently and significantly associated with poor glycemic control, diabetes complications, and functional disability. Based on that, Egede (2005) proposed a conceptualization for the relationship between depression and diabetes outcomes. The author indicated that, in the literature, there are three mechanisms by which depression influenced diabetes outcomes. These mechanisms were classified as biological and

psychological mechanisms. The first mechanism was that distress and neurohormonal and immunological changes were thought to increase the susceptibility to diabetes. The second mechanism was that persistent somatic symptoms of depression worsen the physical health. Finally, depression was thought to impede treatment seeking and adherence. In the proposed conceptualization by Egede (2005), various aspects of diabetes self care management including medication adherence, physical activity, glycemic monitoring, and dietary behaviors were addressed as potential mediators for the relationship between depression and diabetes outcomes and complications.

Egede and Ellis (2010)

Egede and Ellis (2010) conducted a systematic literature review where they assessed the relationships between depression in diabetes and self care management. In this study, the authors indicated that conducting a meta analysis was not possible because of the broad area covered and because of the heterogeneity of the retrieved studies. Instead, a qualitative aggregation of the studies was done. The researchers performed a comprehensive search in Medline for studies published between 1966 and 2009 for studies that examined the association between depression and diabetes. No further description of the study procedure was presented.

In the qualitative aggregation that was done, the researchers identified seven studies that addressed the relationship between depression and DSCM. These seven studies included one meta analysis, three literature reviews, and three descriptive studies. Egede and Ellis did not explicitly identify this description of the studies, but they indicated that all of these studies found that depression negatively affected DSCM aspects including glucose self monitoring, smoking cessation, diet, physical activity, and medication; depression even negatively influenced those

who initiated these behaviors. One of these reviewed study indicated that those with depression were 2.6 times more likely to miss medication doses.

Descriptive Studies

Egede and Ellis (2008)

Egede and Ellis (2008) conducted a cross sectional descriptive study to assess differences in diabetes knowledge, perceived control, and diabetes self care management among depressed and non-depressed persons with diabetes. The authors indicated that diabetes self care management included self care understanding, problems in self care control, positive attitude, self care ability, and self care adherence. This study was conducted as part of another study that used a convenience sample of 201 persons with type 2 diabetes. The sample was collected from an indigent clinic in an academic medical center in United States. Billing records were used to identify persons with T2DM and these persons were contacted by phone to consent them for the study. The sample completed the surveys over a period of 12 months.

The researchers measured different variables that included depression, diabetes knowledge, and understanding diabetes self care management. The Center of Epidemiologic Study Depression scale 20-item version (CESD 20) was used to measure depression. This scale is described elsewhere in the measurement section in chapter 3 (page 52). Diabetes knowledge was measured using Diabetes Knowledge Test (DKT) which will also be described in the same section. Diabetes self care management was measured using Diabetes Care profile (DCP). This scale is a measure of social and psychological factors associated with diabetes and diabetes-related care and is composed of different subscales that measuring understanding management practice, control problems, positive attitude, care ability, and self care adherence. The scale was Likert-type scale with a range from 0 to 5. The overall score is the sum of all score divided by

number of non missing items. A higher overall score meant better self care. The scale was described as valid and reliable but no further information about the scale and its subscales, or its validity and reliability were provided. The researcher designed the study to have 80% power with an alpha level of (.05).

Results of the study showed that about 20% of the sample had depression. Depression in the sample was more prominent in women; 87% of the depressed persons were women; on the other hand, women composed 68% of the non-depressed group ($p < .001$). Other factors including years of education, duration of diabetes, income, ethnicity, and using insulin did not significantly differ in term of depression status. Researchers also found that the means scores for DKT did not differ significantly between the depressed and non-depressed persons (mean depressed=12.9; mean non-depressed=13.5; $p > .05$). However, the means of the DCP, in all its subscales except the perceived performance of self care, differed significantly between the depressed and non-depressed persons.

The subscales included self care understanding (mean (depressed)= 3.1; SD= 0.7); mean (non-depressed)=3.6; SD=4.4) , problems in self care control (mean (depressed)= 2.2; SD= 1.0; mean (non-depressed)= 1.5; SD=0.6), positive attitude (mean depressed) = 2.9; SD=0.7; mean (non-depressed) =3.7; SD=0.5), self care ability (mean (depressed) = 3.2; SD= 0.6; mean (non-depressed) = 3.7; SD= 0.5), and self care adherence (mean (depressed)= 3.3; SD= 0.9; mean (non-depressed) = 4.1; SD = 0.6); $p < .001$). So, the researchers concluded that diabetes knowledge is not a factor that influences the relationship between depression and the complications or outcomes of diabetes. However, depression plays a vital role in influencing the diabetes self care management practices.

Sacco et al. (2005)

Sacco et al. (2005) conducted another cross sectional study to test an integrated model with which the authors proposed to explore the factors that contribute to the link between depression and worsening of diabetes. The proposed model indicated that failure to adhere to diet and exercise prescriptions, along with higher BMI, results in lower self efficacy, which in turn increases depression. The researchers indicated that this model was based the proposition that performance accomplishments, such as adherence or lack of adherence, are considered the most direct and effective means of influencing self efficacy.

The study sample (n=56) was a convenience sample. Participants were between 18 and 65 years old and were English-speaking adults with type 2 diabetes recruited from the Diabetes Center at the University of South Florida Medical Clinic. Participants completed the questionnaire in the clinic, returned them by mail, or filled the questionnaire on a telephone interview. The questionnaires included the Summary of Diabetes Self care Activities Questionnaire (SDSCA), the Multidimensional Diabetes Questionnaire/ Self efficacy subscale, and the Patient Health Questionnaire. BMI was also calculated for the participants.

The SDSCA was a self report measure of diabetes adherence to diet, exercise, glucose testing, and medication. Only the eight diet and exercise items in the scale were analyzed. Raw scores were converted to standard scores and then summed. Sacco et al. (2005) reported test-retest reliability for the diet and exercise items in 3–4 month intervals was .49 and suggested that eating and diet responses are reasonably stable. The internal consistency reliability was reported as ($\alpha=.82$). No further description of the scale was reported. The Self efficacy subscale was described as a measure for diet, regularly exercise, keeping weight under control, and resisting food temptations. Participants indicated how confident they were in performing these four

behaviors using a scale ranged from 0 (not at all confident) to 100 (very confident). The subscale had an alpha level of (.89). No further details were provided.

The Patient Health Questionnaire is a nine Symptom Depression Checklist, each with 4 points ranged from not at all to nearly every day. Respondents indicated how bothered they had been over the past 2 weeks by each of the nine symptoms of a major depressive disorder; dysphoria, anhedonia, sleep difficulty, lethargy, suicidal ideation, difficulty concentrating, poor appetite or overeating, psychomotor retardation, or agitation. Responses were summed to yield an index of depressive symptomology. Alpha level was reported (.90). No further description was provided.

Sacco et al. (2005) found that 55% of the sample was female, mostly Caucasian, and about half the sample was taking insulin. Nine participants (16%) were reported to have depression. Self efficacy was significantly and inversely correlated with depression (Pearson $r = -.41$; $R^2 = .20$; $p < .05$). In addition, self efficacy was found to fully mediate the relationship between adherence and depression. Adherence was significantly related to depression ($b = .35$, $p < .01$). However, when self efficacy inserted into the regression equation model the effect of adherence on depression was no longer significant ($b = .05$, $p > .05$), but self efficacy remained a significant predictor of depression ($b = .41$, $p < .05$). Self efficacy was also found to fully mediate the relationship between BMI and depression. BMI was significantly related to depression ($b = .33$, $p < .05$). However, with self efficacy entered to the regression equation, the effect of BMI on depression was no longer significant ($b = .13$, $p > .05$), but self efficacy remained a significant predictor of depression ($b = .38$, $p < .05$). The researchers concluded that the presence of reciprocal relationship between self efficacy and behavior. That is, low self efficacy is also a reaction to negative behaviors and therefore self efficacy adversely affects health by increasing depression.

Cherrington et al. (2010)

Cherrington et al. (2010) conducted a cross sectional study to assess the associations between depressive symptoms, self efficacy, and glycemic control among men and women with type 2 diabetes, and to see if self efficacy mediates the relationship between depression and glycemic control. This study was a part of another larger study that had a sample (n=162) collected from two primary care clinics; Vanderbilt University Medical Center and University of North Carolina School of Medicine. The participants were identified by health-care providers in these areas and referred for participation in the main study. Inclusion criteria included diagnosis of type 2 diabetes mellitus, age of 18 to 85 years, and the ability to speak English. Exclusion criteria were a previous diagnosis of dementia, psychosis, or blindness.

Three variables were measured in the study and included depression, self efficacy, and glycemic control. Depression was measured using the CESD 20-item scale. Glycemic control was measured using testing the level of HbA1c. And self efficacy was measured using Perceived Diabetes Self Management Scale (PDSMS), which was developed by (Wallston et al. 2007). Cherrington et al. described the PDSMS scale as internally consistent (Cronbach's alpha = .83) and responses for each individual item ranged from 1 to 5, with total scores ranging from 8 to 40. Higher scores meant higher levels of self efficacy. No further description of the scale was presented.

Cherrington et al. (2010) indicated that 60% of the sample were women (n=98). Results showed that about 44% of the total sample had CESD scores of 16 or greater, indicating possible depression. Generally, men had lower levels of depressive symptoms (mean (men)=13.1; SD=11.87; mean (women)= 17.5; SD=11.19; $p<.05$) and higher levels of self efficacy (mean (men)=30.0; SD=5.89; mean (women)= 27.4; SD=6.99; $p<.05$) than women. In addition, there

was a significant correlation between depressive symptoms and diabetes self efficacy for the whole sample and for men; but not for women ($r = -0.25$; $r = 0.41$; $p < .001$; and $r = -0.12$; $p > .01$ for whole sample, men, and women respectively).

To test the mediation effect of self efficacy on the relationship between depressive symptoms and glycemic control; first, the correlation between CESD and HbA1c was tested and a significant association was found for the total sample and for the men but not the women ($r = 0.17$; $r = 0.34$; $p < .05$; $r = 0.05$; $p > .05$ for whole sample, men, and women respectively). Then, the association between self efficacy and depressive symptoms was tested using multiple regression test and was found significant for the sample as a whole and for men but not for women ($b = -.23$; $b = -.40$; $p < .1$; $b = -.09$; $p > .1$ for whole sample, men, women respectively). Because the associations in the female subsample were not significant, mediation analysis of self efficacy on the relationship between depression and glycemic control in the female subsample was not attempted. In the final step, self efficacy was entered in the regression model to test the association between depression and glycemic control. Self efficacy was significantly associated with glycemic control for the total sample and for men ($b = -.25$ and $.41$ respectively; $p < .05$), but the association between depressive symptoms and glycemic control was no longer significant ($b = .11$ and $.20$ respectively; $p > .1$) once self efficacy was entered into the model. These findings indicated presence of complete mediation of self efficacy on the relationship between depression and glycemic control. The researchers stated that these findings are congruent with the literature where the effect of depression differed in genders and that the difference could be due to differences in coping techniques between men and women and/or by other unmeasured variables.

Coffman (2008)

Coffman (2008) conducted a descriptive correlational study to examine the effect of depression on self efficacy in Hispanic older adults with diabetes in United States. In this study, the author indicated that depression in persons with diabetes in Hispanic communities is higher in the women than in men and higher in immigrant than natives. A convenience sample of 115 participants was recruited using verbal invitations and snowball methods. Data were collected in face-to-face interviews by the author and a trained research assistant. Interviews were conducted in Spanish.

In these interviews, demographic data were collected and questionnaires were given to the participants. The questionnaires included the Center for Epidemiological Studies Depression Scale (CESD 20) and The Diabetes Management Self efficacy Scale (DMSES). The CESD scale is described elsewhere. This scale is also available in Spanish and has been shown to be reliable and valid in both Spanish and English. The Cronbach's alpha coefficient for the Spanish language version was reported 0.90 and it was 0.89 for this study. The DMSES scale was described as a 20-item, Likert-type instrument composed of four subscales; diet, exercise, disease monitoring, and medication. Participants rated their self efficacy from 1 (low confidence) to 4 (high confidence). Coffman (2008) indicated that the test retest reliability of this scale was examined in Netherlands and was (.79). The DMSES was translated into Spanish. The translation procedure was explained in another study by the same author. Cronbach's alpha for the scale in this study was (0.87). No further information was identified and the validity was not reported.

Coffman (2008) found that more than one third of the participants had a CESD score above 15; indicating depression. About 37.2% of them were men (n=43) and 37.5% were women (n=72). Participants who were depressed were more likely to be taking insulin; 44.2% (n= 19) of

the depressed participants were taking insulin while 34.7 % (n=25) of the non-depressed participants were taking insulin. In this study, research variables were self efficacy (SE), depression, demographic variables, and tangible support. The researcher conducted two regression analyses; one where self efficacy was the dependent variable (DV) and all the other variables, including depression, as independent variables (IVs); and the second one where depression was the DV and the other variables, including SE, were IVs. In both these analyses, the researcher reported that the relationship between depression and diabetes self efficacy was found not significant (b was not reported; $p > .05$).

The author reported only the means and the SDs of SE scores for the depressed and non-depressed groups (mean (non-depressed)= 58.2; SD=10.73; mean (depressed)= 59.6; SD=11.43; F statistics was not reported). In this study, demographic variables such as diabetes education and years of education were found to significantly affect SE ($b = .004$; $b = .04$ respectively; $p < .05$). Other demographic variables were found to significantly affect depression such as age and years of diabetes ($b = .02$; $b = .05$ respectively; $p < .05$). The author did not provide detailed discussion of the results, but stated that little is known about the relationship between depression and self efficacy; however, literature indicated presence of link between depression in diabetes and worse self care management and poor motivation for care.

Summary

All the studies indicated that diabetes education can be implemented in various ways, but the effect of the education can vary. The variation in the effect of diabetes education on diabetes knowledge is related to the influence of other factors such as self efficacy. The relationship between diabetes education and diabetes knowledge is direct. Complex relationships exist between diabetes knowledge, self efficacy, self care agency, and DSCM. These relationships

were not widely tested or explored in the literature. Only one study (Sousa et al., 2004) in the available literature addressed these relationships altogether. In these relationships, diabetes knowledge is related to DSCM but does not affect it. Absence of effect of diabetes knowledge on DSCM is an indicator of indirect relationship. This indirect relationship exists because the effect of diabetes knowledge is on self efficacy and SCA, which in turn, affects DSCM. The relationship between diabetes knowledge and self efficacy is mediated by SCA. The findings of the reviewed studies support each other. Diabetes knowledge was found to have a significant relationship with DSCM. Although diabetes knowledge affected some areas of DSCM such as diet, physical activity, and managing acute complications, these effects were limited and diabetes knowledge did not directly affect DSCM. Studies considered diabetes knowledge as necessary, but not sufficient alone to affect DSCM.

Depression was thought to have relationships with diabetes knowledge, SE, and DSCM. These relations are also complex and not fully understood. For example, one study found that SE mediated the effect of depression on glycemic control. This mediation effect was affected by gender where the mediation effect was not present in female. Another study found that SE mediated the effect of depression on adherence. A third study found that the relationship between depression and SE was not even significant controlling for certain demographic variables and tangible support.

Meanwhile, all the studies that addressed the effect of depression on DSCM indicated a direct and significant relationship between them. All aspects of DSCM were affected by depression as the reviewed studies indicated. On the other hand, no study was found to address the relationship between depression and diabetes SCA. One of the reviewed studies included using an instrument in which one of its subscales measured self care ability. SCA as a concept

includes the aspect of self care ability. However, no link was provided between self care ability and self care agency and only referred to self care ability as an aspect of diabetes self care management. In this relationship, self care ability was found to be significantly lower in depressed persons with diabetes.

This study will examine the relationships among diabetes knowledge, self efficacy, self care agency, and diabetes self care management.

