

THE EFFECTS OF STRUCTURED INTENSIVE DIABETES EDUCATION
PROGRAMS IN PATIENTS WITH TYPE 2 DIABETES

A RESEARCH PAPER

SUBMITTED TO THE GRADUATE SCHOOL

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE

MASTERS OF SCIENCE

BY

MICHAEL DILJAK

DR. ANN WIESEKE - ADVISOR –

BALL STATE UNIVERSITY

MUNCIE, INDIANA

MAY 2010

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Abstract

RESEARCH SUBJECT: The Effects of Structured Intensive Diabetes Education Programs in patients with Type 2 Diabetes.

STUDENT: Michael S. Diljak

DEGREE: Masters of Science

COLLEGE: College of Applied Sciences and Technology

DATE: May, 2010

The Centers for Disease Control and Prevention (CDC) estimates morbidity rates for diabetes (diagnosed or undiagnosed) at 10% of non-institutionalized adults 20 years and older. In addition, there were 28.6 million ambulatory care visits with diabetes as the primary diagnosis and 584,000 hospital discharges with diabetes as the primary diagnosis in 2006. There were also 72,449 deaths attributable to diabetes in 2006, which made it the sixth leading cause of death (CDC, 2009).

The purpose of this study is to examine the effectiveness of structured, individualized diabetes education programs for patients with type 2 diabetes. The framework for this study is Orem's Self-Care Deficit Theory. The sample will consist of 100 hospitalized patients with either a primary or recent diagnosis of type 2 diabetes who were given diabetes education while in two hospitals in Kalamazoo, Michigan. The study will examine the efficacy of patient centered, individualized approaches on disease control and patient well-being. Diabetes educators and facilities will use the results to understand and improve diabetes education programs.

Chapter I

Introduction

Diabetes has been characterized as the “disease of the 21st century” (Gallegos, Ovalle-Berumen, & Gomez-Meza, 2006, p 344). In the United States, it is estimated that the disease affects 24 million people, 7.8% of the population (Fitzner, Greenwood, Payne, Thomson, Vukolvjak, McCulloch, & Specker, 2008). These figures are expected to increase by 43% by the year 2020 (Jeffreys, 2008). Worldwide, these numbers increase to 194 million people with half not yet diagnosed (Lindenmeyer, Hearnshaw, Vermeire, Van Royen, Wens, & Biot, 2006). It is projected that the risk of type 2 diabetes in individuals born in the United States in 2000 will be 32.8% for males and 38.5% for females (Gilmer, Roze, Valentine, Emy-Albrecht, Ray, Cobden, Nicklasson, Philis-Tsimikas, & Palmer, 2007). Type 2 diabetes accounts for 90-95% of all diabetes cases (Gavi & Hensley, 2009).

Costs associated with type 2 diabetes are also significant. The total cost in 2002 was \$132 billion with \$92 billion in direct medical expenditures (Erwin, Shrividay, Rajagopalan, Astuto, Wilson, Schaneman, & Kleinman, 2006). This is an increase over the Center for Disease Control (CDC) stated figure of \$98 billion in 1997 (2001). One of every five health care dollars is spent on diabetes health care (Jeffreys, 2008).

Type 2 diabetes is principally related to resistance of insulin sensitive tissues such as liver, adipose, and muscle to insulin. This develops over several years with the body initially producing higher levels of insulin before signs and symptoms are evident and a diagnosis of type 2 diabetes is made (Jones & Huether, 2002). Complications of the disease can include

retinopathy, neuropathy, nephropathy, cerebrovascular, peripheral vascular, and cardiovascular diseases, immunosuppression, and sexual dysfunction as well as early mortality (Gucciardi, DeMelo, Lee, & Grace, 2007). The condition can be divided into pre-diabetes, with a fasting glucose of 100-125mg/dL and glucose levels on an oral glucose tolerance test from 140-199 mg/dL and type 2 diabetes with a fasting glucose of 126 or more and a glucose tolerance test of 200 mg/dL or more (Gavi & Hensely, 2009).

Treatment of pre-diabetes is principally centered on lifestyle changes. Nutrition is one component with dietary changes based on a plan developed with the patient by a nutritionist or other health professional. Exercise also has been shown to be a key component. One study showed a 71% reduction in the development of diabetes with moderate exercise of 150 minutes a week in patients over 60 years old (Gavi & Hensely, 2009).

Treatment of diabetes can take a number of different forms. Pharmacological measures can include Metformin and classes of drugs such as sulfonylureas, alpha-glucosidase inhibitors, dipeptidyl peptidase-4 inhibitors, meglitinides, and glucagon-like peptide 1 agonists (Gavi & Hensely, 2009). Nutrition with weight control is a significant intervention. Carbohydrate consumption should be in small amounts evenly distributed throughout the day. Protein consumption should be 15-20% of total daily calories. Fat calories should be no more than 30% of total caloric intake. Regular exercise of 30 minutes a day for most days of the week is needed in order to gain the maximum benefit.

Central to the control of type 2 diabetes is self-management and central to self-management is patient education (Gavi & Hensely, 2009; Norris, Lau, Smith, Schmid, & Englau, 2002). Diabetes requires the patient to not only develop new skills such as self-monitoring of

glucose but also to engage in a whole series of life style modifications that are necessary for control of glycemic levels and reduction of risks associated with type 2 diabetes such as vascular complications (Chang, Chang, Lee, Chen, Huang, Peng & Yan, 2007; Erwin, et al.2006).

Background and Significance

Diabetes as a condition has been recognized to one degree or another for several thousand years. The Indian physician Susruta noted 5,000 years ago a condition caused by overeating of starches and sugars that resulted in polyuria. The Greek physician Aretreus coined the term diabetes, which means siphon, in the first century after observing excessive thirst combined with polyuria. Sugar in the urine was recognized in the 18th century and was treated with a high protein low carbohydrate diet, which was the first effective treatment for type 2 diabetes. Insulin was isolated in early in the 20th century and first used as a treatment on a 14-year-old boy in 1922. Diabetes was divided into type 1 and type 2 in 1935 (Diabetes Health, 1991).

Patient education has been an important part of diabetes care since the 1930s. The American Diabetes Association recommends that patients with diabetes be assessed for self-management skills and knowledge and that continuing education be encouraged and provided. A goal within the Healthy People 2010 (Norris, et al., 2002) campaign is to raise the percentage of diabetes patients who receive formal diabetes education from 40% to 60%. This need is based on a significant knowledge and skills deficits in 50-80% of diabetes patients and ideal glycemic control in less than half (Norris et al., 2002).

Management of type 2 diabetes is both complex and difficult. The patient must acquire skills in monitoring medications, blood glucose self-monitoring, and sometimes insulin injection. They must also adopt new behaviors in diet and exercise that can be difficult to maintain over

long periods of time. Patient education and social support are necessary in order for the patient to attain the needed skills and knowledge (CDC, 2001). It also is important to note that the new behaviors and skills frequently take place in an environment where the patient may have little support, previous knowledge, or experience.

Diabetes education is not delivered into a void. Awareness of, and tailoring to, the patient's ethnic and cultural heritage, background and level of education, and physical and resource limitations is required for successful education. Gucciardi, et al (2007) found that culturally competent diabetes education combined with individual counseling were effective in improving both glycemic control and adherence to diet. The researchers also stated that interventions targeted to cultural beliefs and language barriers led to greater patient communication and patient satisfaction.

Recognition of the patient's economic and educational barriers also is important. Gallegos, et al. (2006) studied diabetes patient education in a Mexican population in which education levels were low and participants were from a lower socio-economical level. The researchers noted the effect that education levels could have on both compliance and baseline condition of the participants. It was also felt that education levels could have an effect on both knowledge gained and retained by the participants.

Cultural influences can have an effect on both how disease is viewed and on how it impacts a population. Yang, Xiong, Vang, & Pharris (2009) examined diabetes in Hmong American women. This cultural grouping views disease and health as a balance of social, natural, and supernatural forces rather than as a cause and effect relationship more common to Western thought. There also was an influence exerted by Western culture on these women in that there

was an increase of 20 times the incidence of type 2 diabetes among Hmong women living in the United States over those living in Thailand. The researchers stated the need for examining the disease experience within a cultural context (2009).

What makes these studies and experiences relevant is that they address something that is a fact of life in the United States. This country and this culture are in effect many cultures. Patient education should always give consideration to not only what is being taught but also to whom it is being taught.

