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Effectiveness of a Single Individual Diabetes Education Session versus Completion of a Program of Group Classes on Hemoglobin A1c (HbA1c) and Lipids in Type 2 Diabetes Mellitus

by

Devon Marie Hoster

Thesis

Submitted to the School of Health Sciences

Eastern Michigan University

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for the degree of

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in

Dietetics

Thesis Committee:

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Ypsilanti, Michigan
Abstract

**Background:** Diabetes self-management education/training (DSME/DSMT) is a tool for managing diabetes mellitus; however, a research gap exists regarding the clinical effectiveness of completing versus failing to complete a DSME/DSMT program.

**Objective:** This study determined the difference in effectiveness between a single initial individual DSMT session and completion of the full DSMT program via group classes by people with type 2 diabetes.

**Methods:** A retrospective study compared HbA1c and lipid values between the “individual education” and “group education” groups from pre- to post-program from the Presence St. Joseph Medical Center’s DSMT program.

**Results:** Statistically significant differences were not found between groups for HbA1c or lipids (p = 0.612). However, clinically significant differences were noted from pre- to post-program in HbA1c and all lipid values in favor of the program-completing group.

**Conclusions:** This study supports the efficacy of program completion in guiding HbA1c and lipid levels toward clinical targets when compared to the same laboratory values for non-completion.
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Chapter 1: Introduction

Background

Diabetes mellitus (DM), the disease associated with frequent episodes of abnormally high blood glucose, has become an increasingly prevalent condition in the United States during the past several decades. Recent estimates from the United States Centers for Disease Control and Prevention (CDC) indicate that nearly 29.1 million people in the U.S. have diabetes; this estimate includes both diagnosed (21.0 million) and undiagnosed (8.1 million) people, the sum of which amounts to approximately 9.3% of the population (CDC, 2014). Diabetes is also associated with a higher number of occurrences of the following complications: heart disease, stroke, hypertension, blindness, kidney disease, nervous system diseases, amputations, and dental diseases (CDC, 2014). Furthermore, the risk of death is increased nearly twofold for persons who have diabetes in comparison to those who do not (CDC, 2014). Management of the disease is therefore essential to preventing or delaying these complications.

Although diabetes is generally managed through a combination of strategies, including pharmacotherapy and other medical care, diabetes education programs, frequently termed Diabetes Self-Management Education (DSME) or Diabetes Self-Management Training (DSMT), have recently become a vital part of comprehensive care (Jarvis, Skinner, Carey, & Davies, 2010; Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012). These programs, which are usually conducted in an outpatient setting, provide practical management tips and techniques and serve as a support for patients who struggle with handling their disease (Mendoza & Rosenberg, 2013). Varying educational formats are used among programs, including individual counseling sessions, group classes, and combinations of group and individual sessions (Mendoza & Rosenberg, 2013). Educational materials, topics discussed, and accreditation status of the program delivering
the education may also vary (Mendoza & Rosenberg, 2013; Jarvis et al., 2010). However, DSME programs continue to increase in number and are the subject of a growing body of research (Jarvis et al., 2010).

Much of the available research focuses on outcomes related to completion of a DSME program versus standard or usual care as obtained from the primary care provider’s office. A small amount of research has addressed comparisons between differing methods of delivery of the same content within programs, such as through a specified number of individual counseling sessions with a diabetes educator versus the same number of group classes also taught by a diabetes educator (Torres, Franco, Stradioto, Hortale, & Schall, 2009; Dalmau-Llorca, Garcia-Bernal, Aguilar-Martin, & Palau-Galindo, 2003; Campbell, Moffitt, & Sanson-Fisher, 1996; Rickheim, Weaver, Flader, & Kendall, 2002), although these studies’ conclusions do not point to a clear, consistent advantage of one type of educational format over another (Mendoza & Rosenberg, 2013). Even further, studies comparing clinical outcomes of patients who have partially versus fully completed a DSME program are quite rare and inconclusive (Liu, Lee, & Brateanu, 2014). This area, a comparison of the impact of “dropouts” to compliant patients, is a research gap that needs to be filled in order for future studies to target methods that could increase patient attendance and compliance (Liu et al., 2014). Additionally, performing that comparison in the context of a standardized, accredited/recognized DSME program, such as those accredited or recognized by the American Association of Diabetes Educators (AADE) or the American Diabetes Association (ADA), would assist with ensuring uniformity of education provided.
Presence St. Joseph Medical Center Diabetes Self-Management Training Program

The Presence St. Joseph Medical Center (PSJMC) Outpatient Clinic’s (Joliet, Illinois) current DSMT program reopened in April 2014 after a several month hiatus and a full restructuring of the educational curriculum. It is accredited by the AADE and is presided over by a registered nurse (RN) who is also a certified diabetes educator (CDE). Newly enrolled patients begin the program via an initial appointment with the CDE, also called the nurse educator. During this appointment, several basic diabetes management concepts are covered (disease process, hyperglycemia, target blood glucose numbers, glucometer usage, general healthy eating, physical activity, and consistency in meal patterns), and the patient is then scheduled to attend a series of three 2-hour classes at the facility within an approximately two-month time frame. These classes cover the seven AADE diabetes self-care behaviors of healthy eating, being active, monitoring, taking medication, problem solving, reducing risks, and healthy coping. Classes are taught by the CDE, with one session guest-taught by a registered dietitian (RD). Patients may also receive medical nutrition therapy (MNT) services from an RD while completing the program; however, not all patients choose to do so, as it is an optional complement to the program.

The pre- and post-program laboratory values hemoglobin A1c (HbA1c), total cholesterol (TC), high-density lipoprotein cholesterol (HDL), low-density lipoprotein cholesterol (LDL), and triglycerides (TG) are requested from each patient’s primary care provider’s office to assist with monitoring patient progress and providing outcomes data to the AADE. Those results are kept both within individual patient charts as well as in the CDE’s program login on the AADE website. To ensure relevance, the CDE specifies on each faxed request form that the most recent laboratory values pre- and post-program should be sent for each patient. The usual time frame for
the physician’s having collected these results is within one year pre- and post-program, although post-program values have usually been collected within six months of the patient’s completing the program.

Furthermore, during the past year, a fair percentage of patients who enrolled in the DSMT program failed to complete it. While some of these patients attended the majority of sessions, others attended only the initial individual session with the CDE. Upon preliminary analysis, it appeared that this program contained sufficient “dropouts” to be compared with patients who had completed the program. Laboratory values for these dropouts were also available, as the same protocol is followed in obtaining all patients’ data regardless of whether they have completed the program. To emphasize the extremes between groups and due to the number of patient records available for comparison, it was decided to compare patients who had attended only the initial individual session with those who had completed the entire program by attending the initial session and all of the group classes.