Chapter III

Methodology

This chapter includes a description of the study design, sample and settings, procedures for recruiting participants, procedures for data collection, measures, statistical analyses, and ethical considerations.

Primary Aim:

To examine the relationships among depression, diabetes knowledge, self care agency, self efficacy, and self care management using Sousa's model (Sousa et al., 2004).

Secondary Aim

To evaluate the item characteristics and reliability of the Diabetes Self Management Scale (DSMS).

Study Design

A correlational model testing design was used to examine the relationships within the proposed conceptual framework. The purpose of a model testing design was to verify the accuracy of empirical and theoretical relationships and provide the foundation for testing study hypotheses that included the relationship between depression and diabetes knowledge, depression and diabetes self efficacy, depression and diabetes self care agency, depression and diabetes self care management. In addition, the model testing design allowed exploration of mediation effects among the addressed relationships.

Sampling and Setting

Sample

A convenience sample of 78 participants with complete data was recruited for the study. The inclusion criteria for the sample were:

- 1) 18 years or older,

- 2) Medical diagnosis of either T1DM or T2DM,
- 3) Minimum diabetes duration of 6 months,
- 4) Taking insulin, and
- 5) Ability to understand, speak, and write in English.

The reason for limiting the sample to those taking insulin was to obtain participants who required more complex capabilities to perform specific self care activities to appropriately manage diabetes and to maintain consistency with inclusion criteria used by Sousa et al. (2004). Also, depression is highest among those who take insulin. Individuals who were pregnant, not managed by insulin, or had cognitive impairments were excluded from the study. Cognitive impairment was defined as those who have been diagnosed with psychological or physical disorder that was associated with poor mental function, such as confusion, forgetfulness, and difficulty concentrating.

Sample Collection Sites

Five sites agreed to participate in the study. The sites were 1) a diabetes self management Center, 2) a family medicine clinic, 3) a convenience store 4) a diabetes clinic, and 5) a gas station with convenience store. The self management center is a clinic founded on the belief that the acquisition of self care skills is a central component of good medical care for persons with diabetes. The clinic provides diabetes self care programs that are easily accessed; promote knowledge; promote behavioral changes; and empower health care providers, persons with diabetes and their families by providing group and one-on-one education, nutritional management, and referral to support groups.

The family medicine clinic provides high quality, complete health care for all people from newborns to senior citizens. This health care is provided using a comprehensive approach

where all aspects of life are considered when treating illness or helping people stay healthy. The clinic includes many physicians and Advanced Registered Nurse Practitioners (ARNP) that can effectively treat most health care problems any family member may experience, including diabetes. If more specialized care is required, the clinicians can refer to highly-qualified specialists.

The convenience store is located in a Midwest metropolitan area. A fair number of diabetic persons frequent the store and they are considered regular customers. The reason for selecting the store as a site is that to provide more variability in the sample.

The diabetes clinic is an outpatient clinic. The goal of this clinic is to optimize the health and well being of children and their families through excellence in patient care, education, research and operations. Adult persons with both type 1 and type 2 diabetes come to this clinic for continuing care and monitoring.

The gas station with convenience store is located in a Midwest metropolitan area. A fair number of diabetic persons frequent the store and they are considered regular customers. The reason for selecting the gas station as a site is that to provide more variability in the sample.

Study Instrumentation

The following measures were by the study participants (Appendix B). The measures were bundled into one study packet for convenience of the participant.

The Diabetes Self Efficacy Scale

The DSES was developed and tested for validity by Sousa, Hartman, Miller, and Carroll (2009), who indicated that the conceptual bases of the DSES were Bandura's Theory, the ADA standards of diabetes care (ADA 2008), the AADE self care behaviors (Funnell et al. 2008), and empirical works by many authors. Self efficacy was defined by Sousa and Zauszniewski (2005)

as confidence in capability for diabetes self management. The DSES assesses the aspects of efficacy of healthy eating, being active, monitoring blood glucose, taking medication, problem solving, and reducing risks for diabetic complications.

The DSES is composed of 60 Likert-type items. Each item has response options of 0 (strongly disagree), 1 (moderately disagree), 2 (slightly disagree), 3 (slightly agree), 4 (moderately agree), and 5 (strongly agree). Items on the scale are worded so that higher scores indicate higher diabetes self efficacy. The DSES total score can range from a minimum of 0 to a maximum of 300. The DSES has no subscales.

Sousa et al. (2009) studied the validity and reliability of the DSES. A sample of 10 clinicians and 10 insulin-treated persons with type 2 diabetes (T2DM) was used. The researchers assessed the consistency with standards of diabetes care and current diabetes care practices, the inter-rater agreement, and clarity for the individual items and the whole scale. Based on the judgment of the clinical experts, the Item-Content Validity Index (I-CVI) for all the individual items of the DSES ranged from 0.80 to 1.00 and exceeded the minimum recommendations for the I-CVI of 0.78. The overall DSES scale Content Validity Index (S-CVI) was 0.97 and exceeded the minimum recommendation 0.90. The insulin treated sample indicated 100% interrater agreement regarding clarity, except for five items of the DSES that had an interrater agreement of 90%, still exceeding the minimum criterion of 80%. Sousa et al. also reported a 100% inter-rater agreement regarding the clarity of the instructions for the scale. Subjects took a mean of 6 minutes (SD=1.41) to complete the DSES.

The Appraisal of Self care Agency Scale Revised (ASAS-R)

The ASAS-R scale is a revised version of the Appraisal of Self care Agency Scale that was developed by Evers, Isenbrg, Phillipsen, Brouns, and Smeets in 1986 to measure diabetes

self care agency, using Orem's theory of self care as a theoretical framework. The ASAS was revised by Sousa, Zauszniewski, Zeller, and Neese (2008) who indicated the original ASAS scale had 24-items on a 5-point Likert type scale ranging from 1 (totally disagree) to 5 (totally agree). Scores on the ASAS-R scale can range from 24 to 120, with higher scores indicating greater self care agency.

Sousa et al. (2004) reported that content validity of the scale had been established by a team of experts, and the internal consistency reliability of the ASAS ranges from .80 to .85. Sousa et al. (2009) conducted a factor analysis of the scale and revised the ASAS. Four items from the ASAS were revised to develop the ASAS-R. These 4 items had commonalities less than 0.25. Factor analysis yielded a single substantive factor underlying the ASAS-R accounting for 39.98% of the variance among the scale items. Sousa et al. (2009) concluded that the results provided evidence of reliability and validity because the ASAS-R scale had a Cronbach's alpha reliability of .85 and because the ASAS-R scores had high and positive correlation with ASAS scores ($r = .98$) and significant positive correlation with self efficacy scores ($r = 0.64$).

Diabetes Knowledge Test

The Diabetes Knowledge Test (DKT) was developed by the Michigan Diabetes Research and Training Center (MDRTC) in 1990s and tested for reliability and validity by Fitzgerald et al. (1998). The MDRTC (2010) reported that the DKT represents a test of general knowledge of diabetes. However, the test is not recommended for the evaluation of self management education programs because the items had not been matched to the particular educational content of any program.

The test consists of 23 knowledge test items that comprise 2 subscales; the general test and insulin –use subscales. The first 14 items comprise the general test, which is appropriate for

both those who use insulin and those who do not. The remaining 9 items comprise the insulin-use subscale and can be administered to people who use insulin. The items have either 3 or 4 choices and only one choice is correct. For each correct answer one point is assigned. The missing items are scored as incorrect. The score is calculated out of 100 for each person by dividing the number of correct items by the number of applicable items, and multiply the result by one hundred; giving the scale a range of 0 to 100; higher score indicates higher diabetes knowledge.

Fitzgerald et al. (1998) assessed the validity and the reliability of the DKT. Content validity of the test was established by a panel of experts. The researchers found that the alpha reliability coefficients for the general test and insulin-use subscales were greater than .7 in the total sample and the 2 sub-samples of the study. To test the validity of the DKT scale, three hypotheses were formulated and tested. The results supported the validity of the test. The overall reliability of the scale was, later on, confirmed by Sousa et al. (2004), who reported that the reliability coefficient for the DKT scale in their study was ($\alpha = .74$). The item p values for the total sample showed that item difficulty level ranged from .19 to .91 for the overall scale.

Center for Epidemiological Studies Depression Scale (CESD)

Center for Epidemiological Studies Depression Scale (CESD) was developed by Radloff (1977) as a short self report scale designed to measure depressive symptomatology in the general population and useful tool for epidemiologic studies of depression. Zauszniewski and Graham (2009) described the CESD scale and compared it to some of its short forms. The researchers indicated that the scale was consistent with Beck's theory of depression, which categorized the symptoms of depression into four categories; affective, cognitive, behavioral, and somatic. The CESD 20 scale has 20-items that rated the frequency of experiencing each of the symptoms of

depression during the week prior to completing the measure. The symptoms measured included feeling bothered, appetite, mind, effort, sleep, talk, and fatigue, and rated using Likert-type scale ranging from rarely or none of the time (0) to most or all of the time (3). The scores on the scale can range from 0 to 60 with higher scores indicating greater frequency of depressive symptoms. Total severity of depression is calculated by reversing scores for items 4, 8, 12, and 16 then summing all of the scores. A cut off point of 16 or more on the scale has been used frequently to distinguish between depressed and non-depressed persons (Egede & Ellis, 2008). This scale has been widely used in studies of depression in diabetes such as Coffman (2008), Cherrington et al. (2010), and Egede (2005).

Support for reliability of the CESD scale was reported in many studies such as Zauszniewski and Graham (2009) who indicated that alpha coefficients of the CESD 20 ranged from .86 to .82 in the literature and .78 in their study. The construct validity of the scale was supported by significant correlations with theoretically related constructs. Also, normality was assessed for the instrument by examining skewness and kurtosis scores and found these scores were within acceptable parameters for normal distribution. Zauszniewski and Graham (2009) found that there were significant differences in depression scores between genders ($\chi^2 = 16.25$; $p < .01$), ethnicities ($\chi^2 = 8.47$; $p < .05$), and age. Depression was higher among men, African American, and the elderly.

Diabetes Self Management Scale (DSMS)

The Diabetes Self Management Scale (DSMS) was developed by Sousa et al. (2009) to measure diabetes self care management. Diabetes self care management was defined as the actual performance of diabetes self care activities (Sousa & Zauszniewski, 2005). According to the definition, diabetes self care management included the aspects of healthy eating, being active,

monitoring blood glucose, taking medication, problem solving, and reducing risks. The DSMS was developed based on Orem's theory of self care, empirical works in the literature, and the 2008 ADA standards of diabetes care, and the AADE self care behaviors.

The DSMS scale is a 60 item scale with Likert-type response options of 0 (strongly disagree), 1 (moderately disagree), 2 (slightly disagree), 3 (slightly agree), 4 (moderately agree), and 5 (strongly agree). The DSMS total score can range from 0 to 300 with higher score indicating higher self efficacy. The reliability and validity of the scale was assessed by Sousa et al. (2009) using a sample of the 10 clinicians and 10 insulin-treated persons with type 2 diabetes (T2DM). Thirteen items of the DSMS had an interrater agreement for clarity among the expert panel of clinicians that was less than the minimum recommendation of 80%, and two items of the DSMS had an interrater agreement among the expert panel of clinicians regarding consistency with current standards of diabetes care that was less than the minimum recommendation of 80%. However, all the items exceeded the minimum recommendation for I-CVI of 0.78 except for one item (I-CVI=0.70). The overall scale CVI exceeded the minimum recommendation of 0.90 (S-CVI= 0.96). Clarity evaluation of the scales by subject experts showed that all but two items had interrater agreement of 100%. These two items had an interrater agreement of 90%, still exceeding the minimum criterion of 80%. Participants took a mean of 5.7 minutes (SD =0.67) to complete the DSMS. However, item analysis, reliability analysis, and the factor validity of the scale and the scale dimensions were not tested. Further psychometric testing is needed (Sousa et al., 2009). Therefore, a secondary aim was included in this study to evaluate the item characteristics and reliability of the Diabetes Self Management Scale (DSMS).

Demographic Variables

The participant demographic characteristics that were measured in this study were self reported gender, age in years since last birthday, number of years of formal education completed, race/ ethnicity, and type of diabetes (T1DM or T2DM). In addition, questions about number of years of having diabetes, type of medications the participants taken, and self reported depression question were also included.

Data Collection Procedures

Human Subject Committee approval was obtained from the University of Kansas Medical Center (KUMC) Institutional Review Board prior to data collection. A staff member at each clinic and a store manager at each convenience store agreed to screen their patients or clients for study inclusion criteria listed in the sample section above. All had completed the KUMC human subjects tutorials and were trained in screening for study criteria.

Patients and clients who fit the criteria were informed about the study and invited to participate in the study. If they agreed to participate, they were given a questionnaire packet. A cover letter containing a summary of the study, the participant's rights, and the researcher's contact information was included with the questionnaire packet. The cover letter also encouraged the potential participants to complete the questionnaire and return it as soon as possible to the investigator. A \$10.00 compensation was offered for those who complete the questionnaires and return it back to the investigator. Participants were directed to keep the cover letter for their own records.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS) version 20.0 was used to analyze the data. Quality assurance data techniques including error screening and verification of data

following entry were used to minimize data entry errors. Data were examined for missing data, outliers, data distribution, and violation of assumptions for path analysis. Descriptive statistics were used to describe sample demographic characteristics. The descriptive analysis included frequency distribution, measures of central tendency, and measures of dispersion to summarize the demographic variables. The internal consistency reliability of each of the scales used in the study was verified in the sample.

Primary Aim Analysis

The primary research aim was to examine the relationships among depression and diabetes knowledge, self care agency, self efficacy, and self care management. Path analysis techniques were used to examine the relationships among the study variables. These research questions were:

1. Is there a relationship between depression and diabetes Self care Agency (SCA)?
2. Does depression affect diabetes Self Efficacy (SE)?
3. Does depression affect Diabetes Self care Management (DSCM)?
4. Are there any mediation effects in these relationships?

The path analysis procedures included multiple regression analyses to study the relationships between the independent and the dependent variables in the proposed hypotheses to assess the causality and strength of these relationships after adding depression to the model (See Figure 2, page14). Forward multiple regression procedures provided estimates of the contribution of variables at each stage of the model. All relationships were assessed for presence of mediation effect among the relationships between the variables in the model.

The mediation effect was assessed using Baron and Kenny's (1986) steps. Step one is to show that the initial variable (Independent Variable (IV)) is correlated with the outcome. This

step establishes that there is an effect that may be mediated. Step two is to show that the initial variable is correlated with the Mediator (M). This step essentially involves treating the mediator as if it were an outcome variable to assess for presence of relationship between the independent variable and the moderator. Step three is to show that the mediator affects the outcome variable (Dependent Variable (DV)). The last step is to establish that the mediator completely mediates the relationship between the independent variable and the dependent variable. The effect of IV on DV controlling for M should become insignificant. Correlating the mediator with the outcome is not sufficient; the mediator and the outcome may be correlated because they are both affected by the initial variable; the IV. Thus, the initial variable must be controlled in establishing the effect of the mediator on the outcome.

The assumptions for the path analysis are that all the examined relationships are linear and additive as shown in the model diagram, the residuals are uncorrelated with the variables in the model and with each other, the causal flow and the direction of the relationship are one way, and the variables are measured without error.

Sample Size Determination

The sample size was determined based on VanVoorhis and Morgan (2007) rules of thumb; the general rule of thumb is that sample size should not be less than 50 participants for a correlation or regression. Also, they stated that to determine the number of participants needed for statistics used to examine relationships, Harris's (1985) formula can be used for yielding the minimum number of participants, where the number of participants should exceed the number of predictors by at least 50. The study was determined to include 15 parameters (See table 3). A total of 13 parameters were identified in the study. Also, two more parameters are needed; one more variable needed for intercept and another for residual variance. Level of education shall be

divided into 4 categories, so 3 parameters are needed because of dummy coding. Based on the number of parameters in the study, a sample of at least 75 participants with complete data was needed for this study.