Another consideration of patient teaching, and what this study hopes to address, is how the information is presented. Several of the studies within this paper look at the way in which the information about type 2 diabetes is presented. One of them, Ko, Song, Kim Lee, Kim, Shint, Cho, Parks, Jeong, Yoon, Cha, Son, & Ahn (2007), examines the effect of a structured intensive diabetes education program on patients with type 2 diabetes. This study is a partial replication of that study.

Statement of Problem

The Center for Disease Control and Prevention estimates morbidity rates for diabetes (diagnosed or undiagnosed) at 10% of non-institutionalized adults 20 years and older. In addition, there were 28.6 million ambulatory care visits with diabetes as the primary diagnosis and 584,000 hospital discharges with diabetes as the primary diagnosis in 2006. There were also 72,449 deaths attributable to diabetes in 2006, which made it the sixth leading cause of death (CDC, 2009).

Purpose of the Study

The purpose of this study is to examine the effectiveness of structured, intensive versus traditional diabetes education programs for patients with type 2 diabetes. This study is a partial replication of Ko, et al. (2007) study.

Research Questions

1. Does a structured intensive diabetes education program have an effect on self-care behaviors in patients with type 2 diabetes?
2. If so, is this effect reflected in clinical values?
3. Is there an increase in patient well being with diabetes education?

Theoretical Framework

The theoretical framework for this research is Orem's Self-Care Deficit Theory. This framework is ideally suited to this topic because diabetes education seeks to overcome a self-care deficit within patients regarding new knowledge, skills, and lifestyle changes that are required for successful management of type 2 diabetes. Self-care is defined as those actions and behaviors, that a patient undertakes in order to maintain life, health, and well-being. A self-care deficit is the inability of the person to provide self-care therefore requiring a nursing intervention. Nursing systems unites the nurse and patient through assessment of self-care deficits in combination with assessment of patient needs and abilities (Orem, 2001a).

Definition of Terms

Glycemic control: Conceptual

Gallegos, et al. state that maintaining type 2 diabetes control "means keeping glycemia values within normal parameters" (2006, p. 345). Ko, et al. state "Glycemic control can reduce morbidity and mortality of diabetes and related diseases" (2007, p 56).

Glycemic control: Operational

Participants will be asked to maintain a log of blood glucose self-monitoring. HgbA1C will be measured at baseline, three months, six months, one year, and two years.

Self-Management: Conceptual

“Self-management of diabetes, developed with Mexican samples, have had the goal of improving the knowledge about the illness and its treatment, controlling glucose and lipid levels, and physical fitness, all included in the self-care measures (Gallegos, et al., 2006, p. 345).

Self-management: Operational

Self-management will be measured using four tools; The Diabetes Self-Care Activities Questionnaire (Gallegos, et al., 2008) – an 11 question, multiple choice questionnaire that assesses compliance with type 2 diabetes treatment, the Barriers to Self-Care Scale – 31 questions about environmental barriers to self care (Gallegos, et al., 2006), the Specialized Self-Care Capabilities Scale – a 14 item Likert scaled questionnaire about specific skills to manage diabetes (Gallegos, et al., 2006), and the Diabetes Quality of Life questionnaire – a 46 item Likert scaled questionnaire relating to quality of life for patients with diabetes (Watkins & Connell, 2004).

Limitations

Generalization could be limited due to sample size and because this study is conducted within a single geographical area. Behavior measurement may have some inaccuracies because the data are self-reported by the participants. The degree to which behavioral changes of participants become life long cannot be measured because of the limited time over which this study takes place.

Assumptions

This quasi-experimental study makes the following assumptions:

1. Improved control of type 2 diabetes can be achieved through intensive diabetes education.
2. Self-management of type 2 diabetes is necessary to reduce morbidity and mortality.
3. Intensive diabetes education of patients with type 2 diabetes by healthcare professionals is needed to optimize patient self-care.

Summary

Type 2 diabetes is a disease of growing prevalence throughout the world. This chronic condition requires those who have the disease to engage in a lifetime of careful self-management. This can only be achieved through a system of education and support that allows the patient to gain new knowledge and integrate in new behaviors. This study, a partial replication of Ko, et al.'s (2007) study and will use Orem's Theory of Self-Care as a framework, will attempt to measure effect of a structured intensive diabetes education program on the behaviors and glycemic control of patients with type 2 diabetes.

Chapter II

Management of type 2 diabetes is a responsibility that in the end lies primarily on the shoulders of the patient. The patient is responsible for making and maintaining both lifestyle changes and monitoring physiological outcomes. The question is, what knowledge and skills does the patient need to accomplish these goals. This study, in an attempt to answer this question, replicates a study by Ko et al. (2007), examining the effect of a structured intensive diabetes education program on patients with type 2 diabetes.

Organization of Literature

The literature review discusses selected studies of the patient education experience to examine strategies that have shown success or have shown opportunities for improvement within the educational program. Literature about the patient experience and expectations of patient education is also described. The literature review is divided into the following sections:

1. Theoretical framework: Orem's Self-Care Deficit Theory of Nursing
2. Patient experiences
3. Individual studies

Literature Review

Theoretical Framework

The basis for effective management of type 2 diabetes is patient self-management. The patient manages diet, blood sugar levels, exercise and activity levels, and monitors for potential side effects of the disease process. For all of these reasons, Dorothea Orem's Self-Care Deficit Theory is well suited to function both as a framework for this paper and as a practical approach to patient education for type 2 diabetics.

Patients with a diagnosis of type 2 diabetes are required to learn an entirely new set of skills that they did not previously possess. Orem terms this a self-care deficit wherein “care abilities are less than those required for meeting a known self-care demand” (Orem, 2001a, p. 147). Orem also states, “Persons ... must have the powers and capabilities specific to the type of action to be engaged as well as the foundational human capabilities, dispositions, and orientations to self, others, and their environments that are necessary to engagement in any type of deliberate action” (Orem, 2001b, p. 553).

Patient education, especially within a framework of new experiences and related skill sets, is driven on these principals. Orem is widely acknowledged as a theorist and has served as a basis for nursing research. This theory consists of three interrelated concepts.

Theory of Self-Care

Orem defines self-care as the actions that a person takes in order to maintain life, health, and well-being. Self-care agency is those skills and actions that a person acquires in order to maintain self-care. Self-care requisites are the reasons that drive self-care and delineate the intended results. Therapeutic self-care demand is the actions taken in order to address those needs (Orem, 2001a).

Theory of Self-Care Deficit

Orem defines a self-care deficit as the inability of the person to provide self-care that then requires the intervention of nursing in order to provide the needed skills and knowledge. Nursing functions to give the individual the means necessary to accomplish self-care. These actions are, in effect, the response of nursing to the need of the patient in order to achieve desired outcomes (Orem, 2001a).

Theory of nursing systems

Nursing systems are what unites the nurse and patient through the assessment of self-care deficits in combination with the assessment of patient needs and abilities. This is divided into the wholly compensatory nursing system, the partially compensatory nursing system, and the supportive-educative nursing system. This last system is relevant to this study in that it is the agency through which the nurse assists the patient in acquiring the knowledge and skills necessary to overcome a self-care deficit (Orem, 2001a, & Foster & Bennett, 2002).

The ability of the patient to provide effective self-care in a chronic disease situation such as type 2 diabetes is a principal measure of the successful management of the disease. Patients with type 2 diabetes are essentially facing a new way of life that requires both new skills and a new mindset in order to thrive. The principal nursing intervention is the provision of knowledge and skills to the patient. This is the essence of Orem's theory (Orem, 2001a).

Patient Experiences

Effective patient education for any chronic disease must take into account what the patients' goals are and how they express those goals. Huang, Gorawara, & Chin (2005) conducted an exploratory study to examine those goals. The structure of this grounded theory, qualitative study was semi-structured interviews that were conducted one on one with type 2 diabetes patients. The interviews were designed to explore healthcare goals, diabetes care goals, experiences with diabetes, priorities, and self-care.

The study was conducted in four clinics connected with the University of Chicago. The sample size was 28. Criteria for inclusion were a diagnosis of diabetes as well as an additional

cardiovascular diagnosis. Patients with known cognitive deficits or who lived in a nursing home were excluded (Huang, et al., 2005).

The researchers examined the interview transcripts separately and jointly for common themes. They systematically coded the interviews, and ranked the stated patient goals based on of how much time they occupied within the content and how often they were brought up. Values were expressed as percentages and, where applicable, actual numeric values (Huang, et al., 2005). Patient charts were also analyzed for diagnosis, demographics, comorbidities, clinical measures, and medications (Huang, et al., 2005).

