EFFECT OF DIABETES MANAGEMENT PROGRAM ON GLYCEMIC CONTROL AND QUALITY OF LIFE IN ADULTS

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ABSTRACT

RESEARCH SUBJECT: Effect of Diabetes Management Program on Glycemic Control and Quality of Life in Adults with Diabetes

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Diabetes Mellitus is a common disorder that can lead to multiple costly health complications. Disease management programs that control blood glucose can prevent complications and chronic co-morbidities. Research has not yet confirmed the elements of an effective management program that ensures optimal glycemic control. The purpose of this study was to determine the effect of a tailored management program on glycemic control and quality of life. The program was based on the standards of the American Diabetes Association. This longitudinal study was a partial replication of a study by Malijanian, Grey, Staff, and Aponte (2002). The target population included adults referred to the Diabetes Life Care program at one Midwestern hospital. Potential participants had a new diagnosis or a history of type 1 or type 2 diabetes mellitus. The sample was 50 inpatients. Data were collected at baseline and after 3 months, 6 months, and 12 months in the program. Health-related quality of life was measured by the Medical Outcomes Study 36-Item Short-Form (SF-36) health survey (Ware & Sherbourne, 1992). Findings add to what is known about the effectiveness of a management program in a broad range of adult patients with diabetes mellitus.
Chapter I

Introduction

Diabetes affects 20.8 million people or roughly 7% of the population in the United States. Diabetes is increasing at epidemic levels, and, within the next fifty years, diabetes is expected to increase by 165% (Dally, 2007). Hispanics and African Americans have a higher likelihood than any other nationality for developing diabetes, especially within the younger age groups. Diabetes is a dangerous disease that leads to an increased risk of neurological symptoms, peripheral vascular disease, cardiovascular disease, renal complications, a variety of metabolic disorders, and ophthalmic complications (Dall et al., 2008).

Diabetes care places a significant burden on individuals, families, communities, and healthcare (Dall et al., 2008). In 2007, it was estimated that the cost of diabetes was $174 billion per year, which included $116 billion in medical expenditures and $58 billion in reduced national productivity. Medical costs directly related to diabetes have totaled $27 billion, and $58 billion has been used to treat chronic complications related to diabetes. On average, people with diabetes have a 2.3 times higher than expected medical costs related to complications from diabetes. It is estimated that two million diabetics have no medical insurance and one in three of the uninsured are undiagnosed diabetics.
Approximately ten million diabetics have government medical insurance, such as Medicare and Medicaid (Dall et al.).

**Background and Significance**

Diabetes is a chronic disease with severe complications and high mortality rates. Living with a chronic illness can negatively affect an individual’s perception of quality of life. Quality of life is particularly affected by diabetic complications that impact all aspects of one’s everyday lifestyle. Diabetes management programs can be utilized to effectively control blood glucose to enhance quality of life. Diabetes management typically focuses on glycemic control to prevent acute and chronic complications while enhancing quality of life. With early recognition and intervention, diabetic complications can be avoided and disease progression can be slowed (Steuten, Bruijsten, & Vrijhoef, 2007).

Diabetes selfmanagement education is critical to the success of diabetes management programs. Diabetic education is essential for the patient to appropriately self manage blood glucose. Education should focus on ways that diabetes and its complications can be reduced by weight loss, healthy eating, increased physical activity and medication compliance. The goal for self management programs is to ensure that patients are comfortable and confident in managing their disease effectively (Funnell et al., 2010).

Glycemic control is the most important management tool to control diabetes. Nurses can significantly impact diabetic management by encouraging patients to appropriately manage glucose and thus enhance quality of life. Nurses can influence patients by providing education and support while encouraging a healthy lifestyle.
Diabetic management programs with nursing oversight have been shown to improve diabetic outcomes and decrease complications by appropriately managing glycemic control. By properly managing glucose, patients are capable of performing everyday activities with fewer physical restrictions that impact quality of life.

A diabetes management program should provide extensive education according to the American Diabetes Association, in order to improve outcomes and quality of life of each diabetic patient. The ultimate goal is to ensure that each patient is comfortable and confident in self-managing their diabetes. Resources need to be readily available for individuals to refer to when necessary. A holistic approach allows the patient to work with a multidisciplinary team to improve outcome and reduce health care costs in the future (Steuten, Vrijhoef, et al., 2007).

Experts agree that glycemic control is the key element in diabetes management programs. Glycemic control is essential to avoid complications and thus control health care costs and maintain quality of life. Self-management programs focused on glycemic control with nursing oversight have been trialed, and outcomes are promising (Steuten, Vrijhoef, et al., 2007). However, the outcomes are not consistent across varied populations. The specific key elements of self-management programs and glycemic control have not been clarified. Therefore, more research is indicated. A study by Malijanian et al. (2002) is replicated in this project to determine the effectiveness of a tailored management program on glycemic control and quality of life.

**Problem Statement**

Diabetes Mellitus is a common disorder that can lead to numerous costly complications if blood glucose control is not adequately managed (Steuten, Bruijsten, et
Disease management programs can focus on controlling glycemia in order to reduce the risk of complications and chronic co-morbidities and improve quality of life. The effects of various management programs on outcomes have been tested, without consistent results across various samples. Furthermore, research has not yet confirmed the elements of an effective management program that ensures optimal glycemic control.

**Purpose**

The purpose of this study was to determine the effect of a tailored management program on glycemic control and quality of life in adults with diabetes mellitus. The program represented a secondary prevention-as-intervention approach to strengthen flexible lines of defense, as addressed in Neuman’s (1989) model. The tailored management program was based on the guidelines provided by the American Diabetes Association.

**Research Question**

The research question that directed this study was: What is the effect of a tailored diabetes management program on glycemic control and quality of life in adults with type 2 diabetes mellitus?

**Conceptual Framework**

Betty Neuman’s systems model (1974) provided the theoretical framework for this study. The model was developed to guide nursing care of individuals, groups or communities. It focused on prevention-as-intervention and described levels of prevention that were amendable to autonomous nursing actions. This model provided a broad, flexible framework that could guide the development of clear and concise strategies for health promotion and for illness prevention.
Neuman (1974) emphasized a holistic, interdisciplinary, wellness-oriented approach to nursing. Neuman’s systems model viewed the person or patient as a holistic system that could be influenced by environmental stressors. Neuman’s model focused on each individual’s perception of stress, the reactive components of stress, and each individual’s reaction to the stressor. This framework encouraged nurses to become proactive and empower individuals in the community to manage perception and reactions to stress and thus improve health and well-being.

Neuman (1974) contended that nursing aims for wellness for patient systems. Wellness was defined as a stable condition in which the patient was able to interrelate in synchronization within the whole system. The individual could retain, attain, or maintain stability with the help of nursing interventions. In Neuman’s model, the patient system was impacted by internal and external stressors, which Neuman labeled interpersonal, intrapersonal, and extrapersonal. Stressors could disturb the stability of system, and the system had to adjust to the stressor by using energy to acclimate to the situation. The stressors strained the patient’s normal and flexible lines of defense. The lines of defense were supple and protected the client in a normal response or wellness state. In the diabetic patient in particular, the lines of defense served as a barrier to protect the diabetic client from complications. Eventually, if the client continually was exposed to stressors, a change in wellness occurred, as the lines became weakened or broken, resulting in a negative effect on systems in the body.

Neuman’s (1989) revised model had three levels of prevention-as-interventions that were identified to keep system stability. Primary prevention, the first level, was utilized when a stressor was suspected and had not been identified. Secondary prevention
consisted of interventions or treatment regimens required to provide system stability. The third level included tertiary prevention, which occurred after secondary prevention or after active treatment was completed. This level focused on modifications required to maintain optimal system stability within the client. Reconstitution in tertiary prevention was achieved at a higher or lower level of wellness compared to when the stressor disrupted system stability.

In a person with diabetes, common stressors might include the intrapersonal stressor of hyperglycemia, the interpersonal stressor of low social support, and the extrapersonal stressor of limited financial resources. Diabetic patients may have multiple stressors that could negatively impact well-being and overall health. The interrelationship of physiological, psychological, sociocultural, developmental, and spiritual variables could affect how an individual with diabetes viewed quality of life. Quality of life was impacted by one’s physical restrictions and mental and social wellbeing. Unknown stressors may exist, which also may lead to disease progression in the diabetic client. The diabetic patient’s normal and flexible lines of defense may be weakened by glycemia and its possible effect on organs of the body. Once the flexible lines of defense are weakened, it is essential to assist the diabetic patient in retaining, attaining, or maintaining stability. When a diabetic patient’s flexible line of defense is weakened or broken, perceived quality of life can be affected. A diabetes management program that focused on the diabetic patient as a whole and examined all stressors could potentially impact how quality of life was perceived. A tailored diabetes management program could strengthen the lines of defense for the adult diabetic.
In summary, this study examined the effect of a secondary preventive strategy on glycemic control, as an intrapersonal stressor, and quality of life, as one key element of the flexible line of defense. Using this framework to test a preventive approach to diabetic care, nurses may gain knowledge to assist diabetic patients in actively dealing with the stressor of glycemic control, which could be instrumental in improving outcomes and quality of life.

Definition of Terms

**Quality of life.**

Conceptual: The perception of well-being that individuals hold as a reflection of personal and environmental factors.

Operational: Functional, physical, and mental well-being measured as three subscale scores on the Medical Outcomes Study 36-Item Short-Form (SF-36) Health Survey (Ware, Kosinski, & Keller, 1994).

**Glycemic control.**

Conceptual: Regulation of blood glucose within a defined range for diabetes management.

Operational: Blood glucose range measured as HbA$_{1c}$ results determined from venous blood. The BIO-RAD Micromat II by Bio-Rad Laboratories is the instrument utilized for all blood samples for all patients in the study.

**Patient outcomes.**

Conceptual: Result or consequence of a disease, drug, treatment, or medical regimen.
Operational: The result of glycemic management within the diabetic patient. In this study, the patient outcomes are glycemic control and perceived quality of life.