**Purpose of the Study**

As the body of research regarding differences in effectiveness between patients who have completed versus not completed DSME/DSMT programs is small, further quantitative research was warranted in order to add to the current knowledge base and to provide diabetes educators and program-accrediting associations with information for refinement of program materials and standards to encourage continued patient participation and success. The purpose of this study was to determine the degree of difference in effectiveness between a single individual counseling session versus the completion of that session and all group diabetes education classes in the outpatient setting as evidenced by HbA1c and lipid data from medical profiles of patients diagnosed with type 2 diabetes mellitus (T2DM), who constitute the majority of patients with
DM, in an AADE-accredited program. It was hypothesized that there would be a significant degree of difference in effectiveness between the two groups with a greater degree of improvement in laboratory values in the group that completed the entire program.

**Research Questions**

1. Is there a significant difference in the average degree of reduction in HbA1c levels between patients with T2DM who attended an individual education session versus patients with T2DM who completed an individual session and all group education classes from pre- to post-program?

2. Is there a significant difference in the average degree of reduction in lipid levels between patients with T2DM who attended an individual education session versus patients with T2DM who completed an individual session and all group education classes from pre- to post-program?

**Justification for the Study**

This study was designed to assess the impact of dropping out in relation to program efficacy in an accredited DSME/DSMT program. Study results can be shared with other diabetes centers currently accredited or recognized; these sites may use the data to judge how effective their programs are and to use as a starting point for the further investigation of remedies to patient compliance barriers. The findings also serve to demonstrate the effectiveness of AADE-accredited programs and add to the organization’s growing body of diabetes education research. Lastly, the PSJMC Outpatient Clinic, where the study was conducted, gained quantitative data pertaining to the effectiveness of its current DSMT program from its inception to the present.
Chapter 2: Review of Literature

Introduction to Diabetes

Diabetes mellitus is a complex disease that continues to affect a greater percentage of the world’s population as the years pass. The continuously increasing prevalence of DM demands that healthcare practitioners achieve a solid understanding of the disease itself as well as its currently practiced prevention and treatment methods. The following sections will provide an overview of DM, from its development and classifications to its complications and treatment options. The chapter will conclude with an explanation of the significance of diabetes education programs in relation to disease management.

Pathology. A brief overview of normal food digestion and absorption provides the necessary background against which the metabolic abnormalities of DM may be contrasted. When food is consumed, it is chewed in the mouth, transported down the esophagus into the stomach, churned in the stomach, and broken down even further in the small intestine into tiny molecules that are absorbed into the bloodstream or the lymphatic system (Gropper & Smith, 2013). A molecule’s macronutrient type (either protein, fat, or carbohydrate) determines which route it will take (Gropper & Smith, 2013). Carbohydrates, the main macronutrient of concern in DM, are enzymatically broken down into single molecular units, the majority of which are glucose, before being absorbed from the small intestine (Gropper & Smith, 2013). Glucose enters the bloodstream and is transported to body cells where it is needed, such as those in the brain, heart, liver, and skeletal muscles (Gropper & Smith, 2013). However, before glucose can enter the cells, the hormone insulin, which is made by the pancreas, must attach to receptors on cells’ surfaces to trigger the response that allows entry (Gropper & Smith, 2013). After glucose enters
the cell, it continues down specific pathways to be utilized for energy or stored as energy reserves (Gropper & Smith, 2013).

In DM, however, glucose is unable to enter body cells due to either a lack of insulin, cell receptor resistance to insulin’s action, or a combination of both events (American Diabetes Association [ADA], 2014a). Glucose, in excess, remains in the bloodstream, where it eventually bonds with proteins and lipids in an irreversible process called glycation (Goldin, Beckman, Schmidt, & Creager, 2006). The end result of the series of reactions in the glycation process is the production of advanced glycation end products (AGEs), which tend to build up and cause damage to vascular tissue (Goldin et al., 2006), thus leading to vascular complications, including heart attack, retinopathy, and kidney disease (CDC, 2014).

**Classifications.** Based on these mechanisms, DM is broadly classified as a metabolic disease of the endocrine system in which defects in the secretion and/or action of the hormone insulin result in hyperglycemia, or high blood sugar (ADA, 2014a). Insulin secretion defects are often associated with pancreatic beta cell destruction as the result of an autoimmune response, while insulin action defects are usually related to body tissues’ failure to respond to insulin and may be seen in combination with decreased insulin production not stemming from an autoimmune response (ADA, 2014a). One or both types of insulin defects may occur in individuals, although one of the two faulty mechanisms is usually considered the primary causative factor of the hyperglycemic response (ADA, 2014a). Therefore, DM has been categorized into two main types based on etiology: type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) (ADA, 2014a).

Type 1 diabetes mellitus, which affects approximately 5% to 10% of people with DM, is the result of sharply decreased insulin secretion due to the death of pancreatic beta cells caused
by an autoimmune dysfunction (ADA, 2014a). Type 2 diabetes mellitus, by which 90% to 95% of those with DM are affected, is caused by defective insulin action in relation to poor tissue response, a phenomenon called insulin resistance (ADA, 2014a). Frequently found in combination with insulin resistance are decreases in pancreatic beta cell number and mass, possibly due to the presence of specific genes, and lessened suppression of the hormone glucagon (Spellman, 2010).

Two other classes of DM exist, although they are seen far less frequently and have differing causes (ADA, 2014a). Gestational diabetes mellitus (GDM) is described as glucose intolerance that affects only pregnant mothers; it is usually resolved after the baby’s birth, although it can develop into T2DM (ADA, 2014a). The “other specific types of diabetes” category includes causes such as pancreatic disease, genetic defects in insulin action or beta-cell function, drugs, infections, and endocrinopathies (ADA, 2014a; ADA, 2014b; ADA, 2015).

**Risk factors.** As the etiologies for each type of DM differ, risk factors follow a similar pattern. Those related to T1DM include family history, environmental influences such as a virus, geographic location, earlier-than-recommended exposure to foods like cow’s milk and cereal in infancy, and the presence of diabetes-related autoantibodies (Mayo Clinic Staff, 2014). It should be noted that these specific factors are generally outside the individual’s control, or non-modifiable. In contrast, T2DM features a combination of non-modifiable and modifiable risk factors, including family history, age, race, history of GDM, polycystic ovarian syndrome, weight, physical inactivity, dyslipidemia, and hypertension (Mayo Clinic Staff, 2014). Risk factors for GDM are similar to T2DM, including age, race, family history, and weight (Mayo Clinic Staff, 2014). A cluster of generally modifiable risk factors called the metabolic syndrome, or MetS, also heightens the risk for both T2DM and GDM (Gropper & Smith, 2013). Diagnosis
of MetS necessitates the presence of at least three of the following five conditions: increased waist circumference (≥40 inches for men, ≥35 inches for women), decreased HDL cholesterol (<50 mg/dl in females, <40 mg/dl in males), increased triglycerides (≥150 mg/dl), increased fasting blood glucose (≥100 mg/dl), and increased blood pressure (≥130/85 mm Hg) (Gropper & Smith, 2013). Several of these criteria are also individual risk factors for DM. Especially for T2DM and in part for GDM, the modifiable risk factors are those that are addressed in diabetes prevention efforts.