The average age of the participants was 74 with 61% being between 65 and 74. The majority of the participants were African American (79%) and female (57%). All had hypertension, 48% had hyperlipidemia, and 44% had a history of coronary artery disease or cerebral vascular accident (Huang, et al., 2005). A small portion had met American Diabetes Association standards for glucose control (37%), systolic blood pressure control (15%), and low-density cholesterol control (Huang, et al., 2005).

Independence in activities of daily living was reported by 43% of the sample and 29% stated primary healthcare goals as to be alive and healthy. Only 3.5% percent stated either adherence to diet, exercise, or medication, avoidance of symptoms, or control of blood sugar levels as primary goals. The greatest external influences on healthcare goals were peers or family members experiences with healthcare (50%) healthcare providers (47%), and beliefs (3%) (Huang, et al., 2005).

Diet restrictions varied from some restrictions (67%) to none (29%). Many made some attempt to limit fats or portion sizes but some stated that they made no effort to change their diet

at all, preferring to “eat whatever were used to” (Huang, et al., 2005, p. 309). Exercise was also a fairly low priority for these patients with 36% stating that they did none (Huang, et al., 2005).

The researchers concluded that the majority of the participants expressed their healthcare goals in social and functional language. Diabetes care education has become more complex but providers need to communicate with patients in the patient’s own language rather than the biomedical language of risk factors and complication prevention. Providers could facilitate their involvement by invoking the experiences and language of other patients (Huang, et al., 2005).

Self-management is a cornerstone of diabetes care and is often taught and facilitated using goal setting. Sprague, Schultz, and Branen (2006) conducted a survey to assess patient experiences with goals after diabetes education. The objectives were to compare goals that patients set during education versus current goals, to describe patients’ experiences with goal setting, and to compare goal-setting experiences to adherence to goals after education.

A sample of 97 was drawn from one hospital in eastern Washington State and two in northern Idaho. Inclusion criteria were a diagnosis of type 2 diabetes and completion of diabetes education between 6 months and 2 years prior to the start of the study (Sprague, et al., 2006).

A 38-item questionnaire, developed using a preliminary focus group of eight patients who were excluded from the study, was mailed to study participants. The questionnaire asked about goal setting during and after education; patient-generated beliefs and behaviors related to monitoring and evaluating self-care; self-reported adherence to diet, exercise, and glucose monitoring; attitudes towards self-care; and personal information. The questionnaire was peer reviewed for face and content validity by dietitians, nutritionists, and certified diabetes

educators. Survey specialists reviewed the questionnaire style, consistency, and readability (Sprague, et al., 2006). Reliability was not reported.

Most patients (65%) set goals and 86% said they were at least moderately useful. Thirty five percent said they had changed their goals after education. Those who had changed their goals were more likely to experience a higher degree of difficulty with diet adherence ($P < 0.01$) and conducting regular glucose monitoring ($P < 0.05$). Many were currently setting goals for glucose monitoring (76%), exercise (72%), or diet (71%). The median number of goals was three (Sprague, et al., 2006).

More than half of participants felt successful at managing diabetes when they adhered to: diet (70%), glucose monitoring (63%), medications (60%), or exercise (57%). Behaviors that patients used to determine diabetes control included glucose readings (67%), how closely they followed a diet (58%) or exercise program (26%), and weight loss guidelines (31%). Many patients indicated that they used how they felt emotionally (43%) or physically (50%) to determine diabetes control (Sprague, et al., 2006).

Fifty one percent of respondents stated that they had a diet or meal plan and of those 68% reported that they followed it. Twenty six percent had a prescribed exercise plan and of those only 37% adhered to it usually or always. Sixty eight percent indicated that they were given a goal for frequency of glucose monitoring; 77% of those indicated that they usually or always complied with it. For those taking oral medications (67%), 90% reported taking them as prescribed usually or always. Eleven percent of patients used insulin with 59% usually or always taking insulin as prescribed (Sprague, et al., 2006).

Most patients reported usually feeling adequate (63%), with fewer always adequate (10%), occasionally adequate (14%), or rarely adequate (6%). Thirty eight percent found it difficult to balance all areas of self-care, 33% found it easy, and 27% found it neither difficult nor easy. Diet (56%), exercise (56%), and managing stress (40%) were associated with a moderate or high degree of difficulty. Glucose monitoring (64%), oral medications (62%), keeping records (61%), following up with a physician (72%), and problem-solving skills (50%) posed either no difficulty or a slight degree of difficulty for most participants (Sprague, et al., 2006).

There was a significant positive relationship between patient adherence and behaviors that determine diabetes control between and within regimen areas. There is no significant relationship between patient beliefs and adherence. Self-care behaviors that patients associate with successful control may reflect what they need to do rather than what they actually do.

Individual Studies

While day-to day clinical care of patients with type 2 diabetes is driven by the understanding that long-term complications can be delayed or prevented by improved metabolic control, medical management alone may not be sufficient by itself. Polonsky, Earles, Smith, Pease, Macmillan, Christiansen, Taylor, Dickert, & Jackson (2003) conducted a study to determine the effect of added education. The study compared the Diabetes Outpatient Intensive Treatment program (DOIT) to EDUPOST, standard diabetes care combined with quarterly educational mailings. DOIT is a multiday group education and skills training experience combined with medical management and followed by case management over 6 months with frequency of follow-up being determined by individual patient need.

The sample was 96 patients randomly selected from Tripler Army Medical Center in Hawaii. They were randomly assigned to either DOIT or EDUPOST with 117 completing both baseline measures and 6-month follow-up. Inclusion criteria were a diagnosis of type 1 or type 2 diabetes, 18 years of age or older, and a HgbA1C of at least 8.5% (Polonsky, et al., 2003).

The variables that were measured were changes in HgbA1C levels and diabetes self-care behavior. Self-care was measured using the Summary of Diabetes Self-Care Activities, a 12 item self-report scale that assessed frequency of blood glucose monitoring, medication usage, and exercise and dietary behaviors over the previous 7 days (Polonsky, et al., 2003). The researchers stated that several of the scales were modified to focus attention on glucose monitoring and dietary behavior. Reliability was not reported for either the original or modified scales. The researchers did not report reliability and validity.

Baseline differences between the DOIT group and the EDUPOST group were analyzed using *t* tests and ANCOVA with no differences found between groups. HgbA1C levels dropped for both groups over the 6-month period however DOIT group had a significantly greater improvement (10.2 to 7.9) than the EDUPOST group (10.4 to 8.7). Analysis also showed that there was no difference in impact on HgbA1c based gender or type of diabetes (type 1 versus type 2) (Polonsky, et al., 2003).

DOIT group patients reported significant improvements in glucose monitoring (58.3% to 88.9%), diet (27.8% to 38.9%), and exercise (2.8 days to 3.6). The EDUPOST group showed declines in glucose monitoring (62.2% to 56.8%) and diet (21.6% to 11.1%) and an increase in exercise (3.3 days to 3.7) (Polonsky, et al., 2003). There was a positive correlation between diet changes and glycemic improvement over the 6 months within the DOIT group ($r = 0.41, p <$

0.02) (Polonsky, et al., 2003). HgbA1C showed a greater drop (10.2 to 7.6%) in those DOIT patients with more than two follow up contacts than those with two or less (10.4 to 8.7%) (Polonsky, et al., 2003).

The researchers concluded that there was a significant improvement over the 6-month period in patients who were in the DOIT group compared to those in the EDUPOST group. They also concluded that there was a positive correlation between the number of follow-up contacts and the glyceimic control within the DOIT group (Polonsky, et al., 2003).

Patient education based on specific teaching models, and retention of knowledge is directly tied to quality diabetes care. Trento, Passera, Borgo, Tomalino, Bajarda, Cavallo, & Porto (2004) conducted a 5-year randomized controlled clinical trial to study changes in knowledge, problem solving ability, and quality of life. The intervention group was given systematic group based education that was initially divided into four sessions, repeated in years 1 and 2, spread over seven sessions in years 3 and 4, and then started over again in year 5. The control group was managed by traditional one-to-one clinical education sessions.

The study was conducted in a hospital-based, secondary care diabetes unit. A convenience sample of 120 patients with type 2 diabetes were initially chosen, eight of whom did not meet inclusion criteria, and were randomly assigned to either a control group (n = 56) or intervention group (n = 56). Inclusion criteria were not stated in the study. The control group received individual diabetes care. The intervention group was divided into six education groups each of which received the same intervention (Trento, et al., 2004).