**Diabetes Management Program.**

Conceptual: A nurse-supervised program specifically designed for adult patients with type 2 diabetes which provided non-judgmental care with the aim of controlling glycemia and avoiding further complications of diabetes.

Operational: A diabetes management program 12-months in duration in which nurses assessed, educated, and provided social support to diabetic patients

**Limitations**

Limitations of this study included the small, non-random sample recruited from a single local setting. A second limitation was that multiple nurses and health care personnel administered the program, which could have resulted in some variability in the delivery of the program strategies. A third limitation was the lack of a control group that received no management program. Such a group could not be orchestrated ethically in a research study. The likelihood of finding such a naturally-occurring group in the general population of diabetics that would like to participate in a research study was minimal.

**Assumptions**

Study assumptions included:

1. Participants honestly completed study questionnaires.
2. Participants followed program management instructions.
3. Participants followed instructions for laboratory testing at specified intervals.
4. The healthcare professionals worked earnestly with participants to ensure understanding of diabetic management content to control blood glucose.

**Summary**

Diabetes is a complicated disease that can detrimentally affect the entire body and significantly burden our healthcare system due to complications and complex care required. Nurses can greatly enhance quality of life and diabetic management by ensuring patients have the tools and knowledge base to manage their disease. The purpose of this study was to determine how an individualized diabetes management program affected glycemic control and quality of life. The significance of this study was to highlight how quality of life and glycemic control could be improved using a diabetic management program.
Chapter 2

Literature Review

Diabetes is a complex disease that leads to an increased risk of various severe complications and reduced quality of life (Dall et al., 2008). Achieving adequate glycemic control can reduce the impact of the disease on human lives and the health care system and can improve quality of life (Steuten, Bruijsten, et al., 2007). Approaches for effective glycemic control have not yet been clarified through rigorous research in a variety of populations through self-managed programs. The purpose of this study was to determine the effect of a tailored management program on glycemic control and quality of life among adults with diabetes. This study is a partial replication of a study by Maljianian and colleagues (2002).

Organization of Literature

The review of literature included research studies pertaining to management of glycemic control and quality of life among adult diabetics. The literature review was divided into four sections:

1. Theoretical Framework: Betty Neumans’ Systems Model
2. Quality of Life
3. Diabetic Outcomes
4. Glycemic Control
Theoretical Framework

Betty Neuman’s systems model (1974) provided the theoretical framework for this study. The model was developed to guide nursing care of individuals, groups, or communities. It focused on prevention-as-intervention and described three levels of prevention that were amendable to autonomous nursing actions. This model provided a broad, flexible framework for nursing that has guided the development of clear and concise strategies for health promotion and for illness prevention.

Neuman (1989) stressed a holistic, interdisciplinary, wellness-oriented approach to prevention. Neuman’s systems model viewed the person or patient as a holistic system influenced by environmental stressors. This model recognized the client as an open system; the client could be an individual, family, group, community, or society. The client system was composed of interrelationships among physiological, psychological, sociocultural, developmental, and spiritual factors that were in continual change. Neuman described wellness as a stable condition that allowed the client system to interact in synchronization with the whole system. Illness was described as occurring when needs were not fulfilled and energy was depleted. Stressors had the ability to disrupt the system’s stability and diminish health. Stressors consisted of: intrapersonal forces that were individually conditioned responses; interpersonal forces that occurred between one or more individuals; and extrapersonal forces, which occurred outside the individual.

Neuman (1989) explained that the system adjusted to stressors by utilization of energy required to adapt to the situation. In each client system was a set of internal resistance factors, known as lines of resistance, which functioned to stabilize and return the client to the usual state of wellness or normal line of defense or a higher level of
stability following a stressor reaction. Overtime, each client system evolved a normal range of response to the environment that was referred to as a normal line of defense, or the usual state of wellness state. The interrelationship of client variables, labeled physiological, psychological, sociocultural, developmental, and spiritual, affected the degree to which a client was protected by the flexible line of defense against a single or combination of stressors at any given time.

Neuman’s (1989) systems model can be utilized as a model for prevention. Prevention allowed the system to retain, attain, or maintain stability through interventions. Prevention interventions could occur at any time before or after recognition of a stressor, which, if unaddressed, could break down flexible lines of defense. Neuman’s model had three levels of prevention interventions that were identified to keep system stable. Primary prevention was utilized when a stressor was suspected and had not been identified. The goal during primary prevention was to strengthen the individual’s flexible line of defense by reducing the susceptibility to stressors. Secondary prevention consisted of interventions or treatment regimens required to provide system stability after stressors were identified or symptoms appeared. Goals during secondary prevention included interventions or treatment that focused on strengthening lines of resistance, reducing the degree of energy required to maintain stability, and increasing the resistance factors. The third level included tertiary prevention, which occurred after secondary prevention or after active treatment was completed. This level focused on modifications required to achieve optimal system stability within the client. The goal during the tertiary level was to strengthen resistance to stressors to prevent the return of a negative reaction and deterioration of the system’s
organization. Reconstitution occurred after active treatment of the stressor reaction and system stability was achieved. Reconstitution could be achieved at a higher or lower level of wellness compared to when the stressor disrupted system stability.

Neuman’s (1989) system model provided a framework to guide nursing care to improve quality of life and improve outcomes in the diabetic client. In applying Neuman’s theory to this study, the client was an individual patient with type 2 diabetes. Because the patient participants had been diagnosed with diabetes, they had passed the asymptomatic stage of primary prevention and were in need of secondary or tertiary prevention. Environmental stressors and/or internal pathophysiological extrapersonal and intrapersonal stressors had broken through the normal lines of defense and possibly the flexible lines of defense, depending on the severity of symptoms and the disease state. This study proposed to explore strategies and programs that improved the management of stressors related to diabetes. The strategies and programs were designed to ideally strengthen the lines of resistance and reduce the impact of stressors on the client. Thus, by utilizing this preventive model, the nurse as a caring professional could act to shield diabetic patients from the detrimental effects of stressors.

The present study did not test propositions from Neuman’s (1989) theory but used the concepts of the theory to frame the study and guide the formation of the interventional programs. The results of this study indirectly offered support for the relevance of Neuman’s theory to the discipline of nursing. This was a replication of a study by Malijanian and colleagues (2002), which did not cite a theoretical framework. The conceptualization of this study within Neuman’s framework strengthened the rigor of the project and enhanced the usefulness of the results to the discipline.
Quality of Life

Research has suggested that perceptions of quality of life and clinical patient outcomes are associated. Sundaram, Kavookjian, Patrick, Miller, Madhavan, and Scott (2006) conducted a study to examine relationships between quality of life and clinical outcomes among type 2 diabetes patients. No theoretical framework was cited.

The population for this study included those receiving care at the West Virginia Diabetes Institute. Participants in the convenience sample were chosen from an electronic medical record (EMR) database and included adults diagnosed with type 2 diabetes mellitus. Criteria for patients to participate were that they had to have an HbA_1c within the last 90-120 days. The initial sample consisted of 989 patients who were adults with type 2 diabetes. Sundaram et al. (2006) included data from patients that were not retrieved from the EMR but rather were self-reported, including age, gender, marital status, education, type of insurance, duration of diabetes, and treatment of diabetes (insulin or no insulin).

Patient outcomes were measured by the Medical Outcomes Study Short-Form 12 (SF-12) (Ware, Kosinski, Turner-Bowker, & Gandek, 2002). The 12 questions were utilized to measure 8 domains of health status. The Physical Component Summary (PCS-12) was utilized to determine patients’ perceptions of physical health. The Mental Component Summary (MCS-12) scores provided information on patients’ mental status. Perceptions of quality of life were measured by utilization of the Audit of Diabetes Dependent Quality of Life (ADDQoL) (Bradley, Todd, Gorton, Symonds, Martin, & Plowright, 1999). The ADDQoL allowed patients to report important domains in their lives. The scores ranged from -9 to +9, with the more negative numbers indicating the
more negative impact that diabetes had on their life. Depressive symptoms were measured by utilizing the Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1977). The CES-D provided researchers with information regarding the presence of persistent depressive symptoms. The CES-D has been utilized within the diabetes population and has demonstrated good reliability and validity in multiple samples (Sundaram et al., 2006).

Demographic information for the 385 respondents showed that 27.8% ranged from 50-59 years in age; 57.1% were females; 61.8% were married/living with partner. The majority (93.8%) of the participants were white; 51.9% had an educational level of high school or less; and 57.9% had state/federal insurance (Sundaram et al., 2006).

Medical histories of patients with diabetes revealed that 54.5% of patients reported excellent glycemic control ($\text{HbA}_{1c} \leq 7.0$). Of respondents with type 2 diabetes, 49.1% were treated with oral medications only, and 41% used insulin. Of the respondents, 72.2% did not have emergency room visits, and 79.7% had no hospitalizations related to diabetes. The duration of diabetes in mean number of years was 10.20 ($\pm$ 9.10). HbA$_{1c}$ was available for 360 respondents; the mean was 7.20 ($\pm$ 1.40). The average HbA$_{1c}$ was calculated for 384 respondents from the previous year as 7.24 ($\pm$ 1.30). There were no significant differences between the most recent HbA$_{1c}$ and the average HbA$_{1c}$ value. The mean BMI for the respondents was 33.5 ($\pm$ 8.10). A majority of the sample (62.1%) had a BMI greater than 30.0 (Sundaram et al., 2006).

From 377 respondents, 348 PCS-12 and MCS-12 scores were available to be calculated. The PCS mean score was 45.54 ($\pm$ 12.30) and the mean MCS score was 38.44 ($\pm$ 13.1). The range of the PCS and MCS scores were from 0 to 100, with 0
signifying poorest health status. A mean ADDQoL score was -1.95 (+ 1.76) indicating that diabetes had a negative impact on quality of life. The CES-D mean score was 17.23 (+ 11.85). Depressive symptoms were found in 39% of the respondents; 8.3% had a clinical diagnosis of depression (Sundaram et al., 2006).