Table 3.

Types of variables and number of parameters in the study.

Variable	Type of Measurement	Number of Parameters Needed
Gender	Categorical	1
Race/ ethnicity	Categorical	1
Type of diabetes	Categorical	1
Insulin use	Categorical	1
Level of education	Categorical	3
Years of having diabetes	Continuous	1
Diabetes knowledge	Continuous	1
Self efficacy	Continuous	1
Self care-agency	Continuous	1
Self care management	Continuous	1
Depression	Continuous	1

Secondary Aim Analysis

For the secondary research aim, to evaluate the item characteristics and reliability of the Diabetes Self Management Scale (DSMS), a review of the content and wording of the items was done to assess for presence of statements that may create confusion in understanding the item and earmark these items to monitor in remaining item analyses.

Then, a descriptive analysis for all the 60 items of the scale was conducted to assess the responses of the participants on these items in terms of central tendency and dispersion. The items of the DSMS were assessed using Ferketich (1991) techniques that help in making a decision about whether any given item should be retained or deleted. These techniques included assessing the average correlations of the items, inter-item correlation matrix, corrected item-total correlation, alpha if item deleted, item validity estimate, and item variability. The average

correlation of the item with the other items on the scale and the correlation define if the item is unnecessary or not related to the scale. The rule of thumb is that items that correlate below .3 are not sufficiently related to the measure and items that correlate over .7 are redundant. Item total correlation describes if the item is a large part of the total. In other words, the stronger the item-total correlation, the better the item. In general, item total correlation above .3 is considered good. Item validity was assessed by correlating the item with an outside criterion. In this study the items were correlated with self efficacy because self efficacy was found to have strong correlation with DSCM. Item variability was assessed by measuring the SD for the item. A second reliability analysis was done after deleting the identified 'problem' items in the scale.

Ethical Considerations

The Institutional Review Boards (IRB) at University of Kansas Medical Center approved all recruitment and/or consent procedures. The goal was to include all individuals with diabetes at each site regardless of age, sex/ gender, and racial/ ethnic group. All data collected from participants was used solely for research purposes. Any participation in the study was voluntary. Potential risks to study participants were minimal and unlikely to occur. There was no physical risk to participants. The potential scientific and public health impact of the knowledge gained from this study regarding the relationship of depression to diabetes knowledge, self care agency, self efficacy, and self care management outweighed any potential risks. Participants were informed of the potential risks and benefits, and they had the right to withdraw their participation in the study at any time without prejudice. Data analysis is presented in group form only. Individual participants will not be identified in publications, presentations, and the like.

Summary

A correlational model testing design was used to examine the study hypotheses. A convenience sample of 78 participants with completed questionnaires was recruited for the study. Data was collected in 5 sites. Each participant was asked to fill out 5 questionnaires (Diabetes Knowledge Test, Diabetes Self care Management Scale, Center for Epidemiological Studies Depression Scale, The Appraisal of Self care Agency Scale Revised, and The Diabetes Self Efficacy Scale. Path analysis techniques were used to examine the proposed relationships among the model's variables. Also, data were examined for presence of mediation effect between these variables.

Chapter IV

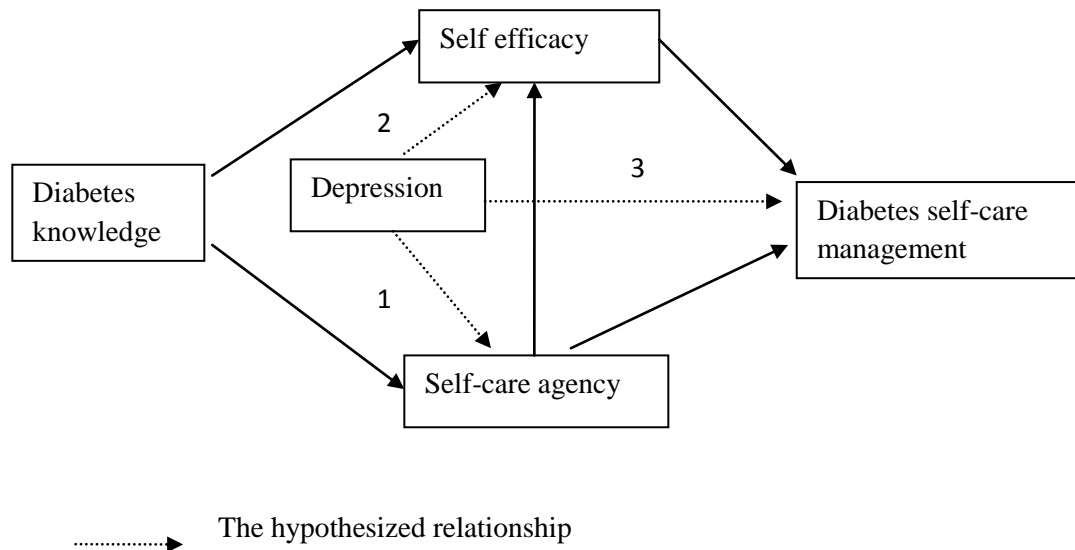
Chapter IV presents the procedure of data preparation, description of the study sample, description of variables, and the results of analyses for study primary and secondary aims. The Primary Study aim was to examine the relationship between depression and diabetes knowledge, self care agency, self efficacy, and self care management using the modified Research Model for DSCM (Sousa et al., 2004). (See Figure 3)

The analyses were conducted to evaluate the research questions derived for the primary aim:

1. Is there a relationship between depression and diabetes Self care Agency (SCA)?
2. Does depression affect diabetes Self Efficacy (SE)?
3. Does depression affect Diabetes Self Care Management (DSCM)?
4. Are there any mediation effects in these relationships?

Figure 3.

The proposed revision of integrating depression into the research model for DSCM.



The Secondary Aim was to evaluate the item characteristics and reliability of the Diabetes Self Management Scale (DSMS).

Data Preparation and Missing Data Management

SPSS version 20.0 statistical software was used to enter and analyze the data. Items scores were read and read back between the 2 people working on data entry. Once data were entered, quality assurance techniques including error screening and verification of data were used to minimize data errors. Descriptive statistics were run to check for out of range results, and cases with outliers were rechecked to assure no error in data entry. Stem and leaf plots for the main study variables -- depression, self efficacy, diabetes knowledge, self care agency, and diabetes self care management -- were done to check for outliers. Only one outlier was noted in the plot for the total score on self care agency where one participant scored the maximum score on the scale. The case was not removed from the analysis because the scores on other scales for this participant were not outliers and the overall average of the ASAS-R was high at 85.7 (SD=12.5).

Data also were evaluated for missing values. Percentage of missing data for each study variable and the pattern of missing data was examined. The percentage of missing data was low at less than 10%, therefore the method of replacing missing data with the series mean was used.

After replacing the missing values and reverse coding items on the ASAS-R and CESD 20 that required reverse coding, the total scores for depression, Self Care Agency (SCA), Self Efficacy (SE), Diabetes Knowledge (DK), and Diabetes Self Care Management (DSCM) were computed. In addition, a new variable of whether or not the participant had depression based on his CESD score was computed (See Description of Sample section).

Description of Sample

A total of 78 participants returned complete questionnaires. The proportion of participants from each study site varied widely, from 3.8% (n = 3) at Site 4, a diabetes clinic, to 38.5% (n = 30) at Site 2, a convenience store (See Table 4).

Table 4.
Proportion of Participants by Study Site

Study Site	Number of Participants	Percentage of Participants
Site 1 (Diabetes Self Care Management Center)	15	19.2
Site 2 (Convenience Store)	30	38.5
Site 3 (Family Medicine Clinic)	5	6.4
Site 4 (Diabetes Clinic)	3	3.8
Site 5 (Gas Station)	25	32.1
Total	78	100.0

The typical study participant was a 47 year-old Caucasian (52.6%) male (56.4%), who was married (47.4%) and had at least a high school education (88.5%). No Latino, Native Hawaiian or Pacific Islander participated in the study. Just over half of participants were persons with T2DM (55.1%, n=43) and 44.9% were persons with T1DM (n=35). The mean years of having diabetes was 11.9 (SD=10.3) and ranged from 1 to 41 years. High cholesterol level (n=34) and high blood pressure (n=30) were the 2 most reported complications by participants. About a quarter of participants (23.7%) reported having depression. Half of participants (50%, n=39) reported taking insulin injections only and the other half (50%, n=39) reported taking insulin injections and pills. Most participants reported they either did not smoke (61%, n=48) or did not drink (76%, n=60). Those who both did not smoke and drink composed about 52% (n=42) of participants (See Table 5 and Table 6 for more detailed information about participant characteristics).

Table 5.
Participant Characteristics

Participant Characteristic	Mean (SD) Range
Age	46.6 (13.7) 18 - 81
Body Mass Index*	31.4 (6.98) 20.7 - 49.1
Years of having Diabetes Mellitus*	11.9 (10.1) 1 - 41

*Note: data reflects participants with valid data on the variable.

Table 6.
Participant Characteristics

Participant Characteristic	N(%)
Gender	
Male	44(56.4%)
Female	34 (43.6%)
Race*	
White or Caucasian	41 (52.6%)
Black or African American	32 (41%)
Hispanic or Latino	0 (0%)
American Indian or Alaska Native	0 (0%)
Asian	3 (3.8%)
Native Hawaiian or other Pacific Islander	0 (0%)
Other	1 (1.3%)
Marital Status	
Single, living alone	25 (32%)
Never married, but living with partner	4 (5.1%)
Married	37 (47.4%)
Divorced/Separated	9 (11.5%)
Widowed	3 (3.8%)
Type of Diabetes	
Type 1	35 (44.9%)
Type 2	43 (55.1%)
Self Reported Depression	
No	60 (76.9%)
Yes	18 (23.1%)
Smoking Status *	
No	48 (61.5%)
< 10	13 (16.7%)
10 to 20	14 (17.9%)
> 20	2 (2.6%)

Participant Characteristic	N(%)
Drinking Status	
No	60 (76.9%)
< 2 drinks a week	8 (10.3%)
2 – 3 drinks a week	5 (6.4%)
4 – 5 drinks a week	4 (5.1%)
6 or more drinks a week	1 (1.3%)
Type of Medication	
Insulin injection only	39 (50%)
Insulin injection and pills	39 (50%)
Level of education	
< 4 years	2 (2.6%)
5-8 years	7 (9.0%)
High school	23 (29.5%)
Some college	12 (15.4%)
College	18 (23.1%)
Some graduate school	5 (6.4%)
Masters	11 (14.1%)

*Note: data reflects participants with valid data on the variable.

Description of Variables

The main study variables were examined individually before the main study questions were analyzed. Frequency distributions were obtained on all the scale scores, as well as means, standard deviations, and ranges for all scales. Internal consistency reliability estimates for all scales were determined with Cronbach's alpha or KR 20 as appropriate. A coefficient of .70 or higher was considered evidence of internal consistency (Waltz, Strickland, & Lenz, 2005).

Because the Diabetes Self Management Scale (DSMS) had not been examined previously for psychometric properties, individual item analysis was conducted as the secondary aim of the study. This analysis was conducted before analyses for the primary aim. Results are reported in this section. Also, reliability analysis was conducted on the DSMS and reported here as well.

Diabetes Knowledge

Diabetes knowledge (DK) was operationalized using the Diabetes Knowledge Test (DKT). The test consists of 23 knowledge test items that comprise 2 subscales; the general test and insulin–use subscales. The items have either 3 or 4 choices and only one choice is correct. For each correct answer one point is assigned. The missing items are scored as incorrect. The score is calculated out of 100 for each person by dividing the number of correct items by the number of applicable items, and multiply the result by one hundred; giving the scale a range of 0 to 100; higher score indicates higher diabetes knowledge. In the current sample, the mean score for the DKT was 60.4 and the SD was (22.4). KR 20 for the DKT scale was measured to assess the scales reliability in this study; KR 20 was 0.85. (See Table 7 for descriptive statistics for DKT scores.

Table 7.
Descriptive Statistics and Reliability Estimates for the Main Study Variables (n = 78)

	Possible Range	Actual Range	Mean (SD)	Cronbach's alpha
DK	0-100	21.74- 95.65	60.4 (22.4)	.850*
SE	0-300	131.00 -293.00	214.8 (38.4)	.949
SCA	24-120	59.03 - 120.00	85.7 (12.5)	.752
Depression	0-80	1.00 - 46.00	20.5 (11.4)	.824
DSCM (40 item- scale)	0-200	53.00 – 192.00	129.9 (33.2)	.947

*The value of KR 20 for the scale.

Note: DK= Diabetes Knowledge, SE= Self Efficacy, SCA= Self Care Agency, DSCM= Diabetes Self Care Management.

Self Efficacy

In this study, SE was operationalized using The Diabetes Self Efficacy Scale (DSES). The DSES is composed of 60 Likert-type items. Each item has response options of 0 (strongly

disagree), 1 (moderately disagree), 2 (slightly disagree), 3 (slightly agree), 4 (moderately agree), and 5 (strongly agree). Items on the scale are worded so that higher score indicate higher diabetes self efficacy. That is, there is no need to reverse score any item in the analysis. The DSES total score can range from a minimum of 0 to a maximum of 300. In the current sample, the mean score for the DSES was 214.8 and the SD was (38.4). (See Table 7).

Self Care Agency

Self Care Agency (SCA) was operationalized using the Appraisal of Self Care Agency Scale Revised (ASAS-R). The scale contains 24 Likert-type items and each item has response options ranging 1 “Totally Disagree” to 5 “Totally Agree”. Items 2, 6, 11, 13, 14, 15, 20, 23, and 24 are reversed scored, and then all items were added to yield a total score for Self Care Agency. A higher score on the scale indicates higher level of SCA. In the current sample, the mean score for the ASAS-R was 85.7 and the SD was (12.5). (See Table 7).

Depression

Depression was operationalized using the CESD 20 Scale. The original CESD 20 scale has 20-items that rated the frequency of experiencing each of the symptoms of depression during the week prior to completing the measure. The symptoms measured included feeling bothered, appetite, mind, effort, sleep, talk, and fatigue, and rated using Likert-type scaling ranging from rarely or none of the time (0) to most or all of the time (3). The scores on the scale can range from 0 to 60 indicating with higher scores greater frequency of depressive symptoms. Total severity of depression is calculated by reversing scores for items 4, 8, 12, and 16 then summing all of the scores. A cut off point of 16 or more on the scale was used to distinguish between depressed and non-depressed person (Egede & Ellis, 2007). (See Table 7).

Furthermore, the demographic questions included a self reported question of whether the participant is depressed or not. Only 23% (n=18) of participants self reported that they have depression. However, the results of the CESD scores for the sample indicated that about 61% (n=48) were depressed because they scored 16 or more on the scale (See Table 8). The results showed that there is statistically significant difference between those who reported depression and those who had a CESD score of 16 or more ($\chi^2=7.4$; $p<.05$).

Table 8.
Self-Reported Depression Compared to CESD Score.

		Self reported Depression		Total
		no	yes	
CESD	<16	28(35.9%)	2(2.5%)	30 (38.5%)
	≥ 16	32(41.0%)	16(20.5%)	48 (61.5%)

$\chi^2=7.4$; $p<.05$

Diabetes Self Care Management

Diabetes Self Care Management (DSCM) was the outcome variable for the study and was operationalized using the Diabetes Self Management Scale (DSMS). This scale contained 60 Likert-type items that have response options ranging 0 “Strongly Disagree” to 5 “Strongly Agree”. The final score is calculated by summing the scores of all items. A higher score on the scale indicates higher level of DSCM. A reliability analysis was conducted on the full scale (the 60 item-scale). The results of the analysis indicated that the scale had a high level of internal consistency (Cronbach’s alpha= .958).