Measured variables included knowledge of diabetes, problem solving ability, quality of life, HgbA1C, body mass index (BMI), and HDL cholesterol. Trento et al (2004) used the

following questionnaires; GISED questionnaire (knowledge of diabetes), Condotte di Riferimento (CDR) questionnaire (problem solving ability), and Diabetes Quality of Life questionnaire (quality of life). The researchers stated that all questionnaires were checked for internal consistency using Cronbach's alpha reliability coefficient but values were not stated.

Measurements were taken at baseline and at 5 years. GISED scores (knowledge of diabetes) improved (15.5, +/- 7.9 to 27.9, +/- 5.7) for the intervention group but worsened for the control group (21.4, +/-7.2 to 18.0, +/-8.5). CDR (problem solving abilities) scores improved for the intervention group (11.4, +/- 2.6 to 17.1, +/- 2.4) but worsened for the control group (12.3, +/- 4.2 to 10, +/- 3.8). Quality of life scores, based on a 5-point Likert scale from 1 (very satisfied) to 5 (very dissatisfied), for the intervention group improved (67.4, +/- 19.0 to 43.7, +/- 7.2) and worsened in the control group (70.0, +/- 21.4 to 89.2, +/- 30.1) (Trento, et al., 2004).

The researchers concluded that adults with type 2 diabetes could acquire specific knowledge and behavior patterns through education that is specific to patient needs. Individual care and teaching did not prevent deterioration in knowledge, problem solving ability, and quality of life over time. The researchers suggest that systematic, group based education can empower patients and provide them with the means to manage chronic diseases (Trento, et al., 2004).

Diabetes became the second leading cause of mortality in Mexico by 2005. In addition, 50-60% of the diabetic population had high blood glucose levels, 58% adhered to medication regimens, 38% with diet, and 15% with exercise. Gallegos, Ovalle-Berumen, and Gomez-Meza (2006) conducted a longitudinal study to test the efficacy of a controlled nursing intervention focused on education and counseling.

Participants were chosen from two locations classified as low-middle-class areas of a highly urbanized city. A group was recruited from each area and randomly assigned to either a control or experimental group. An exclusion criterion was a creatinine level above 1.5 ml/dl. The initial sample consisted of 29 in the experimental group and 28 in the control with 25 and 20 respectively completing the full study. The experimental group received an intervention consisting of six 90 minute educational sessions and 20 individual counseling sessions, each 30-90 minutes long, over a period of 50 weeks. The control group was monitored monthly with a physician visit with no additional education or counseling (Gallegos, et al., 2006). Measurements were taken at baseline, 3, 6, 9, and 12 months in both groups. Anthropometrics including height, weight, and blood pressure, and HgbA1C were measured. Four questionnaires were used: the Diabetes Self-care Activities Questionnaire (reliability = .71), the Specialized Self-Care Capabilities Scale, the ATT39 Scale (reliability = .73), and the Barriers to Self-Care Scale (reliability = .79) (Gallegos, et al., 2006). The internal consistency and reliability of each questionnaire was determined using Cronbach's alpha. Reliability for the Specialized Self-Care Capabilities Scale was relatively low at .63, which indicates the need for caution when interpreting and generalizing findings (Gallegos, et al., 2006).

Demographic characteristics of age and education among participants were equivalent. Self-care agency, adaptation, and barriers were considered independent variables and were analyzed to determine whether they were predictors of self-care measures and HgbA1C levels as an exploratory question. The study presented two hypotheses: first that the HgbA1C levels would be lower in the experimental versus control group, and second that at least 60% of the intervention group will achieve acceptable metabolic control as indicated by HgbA1C. The first

hypothesis led the researchers to examine whether variables such as adaptation, self-care agency, and environmental barriers affect self-care behavior (Gallegos, et al., 2006).

Results supported the first hypothesis revealing a significant difference between groups in the second, fourth, and fifth measurements with the experimental group having lower HgbA1C levels. Results supported the second hypothesis showing an increase in glycemic control at each measurement and at measurement five 60% achieved moderate to good control. Analysis for the first hypothesis indicated a positive correlation although this should be considered with caution due to the low reliability score on of the Specialized Self-Care Capabilities Scale (Gallegos, et al., 2006).

The researchers conclude that group education combined with individual counseling are effective means of improving metabolic control in patients with type 2 diabetes. Individual counseling sessions that took place in the patients' homes were perceived as effective because they gave guidance within the context of the patient's environment and resources. The authors also stated the need to examine the Specialized Self-Care Capabilities Scale for a means to improve the reliability of the scale (Gallegos, et al., 2006).

Patient education is an important part of disease control in patients with type 2 diabetes, however what that entails is still not clear. Ko, Song, Kim Lee, Kim, Shint, Cho, Parks, Jeong, Yoon, Cha, Son, & Ahn (2006) studied a structured diabetes education program at the university affiliated diabetes center of St. Vincent's Hospital in Seoul, South Korea. The purpose of this study was to examine the effects of a structured intensive diabetes program for people with type 2 diabetes with an emphasis on long-term control. A cognitive-behavioral approach was used as the framework for this study.

Patients (547) who were admitted with type 2 diabetes and poor glycemic control symptoms were recruited for the study. Exclusion criteria included age greater than 70, mental illness, inability to participate in the recommended physical activity, and severe medical illness. The 437 patients who met all criteria were randomly assigned to either an intervention group or a control group (Ko, et al., 2006).

The intervention was a 5-day education program that was conducted within a group setting with family members allowed to participate. Patients were assessed 2 weeks after discharge and then every 3 months for 4 years. Blood pressure, body mass index, and random blood glucose were measured at each follow up visit. Fasting glucose and hemoglobin A1C (HgbA1C) were measured 2-3 times a year. Dietary habits (1 = irregular, 5 = tightly controlled), frequency of self-monitoring of blood glucose (SMBG) (1 = never, 5 = daily), and physical activity (1 = never, 5 = 150 minutes a week-daily) were monitored annually (Ko, et al., 2006).

Sample size was determined to be large enough to detect a 0.6% difference in HgbA1C between the intervention and control groups. Clinical characteristics were stated as a means plus or minus standard deviation and an unpaired *t* test was used for comparisons. Diet, SMBG, and physical activity were compared using a χ^2 test and weighted least-square methods determined trends. Subgroup analysis was done to determine any differences in glycemic control within the intervention group. Of the intervention group ($n=219$), 59 were lost during follow up and of the control group ($n=218$), 70 were lost (Ko, et al., 2006).

The researchers found a significantly lower frequency of hospital admissions for the intervention group (median = 0.8) versus the control group (median = 1.0). HgbA1C at year one was lower in the intervention group and month six (7.1, +/- 1.5) versus the control group (7.9, +/-

1.4) and at 4 years (7.9, +/- 1.2) versus the control group (8.7, +/- 1.6) (Ko, et al., 2006). At year one, 79% of the intervention group scored 4-5 for diet versus 10.2% of the control, 67.9% for intervention versus 9.2% for control scored 4-5 for SMBG, and 66.4% intervention versus 24.6% control scored 4-5 for physical activity. Subgroup analysis of the intervention group showed that those who had a mean HgbA1C >7.9% over the four years had diabetes for a significantly longer period of time, at year one the intervention group (76%) demonstrated more tightly controlled diet (score 4-5) than those in the control group (10.2%), a higher initial HgbA1C, and were more likely to be treated with insulin (Ko, et al., 2006).

The researchers (Ko, et al., 2006) concluded that the intervention was effective in producing and maintaining a decrease in HgbA1C scores and physical activity was relatively well sustained. However, results for adherence to lifestyle modifications at the 4-year time for SMBG and diet reduced to about 30% of the intervention group and 20% of the control group. The researchers suggest re-education at 1-year and believe that continuous patient monitoring and encouragement combined with the development of new education programs will improve clinical outcomes.

Minority groups, who have the highest incidence of type 2 diabetes combined with limited access to self-management resources and support, have had limited success with traditional education approaches. Gucciardi, DeMelo, Lee, and Grace (2007) undertook a study to determine the impact of two culturally competent education methods, individual counseling versus individual counseling in conjunction with group education, on Portuguese Canadian adults with type 2 diabetes. The researchers wanted to compare and explain any differences between the two groups. The framework for the study was the Theory of Planned Behavior.