The association between ADDQoL scores and HbA₁c was low and non-significant. Relationships among HbA₁c levels, PCS-12 scores, and MCS-12 scores were also non-significant, but a relationship was noted between MCS-12 and CES-D scores (p < 0.001). Respondents who had an HbA₁c of less than 7.0 had a higher ADDQoL score when compared to those with an HbA₁c greater than 7.0 (p = 0.001) (Sundaram et al., 2006).

Comparing non-obese diabetic patients to obese diabetic patients, obese patients had considerably lower PCS-12 scores (p < 0.001) and MCS-12 scores (p = 0.001). ADDQoL scores did not vary significantly between those that were obese and non-obese. Quality of life was poorer in the obese diabetic patients (p = 0.001). Of the respondents who had depressive symptoms and were type 2 diabetic, PCS-12 scores (p < 0.001), MCS-12 scores (p < 0.001) and ADDQoL scores (p < 0.001) were lower than those who did not have depressive symptoms. Depressive symptoms were found in about 55% of the obese respondents, as compared to 33% of those who were not obese (Sundaram et al., 2006).

Sundaram et al. (2006) concluded that, among diabetic patients, the relationship between quality of life and HbA₁c was not clear. There was no significant relationship between quality of life and HbA₁c, but yet patients with HbA₁c above and below 7 varied in quality of life. Patients with type 2 diabetes who had symptoms of depression reported
a lower quality of life and physical and mental health status. Quality of life scores did not correlate with obesity. Obesity was associated with limited physical and mental health.

In another study of quality of life among adults with diabetes, Paddison, Alpass, and Stephens (2008) examined the relationships between psychological variables, metabolic control, and quality of life (QoL) of adults with type 2 diabetes. The study took place in Wellington, New Zealand. Participants were randomly selected from a medical data base. Criteria to participate in the study included an existing diagnosis of type 2 diabetes and being 18 years of age. The final sample consisted of 615 people with type 2 diabetes. The ages of participants ranged from 27 to 90 years of age with a mean age of 63 years; 47% were female. Paddison et al. included data related to age, ethnicity, gender, length of diagnosis, HbA1c and health complications from diabetes.

The Illness Perception Questionnaire-Revised (IPQ-R) (Moss-Morris, Weinman, Petrie, Horne, Cameron, & Buick, 2002) specific to diabetes was utilized. The tool consisted of 7 subscales that measured cognitive illness representation. Most subscales demonstrated an acceptable internal consistency reliability of greater than .65. One subscale, which assessed emotional illness representation, showed low internal consistency with a reliability of .52. Quality of life was measured by an item from the Audit of Diabetes-Dependent Quality of Life (ADDQoL) (Bradley et al., 1999), specifically “In general, my present quality of life is.” The responses were based on a 7-point scale in which 1 = excellent to 7 = extremely bad. Co-morbid health conditions were assessed by a 9-item self-report checklist. Data from medical records included: length of time since diagnosis, recent body mass index, prescribed treatment regimen
(insulin/no insulin), and HbA1c. HbA1c was assessed using standardized assays compared at previous points in time (Paddison et al., 2008).

A significant negative correlation was found by Paddison et al. (2008) between the psychological perceptions of diabetes and illness outcomes ($r = -21, p < .001$). The authors found a significant relationship between quality of life and illness perception as a subscale of the IPQ-R among diabetics ($n = 590, p < .05$). Seven of the eight IPQ-R subscales were significantly correlated with HbA1c ($p < .001$). Perceived quality of life and HbA1c were significantly affected by psychological variables ($p < .001$).

Fourteen percent of the variance in metabolic control was accounted for by length of diagnosis, BMI, treatment regimen, and psychological perceptions of diabetes. An additional eight percent of the variance in metabolic control was accounted for by length of time since diagnosis, BMI, prescribed treatment regimen, and psychological representations of diabetes after control ($R^2$ change = .08, $p < .001$). HbA1c, prescribed treatment regimen, presence of co-morbidities, and illness representations together explained 31% of the variance in self-reported quality of life ($F (11, 548) = 23.30; p < .001$) (Paddison et al., 2008).

Paddison et al. (2008) reported that psychological representation of those with diabetes can affect metabolic control and quality of life. Changes of one’s personal perception of diabetes possibly will promote positive health outcomes for type 2 diabetics. The authors concluded that quality of life and HbA1c were affected by psychological variables.

In a related study of depression, quality of life, and glycemic control, Lee et al. (2009) evaluated the relationships among diabetic complications, depression, quality of
life, HbA1c, and demographic characteristics. The conceptual framework was a holistic model, developed by Thomas and colleagues (Thomas, Liehr, DeKeyser, & Friedmann, 1993; Thomas & Liehr, 1995; Thomas, Friedmann, Wimbush, & Schron, 1997; Thomas, Liehr, DeKeyser, Frazier, & Friedmann, Wimbush, & Friedmann, 2002; Thomas, Friedmann, Khatta, Cook, & Lann, 2003). This holistic model was utilized to understand the etiology of diabetes.

The study took place in an inner city university affiliated with Joslin diabetes specialty clinic in Baltimore, Maryland. The sample of the cross sectional study included 55 individuals who met the criteria for inclusion: more than 25 years of age who spoke English, were diagnosed with type 2 diabetes, and attended a regular clinic visit over the last year. Self-reported demographic data were retrieved by a questionnaire and included age, gender, ethnic group, marital status and educational level. Medical records were utilized to retrieve data for the onset date of diabetes, most recent HbA1c, medication, related comorbidity, height, and weight (Lee et al., 2009).

Instruments utilized to evaluate depression were the Beck Depression Inventory – II (BDI-II) (Beck, Steer, & Brown, 1996) and the Inventory of Depressive Symptomatology-Self Report (IDS-SR) (Rush, Gullion, Basco, Jarrett, & Trivedi, 1996). A Likert scale with a 0-3 response scale assessed the severity of depressive symptoms; higher the numbers on the BDI-II indicate more severe depressive symptoms. The Cronbach’s alpha for the BDI-II was high in prior studies with similar samples. The IDS-SR evaluated 9 symptom domains for the DSM-IV major depressive episode and was able to distinguish milder symptoms. A Likert scale with 0-3 responses assessed depression, with higher numbers indicating greater depression. The Cronbach’s alpha of
IDS-SR was .93, and the correlation among BDI-II and IDS-SR was .91 in this study (Lee et al., 2009).

Medical Outcomes Study 36 Item Short Form Health Survey (SF-36) (Ware & Kosinski, 2001; Ware, Kosinski, & Keller, 2001) was utilized to evaluate quality of life. On a Likert scale of 1-5, higher numbers indicated better health and quality of life. Subscales from the SF-36 assessed to determine the Physical Component Summary (PCS) and Mental Component Summary (MCS). The Cronbach’s alpha value of both PCS and MCS were 0.99 in this study (Lee et al., 2009).

Control of diabetes was measured as an HbA1c value of 7.0% or lower. Comorbidities were determined by reviewing problem lists from each patient’s medical records. Macro comorbidities included coronary artery disease, hypertension, hyperlipidemia, and obesity. Micro comorbidities included nephropathy, neuropathy, and retinopathy (Lee et al., 2009).

The 55 patients in the study were greater than 35 years of age, with 42% being female and 36% black. At least 62% had a college education. Laboratory results of HbA1c revealed that 40% were within normal range of less than 7%, 44% had a moderate-high level between 7% and 9%, and 16% of patients registered more than 9%. Diabetic-related comorbidities were found in all patients. One or more micro comorbidities were found in 58% and 64% had 2 or 3 macro comorbidities (Lee et al., 2009).

Individuals with type 2 diabetes were found to have a high incidence of depressive symptoms (p < .001). Antidepressant medications were utilized by some patients with, 73% reporting depressive symptoms while taking antidepressants. A
significant correlation was found between the depression scores of the BDI-II (ranged 0 to 40) and IDS-SR (ranged 2 to 54) \( (r(48) = .912, < .001) \). BDI-II scores indicated that 41\% (20 of the 49) showed symptoms of depression with a BDI-II of greater than 13; 15 patients had a BDI-II greater than 20, indicating they were moderately or severely depressed. The IDS-SR scores indicated that 46\% of the patients were depressed. Both the BDI-II and IDS-SR agreed that 96\% of the patients were depressed (46 of the 48). According to the BDI-II 2, patients were not depressed with an IDS-SR score of greater than 18 (Lee et al., 2009).

SF-36 MCS scores ranged from 18.71 to 67.66 with a median score of 52.8; PCS scores ranged from 19.58 to 58.83 with a median score of 44.3. MCS scores were worse for 49\% of the patients when compared to the median for the normative US population and worse than the median for the diabetic population \( (N = 55) \) \( (z = .15, p = .44) \). PCS scores of 71\% of the patients were worse when compared to the national normative US population \( (z(N=55) = 2.98, p = .0014) \). PCS scores were worse for 56\% of the patients when compared to the median PCS diabetic national normative population \( (z(N = 55) = .89, p = .19) \). Patients in this study had a lower quality of life than other adults (Lee et al. 2009).

Demographics and depression were correlated by utilizing BDI-II scores. Depression was recognized in 56\% of women and 32\% of men. Significantly women (50\%) were noted to be moderately to severely depressed when compared to men (19\%) \( (x^2(N=49) = 5.04, p=.025) \). Comparing black patients (53\%) to white patients (33\%) black patients had a tendency to be more depressed. Of those reporting moderate to severe depression, 70\% were black and 80\% were white. Patients with depression had a
mean age of 53.5 years and were younger than those patients not depressed. Correlation of age was negative and significantly related with BDI-II depression scores ($r(49) = - .413$, $p = .003$) (Lee et al., 2009).

Diabetes was uncontrolled in 60% of the patients, 63% of whom were male and 57% were female; 52% of white patients were uncontrolled and 80% of black patients; 50% of married patients were uncontrolled, and 71% of single patients were uncontrolled. Uncontrolled diabetes was more likely to occur in black patients than white patients ($x^2 (N = 53) = 4.30$, $p = .04$). Marital status or gender did not have significant correlation with uncontrolled diabetes (Lee et al., 2009).