Complications. As noted, the underlying characteristic of each type of DM is hyperglycemia, the presence of excess glucose in the bloodstream. Increased blood levels of glucose are believed to cause damage to vascular areas of the body via three main mechanisms: oxidative stress, the production of AGEs and sorbitol, and direct endothelial damage by glucose particles (Vithian & Hurel, 2010). The extent of the damage is great: blood flow in the blood vessels is changed, excess proteins are deposited on blood vessel walls, increased coagulation occurs, and endothelial permeability is altered (Vithian & Hurel, 2010). The resulting condition of the blood vessels paves the way for various vascular diseases to occur (Vithian & Hurel, 2010). Two broad classifications currently categorize complications by the size of the blood vessels that are affected: macrovascular and microvascular (Kanthardis, Wang, Carew, & Lan, 2011). Macrovascular complications include diseases of the cardiovascular and peripherovascular systems, and microvascular complications include retinopathy, neuropathy, and nephropathy (Kanthardis et al., 2011).

Statistics from the updated National Diabetes Statistics Report and the CDC display the frequency and severity of these vascular complications in people with diabetes (CDC, 2014; ADA, 2014c). Regarding macrovascular complications, statistics from 2010 indicate that both
heart attack and stroke rates were amplified in adults with DM in comparison to adults without the disease: heart attack rates were 1.8 times greater, and hospitalizations for stroke occurred 1.5 times more often (ADA, 2014c). Likelihood of death from cardiovascular disease (CVD) during the years 2003 to 2006 was 1.7 times greater as well (ADA, 2014c). Furthermore, dyslipidemia, a condition that heightens the risk of heart disease, was present in 65% of adults with DM during the years 2009 through 2012 (ADA, 2014c). Hypertension, which also increases one’s risk of heart disease, was present in 71% of people with DM during the same time period (ADA, 2014c).

Microvascular complications are prevalent in people with DM as well. During the years 2005 through 2008, 28.5% of the diabetic population experienced retinopathy, which can eventually lead to irreversible loss of vision if not caught early enough (ADA, 2014c). Kidney disease, or nephropathy, frequently leads to kidney failure, for which chronic dialysis or a kidney transplant may be the only solutions (CDC, 2014). In 2011, 44% of kidney failure cases were related to diabetes (ADA, 2014c). Furthermore, damage of the nervous system caused by diabetes can result in loss of feeling in extremities and nerve diseases (CDC, 2014). For the most severe cases, amputation may be the only means of correcting the issue (CDC, 2014)—73,000 diabetes-related amputations occurred in 2010 (ADA, 2014c). Dental disease, reduced immunity to illness, decreased physical functional capacity, and depression are also found more often in people with DM than those without it (CDC, 2014). These complications have great potential to decrease a person’s quality of life.

**The case for glycemic control.** The following recent, large studies have explored the relationship between vascular complications and glycemic control and have assisted with providing the basis for government health organizations’ recommendations: the Action in
Diabetes and Vascular Disease—Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE) trial (ADVANCE Collaborative Group, 2008), the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study (ACCORD Study Group, 2008), the Veterans Affairs Diabetes Trial (VADT; Duckworth et al., 2009), the Diabetes Control and Complications Trial (DCCT; DCCT Research Group, 1993), and the United Kingdom Prospective Diabetes Study (UKPDS; UKPDS Group, 1998). Each study provided a unique contribution to the knowledge regarding diabetes complications and glycemic control.

The ADVANCE study compared intensive glycemic control (modified release gliclazide with the addition of other antihyperglycemic agents and/or insulin) to standard control (another sulfonylurea or none at all) in 11,140 participants with T2DM and either a history of or risk factor for macro- or microvascular disease (ADVANCE Collaborative Group, 2008). It did not bring to light any significant differences in incidence of macrovascular risk between the two groups (ADVANCE Collaborative Group, 2008). However, the intensive control group displayed a significant (p = 0.01) 14% reduction in microvascular occurrences after achieving a target HbA1c goal of 6.5% or lower (ADVANCE Collaborative Group, 2008).

The ACCORD study attempted to compare intensive glycemic control, defined as HbA1c less than or equal to 6.0%, with normal glycemic control, defined as 7.0% to 7.9% HbA1c, in 10,251 middle-aged and older adults with T2DM and either established CVD or two risk factors for CVD (ACCORD Study Group, 2008). However, the study was prematurely terminated 17 months prior to its scheduled end date due to an increased death rate in the intensive therapy group (ACCORD Study Group, 2008). Results from the remaining time of the study did not indicate significant differences in CVD events between groups in a three-year time frame,
although the unanticipated increased risk of death was noted in the intensive therapy group (ACCORD Study Group, 2008).

In the VADT, 1,791 military veterans with poorly controlled T2DM and risk factors for and/or history of vascular complications were randomly assigned to either the standard control group or an intensive therapy group (Duckworth et al., 2009). The mean HbA1c for all participants was 9.4% at baseline, and mean time since diagnosis of T2DM was 11.5 years (Duckworth et al., 2009). The intensive therapy group’s HbA1c was reduced to 6.9% after three months through maximal dosages of two oral agents and insulin if necessary, while the standard control group’s HbA1c reached 8.4% after three months with half dosages of two oral agents and insulin if needed (Duckworth et al., 2009). At six-year follow-up, no significant differences in rates of cardiovascular events, death, and microvascular complications were found between the two groups (Duckworth et al., 2009).

In contrast to the three above-mentioned trials, the DCCT was carried out in a sample of 1,441 patients aged 13 to 39 years with insulin dependent DM (IDDM) and either no complications or very mild retinopathy (DCCT Research Group, 1993). Both the intensive control group and the standard control group were divided into subgroups of primary prevention and secondary intervention in regards to retinopathy and microalbuminuria (DCCT Research Group, 1993). After follow-up for a mean of six and one-half years, the intensive therapy group as a whole displayed reduced risk and progression of microvascular complications by 35% to over 70% (DCCT Research Group, 1993). At the end point, macrovascular complications were collectively reduced in the intensive therapy group by 41%, although this number was not considered statistically significant (DCCT Research Group, 1993).
Lastly, the UKPDS in its initial phase studied 3,867 newly diagnosed patients with T2DM who were either assigned to intensive treatment with varying oral agents (based upon body mass index [BMI]) and/or insulin or a diet-only standard management approach with drugs if absolutely necessary (UKPDS Group, 1998). Mean HbA1c after 10 years was reduced to 7.0% in the intensive group versus 7.9% in the conventional control group (UKPDS Group, 1998). The study demonstrated a significant (p = 0.0099) 25% reduction in risk for microvascular complications but no significant reduction in macrovascular complications (UKPDS Group, 1998).