The sample of 61 patients was drawn from the Toronto Western Hospital Diabetes Education Center in Toronto, Ontario, Canada and patients were randomly assigned to counseling only (n = 36) and counseling plus group education (n = 25). Inclusion criteria were a diagnosis of type 2 diabetes, speaking Portuguese, and willingness to participate. Exclusion criteria were renal dialysis, prior attendance at a similar education program, and mental illness. Individual counseling consisted of a single session lasting 90 minutes to 2 hours. Group classes were 15 hours over 3 consecutive days with five to eight patients per class (Gucciardi, et al., 2007).

HgbA1C levels and responses to questionnaires were assessed at baseline and at 3 months. The questionnaire, based on the Theory of Planned Behavior, consisted of four parts and each part measured on a five-point scale. The first part measured subjects' attitude (reliability = 0.61) with a response range from good (1) to bad (5) and enjoyable (1) to unenjoyable (5). The second part assessed subjective norms (reliability = 0.71) with a response range from strongly disagree (1) to strongly agree (5) or approve (1) to disapprove (5). The third part measures perceived behavioral control (reliability = 0.84) with a response range from strongly disagree (1) to strongly agree (5). The fourth, intentions (reliability = 0.57) with a response range from strongly disagree (1) to strongly agree or definitely do (1) to definitely do not (5) (Gucciardi, et al., 2007). The subjects also completed the nutrition component of the Summary of Diabetes Self-Care Activities Questionnaire that measures diet adherence (1 = never, 5 = always) (reliability = 0.57). The questionnaire was validated using Pearson's correlations. The questionnaire was translated into Portuguese with the translation was examined by a licensed bilingual interpreter and three Portuguese-speaking staff members. A pilot study was completed

with the questionnaire with 20 Portuguese-speaking patients who were not part of the study. Content validation was supported (Gucciardi, et al., 2007).

The researchers stated that the need to commit to 3 consecutive days of classes affected recruitment. Study participants were more likely to be female (68.8%), married (78.7%), have less than a ninth grade education (90%), an income less than \$19,000 (75.4%), and a family history of diabetes (77%). There was no difference found between groups (Gucciardi, et al., 2007).

Statistical analysis was accomplished using chi-square, Pearson's correlations, and *t*-tests. Analysis of covariance also was performed. All participants significantly improved in attitudes (2.28 +/- 0.13, $p < 0.001$), perceived behavioral control (0.37 +/- 0.11, $p < 0.001$), subjective norms (0.43 +/- 0.08, $p < 0.001$), intention to adhere to diet (0.37 +/- 0.05, $p < 0.001$), self-reported nutrition adherence (0.39 +/- 0.08, $p < 0.001$), and HgbA1c levels (0.51 +/- 0.90, $p < 0.001$) (Gucciardi, et al., 2007) Results also indicated that the group that received group education in addition to counseling had a significantly greater perceived behavioral control (0.16 +/- 0.11, $p < 0.05$), more positive intentions (0.20 +/- 0.11, $p < 0.05$), and better adherence to nutrition management (0.42 +/- 0.14, $p < 0.05$) at 3 months than the group who received counseling only (Gucciardi, et al., 2007).

The researchers concluded that there is an additional benefit to culturally competent group education combined with individual counseling over counseling alone. Given the increase in globalization, population migration, and ethnic diversity, there is also a significant need for patient education to be culturally competent (Gucciardi, et al., 2007).

Patients are responsible for day-to-day management of their disease and require the necessary knowledge, skills, confidence and self-care behaviors in order to achieve desired outcomes.

Research is still unclear how to help the patient acquire these resources. Atak, Gurkan, and Kose (2008) evaluated the effect of patient education on knowledge, self-management behaviors, and self-efficacy in patients with type 2 diabetes. This study was a randomized single blind control design (Atak, et al., 2008).

The sample of 80 was drawn from the Diabetes Centre, an outpatient clinic in the Department of Endocrinology and Metabolism, Ankara University, Turkey. Patients regularly attended the centre for treatment. These patients were randomly assigned to either an intervention group ($n=40$) or control group ($n=40$) (Atak, et al., 2008). The intervention consisted of an education program that was given to five groups of 7-12 patients three months after the initial assessment. The program was broken down into two 45 minute sessions one week apart and covered BGSM, hypo and hyperglycemia, exercise, diet, weight control, foot care, and the importance of medical care. This was delivered in a question based patient centered format that consisted of answering patient's questions. A posttest identical to the pretest was given to both groups 2 weeks after the intervention (Atak, et al., 2008).

Participants were administered a questionnaire that asked for patient characteristics including age, gender, educational level, body mass index, duration of diabetes, and type of treatment; knowledge of diabetes; self management behaviors including exercise, preventing hypoglycemia, BGSM, weight control, retinopathy, foot care, and blood pressure. They also completed the Diabetes Self-Efficacy Scale (DSES) which measured confidence about diets and foods, exercise, hypoglycemia and blood sugar variations, changes that required a visit to the

doctor, and ability to control diabetes so that it didn't interfere with the ability to do what they wanted (Atak, et al., 2008). The DSES utilized a Likert scale ranging from 1 (never) to 5 (very good) at 1-5 and had an acceptable Cronbach's reliability coefficient of 0.74 (Atak, et al., 2008).

Results indicated no significant difference in demographics between the intervention and control groups. The researchers reported a limited improvement in patient knowledge in both groups (control group = 0, intervention group = 2, $p = 0.247$ before education, control group = 1, intervention group = 4, $p = 0.179$ after education). The intervention showed improvement in number walking though not significant (not walking, control group = 12, intervention group = 13, $p = 0.88$ before intervention, control group = 16, intervention group = 6, $p = 0.43$ after education). There was a significant improvement in trying to regulate blood glucose to prevent retinopathy (control group = 6, intervention group = 11, $p = 0.274$ before education, control group = 7, intervention group = 21, $p = 0.002$). The researchers also stated an improvement in self-efficacy for the control group (control group = 19.4 +/- 4.3, intervention group = 20.0 +/- 4.0, $p = 0.538$ before education, control group = 19.4, intervention group = 21.9, $p = 0.006$ after education) (Atak, et al., 2008).

The researchers conclude that a short-term education program developed based on patient needs could improve disease management. The need however for longer-term education and support also was necessary. It was proposed that long-term education programs should be developed and modified on the basis of patient needs and concerns (Atak, et al., 2008).

Holidays can have a negative effect on glycemic control in patients with type 2 diabetes. Chen, Wu, Jap, Chen, & Lin (2008) conducted a study to determine the effect of individual patient education and disease management versus education using an eight-page holiday

reminder pamphlet. The quasi-experimental study took place over the Chinese New Year. The study design was quasi experimental.

The convenience sample of 102 patients with type 2 diabetes was drawn from the Taipei Veterans Hospital. Inclusion criteria were a diagnosis of type 2 diabetes, age from 50 to 70, were treated with oral antidiabetic drugs. Exclusion criteria were proliferative retinopathy, pregnancy, insulin therapy, or diabetic nephropathy with chronic kidney disease above stage 4 (Chen, et al., 2008).

Participants were randomly assigned to either program 1 (P1) (50 patients) or program 2 (P2) (52 patients). Program 1 consisted of managed care combined with individual counseling performed quarterly. Program 2 consisted of an eight-page holiday reminder pamphlet about diet, exercise, and travel. Participants in both groups had regular assessment of HgbA1C levels, blood pressure, lipid levels, as well as eye, renal, and foot screenings. Screenings for all participants were completed prior to randomization (Chen, et al., 2008).

Participants were seen on four occasions. Visit one was between November 26 and December 31, 2004. Visit two was between January 1 and February 5, 2005. Visit three was between February 13 and March 20, 2005. Visit four was between March 21 and April 24, 2005. Glycemic change was measured for the preholiday period (visit one to visit two), the holiday period (visit two to visit three), and the post holiday period (visit three to visit four) using fasting plasma glucose and fructosamine levels. HgbA1C levels were measured at visit one, visit four and every four months after through December 2005. Urine albumin to creatinine ratios and serum lipid, creatinine, and alanine aminotransferase levels were checked at visits one and four. Weight, blood pressure, and pulse were measured at each visit (Chen, et al., 2008).