In conclusion, patients with type 2 diabetes experienced symptoms of depression and lower quality of life. Demographics and depression were associated in those with diabetes. Quality of life in individuals with type 2 diabetes can be evaluated and treated appropriately to improve outcomes of patients (Lee et al., 2009).

**Diabetic Outcomes**

Clark, Snyder, Meek, Stutz, and Parkin (2001) focused on improvement of patients’ outcomes and satisfaction within a managed care organization (MCO). The purpose of the study was to verify if improvements could be made in clinical outcomes, patient and provider compliance, and patient and provider satisfaction for patients in a MCO.

The study took place at an MCO out of Las Vegas, Nevada. The managed care organization studied had greater than 180,000 members of the health maintenance organization (HMO). Approximately 70% of the HMO members received care at MCO-owned clinics. Of the MCO members, more than 8,500 members have diabetes. Patients
were selected from a computerized database from the MCO, which identified 1,121 patients with an ICD-9 diagnosis of 250.xx. All of the patients that qualified were invited by to participate by sending letters. Telephone follow-up occurred for 655 randomly selected patients, with 85% (555) successfully contacted. Criteria for the study excluded all but 431 patients of the 555 contacted. Criterion for inclusion in the study was to be within the ages of 21 to 75 years of age and to not have any chronic disease or condition. A total of 370 patients were included in the study; 315 patients completed the study, which was 85% of the initial number enrolled. Of the 315 patients, data were available for 193 of the patients. Demographics of participants included: average age 64 years; duration of diabetes 10.7 years; 76% Caucasian; 14% African-American, 7% Hispanic; and 2% Asian. The median incomes were $10,000 for the control group, and $20,000 for the study group. Seventy percent of the samples had a median income less than $40,000. No significant differences between the control and study groups in regards to demographic information were noted (Clark et al., 2001).

Tools utilized for this study included a questionnaire, which was completed pre and post intervention. The questionnaire requested demographic information, co morbidities, healthcare practices and medical therapies, status of diabetes control, overall satisfaction of healthcare plan, health care staff, and level of knowledge regarding diabetes care. Micral test by Roche Diagnostics measured microalbuminuria. Accu-Check Advantage blood glucose meters by Roche Diagnostics and supplies were provided to each participant. SAS software (version 6.12 for MacIntosh) was utilized to analyze data from laboratory tests and questionnaires. Risk profiles were produced utilizing algorithms and interventions based on the American Diabetes Association
(ADA) Clinical Practice Recommendations. Patients were divided into high, moderate, and low risk groups within 7 categories. Interventions were already agreed upon previously from standing protocols in place. A certified laboratory was utilized to provide lab work. The Semmes-Weinstein 5.07 monofilament (21) test was utilized for foot examinations. The DQIP (Diabetes Quality Improvement Project) analysis measured lab results, which were categorized by DQIP criteria. The Office of Health Policy and Clinical Outcomes from Thomas Jefferson University research group developed a diabetes-specific patient satisfaction survey tool, which consisted of a 5-point Likert response scale (Clark et al., 2001).

The results at 12 months from 193 patients’ data demonstrated improvement in glycemic control as evidenced by the HbA1c. The number of patients in the low risk category having an HbA1c less than 7% increased by 51.1% (47 to 71 patients). The number of patients in the moderate risk category, which was an HbA1c of 7 to less than 8%, increased by 2.5%. The number of patients that were in the high risk category with an HbA1c greater than 8.0% decreased by 58.3% (76 to 48 patients) (Clark et al., 2001).

Blood pressure readings less than 140/90mmHg increased from 38.9% at baseline to 66.8% at 12 months. Patients with blood pressure readings less than 130/85mmHg increased from 23.8% to 44.6%. Medications were adjusted for 63% of patients that had a blood pressure reading greater than 130/85mmHg at baseline (Clark et al., 2001).

The number of patients who underwent lipid profile evaluation increased among patients from 66% at baseline to 100%. Microalbuminuria testing also increased from 17% to 100%. Patients at the highest risk for coronary artery disease decreased over the 12-month period from 25.4% to 20.2%. A change in medication occurred for those
recognized a highest risk for neuropathy, which was 76.7% at 12 months. Eye examinations increased from 53.9% at baseline to 80.3%. Foot examinations increased from 0% at baseline to 100% at 12 months (Clark et al., 2001).

Patient and provider satisfaction scores were increased at 12 months. Of the providers that responded to the survey, 100% reported that they were “very satisfied” with the program. Providers indicated that the diabetic patients were managed better due to the program. Of the providers, 93% believed the program saved time with visits, and 100% would recommend this diabetes management program to other physicians (Clark et al., 2001).

The authors concluded that the program was successful and resulted in improved glycemic control, reduction of hypertension, and decreased lipid levels. Satisfaction levels were increased among both patients and providers. Workflow efficiencies were improved for providers and staff (Clark et al., 2001).

In a similar intervention study by Mazroui et al. (2009), the effect of clinical pharmacy services on diabetic control and quality of life was explored in adults with type 2 diabetes. The study took place at Zayed Military Hospital in the United Arab Emirates. The population included those who met selected criteria: a confirmed diagnosis of type 2 diabetes, receiving oral hypoglycemic therapy, permission by specialist to enter trial, written consent for participation, and no secondary diagnosis of underlying diseases. The sample consisted of 240 patients, which included 120 in the control group and 120 in the intervention group. The sample was recruited over a years’ time in a randomized, controlled, prospective clinical trial from the 400 bed hospital. Specifically, patients
were recruited from the general medical wards and from endocrinology and medical outpatient clinics (Mazroui et al., 2009).

The instrument utilized to measure health-related quality of life was the Medical Outcomes Survey SF36 (Ware, Kosinski, Turner-Bowker, & Gandek, 2002). Each patient was interviewed by the research pharmacist and/or clinical pharmacy staff. The interview allowed information to be obtained on demographics, family history of diabetes, medications being used, frequency of diabetes symptoms, medication knowledge, adherence to medication and lifestyle advice and to record baseline values of body weight and body mass index (BMI), fasting blood glucose, HbA1c, systolic and diastolic blood pressure, serum total cholesterol, serum creatinine, serum HDL-C, and serum triglycerides. Adherence and knowledge also were measured using the survey SF36. Baseline measures were retrieved and recorded prior to the intervention. British National Formulary and Framingham scoring methods were utilized to approximate the scores of coronary heart disease risk at 10 years in all patients. The SPSS package v. 13 was utilized for statistical analyses (Mazroui et al., 2009).

The final sample included 117 patients in both the control and intervention group. Baseline demographics of the study participants showed that the intervention group had 70% males and the control group had 68.3%. The mean age of participants in the intervention group was 48.7 years with a SD ± 8.2, and the mean age of the control group 49.9 years with a SD ± 8.3. In the intervention group, 61.7% were between 35 and 50 years, and the control group had 58.3% in the same age range. The mean number of years since diagnoses of diabetes for the intervention group was 6.1 with a SD ± 2.9, and the control group was 6.2 with a SD ± 2.7. Both groups had a family history of diabetes,
with the intervention group at 44.2% and for the control group of 37.5%. Medication knowledge and adherence were measured at baseline as 60.8% (n = 73) of the intervention group, and 64.2% (n = 77) of the control group demonstrated poor knowledge in relation to medication adherence. At 12 months, 47% of the intervention group and 64.1% of the control group improved glycemic control and reported improved quality of life (p < 0.001). Knowledge of the intervention group also improved after 12 months. Medication non-adherence was measured at baseline as 48.3% of the intervention group and 49.1% in the control group. These values were reduced at the 12-month assessment to 21.4 and 32.5%. Adherence to lifestyle adjustments of diet, exercise, and cessation of smoking and alcohol were significantly different between the intervention and control groups at baseline (p < 0.05). In general, the intervention group improved significantly at the 12 month assessment when compared to the control group (p < 0.05) (Mazroui et al., 2009).

The authors concluded that the pharmaceutical care program reduced cardiovascular risk scores in those with type 2 diabetes. Extensive education regarding type 2 diabetes, medications, diet and exercise can improve the success and management of diabetes. The authors suggested the need for pharmacists to play an increased role in the healthcare system (Mazroui et al., 2009).

**Glycemic Control**

Bland et al. (2005) focused a research study on tight glycemic control and its effect on changing mortality levels of Medical Intensive Care Unit (MICU) patients. The purpose of this study was to compare intensive glucose control with modified conventional control in the medical intensive care unit.
The study took place at Loma Linda University Medical Center at the Medical Intensive Care Unit (MICU), which consisted of 20 beds for non cardiac patients. All patients eligible for the study had been receiving mechanical ventilation for less than 24 hours. Patients were excluded from the study if they were not mechanically ventilated; in a dying state; had do-not-resuscitate orders; were participating in another clinical trial; had a diagnosis of diabetic ketoacidosis or diabetic hyperosmolar nonketotic syndrome; had insurance that required transfer to another facility; and if no informed consent was obtained (Bland et al., 2005).

Blood samples were obtained by finger lancet or from an arterial catheter. Blood glucose level was measured at the bedside with Accu-Chek comfort curve strips and an Accu-Chek Advantage Model 777 glucometer, manufactured by Roche Diagnostics Corp, Indianapolis, IN. Outlook 200 Safety Infusion System pumps, manufactured by Braun Medical Inc., Bethlehem, PA, were utilized for insulin infusions. Insulin infusions were made of the same concentration consisting of regular human insulin 100 units in 100 mL of isotonic sodium chloride solution. Statistical analysis of data was achieved by utilizing SPSS software version 10, SPSS Inc, Chicago, IL (Bland et al., 2005).