Interestingly, patients in both the DCCT and the UKPDS were monitored post-study in two respective follow-up studies. Both follow-up studies provided contrasting results to those of the originals in terms of cardiovascular outcomes. The Epidemiology of Diabetes Interventions and Complications (EDIC) study, which was the 17-year follow-up to the DCCT, determined that participants who had received intensive treatment reduced their risk of an initial cardiovascular event by 42% (p = 0.02) and the first-time occurrence of myocardial infarction (MI), stroke, and death from CVD, collectively, by 57% (p = 0.02) (Nathan et al., 2005). Furthermore, microvascular risk reductions were sustained from the original trial (Nathan et al., 2005). In the UKPDS, both categories of intensive treatment saw reductions in cardiovascular risk over the long-term, defined as approximately 10 years (Holman, Paul, Bethel, Matthews, & Neil, 2008). The sulfonylurea-insulin group demonstrated a 15% (p = 0.01) reduction in MI and a 13% (p = 0.007) reduction in death from any cause, while in the metformin group there was a 39% (p = 0.01) decline in MI and a 36% (p = 0.01) decline in mortality (Holman et al., 2008). In the intensive therapy group as a whole, the microvascular risk reductions from the original intervention were also sustained (Holman et al., 2008).
While the first three studies did not produce significant evidence that glycemic control helps to lower the risk of CVD, the latter two suggest that cardiovascular benefits can still be obtained through glycemic control in the long term (Skyler et al., 2009). However, glycemic control is apparently quite effective in delaying microvascular complications, as several studies have shown (Skyler et al., 2009). Due to these findings, the ADA, the American College of Cardiology Foundation, and the American Heart Association (AHA) still advocate the monitoring and control of cardiovascular risk status in combination with diabetes care and glycemic control (Skyler et al., 2009).

**The relationship of lipids.** In addition to the recommendations for glycemic control, the significance of serum lipid values should not go unnoticed. As people with DM are at an increased risk of developing CVD, it follows that measures commonly used to assess CVD risk and/or disease progress would be of utmost importance in these individuals. One specific measure is the serum lipid profile. Endogenous lipids are transported in the bloodstream as components of lipoproteins, which consist of protein, phospholipids, cholesterol, and triglycerides (Gropper & Smith, 2013). The name of the lipoprotein depends on its composition in terms of protein and lipid. High-density lipoproteins (HDL) contain a higher amount of protein than lipid, while the reverse is true of low-density lipoproteins (LDL) (Gropper & Smith, 2013). Very-low-density lipoproteins (VLDL) and intermediate-density lipoproteins (IDL) follow the same pattern (Gropper & Smith, 2013). In relation to CVD, the end location of the cholesterol transported by these lipoproteins is significant: LDL-transported cholesterol is deposited in peripheral cells as well as in the vascular system, where, given time, it can build up and contribute to the formation of artery-clogging plaques; in contrast, cholesterol carried by HDL is taken away from these areas to the liver and eventually excreted via bile (Gropper &
Smith, 2013). Thus, both an excess of LDL cholesterol and a lack of HDL cholesterol may be damaging to the vascular system in the long term (Gropper & Smith, 2013). Both VLDL and IDL are found in far lower concentrations in the bloodstream than HDL and LDL and as a result are not significant contributors to CVD risk (Gropper & Smith, 2013).

Therefore, due to their concentrations and purposes, HDL and LDL cholesterol constitute two of the most frequently measured serum lipid values. The other two commonly seen in the lipid panel are triglycerides (TG) and total cholesterol (TC). Triglycerides consist of a glycerol backbone with three attached fatty acids; they function as energy storage vessels (Gropper & Smith, 2013). An excess of TG usually accompanies heart disease and may also be a causative factor in its development (Do et al., 2013). Total cholesterol is the sum of HDL cholesterol, LDL cholesterol, and approximately 20% of the TG concentration (American Heart Association [AHA], 2014). Recommended values are as follows: TC: <200 mg/dl; HDL: >40 mg/dl in men, >50 mg/dl in women; LDL: <100 mg/dl; TG: <150 mg/dl (Solano & Goldberg, 2006; Buse et al., 2007).

**Diagnosis and Management**

**Diagnostic criteria.** In light of these statistics, diagnosis of DM becomes even more important for prevention and/or treatment of its complications (CDC, 2014). Diagnostic procedures often begin when a patient presents with any of the classic symptoms of diabetic hyperglycemia: polydipsia, polyphagia, polyuria, blurred vision, and weight loss (ADA, 2014a; van Belle, Coppieters, & von Herrath, 2011). The ADA’s diagnostic criteria are based upon blood glucose levels (ADA, 2014a). Any one of the following positive test results, which are usually repeated to ensure accuracy, allows for diagnosis (ADA, 2014a):
• Presentation of classic symptoms of hyperglycemia or a hyperglycemic crisis with a random plasma glucose measuring $\geq 200$ mg/dl (11.1 mmol/L). These results must occur on at least two separate occasions.

• A two-hour plasma glucose reading of $\geq 200$ mg/dl (11.1 mmol/L) during an oral glucose tolerance test (OGTT).

• A fasting plasma glucose (FPG) reading of $\geq 126$ mg/dl (7.0 mmol/L), where the fasting period has been at least eight hours.

• A HbA1c reading of $\geq 6.5\%$.

Historically, diagnosis has always been related to immediate blood glucose levels (ADA, 2014a). The exact numbers for diagnosis were even re-determined in 1997 after extensive testing of the relationship of blood glucose levels to the presence of retinopathy (ADA, 2014a). However, an indicator of more long-term levels has recently been accepted by the ADA in addition to the current blood glucose readings: HbA1c (ADA, 2014a). Hemoglobin A1c, or glycated hemoglobin, is the product of the binding of excess glucose in the bloodstream with the red blood cell protein hemoglobin to form the compound glycated hemoglobin (Michigan Diabetes and Research Training Center, 2014). As mentioned regarding the AGEs in the complications section, this product is damaging to the vascular system (Michigan Diabetes and Research Training Center, 2014). The greater the amount of glycated hemoglobin, the higher the blood glucose levels have been; this measurement displays an average of one to three months’ worth of blood glucose levels, although it more accurately represents levels from the past two to four weeks (Michigan Diabetes and Research Training Center, 2014).

**Management strategies.** As the recognition and diagnosis of DM have grown in recent decades, management strategies have become a vital part of patient care (ADA, 2014b; ADA,
Medical practitioner involvement and pharmacotherapy are key components in the care process (ADA, 2014b; ADA, 2015). Degree and type of practitioner care may vary based on the situation but often includes MNT by an RD, psychosocial support, treatment or control of comorbid conditions and complications, and regular physical assessments and screenings for prevention of further complications (ADA, 2014b; ADA, 2015). Pharmacotherapy measures include insulin therapy (for both T1DM and more severe cases of T2DM) and oral antihyperglycemic agents, of which metformin is most often preferred (ADA, 2014b; ADA 2015). Regular blood samples (i.e., every six months, yearly, etc.) assist physicians with adjusting dosages of these agents (ADA, 2014b; ADA, 2015).