Subjects were demographically well matched between groups. Ninety three subjects (P1=48, P2=45) completed the four visits over the holiday and 89 (P1=46, P2=43) completed the 12-month study. Fructosamine levels increased for P1 subjects (7.4, SD 8.3) and decreased for P2 subjects (-5.3, SD 8.3) during the preholiday period however there was no significant difference between groups during the holiday and post holiday periods (Chen, et al., 2008). HgbA1c levels during the holiday period increased in both groups and were significantly higher in P1 (0.34%, SD 0.21%) than P2 (0.09%, SD 0.16%). The 12-month changes in HgbA1C levels were 0.18% (95% CI, -0.09% to 0.74%) in P1 and -0.06% (95% CI, -0.34% to 0.22%) in P2 and were not statistically significant. Fasting glucose was significantly higher in P1 (187.1, SD 46.4) than P2 (163.1, SD 42.6) at visit two and higher in P1 (199.9, SD 52.1) than P2 (171.2, SD 43.5) at visit three (Chen, et al., 2008).

The researchers stated that their primary hypothesis was that patients who received regular diabetic management would have better glycemic control during the holidays. They stated that within this experiment P1 was considered the experimental group and P2 was considered the control and that P2 was given the pamphlet out of ethical considerations. They found, however, that patients who received holiday specific educational pamphlets had better glycemic control. The researchers felt that this could be applied to other holidays such as Thanksgiving (Chen, et al., 2008).

Type 2 diabetes has been shown to be a major health concern with long-term complications that can be addressed through patient education as noted previously however research is still needed to determine what is effective. Jeffries (2008) undertook a study that used HgbA1C levels to evaluate a community based diabetes program. The author states three theories

for the framework. The first is the use of Diabetes Self Management Education, which teaches patients to self manage glucose to address symptoms, treatment, physical and social consequences, and lifestyle changes. The second theory is adult learning which engages the participant through respect and with goals that are both practical and of immediate relevance. The final theory is group learning that incorporates increased contact and provides reunion opportunities.

The convenience sample of 19 was drawn from a community clinic in Texas. The sample participated in a five-session Do Well Be Well education program for patients with type 2 diabetes. HgbA1C was measured at least 2 months prior to education and at least 2 months afterword. Inclusion criteria were participation in all five sessions, a diagnosis of type 2 diabetes, 18 years of age or older, and availability of lab data (Jeffreys, 2008).

Results revealed a drop in HgbA1c from $M = 8.72$, $SD = 2.91$ to $M = 6.73$, $SD = 0.73$, $t = 2.63$, $p < .05$. The author stated that research showed that a 1% decrease in HgbA1C resulted in a 21% reduction in mortality, a 14 % reduction in myocardial infarction, and a 37% reduction in microvascular complications (Jeffreys, 2008).

The researcher concluded that the Do Well Be Well program provided an inexpensive, convenient, effective way to positively influence both health and economic outcomes for the adult diabetic population (Jeffreys, 2008). This type of program could be implemented through the collaboration of health providers and community leaders. The researcher also suggested that further research is needed to improve evidence-based guidelines for diabetes education (Jeffreys, 2008).

Diabetes self-management education (DSME) is considered a critical component for clinical control of type 2 diabetes. The Healthy People 2010 campaign has a goal of increasing the number of people who receive diabetes education from 40 % in 1998 to 60% in 2010 (Siminerio, Ruppert, Emerson, Solano, & Piatt (2008). Barriers to education exist including access and delivery models. Siminerio, et al (2008) evaluated the affect of implementing Point-of-Service diabetes Education (POSE) on HgbA1C levels and low-density lipoprotein levels (LDL). The study design was longitudinal quasi-experimental.

The convenience sample of 784 individuals who received the POSE intervention was drawn from 4,560 patients in four practices in the Pittsburg area and referred for the intervention by the physician. The intervention consisted of the POSE education given by a certified diabetic educator either individually or in small groups depending on the availability of suitable space within the practice. Inclusion criteria were at least one lab value for either HgbA1C or LDL prior to the intervention (Siminerio, et al., 2008). The control group received disease management and whatever education or counseling was given by the physician and office staff during normal appointments.

The mean age of the POSE group was 61.0 years versus 63.5 years for the control group and 52.1% in the experimental group were women versus 50.2% for the control group. From January, 2003 to December, 2006, the intervention group had significantly higher HgbA1C levels (7.8% vs. 7.2%) but did not have significantly different LDL levels (113.1 vs. 109.6). There were significant decreases in HgbA1C levels in both the intervention group (-0.29%) and the control group (-0.28%). The proportion of individuals in the POSE group with HgbA1C levels <7% increased from 38.6% to 55.2% and from 53.2% to 62.3% in the control group

(Siminerio, et al., 2008). LDL levels decreased significantly for both POSE patients (-16.1 mg/dL) and control patients (-8.6 mg/dL) with a significant difference between groups of 7.1mg/dL (Siminerio, et al., 2008).

The researchers conclude that use of a certified diabetic educator is an effective way of increasing DSME for diabetic patients. They also acknowledge that between group differences may in part reflect the fact that physicians referred patients for the POSE intervention and may have done so on the basis of perceived need. Additionally, those who did not receive POSE may have received DSME from other sources, as this was not tracked within the control group (Siminerio, et al., 2008).

Diabetes is a significant problem within the Mexican-American community and research has shown that self-management education can reduce comorbidities. Vincent (2009) conducted a study to determine the affect of a culturally tailored diabetes intervention for Mexican-Americans on self-care and conducted a focus group to examine participant satisfaction. The conceptual model was Chronic Disease Self-Management, which is based on Social Cognitive Theory.

The convenience sample of 20 patients with type 2 diabetes was chosen from a community health center in Tucson, Arizona and randomly assigned to either an intervention or control group. Inclusion criteria were a diagnosis of type 2 diabetes, aged 18-75, and self-identity of Mexican-American. Patients who were pregnant, had a health condition such as heart failure, or had participated in a diabetes education program within the previous 12 months were excluded (Vincent, 2009).

The patients were given a series of questionnaires. The 12 item Short Acculturation Scale for Hispanics (SASH) (reliability=0.92) uses a 5-point Likert scale (1=only Spanish/all Hispanics, 5=only English/all Americans) with higher scores indicating greater acculturation. The Spanish version of the Summary of Diabetes Self-Care Activities Questionnaire (reliability=0.68) measured self-care activities including diet, exercise, blood sugar testing, foot care, and tobacco use using a 0-7 self-report scale with higher scores indicating greater self-management (Vincent, 2009). The Diabetes Knowledge Questionnaire – Spanish version (reliability=0.88) used 24 items with the total score of correct answers summed and higher scores equaled greater diabetes knowledge. Response range was not stated The Spanish version of the Self-Efficacy for Diabetes Scale (reliability=0.85) measured self-confidence in performing various diabetes self-management behaviors using eight items. Response range was not stated. Measures of glycemic control included blood glucose, HgbA1C, weight, and body mass index (BMI). All data was collected at baseline, the end of the intervention (week 8), and 4 weeks post intervention (Vincent, 2009).

The 8-week intervention consisted of weekly 2-hour group sessions, which included culturally tailored didactic content including pathophysiology, treatment, diet, exercise, and self-management; cooking demonstrations, and group support sessions. Intervention group members also were given pedometers from which they entered the number of steps in a daily activity log that was monitored by the researchers on a weekly basis. The control group was given care and education, which consisted of a 10-15 minute session with a physician or nurse practitioner two to four times a year (Vincent, 2009).

The researcher found that although acculturation was similar in both groups, formal education was significantly lower in the intervention group (6.4 years, SD=4.2) than in the control group (13.1 years, SD=4.9). The intervention group had a significant decrease in mean weight loss (5 pounds) and BMI decreased from 30.6 at baseline to 29.8 at 4 weeks post intervention while the control group had a slight increase in both measures (Vincent, 2009). Some self-management behaviors including self glucose monitoring and physical activity significantly improved for the intervention group but not for the control group. Numeric results for these findings were not reported in this article by the researcher. Mean number of steps as recorded by pedometers significantly improved from 4175 to 7238 per day ($t=-2.51, p=0.03$) in the intervention group (Vincent, 2009). Control group members were not issued pedometers.

Four members of the intervention group also participated in a focus group. The researcher found two main themes emerging from qualitative analysis of the discussion comments. The first main theme was that participants in the intervention group felt a greater degree of control as a result of increased knowledge about the disease and self-management behaviors. The second main theme was the benefit in terms of healthy behaviors that resulted from participants sharing knowledge gained through the intervention with family members. The researcher suggested that in the future family members should be included in diabetes education (Vincent, 2009).