The research study by Bland et al. (2005) consisted of each protocol having 5 randomized patients in the intensive and conventional group. The mean age of patients was 56.7 years (SD 15.2). Of the 10 patients, 7 were men and 3 were women. The mean length of stay was 32.1 days (SD 23.8), with a median length of stay of 28 days. Blood glucose levels had a mean of 5.8 mmol/L (SD 1.5) (105.3 [SD 26.3] mg/dL) for the intensive group and 9.8 mmol/L (SD 2.5) (177.4 [SD 45.5] mg/dL) for the modified conventional group (p < .001). In the intensive group, 50% (1444 blood glucose
measurements) met target values, and 72% (1348 blood glucose measurements) met target values in the modified conventional group (p < .001). Severe hypoglycemia (glucose < 2.2 mmol/L [ < 40 mg/dL]) occurred two times in the same patient. Severe hypoglycemia occurred in 0.1% of blood glucose measurements for both groups. Moderate hypoglycemia, defined as a blood glucose of 2.2 -3.3 mmol/L [40-60 mg/dL], occurred in 2.1% of the patients in the intensive control group and in 0.2% of the blood glucose measurements in the modified conventional group, a non-significant difference (Bland et al., 2005).

The authors concluded that achievement of target levels of blood glucose was achieved with both protocols. The authors did note that intensive glucose control required additional staffing of nurses (Bland et al., 2005).

In another study on glycemic control in the critical care environment, Malesker, Foral, McPhillips, Christiansen, Chang, and Hilleman (2007) proposed to determine whether or not glucose protocols were effective in maintaining tight glycemic control. The study took place in three intensive care units in Omaha, Nebraska. The tight glycemic control protocol was utilized on 38 patients over a 30-day period. Seventy-five charts were reviewed retrospectively at a fourth ICU that did not participate in the time motion study. A survey was sent to 220 full time nurses with a total of 75 surveys (34%) that were completed and returned.

Time motion data were calculated based on the elapsed time between blood glucose results and treatment. Elapsed time was divided into 3 intervals: time required to obtain a blood glucose result by utilizing a handheld point-of-care glucometer; time required to take appropriate action on glucose results; and time to note the blood glucose
result in the patients chart. Time to take appropriate action was divided into 4 more intervals: the interval when glucose levels were high enough to trigger insulin infusion in patients not receiving an insulin infusion; the interval when the blood glucose result exceeded the upper result of normal and required additional dosage of a patients insulin infusion; the interval when blood glucose result was in therapeutic range and no change was required; and the interval when blood glucose result was hypoglycemic.

Retrospectively, chart reviews were completed to determine if any deviations occurred. Deviations from protocol were sorted as: obtaining blood glucose determinations at a time different than the time indicated in the tight glycemic control protocol; administering insulin different from indicated on protocol; and failure to follow instructions of protocol. Deviations of improper timing meant blood glucose determinations obtained greater than 15 minutes before or after time due. Administering deviations included administration of any dose of insulin other than that indicated by the tight glycemic control protocol. Following instructions deviations included any deviation from the tight glycemic control protocol algorithm (Malesker et al., 2007).

A survey assessing nurse satisfaction with the protocol was distributed to nurses in the 4 intensive care units participating in the study. The survey assessed nursing experience with tight glycemic control protocol and knowledge of appropriate targets of glucose in the critically ill patient. The survey consisted of 7 multiple choice questions that were based on a Likert scale and 3 questions that were open-ended (Malesker et al., 2007).

Data of time-motion were gathered for 454 blood glucose determinations that were completed either electronically or written in the medical record. Results of blood
glucose determinates were retrieved from 38 patients who were cared for by 47 different nurses over a 30-day time frame. An evaluation of the 454 blood glucose determinates showed that 188 results were normal and did not require additional therapy; 188 results were elevated and required initiation of the insulin infusion; 240 results were out of target range and already receiving insulin infusion and required a change in insulin dose; and 8 results were considered hypoglycemic and the insulin infusion was temporarily discontinued (Malesker et al., 2007).

Elapsed time was defined as the meter being picked up and entering the patient rooms, obtaining the blood sample, waiting for result, and reading/noting the result. The mean elapsed time was 5.18 (SD = 1.12) minutes from meter pickup and a blood glucose result. The elapsed time from meter pick up to noting a normal glucose result in the chart that required no action was 19.25 (SD = 2.14) minutes. This time included approximately 5 minutes (mean = 5.17; SD = 3.96) of time in room doing nursing care activities after the blood glucose result was obtained and almost 9 minutes (mean = 8.90; SD = 5.90) of time before the nurse entered the results into the medical records. The mean time from meter pick up to noting a result that indicated hypoglycemia in the medical record was 32.65 (SD = 7.68) minutes. The majority of the time was 19.46 (SD = 8.14) minutes spent caring for the patient after the insulin infusion was stopped. Elapsed time of obtaining the results of hypoglycemia and stopping the insulin infusion was 2.24 (SD = 1.67) minutes. Elapsed time of noting a hyperglycemic result of a patient currently on insulin infusion was 29.67 minutes. Elapsed time included 10.65 minutes reviewing the chart for appropriate algorithm; 5.40 minutes were attributed to performing routine activities related to patient care and 8.42 minutes from the time leaving the room.
and noting results in the medical record. Elapsed time from retrieving the meter to noting the blood glucose result in hyperglycemia and initiating the insulin infusion was 51.57 minutes. The majority of this time was the nurse contacting the physician, verifying the chart and/or tight glycemic protocol, and waiting for pharmacy to deliver the insulin infusion to the ICU (Malesker et al., 2007).

The fourth ICU that adapted the protocol consisted of a 25-bed ICU where the protocol was in effect for 4 months. This sample had a mean age of 63 years and consisted of 68% men, 57% surgical cases, and 43% medical cases. A history of diabetes was documented in 41% of the patients, and the majority had an admitting diagnosis of cardiac disease. Following initiation of the tight glycemic control protocol, patients were followed for an observational period that lasted a mean of 20 hours, with 981 blood glucose levels ordered ranging from 9 to 20 blood glucose readings per patient. A total of 734 deviations from protocol were documented; 57% (n = 418) were related to time due, 38% (n=279) were for incorrect insulin doses, and 5% (n = 37) were related to improper implementation of the algorithm instructions. Mean number of deviations resulted in more than 9 per patient, ranging from 1 – 23 per patient. Of the 75 patients, 50% achieved target glycemic control during the 20-hour observation period. Deviations were present in approximately 75% of all blood glucose levels (Malesker et al., 2007).

Of the total 220 full-time nurses in the 4 ICUs, 75 (34%) completed satisfaction surveys. Of the respondents, 60% had been in practice more than 5 years, and 41% had practiced more than 10 years. The survey indicated that 52% of nurses had used a tight glycemic control protocol; 73% agreed that the protocol was effective in controlling hyperglycemia; and 44% agreed that the protocol was not related to hypoglycemia.
Regarding tight glycemic control on nursing workload, only 60 nurses responded, with 42 indicating that the workload was increased; 13 nurses reported decrease in workload; and 10 nurses reported decreased time spent on calling the physician. Responses of the nurses in regards to the most difficult part of administering the tight glycemic control protocol included: 27% frequent glucose monitoring; 21% communication on glucose management with physicians; 18% determining the insulin infusion rate; and 32% reported that the protocol was too complicated or did not work in achieving target goals (Malesker et al., 2007).

The authors concluded that tight glycemic control protocols were implemented effectively in target ICUs. Insulin protocols appeared to increase the workloads of nurses. Maintaining normoglycemia in the critical care setting has beneficial outcomes (Malesker et al., 2007).

In a third study focused on glycemic control, Malijanian et al. (2002) evaluated disease management programs designed to prevent complications and chronic co-morbidities. The purpose of this study was to determine the effect of a tailored management program on glycemic control and quality of life.

The population included adults referred to the Diabetes Life Care (DLC) program in one city in the northeastern United States who were 18 years of age and older with a new diagnosis or history of type 1 or type 2 diabetes mellitus. The sample (n = 227) participated in baseline assessment and a 3-month follow up. Further analysis was conducted for a subsample of 135 patients, who provided data at the 6-month follow-up (Malijanian et al., 2002).
Instrumentation utilized in the study was the blood test HbA$_{1c}$, which assessed glycemic control. Values were reported by patients or physicians’ office staff. HbA$_{1c}$ tests were performed by the DLC staff for patients unable to provide recent results. Reduction of HbA$_{1c}$ was the main determinant of glycemic control with means and standard deviations reported (Malijanian et al., 2002). The ADA (2010) recommended the goal of HbA$_{1c}$ to be less than 7%, which reduced microvascular and neuropathic complications from type 1 and type 2 diabetes.

Health-related quality of life was measured by utilizing the Medical Outcomes Study 36-Item Short-Form (SF-36) health survey (Ware, Kosinski, & Keller, 1994), which measured health related-quality of life (HR-QOL). Physical Component Summary (PCS) and Mental Component Summary (MCS) scores were compared at each data collection point and then compared to national norms for people with diabetes mellitus (Malijanian et al., 2002).

The DLC’s program adhered to the ADA guidelines recognized in the ADA’s Standards of Medical Care for Patients (American Diabetes Association, 2001). This included annual eye examinations, nutritional counseling, and foot examinations (Malijanian et al., 2002).

One question, taken from the Dartmouth Cooperative Functional Assessment Chart (COOP) (Nelson et al., 1987), was utilized to determine the patients’ perceived social support. The response to the item “Was someone available to help you if you needed and wanted help?” consisted of a 5-point rating from “no”, “not at all”, to “yes”, and “as much as I wanted” (Malijanian et al., 2002).
Demographic data of the participants indicated that 52% were between the ages of 45 – 65 years; 65% were Caucasian; 90% were English speaking; 53% were female; 98% were diagnosed with type 2 diabetes mellitus; and 63% were diagnosed within 12 months of enrollment at DLC. The participants were compared to a group already enrolled at the DLC at the same time, which had more men, a lower percent of newly diagnosed patients, and a greater mean age. Baseline levels of the HbA1c, PCS, and MSC scores did not differ between groups. Of the participants in the study, 56.2% were more compliant with eye examinations before enrollment at the DLC, but no significant differences in compliance of nutritional counseling or foot examinations were noted (Malijanian et al., 2002).