**Empowering the Patient: Diabetes Self-Management Education**

**Description.** In addition to the previously mentioned methods of management, structured diabetes education programs, specifically DSME/DSMT, have become a more widely used means of providing support and reinforcement of key disease-management principles to persons with DM, both in the United States and around the world (Jarvis et al., 2010; Steinsbekk et al., 2012). They are generally based upon program standards created by either an international or national diabetes-related organization, such as the International Diabetes Federation and the United Kingdom’s Department of Health; the United States’ program standards are titled “National Standards for Diabetes Self-Management Education” (Steinsbekk et al., 2012). In general, the main objective of DSME is to facilitate a patient’s ability to confidently and independently manage his or her disease (Steinsbekk et al., 2012). Programs, which are led by trained medical professionals such as nurses or dietitians, may target one or both main types of DM and include topics such as the development of coping skills, medication administration, diet, exercise, problem solving, and blood glucose monitoring, to name a few (Mendoza &
Several formats are currently used for DSME programs, including individual counseling sessions, group classes, and combinations of group and individual sessions (Mendoza & Rosenberg, 2013).

**Program efficacy.** DSME programs do differ among themselves in various ways, including educational materials used and topics covered, accreditation (or lack of) by diabetes-related organizations such as the AADE and the ADA, population served, program format (e.g. individual counseling, group education, a combination of group and individual sessions, other types of special curricula), and ability/time frame in reference to patient follow-up (Mendoza & Rosenberg, 2013; Jarvis et al., 2010). Programs’ success rates may differ from one another to a small or large degree (Steinsbekk et al., 2012; Mendoza & Rosenberg, 2013). However, the available literature displays an overall trend toward success as measured by disease management outcomes as well as the likelihood of a promising future for these educational programs, since DSME programs have become a large and vital presence in the medical realm today (Jarvis et al., 2010). Further study of programs’ effectiveness both long- and short-term will also help to provide more concrete information on various formats of diabetes education (Steinsbekk et al., 2012). The following sections will provide an overview of DSME program effectiveness with a focus on outcomes related to T2DM, which is the more commonly seen type of DM in patients enrolled in most of these programs.

**Clinical/medical benefits.** Clinically, DSME programs have been linked with a reduction in HbA1c in people with T2DM. Several recent studies and meta-analyses provide supporting data for the same effect across multiple DSME formats. First, in a meta-analytic comparison of group DSME versus either standard medical treatment, remaining on an education waiting list while undergoing routine medical care, or non-DSME care based upon the diabetes standards of
care, group DSME participants displayed a more significantly reduced HbA1c than participants in the aforementioned control groups, which were collectively classified as usual care (Deakin, McShane, Cade, & Williams, 2005). In the group DSME participants, a 1.4% (p < 0.00001) greater reduction in HbA1c was seen at six months, a 0.8% (p < 0.00001) greater reduction was visible at 12 months, and a 1.0% (p < 0.00001) greater reduction appeared at two years as compared to the usual care control group (Deakin et al., 2005). In a recent update to that original study, Steinsbekk et al. (2012) likewise identified significant reductions in HbA1c for those enrolled in a group DSME program in comparison to those receiving usual care: 0.44% (p = 0.0006) reduction at six months, 0.46% (p = 0.001) reduction at 12 months, and 0.55% (p < 0.00001) reduction at two years. Second, nurse-led DSME programs with varying durations of follow-up also demonstrated an ability to significantly decrease HbA1c (0.7% reduction) in comparison to usual care (0.21% reduction) with a 0.48% (p < 0.001) net difference between the two groups (Tshiananga et al., 2012). Similarly, a nurse-led telemedicine DSME program in a rural community produced a significantly (p < 0.02) greater decrease in HbA1c than did usual care in the same community at approximately three and six months post-program (Toledo, Ruppert, Humber, & Siminerio, 2014). Finally, two more meta-analyses of multiple methods of DSME indicated an average decrease in HbA1c: Norris and colleagues found a 0.76% greater reduction immediately after program completion, 0.26% at one to three months, and 0.26% at greater than four months in comparison to a control group of usual care (Norris, Lau, Smith, Schmid, & Engelgau, 2002); and Gary and colleagues calculated a mean reduction of 0.43% (p < 0.003) from multiple educational and behavioral methods with varying durations of intervention and follow-up (Gary, Genkinger, Gualiar, Peyrot, & Brancati, 2003).
While not seen as often as HbA1c, the lipid profile has been included in some comparative studies, which indicate that DSME programs may also be effective in assisting the movement of lipid values toward normal limits without the use of medication. The aforementioned nurse-led DSME program meta-analysis also included lipid values and noted slight, yet non-significant, improvements in all of the lipid parameters as compared to usual care (Tshiananga et al., 2012). Second, in a randomized clinical trial, a telehealth DSME program administered by both a nurse and a dietitian in rural South Carolina resulted in a significant ($p < 0.02$) improvement in LDL cholesterol in participants at 12 months in comparison to others who received usual care (Davis et al., 2010). Third, an extremely recent retrospective study of the Cleveland Clinic’s ADE-accredited DSME program indicated significant decreases in TC ($p = 0.01$), LDL cholesterol ($p = 0.02$), and TG ($p < 0.001$) in addition to a significant ($p < 0.001$) increase in HDL cholesterol pre- and post-program up to six months in patients who had completed either three or four of the program’s educational sessions (Liu et al., 2014).

Furthermore, an association between DSME and reduced severity and/or delayed onset of complications is generally accepted by the diabetes research community, although the evidence does not appear to be firmly conclusive at this time (Clark, 2008). However, as was alluded to earlier, because benefit has been found through glycemic control and intensive therapy in reducing the impact of some vascular complications, the inclusion of these strategies as part of DSME is likely advantageous and should continue (Skyler et al., 2009).

**Patient-centered benefits.** In addition to the marked impact on the above-mentioned parameters, DSME has demonstrated the potential to assist patients with gaining a more positive mindset and implementing healthier lifestyle behaviors (Powers et al., 2015). Several studies report increases in participants’ perceptions of quality of life (Deakin et al., 2005; Cochran &
Conn, 2008; Trento et al., 2004; Toobert et al., 2003) and decreases in depression (Hermanns et al., 2015; de Groot et al., 2012) and diabetes-related distress (Fisher et al., 2013; Siminerio, Ruppert, Huber, & Toledo, 2014). Improvements in coping skills (Tang, Funnell, & Oh, 2012; Thorpe et al., 2013) and adherence to a healthy diet pattern (Tang et al., 2012; Toobert et al., 2011) and exercise (Toobert et al., 2011) were also noted.