Reliability Analysis of the Diabetes Self Management Scale (DSMS)

The secondary aim of the study was to examine the reliability and item characteristics of the Diabetes Self Management Scale (DSMS) because Sousa et al. (2009) indicated that the DSMS requires further psychometric analysis and evaluation of its reliability. First, a review of the content and wording of the items was done to assess for presence of statements that may

create confusion in understanding the item. The initial review showed that there are absolute phrases in some items -- such as “all the time” and “every day” -- that may have contributed to confusion between the wording of the item and the available response options (Strongly Disagree to Strongly Agree). These items were earmarked to monitor in remaining item analyses.

Then, a descriptive analysis for all the 60 items of the scale was conducted to assess the responses of the participants on these items in terms of central tendency and dispersion. Several items had low variability ($SD < 1.2$) compared to the other items on the scale; and some items had a median of the highest possible score on the items (See Table 9 for the items with relatively low variability).

Ferketich (1991) identified techniques to help in making a decision about whether any given item should be retained or deleted. These techniques included assessing the average correlations of the items, inter-item correlation matrix, corrected item-total correlation, alpha if item deleted, item validity estimate, and item variability. The average correlation of the item with the other items on the scale and the correlation define if the item is unnecessary or not related to the scale. The rule of thumb is that items that correlate below .3 are not sufficiently related to the measure and items that correlate over .7 are redundant. Item total correlation describes if the item is a large part of the total. In other words, the stronger the item total correlation, the better the item. In general, item total correlation above .3 is considered good.

Table 9.
Item Characteristics for DSMS: Items with Low Variability.

Item number and content	Possible range (Midpoint)	Mean	Median	SD	Corrected item-total correlation	Alpha if item deleted
3 *	0-5 (2.5)	2.64	3	1.17	.644	.957
9*	0-5 (2.5)	2.77	3	1.18	.594	.957
10*	0-5 (2.5)	2.65	3	1.17	.501	.957
29	0-5 (2.5)	4.05	4	1.28	.477	.958
33	0-5 (2.5)	4.12	5	1.17	.450	.958
34	0-5 (2.5)	4.14	5	1.15	.308	.958
37	0-5 (2.5)	4.00	4	1.12	.360	.958
39*	0-5 (2.5)	4.03	4	1.18	.195	.958
43	0-5 (2.5)	3.97	4	1.06	.504	.957
44	0-5 (2.5)	4.45	5	.75	.375	.958
45	0-5 (2.5)	4.42	5	.99	.279	.958
46	0-5 (2.5)	3.65	4	1.14	.578	.957
51	0-5 (2.5)	3.99	4	1.01	.592	.957
52	0-5 (2.5)	3.64	4	1.04	.666	.957

* Item with absolute phrases -- such as “all the time” and “every day”.

The revised alpha if item deleted identifies if deleting the item will improve, fail to improve, or worsen the internal consistency estimate of the scale. The item validity estimate can be obtained by correlating the individual items with an outside criterion. In this study the outside criterion was self efficacy because self efficacy was found to be strongly associated with diabetes self care management. (See Table 10 for the characteristics of DSMS items).

Table 10.
DSMS Items Characteristics.

Item	Average correlation	Item total correlation	Alpha if deleted	Correlation with SE	SD	Number of correlations <0.3	Number of correlations >0.7
1*	0.369	.671	.957	0.544	1.461	23	2
2*	0.160	.270	.958	0.368	1.439	50	0
3*	0.353	.644	.957	0.51	1.170	27	2
4	0.373	.678	.957	0.55	1.276	22	4
5	0.335	.597	.957	0.454	1.243	33	0
6	0.336	.607	.957	0.454	1.429	23	1
7*	0.232	.421	.958	0.319	1.474	40	0
8*	0.377	.694	.957	0.529	1.474	16	1
9*	0.330	.594	.957	0.404	1.183	27	0
10*	0.278	.501	.957	0.373	1.171	33	0
11	0.336	.609	.957	0.497	1.325	26	0
12	0.373	.673	.957	0.448	1.418	21	0
13	0.228	.394	.958	0.391	1.387	44	0
14*	0.357	.638	.957	0.483	1.704	23	0
15*	0.375	.676	.957	0.477	1.515	18	0
16	0.283	.517	.957	0.493	1.623	35	1
17	0.307	.564	.957	0.551	1.654	34	3
18	0.380	.704	.957	0.611	1.562	19	2
19	0.312	.579	.957	0.537	1.493	28	2
20	0.419	.770	.956	0.565	1.356	15	1
21	0.359	.653	.957	0.576	1.434	22	1
22	0.296	.524	.957	0.37	1.518	37	0
23	0.316	.557	.957	0.472	1.488	26	0
24	0.244	.426	.958	0.4	1.413	37	0
25	0.249	.439	.958	0.339	1.518	39	0
26*	0.399	.740	.956	0.595	1.616	19	0
27	0.279	.484	.958	0.462	1.439	38	1
28	0.370	.660	.957	0.621	1.312	19	0
29	0.281	.477	.958	0.312	1.288	37	2
30	0.309	.536	.957	0.401	1.448	30	2
31	0.241	.406	.958	0.208	1.609	43	1
32	0.320	.561	.957	0.37	1.555	27	1
33	0.266	.450	.958	0.365	1.173	40	2
34	0.190	.308	.958	0.256	1.148	45	0
35*	0.215	.384	.958	0.352	1.630	47	0
36	0.276	.490	.957	0.486	1.351	34	1
37	0.211	.360	.958	0.411	1.117	47	1
38*	0.206	.348	.958	0.16	1.448	48	0

Item	Average correlation	Item total correlation	Alpha if deleted	Correlation with SE	SD	Number of correlations <0.3	Number of correlations >0.7
39*	0.130	.195	.958	0.177	1.184	55	0
40*	0.249	.425	.958	0.353	1.352	38	0
41	0.290	.519	.957	0.434	1.688	30	0
42	0.305	.534	.957	0.483	1.121	31	0
43	0.294	.504	.957	0.46	1.057	28	1
44	0.227	.375	.958	0.302	.750	41	0
45	0.176	.279	.958	0.249	.989	45	0
46	0.333	.578	.957	0.492	1.138	26	1
47*	0.237	.422	.958	0.215	1.493	38	0
48*	0.250	.446	.958	0.269	1.928	38	0
49	0.281	.491	.957	0.473	1.271	36	1
50	0.194	.333	.958	0.312	1.678	42	0
51	0.335	.592	.957	0.569	1.013	29	0
52	0.374	.666	.957	0.587	1.043	21	2
53	0.403	.725	.957	0.643	1.305	17	2
54*	0.375	.674	.957	0.579	1.385	21	2
55	0.278	.484	.957	0.446	1.304	40	0
56	0.178	.302	.958	0.346	1.663	52	0
57	0.295	.529	.957	0.493	1.633	27	0
58	0.265	.466	.958	0.531	1.469	39	0
59	0.320	.563	.957	0.54	1.402	26	0
60	0.267	.471	.958	0.395	1.739	32	0

* Item with absolute phrase like “all the time” or “everyday”.

A correlation matrix with the average correlation for the 60 items of the DSMS was made to assess the characteristics of the items. The correlation matrix showed that 25 items had correlations over 0.7 with other items on the scale. Such high correlations indicate redundancy Ferketich (1991). The items that had strong correlations with each other were aggregated into groups (See table 11). These items in the groups were then evaluated for their characteristics and compared with each other. The items with the less desirable characteristics or less desirable wording were deleted (See Table 12 for the items that were deleted and the rationales for deleting them)

Table 11.
The Aggregations of the Items with Strong Correlations ($>.70$).

Item	Number of Strong Correlation	Correlates Strongly with
SCM1	2	SCM3, SCM4
SCM3	2	SCM1, SCM4
SCM4	4	SCM1, SCM3, SCM6, SCM8
SCM6	1	SCM4
SCM8	1	SCM4
SCM16	1	SCM17
SCM17	3	SCM16, SCM 18, SCM 19
SCM18	2	SCM17, SCM 19
SCM19	2	SCM17, SCM 18
SCM20	1	SCM21
SCM21	1	SCM20
SCM27	1	SCM 49
SCM29	2	SCM 30, SCM 33
SCM30	2	SCM 29, SCM 33
SCM31	1	SCM 32
SCM32	1	SCM 31
SCM33	2	SCM 29, SCM 30
SCM36	1	SCM 37
SCM37	1	SCM 36
SCM43	1	SCM 46
SCM46	1	SCM 43
SCM49	1	SCM 27
SCM52	2	SCM 53, SCM 54
SCM53	2	SCM 52, SCM 54
SCM54	2	SCM 52, SCM 53

Table 12.
The Deleted DSMS Items and the Rationale.

Item	Decision	Rationale
1	Keep	Seems redundant (2 correlations >0.7). Redundant of items 3 and 4, best among items 1, 3, and 4.
2	Delete	Low average correlation and low item-total correlation. Low correlation with most the other items on the scale.

Item	Decision	Rationale
3	Delete	Seems redundant (2 correlations >0.7). Redundant of items 1 and 4, but has less desirable item characteristics.
4	Delete	Seems redundant (High correlation with 4 other items). Had the highest number of correlations over 0.7). Redundant of items 1, 3, 6, 8.
7	Delete	Low average correlation. Low correlation with many the other items on the scale. Contains absolute phrase
10	Delete	Low average correlation. Low correlation with over half the items on the scale. Low variability. Contains absolute phrase
17	Delete	Seems redundant (3 correlations >0.7). Redundant of items 16, 18, 19. Less desirable item characteristics than item 18. Low correlation with many items.
18	Keep	Seems redundant (2 correlations >0.7). Best among 17, 18, 19. Better item total correlation. Better item validity.
19	Delete	Seems redundant (2 correlations >0.7). Less desirable characteristics than item 18 from the group. Lower item validity. Lower item total correlation.
29	Delete	Seems redundant (2 correlations >0.7). Redundant of items 30, 33. Less desirable characteristics than item 30. Low average correlation. Lower item total correlation.
30	Keep	Seems redundant (2 correlations >0.7). Best among items 29 and 30. Better average correlation. Stronger item total correlation. Better item

Item	Decision	Rationale
		validity.
31	Delete	Low average correlation. Low item validity. Low correlation with many other items on the scale. Less desirable characteristics than item 32.
32	Keep	Better item characteristics than item 31. Good average correlation. Better item total correlation. Better item validity.
33	Delete	Low variance. Low average correlation. Low correlation with many other items on the scale. Low variance. Seems redundant (2 correlations >0.7) of items 29, 30.
34	Delete	Low average correlation. Low item validity. Low correlation with many the other items on the scale. Low variability.
35	Delete	Low average correlation. Low correlation with many the other items on the scale. Contains absolute phrase.
37	Delete	Low item variability. Low average correlation. Low correlation with many the other items on the scale.
38	Delete	Low average correlation. Low correlation with many the other items on the scale. Contains absolute phrase. Low item validity.
39	Delete	Low average correlation. Low correlation with most the other items on the scale. Contains absolute phrase. Low item validity. Low item total correlation.
44	Delete	Low average correlation. Low correlation with most the other items on the scale. Low variance.

Item	Decision	Rationale
45	Delete	Low average correlation. Low correlation with many other items on the scale. Low variance. Low validity.
47	Delete	Low item validity. Low average correlation. Alpha if deleted fails to improve. Contains absolute phrase.
52	Delete	Seems redundant (2 correlations >0.7). Redundant of 53, 54. Less desirable characteristics than item 53.
53	Keep	Seems redundant (2 correlations >0.7). Best of 52 and 53.
54	Delete	Seems redundant (2 correlations >0.7). Contains absolute phrase.

Out of the 60 items that compose the original scale, 20 items were deleted due to poor item characteristics and redundancy. A second reliability analysis was done after deleting the identified ‘problem’ items in the scale. After deleting the items, the scale was composed of 40 items with good item characteristics. (See Table 7 for Descriptive Statistics and Reliability Estimates for the 40-item scale). The results indicated that the scale had high level of internal consistency (Cronbach’s alpha= .947) (See Table 13).

Table 13.
Item Characteristics for the 40-Item DSMS

Item	Possible Range	Mean (SD)	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
SCM1	0-5	2.76 (1.46)	.674	.945
SCM5	0-5	2.96 (1.24)	.611	.946
SCM6	0-5	2.54 (1.43)	.623	.946
SCM8	0-5	2.55 (1.47)	.726	.945

SCM9	0-5	2.77 (1.18)	.590	.946
SCM11	0-5	2.90 (1.32)	.621	.946
SCM12	0-5	3.04 (1.41)	.649	.945
SCM13	0-5	3.71 (1.38)	.370	.947
SCM14	0-5	3.08 (1.70)	.643	.945
SCM15	0-5	2.87 (1.51)	.679	.945
SCM16	0-5	2.74 (1.62)	.501	.946
SCM18	0-5	2.12 (1.56)	.675	.945
SCM20	0-5	2.49 (1.35)	.760	.945
SCM21	0-5	2.91 (1.43)	.639	.945
SCM22	0-5	3.08 (1.51)	.513	.946
SCM23	0-5	3.38 (1.48)	.583	.946
SCM24	0-5	3.65 (1.41)	.445	.947
SCM25	0-5	3.27 (1.51)	.438	.947
SCM26	0-5	2.56 (1.61)	.733	.945
SCM27	0-5	3.73 (1.43)	.483	.947
SCM28	0-5	3.62 (1.31)	.655	.945
SCM30	0-5	3.86 (1.44)	.523	.946
SCM32	0-5	3.15 (1.55)	.526	.946
SCM36	0-5	3.69 (1.35)	.481	.947
SCM40	0-5	3.87 (1.35)	.373	.947
SCM41	0-5	3.22 (1.68)	.518	.946
SCM42	0-5	3.94 (1.12)	.532	.946

SCM43	0-5	3.97 (1.05)	.504	.946
SCM46	0-5	3.65 (1.13)	.561	.946
SCM48	0-5	2.63 (1.92)	.435	.947
SCM49	0-5	3.91 (1.27)	.497	.946
SCM50	0-5	3.60 (1.67)	.326	.948
SCM51	0-5	3.99 (1.01)	.592	.946
SCM53	0-5	3.10 (1.30)	.720	.945
SCM55	0-5	3.68 (1.30)	.478	.947
SCM56	0-5	3.58 (1.63)	.316	.948
SCM57	0-5	3.14 (1.63)	.535	.946
SCM58	0-5	3.71 (1.46)	.458	.947
SCM59	0-5	3.82 (1.40)	.561	.946
SCM60	0-5	2.74 (1.73)	.463	.947

Description of the Relationships in the Study Framework

Sousa and colleagues (2004, 2005) tested the presence of direct relations between the concepts in the Research Model for Diabetes Self care Management. Then they tested for indirect relations through examining the presence of mediating or moderating effects among the concepts. Sousa et al. (2004) found that there were direct relations between diabetes knowledge and self efficacy and diabetes knowledge and Self Care Agency. Also, there were direct relations between Self Care Agency and Self Efficacy, Self care Agency and DSCM, and Self Efficacy and DSCM. An indirect relationship was found in that Self Care Agency mediated the effect of SE on DSCM. Diabetes Knowledge was found to have no direct effect on DSCM.

Zero-order correlations (Pearson Product-Moment Correlations (r), Point-Biserial Correlation, and Spearman's rank correlation coefficient (ρ)) between DK, SE, SCA, CESD, DSCM, and the demographic variables of age, gender, years of having diabetes, type of diabetes, race, and level of education were examined (See Table 14 for Pearson and Point Biserial correlations, Table 12 for Spearman correlations).

The correlation tables show that there is a strong correlation between Self Efficacy (SE) and Diabetes Self Care Management (DSCM) ($r=.8$; $p<0.01$). Also, moderate correlations exist between SE and Self Care Agency (SCA) ($r=.64$; $p<.01$), SE and depression ($r=-.42$; $p<.01$), SCA and depression ($r=-.48$; $p<.01$), and SCA and DSCM ($r=.62$; $p<.01$). The Point Biserial correlations show that the correlations between type of diabetes and DSCM ($r_{pb}=-.314$, $p<.01$), and type of medication and DSCM ($r_{pb}=-.25$, $p<.05$) are significant. The negative correlations between DSCM, and type of diabetes and type of medication mean that participants with T1DM had lower levels of DSCM than those with T2DM. Moreover, the participants who were taking insulin injections and oral diabetic medications simultaneously had lower levels of DSCM than those who were taking insulin injections only. The Spearman's correlations table (See Table 15) shows that both race and level of education are insignificantly correlated with diabetes self care management ($\rho=-.204$, and $.198$ respectively).