Glycemic control at 3 months after enrollment to the DLC program (n = 142) showed a mean decrease of HbA1c from 9.3 to 7.2 (p < 0.001). Participants (n = 66) with data at 6 months had a decrease in HbA1c from 9.23 to 7.22 at 3 months (p < 0.001) and to 6.80 at 6 months (p < 0.001). Data analyses specified that the 3 month (p < 0.001) and 6 month (p < 0.001) results of PCS scores differed significantly from the results at 3 months (p < 0.007) (Malijanian et al., 2002).

The 227 participants in the study were evaluated to determine adherence to the ADA guidelines. At the initial visit, 36.1% were not in compliance as they did not receive an eye exam within one year of enrollment to the DLC. At the 3 month visit, only 40.6% had received an eye exam, with 56% having an eye examination before the 6 month visit. ADA guidelines on eye examinations finally were completed by 81.5% of participants (185 of 227) (Malijanian et al., 2002).
Regarding nutritional counseling per ADA guidelines at baseline, only 1.3% of participants reported counseling within the last 12 months. By the 3-month visit, 225 of 227 participants (99.1%) reported nutritional counseling. Two participants still did not adhere to the ADA guidelines by the 6-month visit (Malijanian et al., 2002).

Foot examinations at baseline were completed by 65.6% (149 of 227) of participants. At the 3-month visit, an increase of 79.3% (180) had foot examinations with a significant increase (p < 0.001). At the 6-month visit, 84.8% (112) reported a foot examination. A significant increase of those who had foot examinations at baseline to 6-months was significant (p = 0.001) but not from baseline 3-months. A foot examination was finally completed by 86.8% (197 of 227 participants) (Malijanian et al., 2002).

Health-related Quality of Life (HR-QOL) was evaluated. Of the 227 participants in the study, 179 completed the HR-QOL data at enrollment and at 3 months. The PCS indicated their mean scores were 42.75 (SD=11.17) at enrollment and 45.12 (SD=10.52) at 3 months (p < 0.001) (Malijanian et al., 2002). The SF-36 data were completed at all 3 data collection points. The PCS scores increased from 42.60 (SD = 10.81) at enrollment, to 46.21 (SD = 9.84) at 3 months, and 46.13 (SD = 10.86) at 6 months (p < 0.001). No significant change was noted between 3 and 6 months. The PCS score of the national norm for participants with type 2 diabetes mellitus was reported as 41.52 (Malijanian et al., 2002).

A significant increase in MCS scores was reported from enrollment to the 3-month visit. An increase in MCS scores of the 179 participants went from 47.52 (SD = 11.90) to 50.83 (SD = 10.47) (p < 0.001) at 3 months. The 83 participants at the 6-month sample had MCS scores that increased from 49.08 (SD = 10.87) to 51.31 (SD = 10.38) at
3 months and then decreased to 50.51 (SD = 11.48) at 6 months. The MCS score of the national norm for participants with diabetes mellitus was reported as 51.90 (Malijanian et al., 2002).

In conclusion, the effectiveness of an intensive diabetes mellitus program demonstrated significant improvements in glycemic control and attaining standards of care. The comprehensive collaborative program can minimize acute metabolic complications (Malijanian et al., 2002).

In a fourth study, Oeyen, Hoste, Roosens, Decruyenaere, and Blot (2007) focused on hyperglycemia at the time of ICU admission. Hyperglycemia was reported as an independent risk factor for increased mortality and morbidity. The purpose of this study was to determine if tight glycemic improved outcomes during acute illness.

The study took place in Ghent, Belgium at Ghent University Hospital, a tertiary teaching hospital. The study took place over a 2-month period. Participants were 30 patients. Criteria for inclusion in the study were admission in the surgical intensive care unit (SICU) or medical intensive care unit (MICU), expected stay of at least 72 hours, older than 16 years of age, presence of arterial catheter, and required insulin therapy. Exclusion criteria included those with diabetic ketoacidosis, cardiac surgery patients, patients included in other studies, and patients transferred from other hospitals (Oeyen et al., 2007).

In this observational study, data were collected prospectively utilizing the Acute Physiologically and Chronic Health Evaluation II scale (APACHE II) (Knaus, Draper, Wagner, & Zimmerman, 1985) to classify illness severity. Characteristics of patients’ were obtained. Data were collected daily during the study and included: caloric intake,
feeding regiments, use of corticosteroids, blood glucose and correlation of insulin infusion rates, and documentation in rate adjustments. The Sepsis-Related Organ Failure Assessment (SOFA) was utilized to determine organ dysfunction (Vincent, Moreno, Takala, Willatts, De Mendonca, Bruining, et al., 1996). Blood glucose was measured by utilizing undiluted heparinized arterial blood and bedside glucometers manufactured by GlucoTouch, LifeScan in Benelux, Beerse, Belgium. Quality control checks were completed monthly. The SICU and MICU staff received special training for a 4-week period on the insulin protocol to ensure competency of the protocol. Humulin Regular Insulin infused continuously through central venous catheters by a 50ml pump syringe (Asena CC, Alaris Medical Systems, Inc, San Diego, California). Standard concentrations of insulin of 1 IU/ml (50IU of insulin/50ml of isotonic saline) were utilized throughout the study (Oeyen et al., 2007).

Univariate analysis, chi-square tests, and linear regression were utilized to analyze the data. Multivariate linear regression was utilized to detect independent factors that could influence blood glucose results. The univariate analysis indicated which variables were to be included in the multivariate model (Oeyen et al., 2007).

Adherence was measured during the 2-month study, which included a total of 352 days of implementing the insulin protocol with 30 patients. Total measurements of 6016 glucose readings were obtained, with 71% (4267 measurements) adhering to the protocol. Deviations from the protocol accounted for 29% of the blood glucose levels within the acceptable range (40.5%), hyperglycemic (64.5%), and severe hyperglycemic (43.7%) ranges. Justification of 87 of the total 1749 deviations occurred due to alterations in nutrition or transport of the patient (Oeyen et al., 2007).
Efficacy of the insulin protocol was evaluated. At initiation of the protocol only 8 of the 30 (27%) had glucose levels within target (81-110 mg/dl) and acceptable ranges (111-150mg/dl); 7 (23%) had levels considered hyperglycemic (151-200 mg/dl); and 15 (50%) were severely hyperglycemic with levels greater than 200mg/dl (Oeyen et al., 2007). Of those that were nonadherent with the protocol, 28% were within target range. Compliance with the protocol increased by 65% with utilization of the protocol (p < 0.001), with a 4.9 (95% confidence interval, 3.1-7.6) times higher chance of attaining adequate daily blood glucose control (Oeyen et al., 2007).

Of the 6016 glucose measurements, hypoglycemia, occurred 111 (1.8%) times in 18 patients (60%), and 25 events occurred in one patient with 775 measurements (3.2%). Hypoglycemia occurred with a total of 34 episodes in 11 patients (37%), which required intervention of a dextrose bolus. Of the hypoglycemia events, a total of 7 values (0.1%) in 6 different patients (2%) were 40mg/dl or less. Complications did not arise from any hypoglycemic event (Oeyen et al., 2007).

Insulin therapy and feeding were evaluated. The median dose of insulin infusion was 2.0IU/h (interquartile range of 1.0-4.0IU/h) to a maximum of 20.0IU/h. Enteral feeding was given during 73% of the study period, and total parenteral nutrition was given 46% of the 2-month study. Patients in the study received a median of 1640kcal/d (interquartile range, 1323-1973 kcal/d) (Oeyen et al., 2007).

In conclusion, utilizing an insulin protocol improved patient outcomes while enhancing the autonomy of nursing. Each patient was viewed as unique, and variability in protocol applications was recommended. Authors noted that the maintenance of tight
glycemic control in the critically ill trauma patients required close monitoring to prevent hypoglycemia (Oeyen et al., 2007).

In another 2007 study, Wattana, Srisuphan, Pothiban, and Upchurch conducted a study to examine the effectiveness of a diabetes self management program in comparison to patients receiving nursing care. The framework was based on theories of self-efficacy and self management for the diabetes self management program.

The study took place in Eastern Thailand in two diabetic clinics at two community hospitals. The study was a randomized controlled trial with 147 patients randomly placed into an experimental or control group. The sample included 75 patients in the experimental group and 72 patients in the control group. Recruitment criteria for inclusion in the study included: greater than 35 years old; diagnosed with type 2 diabetes for at least 6 months; fasting glucose greater than 140mg for 2 follow up visits; and could speak, read, and write in Thai. Patients were excluded from the study if they were on insulin or had severe diabetic complications. Demographic information was obtained, which included age, marital status, educational level, income, and duration of diabetes (Wattana et al., 2007).

As a measure of glycemic control, HbA1c blood samples were taken by laboratory technicians and were analyzed at the same laboratory. The Thai Medical Science Center approved the laboratories quality control. The SF-36 Thai version 2 survey (Ware, Kosinski, & Keller, 1994) was utilized to determine quality of life. The reliability was 0.75 during pilot testing and 0.94 for final testing of 147 patients. For patients with vision problems, the questionnaire was read to them, and the patient was allowed to choose the answer. The Coronary Heart Disease (CHD) risk profile was utilized from the
Framingham Heart Study Coronary Heart Disease Risk Profile (Anderson, Wilson, Odel, & Kannel, 1991; Grundy, Pasternak, Greenland, Smith, & Fuster, 1999). Data were collected at baseline and at the end of the interaction. The interval between baseline and end was 24 weeks. The independent sample t-test was utilized to assess outcomes between the experimental and control groups. Fisher’s Exact test, rank sum Mann-Whitney U-test, and chi square tests were used for categorical data. Analysis of covariance was performed to examine the difference in the mean score of HbA1c, CHD risk, and QOL (Wattana et al., 2007).