**Decreased healthcare costs.** The benefits discussion would be incomplete without mentioning the cost-effectiveness aspect of DSME programs. Diabetes education is believed to contribute to lowered healthcare costs through the alleviation of a portion of the need for care related to diabetes complications as well as through a reduction in the number of hospital visits accrued by patients who participate (Powers et al., 2015). Inpatient, outpatient, and community programs have been the subjects of interest, although some studies only provide a basis for the assumption while others actually estimate the healthcare costs. Criteria for inclusion were also fairly heterogeneous among studies. For example, in the inpatient setting, a retrospective analysis of data for 2,265 patients with poorly controlled diabetes (as demonstrated by a HbA1c >9%) indicated a significantly decreased number of readmissions for patients who had received inpatient diabetes education by CDEs as compared to patients who had not at both 30 (p = 0.0001) and 180 (p = 0.001) days; no costs were calculated in this study design (Healy, Black, Harris, Lorenz, & Dungan, 2013).

The Urban Diabetes Study, which included 18,404 patients with diabetes who had received outpatient medical care of any kind at the Philadelphia Health Care Centers, calculated both costs and number of hospital readmissions (Robbins, Thatcher, Webb, & Valdmanis, 2008). Patients who had attended one or more educational visits of select kinds (including diabetes classes, nutritionist visits, and general health education) had a mean reduction of $11,571 per
person-year (p < 0.001) in hospital-associated costs and a nine-visit hospitalization reduction per 100 person-years (p < 0.001) in comparison to those who had not attended an educational session (Robbins et al., 2008). Patients who had attended at least one diabetes class had a mean reduction of $6,913 per person-year in hospital costs and a five-and-one-half-visit hospitalization reduction per 100 person-years; however, at p = 0.07 these numbers were not statistically significant (Robbins et al., 2008).

In the community setting, community-health-worker-run programs for Hispanics with T2DM seem to be cost effective (Prezio, Pagan, Shuval, & Culica, 2014; Brown et al., 2009). In their analysis of data for 180 Hispanic patients with T2DM, Prezio et al. (2014) estimated a $355 medical cost per quality-adjusted life year for a 20-year time frame in 90 participants who had participated in the educational program versus the 90 who had not. Similarly, using data from a cohort of 6,551 Hispanic adults with T2DM, Brown et al. (2012) estimated a lifestyle intervention cost range of $10,995 to $33,319 per quality-adjusted life year gained for 20 years. Both estimates were deemed cost-effective as compared to the usual care estimate of $50,000 (Eddy, Schlessinger, & Kahn, 2005).

In addition to these studies, others have reached the same conclusions. Urbansi and colleagues’ review of approximately 11 studies (five systematic reviews, two randomized controlled trials, one controlled clinical trial, one longitudinal cohort study, one simulation model, and one observational study) indicated that not all studies relating to cost-effectiveness of DSME actually performed cost analyses (Urbanski, Wolf, & Herman, 2008). Those that did, however, found some cost benefit, and the remaining studies suggested that cost benefit was likely (Urbanski et al., 2008). Boren and colleagues’ review of DSME-related literature classified 26 studies into three main categories based upon effects in terms of monetary savings
or losses (Boren, Fitzner, Pahnalkar, & Specker, 2009). Out of 26 total studies, 18 were associated with cost effectiveness, while the remainder indicated a neutral effect (four studies), increased costs (one study), or an effect that did not fit in the three previous categories (three studies) (Boren et al., 2009). The authors concluded that DSME programs are cost effective and should continue to be tested as such to form firm conclusions on the topic (Boren et al., 2009). Although the research may not be conclusive, it does appear to point to a positive view on the cost effectiveness of DSME overall.

**Dosage-response to education.** One new area of interest in DSME research is dosage-response to education (Duncan et al., 2011). While previous works have identified a correlation between increasing hours of education and decreasing HbA1c, their heterogeneity in method and educational focus is evident (Norris et al., 2002). Furthermore, at this time there is limited research regarding clinical outcomes in accredited/recognized DSME/DSMT programs in regards to number of sessions attended (Duncan et al., 2011). This study attempted to fill that knowledge gap through a comparison of attendance at an initial education session versus completion of an entire program of DSME/DSMT.
Chapter 3: Research Design and Methodology

Research Design

A quantitative, retrospective study was conducted using existing data from the years 2014 and 2015 drawn from all qualifying patient medical records from the newly restructured DSMT program at the Presence St. Joseph Medical Center (PSJMC) Outpatient Clinic (Joliet, Illinois). The study determined the degree of difference in effectiveness between “individual” and “group” diabetes education (the independent variable) through a comparison of average HbA1c and lipid values pre- and post-program (the dependent variables) from patients who matched the requirements for those educational categories. Placement in either education category was non-random and depended on the decisions of both the patient and the diabetes educator, who delivered all educational sessions, thus making the study a quasi-experimental design.

Patient medical and program records are kept in both paper and electronic form in the outpatient office. Records of all patients with any association to the diabetes and nutrition programs are kept in paper form, while only the records of patients who have been enrolled in the group classes (whether they actually attended or not) are included in the electronic records within the AADE website under the nurse educator’s login. Therefore, the patients who attended an initial appointment but chose not to enroll in the group classes are not included in the online registry. The nurse educator is responsible for updating the online information as she updates it in patients’ paper charts.

The medical records were divided into two groups based on the type of education received in the DSMT program as notated within each record. One group contained patients who participated only in a single initial individual DSMT counseling session, the individual education group (IE), which is a precursor to class enrollment. Patients in this group received no further
education in the program. The other group included patients who had attended both the initial individual education session as well as all DSMT classes, the group education group (GE), for a total of three 2-hour classes. Classes are held every other week, and the patient may choose either a morning or afternoon session to accommodate his or her schedule. Thus, one rotation through the cycle of three classes takes approximately one and one-half months. Data were obtained from each patient’s medical record and entered into an Excel spreadsheet under the category of “individual education” or “group education,” depending on the type of education the patient had received. Values collected from each record included height, weight, BMI, age, race, gender, notation of previous diabetes education, HbA1c levels pre- and post-education, and lipid panel (TC, HDL, LDL, and TG) pre- and post-education. Medication information, details of disease progression, and post-program BMI were not always available within each record and therefore, were not collected.

**Study Population**

The study population included all patients with T2DM who had completed either an initial individual diabetes education appointment or the full program of an individual appointment plus all group diabetes education classes at the PSJMC Outpatient Clinic and whose medical records were available from the facility. At the time of entry into their respective programs, participants must have been at least 18 years of age or older with either a recent or past diagnosis of T2DM. Additionally, patients must have either completed the program in its entirety through group classes (in addition to the initial individual session) or have received only the initial individual session.

Criteria for exclusion included patients who were under 18 years of age when they enrolled in the program; patients with pre-diabetes, GDM, T1DM, or diabetes with an etiology
other than that of T2DM; patients in the GE category who did not complete the program in its entirety; and patients who were found to be deceased. Data were extracted from approximately 136 patient records.