The researcher concluded by stating that culturally competent diabetes education is beneficial to both patient and family members. Physical activity rather than exercise should be stressed due to the negative connotations that many people place on the term exercise. The researcher stated the need for further research to determine if decreases in weight and BMI

would continue over time. The limited time span and small group size are limitations of this study (Vincent, 2009).

Summary

Type 2 diabetes is becoming increasingly prevalent in our society today. This is supported by both CDC figures (2001, 2009) and by virtually all of the research papers cited here. Research supports that the key to management of the disease is patient education. Current research addresses the question of what is the most effective way to provide this education.

Several studies including that of Ko, et al (2007) and Gucciardi, et al (2007) support delivering education within a structured group setting. Benefits derived from this type of education include not only improvement of physiologic measures and lab values that are frequently used to monitor disease management (Jeffreys, 2008) (Siminerio, et al., 2008) (Polonsky, et al., 2003), but also on self care behaviors (Gallegos, et al. 2006) Gucciardi, et al., 2006) and self efficacy (Atak, et al., 2005). Patients expressed greater satisfaction with a formalized group approach (Gallegos, et al., 2006) (Vincent, 2009).

It also was apparent from the research that any educational approach must take into account the patients' circumstances, culture, and resources. Something as simple as holidays could have a major impact on glycemic control (Chen, et al., 2008). Language and culture also appeared to have a direct impact on education (Vincent, 2009) (Gucciardi, et al., 2007). Patient resources and background can have an effect on not only the patient's ability to learn but also the ability to participate in the educational experience (Gallegos, et al., 2006).

The literature supported the idea of providing patient education within an ongoing, structured format. It supported the idea of providing that education in a way that was relevant to

the person being educated using a language and approach that the patient could understand.

Above all, the literature supported patient education as not only needed but also desired.

Chapter III

Methods and Procedure

Successful management of type 2 diabetes depends on the ability of the patient to self-manage the disease and that in turn depends on the patient being equipped with the skills and knowledge necessary. This knowledge can only come about through a patient education program that is comprehensive and ongoing. This study is a partial replication of Ko, et al.'s (2007) study. The purpose of this study is to examine the effects of a structured intensive diabetes education program on self-care behaviors and disease management based on Orem's self-care deficit theory. This chapter includes information about population, sample, procedure, measurement, and design used to guide this study.

Research Questions

1. Does a structured intensive diabetes education program have an effect on self-care behaviors in patients with type 2 diabetes?
2. If so, is this effect reflected in clinical values?
3. Is there an increase in patient well being with diabetes education?

Population, Sample, and Setting

The population will consist of patients with either a primary or recent diagnosis of type 2 diabetes who will be given diabetes education while in two hospitals in Kalamazoo, Michigan. The anticipated convenience sample will be 100 patients who meet inclusion criteria. Inclusion criteria will be an age of at least 18 years of age, a primary or recent diagnosis of type 2 diabetes and consent for participation. Exclusion criteria are dementia and previous systematic diabetes education.

The settings are Bronson Hospital, a 400-bed acute care facility and Borgess Medical Center, a 343-bed acute care facility. Both are located in Kalamazoo, Michigan and, between the two, provide virtually all of the inpatient care within the greater Kalamazoo area. Each facility sees approximately 400 patients a year who meet the criteria for this study.

Protection of Human Subjects

This study will be submitted to the institutional review boards of Ball State University, Bronson Hospital, and Ascension Health, the parent organization of Borgess Medical Center for approval prior to the beginning of the study. Consideration will be based on adherence to ethical principals for research. Prior to initiation of this study, a thoughtful and thorough identification of risks versus benefits will occur. Subjects will be informed of risks and benefits in a cover letter. Benefits include an increase in knowledge for health care professionals of the methods necessary for efficacious diabetes education. No risks were identified. Voluntary participation including the right to refuse to participate at any time during the study will be thoroughly explained to participants prior to enrollment. A cover letter with full disclosure of the study will be provided to the participants. All data collected will be anonymous.

Procedure

After receiving approval from the three agencies that are principally responsible, the project will be introduced to the diabetes nurse educators as well as affected physicians and staff for approval and comments. Content and timeframe of the intervention will be developed in cooperation with both facilities. Content of specific sections within the intervention will be developed in cooperation with the specific personnel including diabetes educators, nutritionists,

and pharmacists. One goal will be to develop a common teaching intervention that is acceptable to both facilities.

The subjects will be recruited from inpatients with a primary or new diagnosis of type 2 diabetes with a goal of 50 patients from each facility as a convenience sample. All subjects will be provided with a full disclosure and, if they approve, will be asked to sign a written consent. Subjects then will be randomly divided into an interventional group and a control group that are as equally populated as possible. The researcher will obtain demographic data at baseline and administer study instruments at baseline, three months, six months, one year, and two years. All measurements will be done through the mail and anonymity and confidentiality will be assured through the use of an assigned number given to the patient with the first mailing.

Research Design.

This study will use a quasi-experimental design. The purpose of this design is to examine the cause and effect relationship between independent and dependent variables. The dependent variables will be the type of diabetes education provided to the patient – structured intensive diabetes education that takes place in small group sessions of eight to ten patients versus the traditional one on one approach. The independent variables will be physiological measures including HgbA1C levels, total cholesterol, blood urea nitrogen, serum creatinine, and fasting glucose, self care behaviors, and well-being, both of which will be measured by the questionnaires.

Instrumentation, Validity, and Reliability

Demographic data will include age, gender, education, employment status, smoking and alcohol habits, and living arrangements – whether the patient lives alone or with others. This will

help to assess whether group characteristics are similar and, if they differ, how so and do the differences impact the results of the study. This data will be collected at the beginning of the study.

The intervention and control groups will be subject to demographic analysis, intermittent assessment of lab values including HgbA1C levels, total cholesterol, blood urea nitrogen, serum creatinine, and fasting glucose, physiological measures including height, weight, pulse, respirations, and blood pressure, and application of questionnaires. Measurements will be taken at the beginning of the study, at three months, six months, twelve months, and two years. This time frame should provide data that will indicate how well the subject was able to learn as well as how well the subject was able to retain and incorporate the material for glycemic control. This time frame also may give some indication as to when a refresher course would be appropriate. Subjects in both groups will be asked to maintain a log of blood glucose self tests to determine frequency of testing and degree of control. Physiological measures will include height, weight, blood pressure, and body mass index. These measures will occur at baseline, three months, six months, one year, and two years.

Four questionnaires will be administered under the same time frame. The Diabetes Self-care Activities Questionnaire (Gallegos, Ovalle-Berumen, and Gomez-Meza, 2008) which consists of 11 multiple choice questions that examine compliance with type 2 diabetes treatment such as eating habits, exercise, medication, and blood glucose monitoring with low scores indicating poor compliance. Internal consistency was reported at a Cronbach's alpha reliability of .71 (Gallegos, et al., 2008) to .80 (Sacco, Wells, Friedman, Matthew, Perez, & Vaughan, 2007). A panel of experts will determine content validity.

The Barriers to Self-Care Scale (Gallegos, et al., 2008) contains 31 questions with answers ranging from 1 to 7 about environmental circumstances that may interfere with diabetes self care. Low scores indicate less difficulty in following self-care routines. For this study only the 19 questions pertaining to barriers to diet and exercise will be used. Internal consistency of the 19 question format was reported a strong Cronbach's alpha reliability of .79 (Gallegos, et al., 2008). A panel of experts will determine content validity.

The Specialized Self-Care Capabilities Scale (Gallegos, et al., 2008) consists of 14 items about specific skills to manage diabetes care. The questionnaire uses a Likert format with scores ranging from 1 to 4. Low scores indicate fewer skills. Internal consistency for this questionnaire was reported a Cronbach's alpha reliability of .63 which indicates the need for caution in its use (Gallegos, et al., 2008). A panel of experts will determine content validity.

The Diabetes Quality of Life Measure (Watkins & Connell, 2004) is comprised of 46 items that measure life satisfaction, impact of treatment, worry, and general well-being in patients with diabetes. The questionnaire uses a 5-point Likert scale with high scores indicating a worse quality of life. Internal consistency for this questionnaire was reported a Cronbach's alpha reliability of .67-.88 (Watkins, et al., 2004). A panel of experts will determine content validity.