Demographic information revealed that 76.2% were women and had an average age of 56.8 (SD = 10.23). Nearly 70% were married. Educational level of at least 4th grade was reported by 92.5% of the participants. Monthly reported household income was equivalent to $125 in United States dollars for 76.87% of participants. Duration of diagnosis of type 2 diabetes was 6.18 years (SD = 5.01) with a mean HbA1c of 8.09% (SD = 1.91). Hypertension as a comorbidity was found in 48.9% of participants. Combined hypoglycemic drugs were utilized in 89.8% (Wattana et al., 2007).

Regarding glycemic control, the experimental group had statistically significantly lower HbA1c levels than the control group at 24 weeks [F(1,143) = 6.19, p < 0.05]. The experimental group decreased mean HbA1c scores from 8.08% to 7.40% (p < 0.05), and the control group decreased also at 24 weeks from 8.09% to 8.02% respectively (Wattana et al., 2007).

Likewise, regarding CHD risk, the experimental group achieved a statistically significant decrease in CHD risk as compared to the control group [F (1,143) = 6.17, p < 0.05]. CHD risk factors that decreased in the experimental group were: total cholesterol,
triglycerides, low-density lipoprotein cholesterol, diastolic blood pressure and BMI, and a greater increase of HDL-C levels compared to the control group. The control group showed a decrease of systolic blood pressure when compared to the experimental group (27.78 to 25.47 mmHg). Patients being treated for hyperlipidemia were statistically significantly higher in the control group when compared to the experimental group (31 to 24 patients). The results in regards to quality of life demonstrated a significant difference, with the experimental group achieving a greater quality of life when compared to the control group [F(1,143) = 24.05, p < 0.001] (Wattana et al., 2007).

The authors concluded that a diabetes self management program improved glycemic control, decreased CHD risk, and increased QOL. The authors’ expressed concern that a low educational level for the participants could have biased the results. The authors recommended that further research be aimed at studying a larger sample of poorly controlled diabetic patients (Wattana et al., 2007).

In another recent study, Holzinger et al. (2008) focused on maintaining tight glycemic management of critically ill patients. The purpose of this study was to determine the effectiveness of staff education and implementation of a glucose control protocol for the critically ill patient.

The population for this study was the Medical Intensive Care Unit (MICU) at the General Hospital Vienna. The sample included 36 critically ill MICU patients admitted consecutively over a 3-month time period before the implementation of the insulin infusion protocol. The sample also included 44 critically ill MICU patients admitted consecutively after the implementation of the protocol. The criteria for this sample included MICU patients who stayed in the unit for more than 48 hours and also received
a continuous insulin infusion for more than 24 hours. The patients were separated into sub-groups based on known diagnoses of diabetes type I or II and non-diabetics and also pre-implementation or post-implementation of the glucose protocol. Both before and after implementation of the insulin protocol, the nursing staff used a blood gas analyzer to measure blood glucose in arterial samples (Holzinger et al., 2008).

The use of insulin therapy increased significantly after the implementation of the glucose control protocol and the educational efforts regarding the importance of controlled blood glucose in the critically ill (p < 0.001). After implementation of the insulin protocol, there was a significant decrease in the length of time that a patient’s blood glucose remained out of the expected range between 110 mg/dL and 150 mg/dL (p < .001). Median blood glucose levels after implementation of the protocol decreased; before implementation 133 mg/dL to 110 mg/dL after implementation (p < .01) (Holzinger et al., 2008).

The group of 36 patients examined before the protocol was initiated consisted of 14 (39%) diabetics. The group of 44 patients observed after the protocol was initiated consisted of 16 (36%) diabetics. Both diabetic and non-diabetic subgroups demonstrated significantly higher insulin use before implementation (33 vs 26 IU/day, p < .04; after implementation, 46 vs 30 IU/day, p < .001). Median blood glucose levels were significantly lower than before implementation (138 vs 131 mg/dL, p < .001) and after implementation (115 vs 108 mg/dL, p < .001) of the protocol. There was not a difference between the subgroups before implementation in the length of time that blood glucose levels remained less than 110 mg/dL. After implementation of the protocol, the median amount of insulin given increased (28 vs 35 IU/day, p < .002) and the amount of time that
blood glucose levels were less than 110mg/dL was significantly shorter in the diabetic patient versus the non-diabetic patient (p < .001) (Holzinger et al., 2008).

This study demonstrated that education about the implementation of a glucose control protocol was effective for staff learning and beneficial to the critically ill patient. The utilization of an intensive insulin algorithm by the nursing staff led to normoglycemia more often than insulin ordered at the physician’s discretion. Collaboration and effective education between the nursing staff and physicians led to decreased median blood glucose levels in the critically ill patient, which potentially could lead to better patient outcomes (Holzinger et al., 2008).

Another recent study tested the effect of a t’ai chi program on glycemic control and quality of life (Song, Ahn, Roberts, Lee, & Ahn, 2009). The purpose of the study was to examine the effect of a 6-month t’ai chi exercise program on glucose control, diabetic self-care activities, and quality of life in patients with type 2 diabetes.

The quasi-experimental study took place in Korea at selected health promotion centers. The sample initially included 99 adults with type 2 diabetes; 62 adults completed pretest and post-test measures at both 3 and 6 months. Criteria for inclusion in the study were having a diagnosis of type 2 diabetes in accordance to the criteria of the Korean Diabetes Association for at least 12 months and having an HbA1c of 6.0 or higher at baseline. Patients were divided into 2 groups adherent (n = 31) and non-adherent (n = 31). The participants’ mean age was 64 years old, with a mean BMI of 25.9 (SD = 3.6) for the adherent group. The non-adherent group had a mean BMI of 24.4 (SD = 2.57). The majority of participants were 80% female with 84% married, and 85% of participants not employed. The majority had less than 12 years of education. Over two-thirds of the
participants had hypertension, and 35% had arthritis. Demographic characteristics were similar among both the adherent and non-adherent groups (Song et al., 2009).

The American College of Sports Medicine (ACSM) determined the definition of adherent as patients who attended 80% of exercise session or 38 sessions. The ACSM asserted that 80% attendance was essential to achieve important results. The non-adherent group was defined as participating in less than 80% of exercise. The t’ai chi program had trained certified instructors and used instructional video tapes to ensure consistency. Glucose control was calculated by fasting blood sugars and HbA\textsubscript{1c}. The same laboratory provided testing of all blood samples to ensure consistent analysis and reduction in errors of results. The Diabetes Self Care Activity Scale (Stanford Patient Education Research Center, 2008) was utilized to assess occurrence of activities. The scale consisted of 7 items rated on a 4-point scale (1 = never do - to 4 = always do). Song et al. (2009) summed the rating and divided by the number of items for an item mean, the higher scores meaning more regularly completed diabetes self care activities. Cronbach’s alpha for the scale was 0.79. The Korean version of the 36-Item Short Form Health Survey version 2 (SF-36 v2) was utilized to measure quality of life. The tool examined 8 dimensions of quality of life and provided physical and mental component summary scores. Each dimension of quality of life was scored with weighted items as 100 points, which indicated higher quality of life equivalent to higher scores. The reliability coefficient was 0.85. Cronbach’s alpha for subscale ranges were 0.75 - 0.85 (Song et al., 2009).

The effects of adhering to the t’ai chi program were significant for reducing serum glucose (F = 7.76, df = 2, p < 0.001). Adhering to the t’ai chi program
significantly reduced the HbA$_{1c}$ ($F = 5.20, \text{df} = 2, p < 0.001$). The adherent group that
attended 80% of *t’ai chi* sessions demonstrated better glucose control at baseline and 6
months when compared to the non-adherent group[$F = 5.60, p < 0.006$] (Song et al.,
2009).

The adherent group was involved in additional self care activities at 6 months [$F = 5.13, \text{df} = 2, p < 0.009$] when compared to the non-adherent group. After adjusting for
the influence of self care activities, serum glucose and HbA$_{1c}$ did not change significantly
over time. Quality of life among the adherent group notably enhanced in the mental
component summary, social functioning, mental health, and vitality when compared to
the non-adherent group (Song et al., 2009).

The authors concluded that a *t’ai chi* program improved glucose control along
with improving mental dimensions of quality of life. Alternative exercise regimens, such
as *t’ai chi*, need further research to determine the preventative and long term effects in
patients with diabetes (Song et al., 2009).

**Summary**

Diabetes is a common disease of adulthood, present in approximately 7% of the
population. The prevalence of diabetes is rising at epidemic levels and is expected to
increase by 165% in the next few years (Dally, 2007). Experts agree that diabetes can be
adequately controlled by maintaining glucose levels to reduce health related
complications, such as diabetic retinopathy, neuropathy, and cardiac disease. In addition,
quality of life may be greatly enhanced if diabetics could adequately control blood
glucose.
Strategies to provide adequate diabetic control have been examined in research studies, often through nurse-centered or self-care management programs. Various programs in the studies utilized a multitude of strategies to determine the effectiveness of management of glycemic control, such as the *t’ai chi* program, intensive glucose control protocols with modifications, tight glycemic control in the critical care setting, and disease management programs for prevention.

In the studies reviewed, instrumentation to measure glycemic control was most often the HbA$_{1c}$. Guidelines from the American Diabetic Association for normal values of HbA$_{1c}$ were usually followed in research studies. In the studies reviewed, health-related quality of life was measured by utilizing a variety of forms of the Medical Outcomes Study Short-Form health survey (Ware & Kosinski, 2001; Ware, Kosinski, & Keller, 1994; Ware, Kosinski, & Keller, 2001; Ware, Kosinski, Turner-Bowker, & Gandek, 2002). Other frequently measured variables included patients’ perceptions of physical health, reported on a subscale of the SF-36. Mental component summary scores were used to provide information on patients’ mental status. Reliability of the SF-36 was adequate, as reported in these studies. Little information on validity of instrumentation was offered, although it has been reported for the SF-36 in other publications.

The samples examined in this literature review were exclusively adults with type 2 diabetes. Samples were drawn from communities in a variety of countries on three continents. Samples included patients who were critically ill and those who were in an outpatient setting.
No studies overviewed in this review were based on a theoretical framework. There is not yet a leading middle-range or grant theory that is undergirding this area of research.