The correlation between self efficacy and the dependent variable in this study (diabetes self care management) was strong ($r=.80$). Such a high correlation may be considered an indication of coliniarity. (Shrout, 1998) indicated that the inferences about reliability are better made about clinical and research interest rather than the subtle differences in precision of the reliability estimates. So, both of these variables (SE and DSCM) were kept in the analysis because they are considered essential concepts in the Research Model for Diabetes Self Care

Management. Also, the correlation between these two concepts was also strong ($r=.75$) in Sousa et al.'s (2004) study and both concepts were kept in the model.

Table 14.
Pearson's and Point Biserial correlations among Model Variables and Selected Demographic Variables.

	1	2	3	4	5	6	7	8	9	10
DSMS_40_Items	1									
Depression	-.421**	1								
Diabetes Knowledge	.262*	-.337**	1							
Self Care Agency	.629**	-.476**	.378**	1						
Self Efficacy	.801**	-.424**	.251*	.641**	1					
Age	-0.039	-0.001	-0.045	-0.023	-0.101	1				
Gender	-0.066	0.167	-0.078	0.03	-0.088	0.029	1			
type of diabetes	-.314** [†]	.270* [†]	-0.074 [†]	-0.197 [†]	-.258* [†]	.421** [†]	0.221 [†]	1		
years of having diabetes	.361**	-0.171	.394**	0.212	0.192	.346**	0.037	-0.076	1	
Type of medication	-.248* [†]	0.093 [†]	-0.041 [†]	-0.042 [†]	-.244* [†]	.366** [†]	0.207 [†]	.696** [†]	-0.063 [†]	1

** . Correlation is significant at the 0.01 level (2-tailed).

* . Correlation is significant at the 0.05 level (2-tailed).

[†] Point Biserial Correlation.

1=Diabetes Self Care Management (DSCM) (40-item scale), 2=Depression (CESD-20 scale), 3=Diabetes Knowledge (DK), 4=Self Care Agency (SCA), 5=Self Efficacy (SE), 6=age, 7=Gender, 8= Type of Diabetes, 9=Years of Having diabetes, 10= Type of Medication.

Table 15.
Spearman's Correlations between DSCM and Selected Demographic Variables.

	DSCM
Race	-.204
Level of Education	.198

*Correlation is significant at the .05 level.

Hypothesis Testing

Is there a Relationship between Depression and Diabetes Self care Agency?

Multiple regression analyses were done to test the relationship between depression and SCA. First, multiple regression analysis was conducted to test the influence of demographic variables (age, gender, race, type of diabetes, years of having diabetes, level of education, and type of medication) on SCA and depression. Race and level of education were originally

measured as categorical variables, in the regression analyses, they were both computed into dichotomous variables (race was coded as white=1, others=2; level of education was coded as high school or lower=1, above high school=2). Results indicated that there were no demographic variables that significantly influenced SCA. However, the type of diabetes and race had significant associations with depression scores measured by CESD (see Table 16 for the unstandardized coefficients (B values) of the regression between demographics and main study variables).

Next, a multiple regression analysis was conducted to test the influence of depression on SCA. Results showed that depression significantly affects SCA ($B=0.53$; $p<.01$). However, depression alone explained about 23% of the variability in SCA ($r^2=.23$).

Is there a Relationship between Depression and Self Efficacy?

Multiple regression analyses were done to test the relationship between depression and Self Efficacy. First, multiple regression analysis was conducted to test the influence of demographic variables (age, gender, race, type of diabetes, years of having diabetes, level of education, and type of medication) on Self Efficacy (SE) and depression. Results indicated that the no demographics influenced SE. On the other hand, the type of diabetes and race had significant influence on depression scores measure by CESD (see Table 16).

Second, a multiple regression analysis was conducted to test the influence of depression on Self Efficacy (SE). Results showed that depression significantly affects SE ($B=-1.43$; $p<.01$). The regression model explained about 18% of the variability in SE ($r^2=.18$).

Table 16.
Demographic variables that influence main study variables.

	DK B	SE B	SCA B	CESD B	DSCM B
Age	-.47*	-.143	.018	-.053	-.038
Gender					
1=Male	2.54	-2.38	3.41	.948	4.654
2=Female					
Race					
1=White					
2=African American, Asian, others	-22.39*	-5.61	-1.71	6.581*	-8.820
Type of diabetes					
1=Type1	3.74	-6.29	-6.30	8.249*	-10.123
2= Type2					
Years of having diabetes	.92*	.61	.227	-.160	1.114*
Level of education					
1= high school or lower	14.45*	17.33	4.287	.597	3.804
2=Above high school					
Type of medication					
1=insulin only	5.55	-10.47	3.691	-5.135	-6.848
2=pills and insulin					

*Beta is significant at the .05 level

Does Depression Affect Diabetes Self Care Management?

Multiple regression analyses were done to test the relationship between depression and Diabetes Self Care Management (DSCM). First, multiple regression analysis was conducted to test the influence of demographic variables (age, gender, race, type of diabetes, years of having diabetes, level of education, and type of medication) on Diabetes Self Care Management (DSCM), measure by the 40-item scale, and depression. Results indicated that years of having diabetes significantly influenced DSCM ($B=1.11$, $p<.01$). On the other hand, the type of diabetes and race had significant influence on depression scores measure by CESD (see Table 13).

Second, a multiple regression analysis was conducted to test the influence of depression on DSCM while controlling for years of having diabetes. Results showed that depression

significantly affects DSCM ($B=-1.01$; $p<.01$). The regression model explained about 25% of the variability in SE ($r^2=.249$).

Effect of the Linear Combinations of Diabetes Knowledge, Depression, Self Care Agency, Self Efficacy, and Diabetes Self Care Management

Multiple regression analyses were done to test the linear combination of the main study variables and controlling for the relevant demographics. First, regression analysis was done to assess the effect of the linear combination of diabetes knowledge, depression, Self Care Agency (SCA), and Self Efficacy (SE) on Diabetes Self Care management (DSCM) controlling for years of having diabetes (See Table 17). The results showed that self efficacy and years of having diabetes contributed to the model and significantly predicted DSCM, which accounted for about 72% of the variability of the DSCM scores. Second, regression analysis was done to assess the effect of the linear combination of diabetes knowledge, depression, and self care agency on self efficacy. The results showed that self care agency significantly affected self efficacy and the model accounted for about 43% of the variability in the SE scores. Third, regression analysis was done to assess the effect of the linear combination of diabetes knowledge and depression on self care agency. The results showed that both diabetes knowledge and depression significantly contributed to the model and the model accounted for about 28% of the variability of the SCA scores.

Table 17.
Unstandardized Regression Coefficients and Increments in Explained Variance (R^2) of the Revised Model Variables.

Predictor Variables	Self Care Agency	Self Efficacy	Diabetes Self Care Management
Diabetes Knowledge	.138**	-.033	NA
Depression	-.434*	-.532	-.039
Self Care Agency	NA	1.76*	.349
Self Efficacy	NA	NA	.578*
Years of having Diabetes	NA	NA	.638*
R^2	.28	.43	.72

* $p < .01$

** $p < .05$

NA indicates Not Applicable.

Are There Any Mediation Effects in These Relationships?

Hierarchical multiple regression analysis was used to test for the presence of mediation effects between SE, depression (measured by CESD), and DSCM (measured by 40-item scale), and SCA, depression, and DSCM. The mediation effect was assessed using Baron and Kenny's (1986) steps. These steps are described in Chapter 3 page 56.

Mediation Effect of Self Efficacy on the Relationship between Depression and Diabetes Self Care Management

To test for mediation effect of SE on the relationship between depression and DSCM (where depression is the independent variable (IV), SE is mediator (M), and DSCM is the outcome); first, a regression analysis was conducted to test the effect of depression on DSCM controlling for years of having diabetes. The test showed that depression significantly affected DSCM ($B = -1.01$; $p < .01$). In the second step, another regression test was done to assess the effect of depression on SE (mediator). The results showed that depression had significant effect on SE ($B = -1.43$; $p < .01$). In the final step, a regression analysis was done between depression and

DSCM with controlling for the mediator variable (SE) and years of having diabetes. The results showed that the effect of the mediator (SE) was statistically significant ($B=.638$; $p<.01$) but the effect of depression (IV) became statistically insignificant ($B=-.128$; $p>.05$). Thus, SE mediated the effect of depression on DSCM controlling for demographic variables (See Table 17).

Table 18.
Hierarchical Multiple Regression Analysis: SE as mediator for the Effect of Depression on DSCM.

Source of variation	Outcome Variable	Step	R	R ²	B	p
Depression	DSCM	1	.499	.249	-1.01	<.01
Controlling for years of having diabetes						
Depression	SE	2	.42	.18	-1.43	<.01
Controlling for level of education						
Depression	DSCM	3	.84	.71	-.128	>.05
Controlling for SE and years of having diabetes						

Mediation Effect of Self Care Agency on the Relationship between Depression and Diabetes Self Care Management

To test for mediation effect of SCA on the relationship between depression and DSCM (where depression is the independent variable (IV), SCA is mediator (M), and DSCM is the outcome); first, a regression analysis was done to test the effect of depression on DSCM controlling for years of having diabetes. The test showed that depression significantly affected DSCM ($B=-1.17$; $p<.01$). In the second step, another regression test was done to assess the effect of depression on SCA (mediator). The results showed that depression had significant effect on SCA ($B=-.52$; $p<.01$). In the final step, a regression analysis was done between depression and DSCM with controlling for the mediator variable (SCA). The results showed that the effect of the mediator (SCA) on DSCM was statistically significant ($B=1.64$; $p<.01$) but the effect of depression (IV) became statistically insignificant ($B=-.55$; $p>.01$). Thus, SCA mediated the effect of depression on DSCM controlling for demographic variables (See Table 18).

Table 19.
Hierarchical Multiple Regression Analysis: SCA as Mediator for the Effect of Depression on DSCM

Source of variation	Outcome Variable	Step	R	R ²	B	p
Depression	DSCM	1	.499	.249	-1.01	<.01
Controlling for years of having diabetes						
Depression	SCA	2	.476	.227	-.525	<.01
Depression	DSCM	3	.674	.454	-.34	>.05
Controlling for SCA and years of having diabetes						

Summary

A review of the content and wording of the items of the Diabetes Self Management Scale (DSMS) that measures Diabetes Self Care Management (DSCM) was done to assess for presence of statements that may create confusion in understanding the item. The initial review showed that there are absolute phrases in some items -- such as “all the time” and “every day” -- that may have contributed to confusion between the wording of the item and the available response options (Strongly Disagree to Strongly Agree). Then, a descriptive analysis for all the 60 items of the scale was conducted, several items had low variability ($SD < 1.2$) compared to the other items on the scale; and some items had a median of the highest possible score on the items.

The 60 items of the DSMS were assessed using Ferkitech (1991) recommendations for retaining or deleting items from a scale. The correlation matrices showed that a total of 20 items had poor item characteristics in term of low average correlation, low item- total correlation, low validity, low variability, high number of weak correlations, and redundancy. These 20 items were deleted and the resulting 40- item scale was then assessed for reliability. The 40- item scale had high level of internal consistency (Cronbach’s $\alpha = .947$). The validity of the 40-item scale was then assessed by using the scale in the assessment of the relationships among the study variables.

A cross sectional model testing design was used to assess the relationships addressed in the study questions. Correlation tests were conducted to test the correlations among the main study variables, which are: diabetes knowledge, self efficacy, self care agency, depression, and diabetes self care management, and various demographics. Depression was negatively correlated with Diabetes Knowledge, Self Care Agency, Self Efficacy, and Diabetes Self Care Management. Self efficacy had strong correlation with DSCM; however, these two concepts are integral for the Research Model for DSCM and were addressed in the analyses of the relationships in the model.

Multiple regression analyses were conducted to assess the relationship between depression and Self Care Agency (SCA), depression and Self Efficacy, and depression and DSCM while controlling for demographics. These analyses showed that depression had a direct relationship with SE and SCA. On the other hand, the relationship between depression and DSCM was not direct; SCA as well as SE completely mediated the effect of depression on DSCM because the effect of depression on DSCM became not significant when SCA followed by SE were introduced to the model.

Chapter V

This chapter presents a discussion of the sample and the research findings based on the study questions. Findings are presented and discussed in term of congruency with other current research findings. Then suggested revisions to the Research Model for Diabetes Self Care Management are presented. In addition, limitations of the study, recommendations for further research, and conclusions are presented.

Previous studies focused on the effect of depression on diabetes self care management or glycemic control. In people with diabetes, depression was found to have impact on functionality, self efficacy, and self care management. However, these effects are not completely clear because the pathways of influences have not been explored, and most of these studies were not guided by a theoretical framework (Egede & Ellis, 2008). Also, no study was found that directly assessed the effect of depression on diabetes self care agency. This study examined the relationships between depression and diabetes knowledge, self care agency, self efficacy, and self care management using the Research Model for Diabetes Self Care Management (Sousa et al., 2004) as a guiding model.

Characteristics of the Sample

The majority of the participants in the study were Non-Hispanic whites and African American, 52% and 41%, respectively. The racial and ethnic make-up of the sample is likely due to location of the data collection sites. City-data.com (2012) reported that in 2011 non-Hispanic whites and African Americans composed the majority of the area within which data collection occurred, about 56% and 28% respectively. In Sousa et al.'s 2004 study, Whites composed about 74% and African Americans composed about 20% of the sample. The difference in the ratio of the Whites and the African American between the current study sample and the Sousa et al. study sample can be attributed to the difference in the data collection sites. The Sousa et al.

sample was collected from an area in southeast United States, whereas this study sample was collected from the Midwest region of the US. However, the overall ratio of Whites and African American composed the majority of the sample in these two studies.

In general, the sample characteristics of this study were similar to those in Sousa et al.'s (2004) study. In both samples the majority was either White or African American, had completed some college education, and was married. However, differences existed in terms of gender; about 47% of Sousa et al.'s study sample was male, whereas 56% of this study sample was male. This difference could be attributed to the sampling technique used in this study where most participants were recruited from convenience stores rather than a clinic as it is in Sousa et al. study.

In the study, the ratio of persons with T1DM to T2DM was fairly even, 44.9% and 55.1%, respectively. By comparison, in the general population T1DM composes about 5-10% of people with diabetes, whereas T2DM composes about 90%. The reason for the discrepancy is that persons who are not taking insulin were excluded from the study, therefore reducing the available pool of persons with T2DM for recruitment. The CDC (2011) reported that the 2005–2008 National Health and Nutrition Examination Survey found about 58% of people with diabetes take oral medication only and 16% take no medication. The ratio of T1DM to T2DM in this study (44.9% and 55.1% respectively) was similar to Sousa et al.'s (2004) participant ratio (44.7 and 55.3% respectively).

Depression

Based on CESD scores, the prevalence of depression in study participants was relatively high, with about 61.5% of participants scoring 16 (the cutoff point) or higher. This prevalence of depression is regarded as high. De Groot (2010) reported that the rates of depression in T1DM

and T2DM ranged from 21 to 27% respectively. However, in their meta-analysis, Anderson, Freedland, Clouse, and Lustman (2001) found that the prevalence of depression in diabetes across studies varied by gender, study design, subject source, and method of depression assessment. In addition, the economic downturn may have contributed to the high rate of depression in the current study participants.