Measures of Data Analysis

Descriptive statistics will be used to analyze study variables. Demographic variables will be examined using Pearson's chi-square and independent *t* tests. Paired *t* tests will be used to examine changes within each group between pre-test scores and post-test scores and will be performed at the test intervals as well as at the conclusion of the study. Analysis of covariance will be used to test differences in outcomes between the two groups.

Summary

This study, which is a partial replication of Ko, et al's (2006) study, will examine the effects of a structured intensive diabetes education program versus traditional one on one teaching on a convenience based sample of 100 subjects. The study design will be quasi-experimental with subjects divided randomly into an experimental and control groups. The study will look at the effect of these two teaching methods on physiological parameters, self-care behaviors, and patient well-being. This study will attempt to provide information to researchers and diabetes educators that will suggest teaching methods and influence further research.

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RES 697 Research

Source	Problem	Purpose	Framework or Concepts	Sample	Design	Instrument	Results
Atak, Gurkan, & Kose (2005)	Patients are responsible for day-to-day management of their disease but don't the necessary knowledge, skills, confidence and behaviors in order to be effective	What is the effect of patient education on knowledge, self-management behaviors, and self-efficacy in patients with type 2 diabetes?	Concepts: Patient knowledge, self management, self efficacy	80 patients – 40 in the intervention group and 40 in the control	Randomized single blind controlled experimental study	Researcher created knowledge test Diabetes Self Efficacy Scale Physiological measures Demographics	Limited improvement in patient knowledge. Behaviors significantly improved were walking and trying to regulate blood glucose to prevent retinopathy. Improvement in self-efficacy in experimental group.
Chen, et al (2008)	Patients with type 2 diabetes have reduced glycemic control during holidays	What is the effect of diabetes education versus a pamphlet on glycemic control?	Concepts: Outcomes of diabetes education. Glycemic control.	102 patients – 50 in the intervention group, 52 in the control.	Longitudinal	Physiological measures	Control group had better glycemic control than intervention group.
Gallegos, Ovalle-Berumen,	In Mexico, diabetes has risen to the	What is the efficacy of a controlled	Concepts: Metabolic control, self	Sample consisted of 29 in the	Quasi-experimental longitudinal	Diabetes Self-care Activities Questionnaire	Significant difference in HgbA1C levels between groups in the

<p>& Gomez-Mesa (2006)</p>	<p>second leading cause of mortality in 2005. In addition, 50-60% of the diabetic population had poor self management</p>	<p>nursing intervention focused on education and counseling.</p>	<p>care agency, adaptation</p>	<p>experimental group and 28 in the control with 25 and 20 respectively remaining.</p>		<p>Specialized Self-Care Capabilities Scale ATT39 Scale Barriers to Self-Care Scale. HgbA1c levels</p>	<p>second, fourth, and fifth measurements. An increase in glycemic control within the experimental group at each measurement Positive correlation between adaptation, self care agency, and self care behavior and HgbA1C</p>
<p>Gucciardi, Demelo, Lee, & Grace (2006)</p>	<p>Minority groups, who have the highest incidence of type 2 diabetes combined with limited access to self-management resources and support, have had limited success with traditional</p>	<p>What is the impact of two culturally competent education methods, individual counseling versus individual counseling in conjunction with group education, on Portuguese</p>	<p>Theory of Planned Behavior Concepts: Cultural competency, group education</p>	<p>The sample consisted of 61 patients with 36 in counseling only and 25 in counseling plus group education.</p>	<p>Controlled trial experimental design</p>	<p>HgbA1C levels Questionnaire based on the Theory of Planned Behavior</p>	<p>All those in the study significantly improved in attitudes, perceived behavioral control, subjective norms, intention to adhere to diet, self-reported nutrition adherence, and HgbA1c levels. The group that received group education in addition to counseling had significantly greater perceived behavioral control, more positive</p>

	education approaches.	Canadian adults with type 2 diabetes and to compare and explain the differences between the two groups?					intentions, and better adherence to nutrition management at 3 months than the group who received counseling only.
Huang, Gorowara-Bhat, & Chin (2005)	Patient education must include the patients' goals but they are not well understood	Semi structured interviews to examine patient goals	Grounded theory, qualitative. Concepts: Patient treatment goals	28 type 2 diabetes patients with additional cardiovascular diagnosis	Qualitative, grounded theory	Semi structured interviews	Majority of patients expressed views in social and functional language. Common theme was goal of independence in activities of daily living.
Jeffreys (2008)	Type 2 diabetes has been shown to be a major health concern with long-term complications	What is the validity of HgbA1C levels to evaluate a community diabetes program?	Adult and group learning. Concepts: Community collaboration Diabetes self management	Sample was 19 consenting individuals	Longitudinal	HgbA1C levels	Decreased HgbA1c values associated with decreased mortality and morbidity.

	but information on patient education is needed.		education Self care behaviors				
Ko et al. (2007)	Patient education is an important part of disease control in patients with type 2 diabetes but information is needed on proper approach.	What are the effects, with an emphasis on long-term control, of a structured intensive diabetes program for people with type 2 diabetes?	Cognitive-behavioral	437 patients were randomly assigned to either an intervention group or a control group. Of the intervention group ($n=219$), 59 were lost during follow up and of the control group ($n=218$), 70 were lost during follow up.	Longitudinal	Physiological measures. Researcher written questionnaire on diet, physical activity, and SMBG frequency.	Significantly lower frequency of admissions for the intervention group versus the control group. Lower HgbA1C levels for intervention group. Improved diet and physical activity for intervention group

Polonsky et al. (2003)	Long-term complications can be delayed or prevented by improved metabolic control but information is needed on patient education.	What is the effect of the addition of education to medical management of type 2 diabetes?	Concepts: Group education. Medical management. Skills training.	117 patients were randomly assigned to either DOIT or EDUPOST diabetes education programs	Experimental	HgbA1C levels. Summary of Diabetes Self-Care Activities	Significant improvement in glucose monitoring, diet, exercise, and HgbA1C levels in DOIT group compared to EDUPOST.
Simenerio et al. (2008)	Diabetes education is critical but the number of patients who receive it is small	What is the effect of diabetes education versus traditional disease management?	Concepts: Diabetes Self-Management Education. Disease management. Healthy People 2010.	784 type 2 diabetes patients randomly assigned to intervention or control groups	Longitudinal	Physiological measures	Significant decrease in HgbA1c levels in control and intervention groups. Decrease in LDL was significantly greater for intervention group.
Sprague, Shultz, & Branen (2006)	Information is needed on the effect of goal setting on diabetes self management.	What are goals that patients set during education versus current goals, to describe	Concepts: Diabetes education, goal setting, self care	97 patients. Inclusion criteria were a diagnosis of type 2 diabetes and completion of diabetes	Descriptive correlational	Researcher created Total Design Method questionnaire, 38 items	Significant relationship between patient adherence and control behaviors. No significant relationship between patient beliefs and adherence.

		patients' experiences with goal setting, and to compare goal-setting experiences to adherence?		education between 6 months and 2 years prior to the start of the study.			
Trento et al. (2004)	Patient education based on specific teaching models, and retention of knowledge is directly tied to quality oriented diabetes care but methods are sometimes at conflict with patient needs.	What changes in knowledge, problem solving ability, and quality of life result from systematic group care?	Concepts: Patient knowledge, problem solving ability, quality of life.	The control group consisted of 56 patients and the remaining 56 were divided into six education groups.	Longitudinal	<p>GISSED questionnaire</p> <p>CdR questionnaire</p> <p>DQOL questionnaire</p> <p>Physiological measures</p>	<p>Knowledge of diabetes and problem solving from year 1 improved in group care and worsened in individual. Quality of life improved from year 2 in group care and worsened in individual.</p> <p>HgbA1c increased with individual care but not with group. BMI and HDL levels improved in the intervention group but were not significantly different from the control.</p>

Vincent (2009)	Information is needed on cultural competence in diabetes education	What is the effect of a culturally tailored diabetes education program for Mexican Americans on physical activity? What main themes regarding education are identified by focus group	Concepts: Culturally tailored education. Self care. Adherence.	Quantitative 20 patients randomly assigned to intervention or control groups. Qualitative 4 patients	Longitudinal Descriptive correlational	Short Acculturation Scale for Hispanics Summary of Diabetes Self-Care Activities Questionnaire Diabetes Knowledge Questionnaire Self-Efficacy for Diabetes Scale Physiological measures	Intervention group had significant weight loss and BMI over control group. Intervention group had significant improvement in glucose monitoring and physical activity over control. Themes: Greater degree of control. Benefit to families for healthy behavior.
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