Research designs for studies in this review were primarily correlational or quasi-experimental and longitudinal. Several studies randomized patients into the study or randomized into treatment groups. Data were often collected at baseline, at 3-months and 6-months. There were no studies of long-term outcomes of specific programmatic approaches.

Results of studies that examined quality of life indicated that QOL was significantly related to depressive symptoms, especially in patients with diabetes. QOL was a perceived perception of oneself based on functional, physical and mental well-being. Correlation was found between QOL and HbA1c. Psychological variables affected both QOL and HbA1c. Evaluation of one’s quality of life seemed important if clinicians want to effectively treat and improve outcomes.

Strategies found to be statistically effective in improving management of diabetes were t’ai chi programs, insulin protocols, education of medical staff, multidisciplinary team approaches with modifications, tight glycemic control in the critical care setting, and disease management programs for prevention. Researchers agreed that further research was needed to determine essential elements of an effective management program that ensured optimal glycemic control, improved quality of life, and directly improved diabetic outcomes of individuals. An overview of the studies summarized in this chapter is included in tabular format. The present study aimed to extend what was
known about effective program management of diabetes to reach optimal patient outcomes, including the prevention of complications.
Effective glycemic control in diabetic patients can alleviate long-term complications and may improve quality of life. Researchers have started to explore how glycemic control influences quality of life in diabetic patients, but more research is needed to clarify the effect of individually tailored diabetic management programs that address glycemic control in diverse samples. The purpose of this study was to determine the effect of an individually tailored management program on glycemic control and perceptions of quality of life in adult patients with diabetes mellitus.

**Research Question**

The research question that guided this study was: What is the effect of a tailored diabetes management program on glycemic control and quality of life in adults with type 2 diabetes mellitus?

**Population, Sample, and Setting**

The population for the study included adults who were newly diagnosed with diabetes or had a previous diagnosis of diabetes and were physician-referred to be in the diabetes management program. Inclusion criteria included: 18 years of age or older, primary diagnosis of diabetes mellitus or history of type 1 or type 2 diabetes mellitus, ability to write, read, and speak English, had available transportation to and from the clinic, signed consent to participate in the study, and had baseline documentation of prior HbA$_1c$. 
A convenience sample was recruited of 50 diabetic patients referred to an outpatient diabetes clinic from a primary care physician in a metropolitan acute care hospital in one Midwestern state. The outpatient diabetes clinic was a not-for-profit service. The outpatient diabetic clinic was accredited by the Joint Commission on Accreditation of Healthcare Organizations and certified by Medicare and Medicaid. The outpatient diabetes clinic provided support and information related to self-care needs, meal planning, nutrition, prevention of complications, tips on monitoring blood glucose levels, and physical activity. The outpatient clinic had approximately 200 patients referred to them per year. The clinic employed two full time registered nurses who were specialized in diabetes management and a part time dietician. The nurses and staff at the clinic provided support and pertinent information to individuals at the clinic. The clinic provided care based on the theory of Neuman (1989), which focused on preventive care.

**Research Design**

The research study design was a one-group longitudinal, pre-test-post-test, correlational design and provided a means to answer the research question. The design was utilized to observe subjects in the study over an extended length of time and examine the relationships and differences among variables.

**Protection of Human Subjects**

The study proposal was submitted to the Ball State University Institutional Review board for review and to the Institutional Review Board of the outpatient diabetic clinic to ensure protection of the rights of the participants. Permission was granted from both review boards prior to conducting the study.
A notice about the study was posted in the clinic waiting area advising patients to ask the nurse for details or email the researcher for information about participating. The researcher was available on site several days a week to screen patients for qualification, answer questions and enroll patients in the study. When the researcher was not present, a trained nurse was available to answer questions and obtain patients’ informed consent. All participants who qualified for the study and signed informed consents received a questionnaire packet. The invitation and cover letter included the purpose of the study, participant rights, and informed consent forms. Participants completed the study instrumentation, which included instructions advising them that they could omit any items they wished. Participants placed the completed instrumentation in a sealed envelope and mailed it by postal mail to the researcher or, alternately, placed it in a data collection box located in a private area of the clinic waiting area.

Participation was voluntary, and the patients could withdraw from the study at any time. All data were kept confidential and seen only by the researcher and data entry personnel. Patients were instructed to not write their names on the survey. However, patients were not anonymous in the study, since clinical information had to be retrieved from patients’ medical records and associated with survey instrumentation. Survey forms were coded with a patient number. A list of the participants’ names and code numbers was kept in a locked drawer of the researcher’s office. Study data with unique patient identifying numbers were kept in a locked drawer of the researcher, separate from the list of patients’ codes and names.
Patients’ HbA1c glucose levels and perceived quality of life were monitored prior and after completion of the study. Results were communicated with the participants as conclusion of the study.

Participants were given an opportunity to provide a mailing address so that they could receive the written results at the end of the study. Data were destroyed at the end of the data analysis and dissemination of the results.

There was minimal risk to participants, specifically the risk of not being anonymous and having private medical information recorded. Participants were informed that they could withdraw from the study at any time and could omit answering any items. There were no clear benefits to the participants, other than to contribute to professional knowledge for the discipline. The importance of the study was cited in the cover letter and informed consent and included gaining knowledge about management of diabetes that could guide health care professionals in planning management programs for adults. No one could provide these data except patients with diabetes who were enrolled in management programs. The benefit to science was believed to equal or exceed the risk to participants.

**Procedures**

Following organizational permission, a notice about the study was posted in the clinic waiting area advising patients to ask the nurse for details or email the researcher for information about participating. The researcher communicated directly with potential participants about the study. The researcher was available on site several days a week to screen patients for qualification, answer questions, and enroll patients in the study. When the researcher was not present, a trained nurse was available to answer questions and
have patients sign informed consent materials. The invitation and cover letter included the purpose of the study, participant rights, and informed consent forms.

All participants who qualified for the study and signed informed consents received a questionnaire packet for the initial data collection. Participants were provided with guidelines from the ADA and the study instrumentation, which included instructions advising them that they could omit any items they wished. Participants placed the completed instrumentation in a stamped envelope and mailed it by postal mail to the researcher or, alternately, placed in a data collection box located in a private area of the clinic waiting area.

Participants then began participation in the tailored program. Throughout the course of the program, notification and documentation of the patients’ visit to the outpatient clinic as part of the research study were available for the patients’ primary care physician to review and make appropriate suggestions if needed. Participants were scheduled weekly for the first month to receive information regarding diabetes. After the first month, each participant scheduled an appointment monthly or more frequently if requested by the participant.

The outpatient diabetic clinic routinely provided information that was based on the standards of care set forth by the ADA. The ADA served as a resource to the researcher to provide consistency in information provided to the participants. The ADA serves as a national resource for health care professionals and facilities in providing care for diabetic patients.

The diabetic program included a multidisciplinary approach for all of those involved in the study. The multidisciplinary team consisted of the advanced practice
nurse, dietician, social worker, chaplain, and case manager. Each member of the team spoke with each patient at every visit; adequate time was given for each patient to express questions and/or concerns. The advanced practice nurse provided support and information associated with self-care needs, prevention of complications, monitoring blood glucose levels and exercise. If the patient was not able to see the social worker, chaplain, or case manager, the social worker contacted the patient for follow up. The advanced practice nurse provided secondary prevention-as-interventions (Neuman, 1989), including culturally appropriate education on diabetes and various forms of social and clinical support. Every patient met with the dietician to help plan individualized menus and nutrition. The social worker, chaplain, and case manager worked closely together to provide additional resources within the community. The interprofessional team met twice a month to evaluate each individual patient. This meeting allowed the team to confidentially share necessary information to provide the best outcome for the patient and prevent further complications. Updates were sent to the primary care physician for review and comments.

Questionnaires to determine the participants’ perception quality of life were then completed again at 6 and 12-months. Instrumentation was given to participants at the monthly clinic visit and returned in the same manner as the first survey. HbA1c lab results were obtained by the researcher at 3-months, 6-months, and 12-months of the program and compared to baseline lab results. Completed questionnaires and lab results were filed electronically and became a part of the patients’ electronic medical record.
Instrumentation

The Medical Outcomes Study 36-Item Short-Form version 2 (SF-36 v2) health survey (Ware & Sherbourne, 1992) was utilized to determine each participant’s individual perception of quality of life. The SF-36 survey and other modifications of the SF-36 have been utilized in numerous studies across the nation and assessed as having adequate reliability and validity. The SF-36 questionnaire has 36 questions and measured a variety of construct related to perceptions of health, including the perception of quality of life (QOL). The SF-36 allowed the participant to mark only one answer for each of the 36 questions. The answers available for the participant to select ranged from: excellent to poor; much better to much worse; yes, limited a lot; to no not limited at all; all of the time to none of the time; not at all to extremely; none to very severe; and definitely true to definitely false.

Glycemic control was assessed by utilizing the HbA1c laboratory test. No records were kept of calibration of lab equipment, but the same lab was used to analyze all HbA1c. Data collected were imported into the electronic medical record which is utilized from all health care system sites.

Method of Data Analysis

Descriptive statistics were used for analysis of the demographic data. Level of significance was set at p < .05. The data analysis was completed by utilizing multiple regression analyses. This statistic allowed an evaluation of the effect of the target program on the dependent variables of glycemic control and quality of life (Burns & Grove, 2005).
Summary

This study was a partial replication of a study by Malijanian et al. (2002) intended to provide information about the effect of a tailored management program on glycemic control and quality of life in patients with diabetes mellitus. In this chapter, the methods and procedures were outlined for this study. A convenience sample of 50 diabetic patients referred to an outpatient diabetes clinic from a primary care physician was utilized in this study. The research study design was a one-group longitudinal, pre-test-post-test, correlational design, which observed subjects in the study over a 12 month period. The Medical Outcomes Study 36-Item Short-Form health survey (Ware & Sherbourne, 1992) measured quality of life of the participants. HbA1c was utilized to determine glycemic control throughout the study. Analysis of data was completed by utilizing inferential statistics.
References


*Quality of Life Research, 16,* 165-177.