**Ethics**

No live subjects were used in the study. All laboratory values and relevant demographic information were obtained by the PI from the hospital outpatient center’s medical records; at no time did the PI perform any medical tests or laboratory procedures. All collected patient data were related to individual medical record numbers, which were de-identified to safeguard sensitive patient information. No other personal identifiers were used. All medical records remained in a locked office in the diabetes center, and all electronic data were password protected on the PI’s computer. All identifiable data were destroyed at the conclusion of the study.

**Study Time Frame**

The data were collected on site at PSJMC after approval from both Eastern Michigan University’s Human Subjects Review Committee (Appendix A and B) and the PSJMC Institutional Review Board (Appendix C) was granted. Collection time took approximately three months.

**Data Analysis**

Data were analyzed with the assistance of a statistical consultant using SPSS statistical software (SPSS release 22.0, 2013, IBM Corporation, Armonk, NY). Boxplots were created to provide an initial visual impression of central tendency and variability of the five dependent variables 1) between groups at baseline (also termed “pre-program”) and post-program and 2) within groups from pre- to post-program. After correction for outliers, multivariate analysis of
variance (MANOVA) was run to determine whether significant (p < 0.05) differences existed between groups at baseline and post-program. MANOVA was furthermore used to determine whether significant differences in change scores (i.e., the mean difference from pre- to post-program for each variable) existed between groups. Significant MANOVAs were followed by separate t-tests for each variable with a Bonferroni adjustment added to reduce the risk of Type I error. As there were five dependent variables, t-tests were therefore considered significant at p < 0.01. Results were finally compared to the clinical target values for diabetes-related standards of care.
Chapter 4: Research Results

Demographics

From April 2014 to April 2015, 136 patient records met the established criteria, with 64 patients in the IE group and 72 patients in the GE group. The total number of records from the program was approximately 345; however, the records not included in the analysis consisted of patients with GDM, patients who had attended only one or two group classes, patients who had just begun or were in the process of completing the program during the data collection period, and two patients who were deceased. Within the qualifying medical records, availability of pre-and post-program HbA1c and lipid data ranged from 37% to 78% in the IE group and 64% to 87% in the GE group.

As presented in Table 1, the two groups were similar in composition for the categorical variables of gender (p = 0.390) and race (p = 0.517). As for diabetes education, seven patients in the GE group (9.80%) reported previous education; interestingly, only one reported attending a formal DSME/DSMT program several decades ago, and most could not remember any details of the previous education such as date and number of sessions. Three patients were unsure if they had even received education from a health professional but still answered “yes” to that question on the introductory DSMT self-assessment form that all patients fill out prior to beginning the program (Appendix D).
Table 1
*Categorical Demographic Characteristics for Gender, Race, and Previous Diabetes Education by Education Group*

<table>
<thead>
<tr>
<th></th>
<th>IE (n = 64)</th>
<th>GE (n = 72)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>% of Total</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>32</td>
<td>50.00</td>
</tr>
<tr>
<td>Male</td>
<td>32</td>
<td>50.00</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>31</td>
<td>48.44</td>
</tr>
<tr>
<td>Black</td>
<td>16</td>
<td>25.00</td>
</tr>
<tr>
<td>Hispanic</td>
<td>14</td>
<td>21.88</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>1.56</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>3.13</td>
</tr>
<tr>
<td>Previous Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>64</td>
<td>100.00</td>
</tr>
<tr>
<td>Yes, once</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Yes, once/unsure</td>
<td>0</td>
<td>0.00</td>
</tr>
</tbody>
</table>

*Note.* When added, total percentages may slightly exceed 100% due to rounding.
Abbreviations: IE, individual education; GE, group education.

However, as shown in Table 2, significant differences between groups emerged for the continuous variables of age (p < 0.01), weight (p < 0.05), and BMI (p < 0.05) but not for height (p = 0.280). Participants in the IE group were approximately 6.86 years younger on average but had a higher mean weight (mean difference = 22.86 pounds) and BMI (mean difference = 2.86 kg/m²) than those in the GE group. Furthermore, although the average BMI in each group would be classified in the general obesity category, a differentiation in subcategories of obesity exists between the two groups, with the IE group’s mean BMI of 36.27 kg/m² considered class 2 obesity (BMI of 35.0 to 39.9 kg/m²) and the GE group’s mean BMI of 33.41 kg/m² considered class 1 obesity (BMI of 30 to 34.9 kg/m²) (Nelms, Sucher, Lacey, & Roth, 2011).
Table 2
Continuous Demographic Characteristics for Age, Height, Weight, and BMI by Education Group

<table>
<thead>
<tr>
<th></th>
<th>IE (n = 64)</th>
<th></th>
<th>GE (n = 72)</th>
<th></th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Min</td>
<td>Max</td>
<td>m</td>
<td>SD</td>
</tr>
<tr>
<td>Age, yrs.</td>
<td>64</td>
<td>25.00</td>
<td>74.00</td>
<td>52.22</td>
<td>11.65</td>
</tr>
<tr>
<td>Height, in.</td>
<td>64</td>
<td>59.00</td>
<td>74.00</td>
<td>67.02</td>
<td>3.78</td>
</tr>
<tr>
<td>Weight, lbs.</td>
<td>64</td>
<td>94.00</td>
<td>418.00</td>
<td>231.86</td>
<td>57.60</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>64</td>
<td>16.10</td>
<td>57.80</td>
<td>36.27</td>
<td>8.48</td>
</tr>
</tbody>
</table>

Note. Decimal numbers are rounded to the nearest tenth. Abbreviations: IE, individual education; GE, group education; m, mean; SD, standard deviation. P-values delineate the degree of difference between the IE and GE groups for each variable. P-values are considered significant at p = 0.01.

Initial Pre- and Post-Program Observations

The pre- and post-program dependent variables—HbA1c and lipids—were first analyzed using a boxplot to determine central tendency and distributional qualities (Figures 1–5). Pre-program median HbA1c, TC, HDL, LDL, and TG were noted to be slightly higher in the IE group in comparison to the GE group. Post-program median HbA1c, TC, LDL, and TG remained higher in the IE group than in the GE group, while median HDL appeared lower in the IE group than in the GE group.