Depression was measured in two ways, the CESD scale and a self report of depression question. The CESD measures depressive symptoms 1 week before the completion of the scale; whereas the self report question does not identify a time frame. Only a small percentage (2.5%) of the participants who self reported that they had depression scored below 16 on the CESD. On the other hand, 41% of the participants who did not self report depression scored over 15 on the CESD. This finding could be the result of several factors. Some may not want to self report depression and some may not recognize that they are depressed. In addition, the sensitivity and specificity of the CESD scale among persons with diabetes may need examination.

Depression and Diabetes Knowledge

The relationship between depression and diabetes knowledge has been tested in many studies such as Ciechanowski et al. (2000) and Egede and Ellis (2008). Ciechanowski et al. (2000) indicated that in their study, diabetes knowledge was related to depression only through confounding of other factors. In their study, diabetes knowledge was found to have no statistically significant relationship with depression when controlling for severity of diabetes. Egede and Ellis (2008) found that there were no significant differences in diabetes knowledge between depressed and nondepressed patients. The findings of the current study are congruent with the findings of Ciechanowski et al. (2000) and Egede and Ellis (2008) studies. There was no

significant relationship between diabetes knowledge and depression when controlling for demographics ($B=-.108$, $p>.05$).

Depression and Self Efficacy

The relationship between depression and Self Efficacy (SE) in people with diabetes was examined in this study. The effect of depression on SE was direct and significant where depression negatively impacted SE. This finding was anticipated because other studies tested this relationship and reported direct and significant relationship between depression and SE. For example, Charington et al. (2010) reported a significant correlation between depressive symptoms and diabetes self efficacy in male participants ($r=-0.53$; $p<.01$) ($\beta=-.40$; $P<0.01$), but the correlation for female participants was not statistically significant. On the other hand, some studies indicated that the SE affects depression, but not in the opposite direction. For example, Sacco and Bykowski (2010) reported that SE significantly affected depression ($\beta= -.59$; $p<.01$) and that self efficacy was a mediator in the effect of A1c on depression among people with T1DM. Nevertheless, Sacco and Bykowski (2010) mentioned that theory and research suggest that depression could be an antecedent or a consequence of diabetes-related health outcomes (see Chapter 1 page 6 for Arguments about Temporal Sequence of Depression and Diabetes). In their study, they hypothesized that depression is a consequence and results from negative self relevant cognitions.

Depression and Self Care Agency

The relationship between depression and self care agency in people with diabetes also was tested in this study. Not many studies in the literature directly addressed the relationship between depression and SCA in people with diabetes. A search in PubMed for self care agency and depression or self care capability and depression yielded no results. However, the WHO

definition of depression (Chapter 1 page 12) states that depression can lead to impairments in the ability to take care of everyday responsibilities. Self care Agency is defined as the capability to perform self care activities.

In Chapter II, one study was reviewed in which the researchers discussed the relationship between depression and perceived control (Egede & Ellis, 2008). Egede and Ellis's definition of perceived control was similar to the definition of self care agency, but the authors did not note the similarities. Egede and Ellis stated that the participants with depression were more likely to report self care control problems and less likely to report positive attitude or self care ability. Self care agency is defined as the capabilities to perform self care activities (Sousa et al., 2004). Considering the similarity between SCA and perceived control, the findings of the current study are congruent with the findings of Egede and Ellis (2008). Depression was found to directly but negatively affect SCA, meaning that people with diabetes are less likely to perceive they are capable of caring for themselves when their level of depression is high. This finding was anticipated because Egede and Ellis (2008) found in their study that patients who were depressed had felt they had less control over their disease.

Depression and Diabetes Self Care Management

The relationship between depression and Diabetes Self Care Management (DSCM) was tested and the initial examination of the relationship showed that depression significantly and negatively affected DSCM. Various studies in the literature addressed this relationship and showed similar findings. For example, Egede (2005) conducted a literature review of studies that addressed the effect of depression on Diabetes Self care Management (DSCM) and concluded that studies consistently showed that depression was associated with poor diabetes self care management behavior. Also, Egede and Ellis (2010) conducted a systematic literature review of

studies published between 1966 and 2009 in which they assessed the relationships between depression in diabetes and self care management. The review included meta-analyses, literature reviews, and descriptive studies. Egede and Ellis (2010) indicated that all of these studies found that depression negatively affected DSCM aspects including glucose self monitoring, smoking cessation, diet, physical activity, and medication adherence.

However, in this study, the path analysis techniques showed that the relationship between depression and DSCM is actually an indirect relationship. The negative impact of depression on DSCM was a result of negatively affecting self efficacy and self care agency and those in turn influenced the level of DSCM. In other words, SE and SCA completely mediated the effect of depression on DSCM. Additional information about the mediation effects are described below.

Mediating Effect of Self Efficacy on the Relationship between Depression and Diabetes Self Care Management

Self efficacy was hypothesized to mediate the effect of depression on Diabetes Self Care Management (DSCM), and indeed self efficacy was found to mediate the relationship between depression and diabetes self care management. No other studies have examined this mediation effect. To demonstrate presence of mediation effect of SE on the relationship between depression and DSCM, the effect of depression on DSCM was tested first and found to be significant. This finding is congruent with the findings of Egede's (2005) review of the literature. The author stated that studies consistently reported presence of direct effect of depression on DSCM and depression was associated with poor diabetes self care management behavior.

Second, a significant effect of depression on SE was supported. Charington et al. (2010) reported similar findings where depression affected SE (see Depression and Self Efficacy above). Third, the effect of depression on DSCM became insignificant when SE was introduced

to the regression model indicating presence of complete mediation effect of SE on the relationship between depression and DSCM. This step had not been tested before. Sousa et al. (2004) tested the effect of SE on DSCM and reported a strong correlation between them. In addition, they found that SE significantly affected DSCM and even partially mediated the effect of SCA on DSCM.

The findings of the mediation testing indicate that depression can affect diabetes self care management (DSCM) through Self Efficacy (SE), which means the performance of self care activities would be diminished in people with depression, who also are diabetic and if their beliefs in their capabilities are not changed. In other words, the influence of depression on individual's performance of self care activities cannot be explained directly, but can be explained through the influence of SE.

Sacco and Bykowski (2010) indicated that SE mediated the effect of A1c on depression in people with T1DM. But they did not account for DSCM. A better A1c is believed to be the direct consequence of better DSCM. Sousa et al. (2005) found that Self care management did not mediate between self efficacy or self care agency and glycemic control. In other words, beliefs or capabilities for self care are insufficient to improve glycemic control; self care management is required to improve A1c.

Mediating Effect of Self Care Agency on the Relationship between Depression and Diabetes Self Care Management

Self care Agency (SCA) was hypothesized to mediate the effect of depression on Diabetes Self Care Management (DSCM). No other studies examined this relationship before. To demonstrate presence of mediation effect of SCA on the relationship between depression and DSCM, first the effect of depression on DSCM was tested first and found to be significant. As

discussed earlier in the section above, this finding was supported in other studies. Second, the effect of depression on SCA was tested and found to be significant. No other studies addressed this relationship before; however, the negative correlation between depression and SCA was expected as some studies addressed earlier showed that depression negatively affects individual's abilities. Third, the effect of depression on DSCM became insignificant when SCA was introduced to the regression model to predict DSCM. No studies were found that addressed the combined effect of self care agency and depression on DSCM.

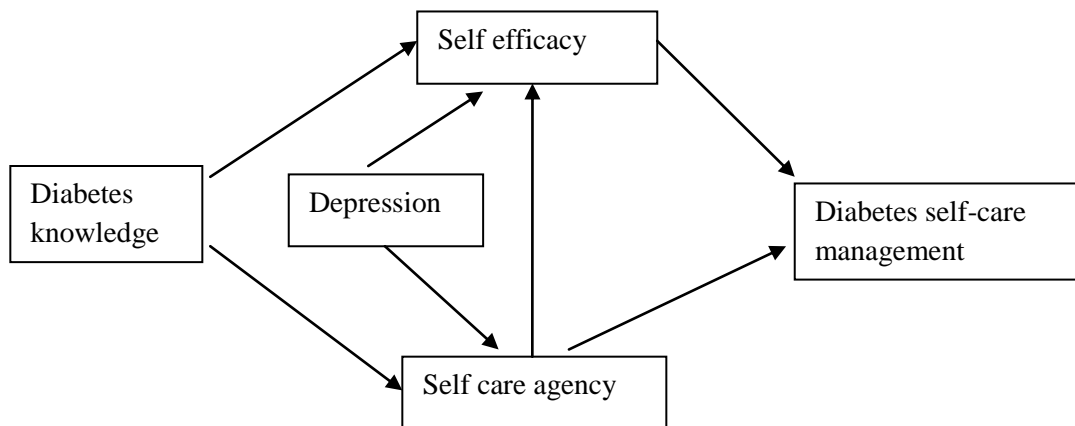
The findings of the mediation effect of self care agency on the relationship between depression and Diabetes Self Care Management (DSCM) means that there is no direct effect of depression on DSCM. The mediation effect also means that depression negatively impacts SCA, which in turn may diminish individual's DSCM. In other words, people with depression and are diabetic would have lower abilities to care for themselves; this in turn would make them less likely to perform self care activities.

Self efficacy was found to partially mediate the effect of self care agency on Diabetes Self Care Management (DSCM) (Sousa et al., 2004). This mediation effect of self efficacy on the relationship between self care agency and diabetes self care management indicates that the influence of depression on DSCM can take multiple pathways of influence – first through affecting self efficacy, which in turn can affect DSCM; second, through affecting SCA, which in turn can affect DSCM; third, through affecting SCA, which in turn can impact SE and then affects DSCM.

Summary of the Relationships between the Concepts in the Revised Research Model for Diabetes Self Care Management

Based on the original model proposed by Sousa et al. (2004), empirical works in the literature, and the findings of this study, the relationships among the concepts of the model (see figure 4) can be described as the following: a direct relationship exists between diabetes knowledge and self efficacy, and diabetes knowledge and self care agency. There is no direct relationship between diabetes knowledge and depression. Depression directly but negatively affects self efficacy and self care agency. Both self care agency and self efficacy have direct relationship with diabetes self care management. Self efficacy partially mediates the relationship between self care agency and diabetes self care management. Self efficacy and self care agency completely mediates the effect of depression on diabetes self care management. Neither diabetes knowledge nor depression have direct effect on diabetes self care management.

Figure 4. Revised and Final Research Model for DSCM.



Item Analysis and Reliability Analysis of the Diabetes Self Management Scale

The Diabetes Self Management Scale (DSMS) was used in this study to operationalize Diabetes Self Care Management (DSCM). The scale contained 60 Likert-type items with response options ranging from 0 “Strongly Disagree” to 5 “Strongly Agree”. The final score is calculated by summing the scores of all items. A higher score on the scale indicates higher level of DSCM.

The secondary aim of the study was to examine the reliability and item characteristics of the Diabetes Self Management Scale (DSMS) because Sousa et al. (2009) indicated that the DSMS requires further psychometric analysis and evaluation of its reliability. Reliable and valid instruments are important for the advancement of research and translation of research findings into practice (Sousa et al., 2010).

In Sousa et al.’s (2009) study to develop new measures of DSCM and other concepts, the authors indicated that various tools to measure DSCM are available in the literature but all have limitations such as low reliability of some subscales, lack of content validity, and inadequate or unknown construct and criterion-related validity. So, Sousa and colleagues developed the DSMS using American Diabetes Association (ADA) and American Association of Diabetes Educators (AADE) current standards of care, empirical works, and Orem’s self care theory. Souse et al. (2009) examined the inter-rater agreement for clarity and consistency with current standards of care among a panel of expert and clinicians. The Scale-Content Validity Index (S-CVI) and the Item-Content Validity Index (I-CVI) for the scale items were also tested. Thirteen items of the DSMS had an inter-rater agreement for clarity that was less than the minimum recommendation of 80%, and two items of the DSMS had an inter-rater agreement regarding consistency with current standards of diabetes care that was less than the minimum recommendation of 80%. The

results of the S-CVI and I-CVI showed that the overall DSMS scale had an S-CVI of .96, exceeding the minimum recommendation for S-CVI of .90. Also, all the items exceeded the minimum recommendation for I-CVI of 0.78 (Polit, Beck, & Owen, 2007) except for one item (I-CVI=0.70). Factor validity of the scale was not conducted. So, Sousa and colleagues recommended conducting further testing and revisions for the DSMS.

In this study, a review of the content and wording of items was conducted and showed that some items may have contributed to confusion between the wording of the item and the available response options due to presence of absolute phrases such as “all the time” and “every day”. The item analysis for the 60 items of the Diabetes Self Management Scale (DSMS) showed that other items might be problematic because they had low variability compared to the other items on the scale; and some items had a median of the highest possible score on the items (a possible ceiling effect).

The recommendations of Ferketich (1991) to identify whether any given item should be retained or deleted were used to revise the DSMS. These recommendations included assessing the average correlations of the items, inter-item correlation matrix, corrected item-total correlation, alpha-if-item deleted, item validity estimate, and item variability. Ferketich (1991) indicated that because scale validity is a function of its adequate measurement of an attribute, then each item in that scale should also be an adequate measure of that attribute. Item validity estimates can be obtained by correlating the score of an individual item with an outside criterion. So, the items of the DSMS scale were correlated with the total scores of SE to assess the validity of the items. The results of the correlation showed that some items had relatively low validity compared to the other items on the DSMS scale. The item validity was also reviewed in the process of reviewing the items to determine which item to keep and which one to delete.

A total of 20 items were identified as ‘problem’ items and they were marked for deletion. Cronbach’s alpha for the resulting 40-item scale showed a high level of internal consistency at .947, which exceeded the recommended minimum criterion of 0.70 or above for determining internal consistency (Waltz et al., 2005). This 40-item scale then was used in the Aim 1 analyses.

Waltz et al. (2005) described construct validity testing for psychometric scales. The authors indicated that to assess construct validity, the items of the scale should show consistency with the theory and the concepts as operationally defined. This consistency can be tested by examining the item interrelationships and investigating the extent of the relationship between the item scores and external variables. In this study, the scores from the 40-item DSMS were correlated with the scores of the Diabetes Self Efficacy Scale (DSES). The relationship between Self Efficacy (SE) and Diabetes Self Care Management (DSCM) was addressed in the literature and in the Research Model for Diabetes Self Care Management and consistently showed strong positive relationship between them. The findings of this study also showed that SE was strongly and positively correlated with DSCM ($r=.80$). Therefore, the construct validity of the 40-item DSMS scale was supported.

Implications

The main study aim was to explore the relationships among diabetes knowledge, self efficacy, self care agency, and depression on diabetes self care management. Self care management in diabetes is crucial in managing diabetes and considered as a cornerstone in delaying or preventing diabetes complications. American Diabetes Association (2012) indicated that diabetes self care management leads to better glycemic control, higher quality of life, and lower cost of therapy in people with Type 1 and Type 2 Diabetes Mellitus. However, self care in diabetes is complex and various factors can affect it. Therefore understanding the factors that

influence individuals' performance of diabetes self care is essential for nursing research and nursing practice. Depression among people with diabetes is not uncommon. Depression in diabetes was associated with hyperglycemia in people with type 1 or type 2 diabetes, and resulted in higher health care costs. So, effective treatment of comorbid depression is considered an essential component of high quality care of persons with diabetes. Understanding the nature and pathways of influence of depression on DSCM should help clinicians provide better treatment and to limit the negative impact of diminished self care activities. Clinicians should be more aware of the problem of depression because better understanding of factors associated with diabetes self care management could lead to better policies and protocols for achieving self care management. Such protocols should consider not only early screening for depression but also doing repeated assessments of depression over time by clinicians. Better detection of this debilitating disorder is essential because depression is underdiagnosed in people with diabetes (Li et al., 2009). Improved screening and treatment for depression can dramatically improve quality of life for people with diabetes (Wua et al., 2011).

The study findings provide a clearer understanding of the relationships among self efficacy, self care agency, diabetes self care management, and depression. The understanding of these pathways of influence can be useful in the education of health professionals. Clearer understanding of these relationships can enable the health professionals to provide more comprehensive care, rather than just focusing on patient education to achieve self care and glycemic control. Also, health care professionals can expand the elements of diabetes education to include the psychological aspects and address the possible psychological aspects that can influence the patient's level of performing self care. Various theories such as self worth, self

efficacy, and depression may enhance performance of self care activities and guide the diabetes education process.

Using this knowledge of pathways, potential effective intervention programs can be designed, tested in research, and applied to nursing practice. Such effective intervention programs can incorporate patient counseling, education, and self care skills training to enhance patient self efficacy, self care agency, and diabetes self care management. Such programs are believed to limit the negative influence of depression on self care activities, which may lead eventually to better glycemic control level. If the effect of depression is not mitigated, people with diabetes and with comorbid depression will be at higher risk for disease-related complications such as retinopathies, nephropathies, neuropathies, coronary artery disease, cerebral vascular disease, and peripheral vascular disease. Therefore, interventions are needed that will provide effective ways to mitigate depression and therefore delay or prevent diabetes-related complications.

The study results show that depression has a direct and negative effect on self efficacy and self care agency in people with diabetes. On the other hand, the relationship between depression and diabetes self care management is indirect because both self efficacy and self care agency mediated this relationship. The findings of this study suggest that not only having greater self care agency and self efficacy improves diabetes self care management, but also it prevents the negative influence depression can have on self care management. Because of the negative impact of depression on diabetes self care management, and given that depression is highly prevalent among people with diabetes and that people with depression are at higher risk to develop diabetes; more attention should be paid to providing insurance coverage to treat depression. Managing depression in people with diabetes using antidepressant medications and

cognitive behavioral therapy may save up to \$2100 per person per year (Ciechanowski et al., 2000).

The secondary aim of this study was to revise the Diabetes Self Management Scale (DSMS) by examining the items characteristics and the reliability of the scale. The developing and testing the scales reliability and validity was conducted by Sousa et al. (2009) and they indicated the need for further testing and investigation of the scale. A review of the scale's items for content and wording of the items was conducted and showed that some items may have contributed to confusion between the wording of the item and the available response options. Further item analysis showed that some items can be considered as 'problem' items. Twenty items were marked for deletion and the resulting 40-items scale was then evaluated for its reliability and showed a high internal consistency. The new 40-item scale was then used in examining the relationships addressed in the study. A reliable and valid instrument that measures Diabetes Self Care Management has the potential to be a useful measure of self care management in clinical practice and research. In clinical practice, the revised measure can be used to screen individuals in respect to their performance of self care behaviors and activities. The revised scale also can help in developing individualized plans of care to promote performance of self care activities. In research, the new 40-item DSMS can be used to collect baseline and outcome data when implementing interventions to promote an individual's performance and engagement in self care management. When individuals achieve substantial levels of self care, they are more likely to attain better glycemic control, quality of life, general health status and well-being and to prevent the disease-related complications.

The sample size in this study was not sufficient to conduct factor analysis for the original DSMS scale or the new 40- item DSMS scale. So, further research to determine the factor

structure, construct validity and criterion-related validity of the scales among a larger sample of insulin-treated individuals with T1DM and T2DM is recommended.

Study Limitations

Several study limitations were identified. Limitations were related to the instruments used to measure the concepts that constitute the framework. Also, limitations were identified with the study design, final sample size, the convenience sample, and data collection procedure.

Limitations of Instruments

Self efficacy, self care agency, and diabetes self care management were measured using questionnaires that were developed using the research model as a theoretical background for development. Self efficacy was measured using the Diabetes Self Efficacy Scale (DSES). Self care agency was measured using the Appraisal of Self care Agency Scale revised (ASAS-R). Diabetes self care management was measured using the Diabetes Self Management Scale (DSMS). Diabetes knowledge was measured using the Diabetes Knowledge Test (DKT), and depression was measured using Center for Epidemiological Studies Depression Scale the 20 item version (CESD 20). All of these instruments are self reported questionnaires that may introduce concerns about the validity of causal conclusions due to possibility of including systematic errors in the answers, restriction of range, and the psychometric reliability and validity of the questionnaires (Shadish, Cook, & Campbell, 2002). Also, each variable in this study was measured using one instrument, which may introduce mono-operation bias.

Limitations of Study Design

The study was a descriptive cross-sectional design. Shadish et al. (2002) indicated that the use of cross-sectional study may introduce threat to the internal validity of the study because the data are gathered at one time, so the researcher may not even know if the cause preceded the

effect. However, this threat can be controlled if much is known about the interpretations of the relationships. More robust designs such as experimental or quasi-experimental design can be used in future studies to assess the addressed relationships in this study in a longitudinal way. Such robust designs allow yielding an estimate of the size of treatment effect.

Limitations of Sample

A convenience sample was used in this study, which limits the generalizability of the study findings. In general, randomization is preferred because it eliminates the confounding influence of alternative causes and reduces the threat to validity (Shadish et al., 2002). Sample characteristics such as age, geographic area, and race also limits generalizations to other groups such as adolescents and children, other geographic areas, and Hispanic population.

The sample size was another study limitation. Because of the timeframe of the study, the availability of a large sample size was difficult to obtain. An inadequate sample size could limit the ability to detect statistically significant relationships between the exogenous and endogenous variables. During the development of the study design, an evaluation was conducted to determine the minimum sample required to evaluate the model based on VanVoorhis and Morgan (2007) rules of thumb; the general rule of thumb is that sample size should not be less than 50 participants for a correlation or regression; and not be less than 300 for factor analysis. Also, they stated that to determine the number of participants needed for statistics used to examine relationships, the number of participants should exceed the number of predictors by at least 50. The study was determined to include 15 parameters. So, a sample of at least 75 participants with complete data was needed for this study.

Conclusions

Diabetes is a condition that impacts the lives of a large population and is associated with higher mortality, morbidity, and health care costs. Diabetes Self Care Management (DSCM) is an essential part of management of diabetes to reduce the risks of diabetic complications.

Diabetes is also associated with higher risk of depression. The co-morbidity of diabetes and depression is associated with even greater risk of diabetic complications and higher costs of management. Complex relationships exist between diabetes knowledge, Self Efficacy (SE), Self Care Agency (SCA), and Diabetes Self Care Management (DSCM). Depression was thought to have relationships with diabetes knowledge, SE, and DSCM. These relations are also complex and not fully understood. On the other hand, no study was found to address the relationship between depression and diabetes Self Care Agency (SCA). A correlational model testing design was used to examine the study hypotheses. A convenience sample of 78 participants with completed questionnaires was recruited for the study. Data was collected in 5 sites.

A review of the content and wording of the items of the Diabetes Self Management Scale (DSMS) that measures Diabetes Self Care Management (DSCM) was done. Then, a descriptive analysis for all the 60 items of the scale was conducted. The 60 items of the DSMS were assessed using Ferkitech (1991) recommendations for retaining or deleting items from a scale. The correlation matrices showed that a total of 20 items had poor item characteristics. These 20 items were deleted and the resulting 40- item scale was then assessed for reliability. The 40- item scale had high level of internal consistency (Cronbach's $\alpha = .947$). The validity of the 40-item scale was then assessed by using the scale in the assessment of the relationships among the study variables. The scores of the 40-item DSMS were strongly correlated with an outside criterion (Self Efficacy) that has theoretically supported relationship with Diabetes Self Care Management. This finding supports the validity of the 40-item DSMS.

Correlation tests were conducted to test the correlations among the main study variables, which are: diabetes knowledge, self efficacy, self care agency, depression, and diabetes self care management, and various demographics. Depression was negatively correlated with Diabetes Knowledge, Self Care Agency, Self Efficacy, and Diabetes Self Care Management. Multiple regression analyses were conducted to assess the relationship between depression and Self Care Agency (SCA), depression and Self Efficacy (SE), and depression and DSCM while controlling for demographics. These analyses showed that depression had a direct relationship with SE and SCA. On the other hand, the relationship between depression and DSCM was not direct; SCA as well as SE completely mediated the effect of depression on DSCM because the effect of depression on DSCM became not significant when SCA followed by SE were introduced to the model.

The findings regarding the nature of the relationships among the study variables were supported by other studies in the literature. However, the mediation effect of self efficacy and self care agency on the relationship between depression and diabetes self care management were never tested before and indicated that the relationship is not direct and the pathway of influence cannot be interpreted without addressing the effect of the mediators.

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Appendix A: Human Subjects Committee Approval letter

The University of Kansas Medical Center

Human Research Protection Program

May 6, 2011

Project Number: 12644
Project Title: Testing a conceptual framework for self care in persons with diabetes:
The effect of depression
Sponsor: None
Protocol Number: N/A
Primary Investigator: Diane K Boyle, Ph.D.
Department: Administration - School of Nursing
Meeting Date: 04/05/2011
HSC Approval Date: 05/05/2011
Type of Approval: Exempt b (2)

Dear Investigator:

This is to certify that your research proposal involving human subject participants has been reviewed and **approved** by the KUMC Human Subjects Committee (HSC). This "exempt" approval is based upon the assurance that you will notify the HSC prior to implementing any revisions to the project. The HSC must determine whether or not the revisions impact the risks to human subjects, thus affecting the project's "exempt" status. Projects that do not meet the "exempt" criteria must comply with all federal regulations regarding research.

If you have any questions regarding the human subject protection process, please do not hesitate to contact our office.

Very truly yours,



Daniel J. Voss, M.S., J.D.
IRB Administrator

Appendix B: Study Questionnaires

DIABETES SELF EFFICACY SCALE (DSES)

Circle the number that represents the extent to which you AGREE or DISAGREE with each statement listed below about your **confidence (think or believe)** in your capability to perform specific diabetes self management activities. Use the following scale:

0 = STRONGLY DISAGREE

1 = MODERATELY DISAGREE

2 = SLIGHTLY DISAGREE

3 = SLIGHTLY AGREE

4 = MODERATELY AGREE

5 = STRONGLY AGREE

1. I think I can make the right food choices all the time.....	0	1	2	3	4	5
2. I think I can eat at least three meals every day.....	0	1	2	3	4	5
3. I think I can stay on my meal plan all the time.....	0	1	2	3	4	5
4. I think I can stay on my meal plan even when I eat outside my home..	0	1	2	3	4	5
5. I think I can stay on my meal plan even when the people around me do not know I have diabetes.....	0	1	2	3	4	5
6. I think I can stay on my meal plan even when I am at parties.....	0	1	2	3	4	5
7. I think I can eat at least five servings of fruits and vegetables every day.....	0	1	2	3	4	5
8. I think I can control my intake of carbohydrates all the time.....	0	1	2	3	4	5
9. I think I can choose to eat foods that are lower in fats and cholesterol all the time.....	0	1	2	3	4	5
10. I think I can eat foods high in fiber all the time.....	0	1	2	3	4	5
11. I think I can control my food portion sizes at every meal.....	0	1	2	3	4	5
12. I think I can adjust my food choices and portion sizes based on my blood sugar results.....	0	1	2	3	4	5
13. I think I can stop eating when I feel full.....	0	1	2	3	4	5
14. I think I can drink plenty of sugar-free fluids every day.....	0	1	2	3	4	5
15. I think I can read food labels all the time.....	0	1	2	3	4	5
16. I think I can engage in one or more forms of exercise (e.g., walking, jogging/running, weightlifting).....	0	1	2	3	4	5
17. I think I can exercise for 30 minutes at least five times a week.....	0	1	2	3	4	5
18. I think I can exercise even when I feel a little tired.....	0	1	2	3	4	5
19. I think I can get enough exercise to meet my desired goals.....	0	1	2	3	4	5
20. I think I can adjust my exercise routine based on my blood sugar						

results.....	0	1	2	3	4	5
21. I think I can adjust my exercise routine when recommended by my health care provider.....	0	1	2	3	4	5
22. I think I can check my blood sugar at least three to four times a day...	0	1	2	3	4	5
23. I think I can check my blood sugar even when I am away from home..	0	1	2	3	4	5
24. I think I can check my blood sugar more often than usual when I feel sick.....	0	1	2	3	4	5
25. I think I can keep a record of my blood sugar tests.....	0	1	2	3	4	5
26. I think I can check my blood sugar level every time before and after I exercise.....	0	1	2	3	4	5
27. I think I can have my blood checked for diabetes control (A1c or HbA1c) at least two times a year.....	0	1	2	3	4	5
28. I think I can discuss the effectiveness of my self care activities based on my diabetes control (A1c or HbA1c) results.....	0	1	2	3	4	5
29. I think I can prepare and inject my insulin correctly.....	0	1	2	3	4	5
30. I think I can take my insulin even when I am away from home.....	0	1	2	3	4	5
31. I think I can adjust my insulin dose based on my blood sugar results...	0	1	2	3	4	5
32. I think I can adjust my insulin dose when my daily routine changes...	0	1	2	3	4	5
33. I think I can adjust my insulin dose when recommended by my health care provider.....	0	1	2	3	4	5
34. I think I can take my insulin or other medications as prescribed by my health care provider.....	0	1	2	3	4	5
35. I think I can inspect my feet every day.....	0	1	2	3	4	5
36. I think I can keep my toenails clean and trimmed.....	0	1	2	3	4	5
37. I think I can completely dry my feet after taking a bath or shower.....	0	1	2	3	4	5
38. I think I can wear closed-toe shoes every time I am outside my home.	0	1	2	3	4	5
39. I think I can wear socks or stockings every time I wear shoes.....	0	1	2	3	4	5
40. I think I can wear comfortable shoes and socks or stockings that fit me well all the time.....	0	1	2	3	4	5
41. I think I can have a complete foot exam at least once a year.....	0	1	2	3	4	5
42. I think I can recognize when my blood sugar is high.....	0	1	2	3	4	5
43. I think I can figure out what to do when my blood sugar is high.....	0	1	2	3	4	5

44. I think I can recognize when my blood sugar is low.....	0	1	2	3	4	5
45. I think I can figure out what to do when my blood sugar is low.....	0	1	2	3	4	5
46. I think I can adjust my diabetes self care routine when I feel sick.....	0	1	2	3	4	5
47. I think I can carry hard candies or glucose tablets every time I am away from home.....	0	1	2	3	4	5
48. I think I can carry or wear my diabetes identification all the time.....	0	1	2	3	4	5
49. I think I can see my healthcare provider at least every three to six months.....	0	1	2	3	4	5
50. I think I can have a dilated eye exam every year.....	0	1	2	3	4	5
51. I think I can check my weight on a regular basis and at least every three months.....	0	1	2	3	4	5
52. I think I can adjust my self care activities to fit changes in my daily routine.....	0	1	2	3	4	5
53. I think I can adjust my self care activities to fit my social activities....	0	1	2	3	4	5
54. I think I can do all my self care activities every day.....	0	1	2	3	4	5
55. I think I can check or have my blood pressure checked on a regular basis and at least every three months.....	0	1	2	3	4	5
56. I think I can get a flu shot every year.....	0	1	2	3	4	5
57. I think I can have a dental check-up at least every six months.....	0	1	2	3	4	5
58. I think I can have my blood checked for cholesterol at least once a year.....	0	1	2	3	4	5
59. I think I can have other tests to screen for diabetes complications when recommended by my health care provider.....	0	1	2	3	4	5
60. I think I can check my urine for ketones when my blood sugar results are greater than 240 mg/dL (or when I feel sick) at least every 4 to 6 hours.....	0	1	2	3	4	5

APPRAISAL OF SELF CARE AGENCY SCALE REVISED (ASAS-R)

Circle the best answer for each statement listed below using the following scale:

1 = TOTALLY DISAGREE

2 = DISAGREE

3 = NEITHER DISAGREE OR AGREE

4 = AGREE

5 = TOTALLY AGREE

1. As circumstances change, I make the needed adjustments to stay healthy...	1	2	3	4	5
2. I rarely check whether the measures I take to stay healthy are adequate.....	1	2	3	4	5
3. If my mobility is decreased, I make the needed adjustments.....	1	2	3	4	5
4. I take measures to maintain sanitary conditions in my environment.....	1	2	3	4	5
5. When needed, I set new priorities in the measures that I take to stay healthy.....	1	2	3	4	5
6. I often lack the energy to care for myself in the way that I know I should...	1	2	3	4	5
7. I look for better ways to care for myself.....	1	2	3	4	5
8. To maintain my hygiene, I adjust the frequency of bathing and showering to the circumstances.....	1	2	3	4	5
9. I eat in a way that maintains my body weight at an appropriate level.....	1	2	3	4	5
10. When needed, I manage to take time to care for myself.....	1	2	3	4	5
11. I often think about including a program of exercise and rest in my daily routine, but I never get around to doing it.....	1	2	3	4	5
12. Over the years I have developed a circle of friends that I can call upon to help me to care for myself.....	1	2	3	4	5
13. I rarely get enough sleep to feel rested.....	1	2	3	4	5
14. When receiving information regarding my health, I seldom ask for clarification of terms I don't understand to adequately care for myself.....	1	2	3	4	5
15. I seldom examine my body to determine the presence of any changes.....	1	2	3	4	5
16. If I take a new medication, I obtain information about the side effects to better care for myself.....	1	2	3	4	5
17. In the past I have changed some of my old habits in order to improve my health.....	1	2	3	4	5
18. I routinely take measures to insure the safety of myself and my family.....	1	2	3	4	5
19. I regularly evaluate the effectiveness of things that I do to stay healthy.....	1	2	3	4	5
20. In my daily activities I seldom take time to care for myself.....	1	2	3	4	5

21. I am able to get the information I need, when my health is threatened.....	1	2	3	4	5
22. I seek help when unable to take care of myself.....	1	2	3	4	5
23. I seldom have time for myself.....	1	2	3	4	5
24. I am not always able to care for myself in a way I would like.....	1	2	3	4	5

Diabetes Knowledge Test (DKT)
Michigan Diabetes Research and Training Center

1. **The diabetes diet is:**
 - a. the way most American people eat
 - b. a healthy diet for most people
 - c. too high in carbohydrate for most people
 - d. too high in protein for most people

2. **Which of the following is highest in carbohydrate?**
 - a, Baked chicken
 - b. Swiss cheese
 - c. Baked potato
 - d. Peanut butter

3. **Which of the following is highest in fat?**
 - a. Low fat milk
 - b. Orange juice
 - c. Corn
 - d. Honey

4. **Which of the following is a “free food”?**
 - a Any unsweetened food
 - b. Any dietetic food
 - c. Any food that says “sugar free” on the label
 - d. Any food that has less than 20 calories per serving

5. **Glycosylated hemoglobin (hemoglobin A1) is a test that is a measure of your average blood glucose level for the past:**
 - a. day
 - b. week
 - c. 6-10 weeks
 - d. 6 months

6. **Which is the best method for testing blood glucose?**
 - a. Urine testing
 - b. Blood testing
 - c. Both are equally good

7. **What effect does unsweetened fruit juice have on blood glucose?**
 - a. Lowers it
 - b. Raises it
 - c. Has no effect

8. **Which should not be used to treat low blood glucose?**
 - a. 3 hard candies

- b. 1/2 cup orange juice
 - c. 1 cup diet soft drink
 - d. 1 cup skim milk
9. **For a person in good control, what effect does exercise have on blood glucose?**
- a. Lowers it
 - b. Raises it
 - c. Has no effect
10. **Infection is likely to cause:**
- a. an increase in blood glucose
 - b. a decrease in blood glucose
 - c. no change in blood glucose
11. **The best way to take care of your feet is to:**
- a. look at and wash them each day
 - b. massage them with alcohol each day
 - c. soak them for one hour each day
 - d. buy shoes a size larger than usual
12. **Eating foods lower in fat decreases your risk for:**
- a. nerve disease
 - b. kidney disease
 - c. heart disease
 - d. eye disease
13. **Numbness and tingling may be symptoms of:**
- a. kidney disease
 - b. nerve disease
 - c. eye disease
 - d. liver disease
14. **Which of the following is usually not associated with diabetes:**
- a. vision problems
 - b. kidney problems
 - c. nerve problems
 - d. lung problems
15. **Signs of ketoacidosis include:**
- a. shakiness
 - b. sweating
 - c. vomiting
 - d. low blood glucose

16. **If you are sick with the flu, which of the following changes should you make?**
- a. Take less insulin
 - b. Drink less liquids
 - c. Eat more proteins
 - d. Test for glucose and ketones more often
17. **If you have taken intermediate-acting insulin (NPH or Lente), you are most likely to have an insulin reaction in:**
- a. 1-3 hours
 - b. 6-12 hours
 - c. 12-15 hours
 - d. more than 15 hours
18. **You realize just before lunch time that you forgot to take your insulin before breakfast. What should you do now?**
- a. Skip lunch to lower your blood glucose
 - b. Take the insulin that you usually take at breakfast
 - c. Take twice as much insulin as you usually take at breakfast
 - d. Check your blood glucose level to decide how much insulin to take
19. **If you are beginning to have an insulin reaction, you should:**
- a. exercise
 - b. lie down and rest
 - c. drink some juice
 - d. take regular insulin
20. **Low blood glucose may be caused by:**
- a. too much insulin
 - b. too little insulin
 - c. too much food
 - d. too little exercise
21. **If you take your morning insulin but skip breakfast your blood glucose level will usually:**
- a. increase
 - b. decrease
 - c. remain the same
22. **High blood glucose may be caused by:**
- a. not enough insulin
 - b. skipping meals
 - c. delaying your snack
 - d. large ketones in your urine

- 23. Which one of the following will most likely cause an insulin reaction:**
- a. heavy exercise
 - b. infection
 - c. overeating
 - d. not taking your insulin

CESD 20**Center for Epidemiologic Studies Depression Scale (CESD)**

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

	During the Past Week			
	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	Most or all of the time (5-7 days)
1. I was bothered by things that usually don't bother me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I did not feel like eating; my appetite was poor.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I felt that I could not shake off the blues even with help from my family or friends.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I felt I was just as good as other people.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I had trouble keeping my mind on what I was doing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. I felt depressed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. I felt that everything I did was an effort.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. I felt hopeful about the future.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. I thought my life had been a failure.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. I felt fearful.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. My sleep was restless.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. I was happy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. I talked less than usual.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I felt lonely.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. People were unfriendly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I enjoyed life.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. I had crying spells.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. I felt sad.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. I felt that people dislike me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. I could not get "going."	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

DIABETES SELF MANAGEMENT SCALE (DSMS)

Circle the number that represents the extent to which you AGREE or DISAGREE with each statement listed below about what you **actually do** to self manage your diabetes. Use the following scale:

0 = STRONGLY DISAGREE
1 = MODERATELY DISAGREE
2 = SLIGHTLY DISAGREE

3 = SLIGHTLY AGREE
4 = MODERATELY AGREE
5 = STRONGLY AGREE

1. I make the right food choices all the time.....	0	1	2	3	4	5
2. I eat at least three meals every day.....	0	1	2	3	4	5
3. I stay on my meal plan all the time.....	0	1	2	3	4	5
4. I stay on my meal plan even when I eat outside my home.....	0	1	2	3	4	5
5. I stay on my meal plan even when the people around me do not know I have diabetes.....	0	1	2	3	4	5
6. I stay on my meal plan even when I am at parties.....	0	1	2	3	4	5
7. I eat at least five servings of fruits and vegetables every day.....	0	1	2	3	4	5
8. I control my intake of carbohydrates all the time.....	0	1	2	3	4	5
9. I choose to eat foods that are lower in fats and cholesterol all the time.....	0	1	2	3	4	5
10. I eat foods high in fiber all the time.....	0	1	2	3	4	5
11. I control my food portion sizes at every meal.....	0	1	2	3	4	5
12. I adjust my food choices and portion sizes based on my blood sugar results.....	0	1	2	3	4	5
13. I stop eating when I feel full.....	0	1	2	3	4	5
14. I drink plenty of sugar-free fluids every day.....	0	1	2	3	4	5
15. I read food labels all the time.....	0	1	2	3	4	5
16. I engage in one or more forms of exercise (e.g., walking, jogging/running, weightlifting).....	0	1	2	3	4	5
17. I exercise for 30 minutes at least five times a week.....	0	1	2	3	4	5
18. I exercise even when I feel a little tired.....	0	1	2	3	4	5
19. I get enough exercise to meet my desired goals.....	0	1	2	3	4	5
20. I adjust my exercise routine based on my blood sugar results.....	0	1	2	3	4	5
21. I adjust my exercise routine when recommended by my health care provider.....	0	1	2	3	4	5

22. I check my blood sugar at least three to four times a day.....	0	1	2	3	4	5
23. I check my blood sugar even when I am away from home.....	0	1	2	3	4	5
24. I check my blood sugar more often than usual when I feel sick.....	0	1	2	3	4	5
25. I keep a record of my blood sugar tests.....	0	1	2	3	4	5
26. I check my blood sugar level every time before and after I exercise....	0	1	2	3	4	5
27. I have my blood checked for diabetes control (A1c or HbA1c) at least two times a year.....	0	1	2	3	4	5
28. I discuss the effectiveness of my self care activities based on my diabetes control (A1c or HbA1c) results.....	0	1	2	3	4	5
29. I prepare and inject my insulin correctly.....	0	1	2	3	4	5
30. I take my insulin even when I am away from home.....	0	1	2	3	4	5
31. I adjust my insulin dose based on my blood sugar results.....	0	1	2	3	4	5
32. I adjust my insulin dose when my daily routine changes.....	0	1	2	3	4	5
33. I adjust my insulin dose when recommended by my health care provider.....	0	1	2	3	4	5
34. I take my insulin or other medications as prescribed by my health care provider.....	0	1	2	3	4	5
35. I inspect my feet every day.....	0	1	2	3	4	5
36. I keep my toenails clean and trimmed.....	0	1	2	3	4	5
37. I dry my feet completely after taking a bath or shower.....	0	1	2	3	4	5
38. I wear closed-toe shoes every time I am outside my home.....	0	1	2	3	4	5
39. I wear socks or stockings every time I wear shoes.....	0	1	2	3	4	5
40. I wear comfortable shoes and socks or stockings that fit me well all the time.....	0	1	2	3	4	5
41. I have a complete foot exam at least once a year.....	0	1	2	3	4	5
42. I recognize when my blood sugar is high.....	0	1	2	3	4	5
43. I figure out what to do when my blood sugar is high.....	0	1	2	3	4	5
44. I recognize when my blood sugar is low.....	0	1	2	3	4	5
45. I figure out what to do when my blood sugar is low.....	0	1	2	3	4	5
46. I adjust my diabetes self care routine when I feel sick.....	0	1	2	3	4	5
	0	1	2	3	4	5

47. I carry hard candies or glucose tablets every time I am away from home.....						
48. I carry or wear my diabetes identification all the time.....	0	1	2	3	4	5
49. I see my healthcare provider at least every three to six months.....	0	1	2	3	4	5
50. I have a dilated eye exam every year.....	0	1	2	3	4	5
51. I check my weight on a regular basis and at least every three months..	0	1	2	3	4	5
52. I am capable to adjust my self care activities to fit changes in my daily routine.....	0	1	2	3	4	5
53. I adjust my self care activities to fit my social activities.....	0	1	2	3	4	5
54. I do all my self care activities every day.....	0	1	2	3	4	5
55. I check or have my blood pressure checked on a regular basis and at least every three months.....	0	1	2	3	4	5
56. I get a flu shot every year.....	0	1	2	3	4	5
57. I have a dental check-up at least every six months.....	0	1	2	3	4	5
58. I have my blood checked for cholesterol at least once a year.....	0	1	2	3	4	5
59. I have other tests to screen for diabetes complications when recommended by my health care provider.....	0	1	2	3	4	5
60. I check my urine for ketones when my blood sugar results are greater than 240 mg/dL (or when I feel sick) at least every 4 to 6 hours.....	0	1	2	3	4	5

Demographic Variables

DEMOGRAPHIC DATA/BACKGROUND INFORMATION

(Fill the blanks or make a check mark by choosing the best correct answer)

1. What was your age on your last birthday?

_____ (in years)

2. What is your height?

_____ (in feet/inches)

3. What is your weight?

_____ (in pounds)

4. What is your gender?

_____ Male

_____ Female

5. What is your ethnic origin/race?

_____ White or Caucasian

_____ Black or African American

_____ Hispanic or Latino

_____ American Indian or Alaska Native

_____ Asian

_____ Native Hawaiian or other Pacific Islander

_____ Other: Please specify _____

6. What is your marital status?

_____ Single, living alone

_____ Never married, but living with boyfriend or girlfriend

_____ Married

_____ Divorced/Separated

_____ Widowed

7. What is your type of diabetes mellitus?

_____ Type 1

_____ Type 2

8. How long have you had diabetes?

_____ (in years) _____ (in months, if in years is not applicable)

9. Do you have any other of the following health problems?

_____ Heart disease
 _____ High blood pressure
 _____ High Cholesterol
 _____ Vascular problems (circulation problems)
 _____ Kidney disease (nephropathy)
 _____ Nerve problems (neuropathy)
 _____ Eye problems (retinopathy)
 _____ Dental problems
 _____ Foot problems
 _____ Ulcers (sores) that are not healing
 _____ Depression
 _____ Amputation
 _____ Others:

Please

specify

10. Have you ever attended diabetes class?

_____ Yes
 _____ No

If you answered yes, how long ago did you attend the diabetes class?

_____ (in years) _____ (in months, if in years is not applicable)

11. Was self care skills training (i.e., demonstration and practice of self blood glucose monitoring, insulin injection, choosing healthy food) part of the diabetes class?

_____ Yes
 _____ No

If you answered yes, what types of self care skills training did you have?

_____ Self blood glucose monitoring
 _____ Insulin preparation and injection
 _____ Insulin adjustment
 _____ Meal planning
 _____ Food label reading
 _____ Choosing healthy food

- _____ Portion sizes
 - _____ Pills taking
 - _____ Goal setting
 - _____ Problem solving
 - _____ Decision making
 - _____ Keeping records
 - _____ Foot assessment and care
 - _____ Others: Please specify
-
-
-

12. Do you smoke?

- _____ Yes
- _____ No

If you smoke, how many cigarettes per day do you smoke?

- _____ Less than 10
- _____ 10 to 20
- _____ More than 20

13. Do you drink alcohol?

- _____ Yes
- _____ No

If you drink alcohol, how often do you drink?

- _____ Less than 2 drinks a week
- _____ 2 – 3 drinks a week
- _____ 4 – 5 drinks a week
- _____ 6 or more drinks a week

14. What kind of medication do you take to control your diabetes?

- _____ None
- _____ Pills only
- _____ Insulin Injections only
- _____ Pills and Insulin Injections

15. How many people do you live with?

- ☐ None
- ☐ 1 to 3
- ☐ 4 to 5
- ☐ More than 5

16. How much schooling have you had (years of formal education completed)? Check only the highest level achieved.

- ☐ Less than 4 years
- ☐ 5 – 8 years (Elementary)
- ☐ Some High School Courses
- ☐ High School or GED
- ☐ Associate Degree
- ☐ Some College Courses
- ☐ College Degree
- ☐ Some Graduate Courses
- ☐ Master's Degree
- ☐ Doctoral Degree

21. Do you have a diabetes health care provider?

- ☐ Yes
- ☐ No

If you have a diabetes health care provider, answer the next three questions:

22. What is the professional category of your diabetes health care provider?

- ☐ Doctor (physician; MD)
- ☐ Nurse Practitioner (NP)
- ☐ Clinical Nurse Specialist (CNS)
- ☐ Physician Assistant (PA)
- ☐ I do not know

If your diabetes health care provider is a physician, what is his or her specialty?

- ☐ Endocrinologist
- ☐ Internal Medicine
- ☐ General Medicine
- ☐ Primary Care
- ☐ I do not know