Within groups, median HbA1c decreased in both the IE and GE groups from pre- to post-program, while median TC and LDL appeared to remain fairly constant in both groups. Median HDL decreased pre- to post-program in the IE group, while a slight rise was noted in the GE group. Lastly, median TG appeared to rise in the IE group and decrease in the GE group from pre- to post-program.
Figure 1. Differences in HbA1c levels (%) pre- and post-program for individual (IE) and group education (GE). In this figure, “individual” corresponds to IE, and “group” corresponds to GE. Outliers are represented by circles. The number associated with each outlier corresponds to its line number in the statistics software database. The horizontal line within each box corresponds to the median value.
Figure 2. Differences in TC levels (mg/dl) pre- and post-program for individual (IE) and group education (GE). In this figure, “individual” corresponds to IE, and “group” corresponds to GE. Outliers are represented by circles. The number associated with each outlier corresponds to its line number in the statistics software database. The horizontal line within each box corresponds to the median value.
Figure 3. Differences in HDL levels (mg/dl) pre- and post-program for individual (IE) and group education (GE). In this figure, “individual” corresponds to IE, and “group” corresponds to GE. Outliers are represented by circles. The number associated with each outlier corresponds to its line number in the statistics software database. The horizontal line within each box corresponds to the median value.
Figure 4. Differences in LDL levels (mg/dl) pre- and post-program for individual (IE) and group education (GE). In this figure, “individual” corresponds to IE, and “group” corresponds to GE. Outliers are represented by circles. The number associated with each outlier corresponds to its line number in the statistics software database. The horizontal line within each box corresponds to the median value.
Figure 5. Differences in TG levels (mg/dl) pre- and post-program for individual (IE) and group education (GE). In this figure, “individual” corresponds to IE, and “group” corresponds to GE. Outliers are represented by circles, and extreme outliers are represented by asterisks. The number associated with each outlier corresponds to its line number in the statistics software database. The horizontal line within each box corresponds to the median value.

Pre-Program Comparisons

Following boxplot analysis and correction for outliers, MANOVA was employed to determine between-group differences in the dependent pre-program variables. A significant (p < 0.001) Box’s M test of the variance-covariance homogeneity assumption necessitated the use of Pillai’s Trace to more reliably estimate significance. This method produced a significant (p =
MANOVA result, and subsequent t-tests with a Bonferroni adjustment for each variable were required.

Results from the t-tests were not uniform in terms of significance, as shown in Table 3. Beginning with HbA1c, although the mean level was slightly higher in the IE group (n = 50) than in the GE group (n = 63), the difference between groups (mean difference = 0.30\%, SE = 0.42) was not significant (p = 0.470). In contrast, there was a significant (p = 0.002) difference between groups for TC (mean difference = 26.45 mg/dl, SE = 8.29), with a notably higher level in the IE group (n = 41) than in the GE group (n = 54). HDL measurements did not demonstrate a significant (p = 0.907) difference between groups (mean difference 0.32 mg/dl, SE = 2.77), as the IE group (n = 41) showed only a very slightly lower average than the GE group (n = 54). A significant (p < 0.001) difference was found in LDL between groups (mean difference = 32.94 mg/dl, SE = 7.40), as participants in the IE group (n = 40) displayed a notably higher average than the GE group (n = 51). Last, no significant (p = 0.764) difference was found in TG values between groups (mean difference = 5.96 mg/dl, SE = 19.79), although the IE group (n = 41) had a slightly lower mean value than the GE group (n = 54).
Table 3
Pre-Program Comparisons for HbA1c (%), TC (mg/dl), HDL (mg/dl), LDL (mg/dl), and TG (mg/dl) between Education Groups

<table>
<thead>
<tr>
<th></th>
<th>IE (n = 64)</th>
<th>GE (n = 72)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>50</td>
<td>63</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>5.50</td>
<td>5.50</td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>15.65</td>
<td>13.80</td>
<td></td>
</tr>
<tr>
<td>m</td>
<td>8.83</td>
<td>8.52</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>2.56</td>
<td>1.89</td>
<td></td>
</tr>
<tr>
<td>TC, mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>41</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>119.00</td>
<td>86.00</td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>276.70</td>
<td>244.00</td>
<td></td>
</tr>
<tr>
<td>m</td>
<td>194.30</td>
<td>167.85</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>43.32</td>
<td>37.32</td>
<td></td>
</tr>
<tr>
<td>HDL, mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>41</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>16.00</td>
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<tr>
<td>Max</td>
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<td>79.00</td>
<td></td>
</tr>
<tr>
<td>m</td>
<td>44.27</td>
<td>44.59</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>13.19</td>
<td>13.55</td>
<td></td>
</tr>
<tr>
<td>LDL, mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>40</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>60.00</td>
<td>29.00</td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>197.35</td>
<td>165.00</td>
<td></td>
</tr>
<tr>
<td>m</td>
<td>121.47</td>
<td>88.53</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>38.07</td>
<td>32.51</td>
<td></td>
</tr>
<tr>
<td>TG, mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>41</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>49.00</td>
<td>43.00</td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td>376.80</td>
<td>421.75</td>
<td></td>
</tr>
<tr>
<td>m</td>
<td>168.92</td>
<td>174.88</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>87.48</td>
<td>101.21</td>
<td></td>
</tr>
</tbody>
</table>

Note. Decimal numbers are rounded to the nearest tenth. Abbreviations: IE, individual education; GE, group education; HbA1c, hemoglobin A1c; TC, total cholesterol; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; TG, triglycerides; m, mean; SD, standard deviation.

As compared to clinical boundaries, pre-program mean HbA1c in both groups measured higher than the target value of 7% or less for people with DM (Buse et al., 2007) by 1.83% for the IE group and 1.52% in the GE group. Mean TC, in contrast, was below the <200 mg/dl target (Solano & Goldberg, 2006; Buse et al., 2007) in both groups by 5.7 mg/dl in the IE group and 32.15 mg/dl in the GE group. HDL was not compared to clinical targets, seeing as analyses by gender were not performed. LDL results contrasted between groups—while the IE group’s mean value rose above the <100 mg/dl goal (Solano & Goldberg, 2006; Buse et al., 2007) by 21.47 mg/dl, the GE group’s mean value measured below the target by 11.47 mg/dl. TG values exceeded the recommended goal of <150 mg/dl (Solano & Goldberg, 2006; Buse et al., 2007) in both groups by 18.92 mg/dl in the IE group and 24.88 mg/dl in the GE group.

Post-Program Comparisons

Post-program data similarly led to a significant (p < 0.001) Box’s M test, which again required the use of Pillai’s Trace; this MANOVA result was significant (p = 0.002). The subsequent t-tests with a Bonferroni adjustment also displayed mixed results, as presented in
Table 4. The difference in HbA1c (mean difference = 0.79%, SE = 0.30) was insignificant (p = 0.011), although the mean value for the IE group (n = 38) did appear substantially higher than that of the GE group (n = 58). A significant (p = 0.007) difference in TC values (mean difference = 21.31 mg/dl, SE = 7.61) did appear between the two groups, with a higher post-program level in the IE group (n = 24) than in the GE group (n = 46). The difference in HDL (mean difference = 3.60 mg/dl, SE = 3.18) was not significant (p = 0.262), but participants in the IE group (n = 24) ended the program with a lower average than did GE participants (n = 46). Similarly to HbA1c, LDL values exhibited a non-significant (p = 0.016) but still substantial difference between groups (mean difference = 17.15 mg/dl, SE = 6.97), with a higher mean value in the IE group (n = 24) than in the GE group (n = 45). Finally, TG displayed a pattern similar to that of HbA1c and LDL, with a non-significant (p = 0.034) yet large difference between groups (mean difference = 46.85 mg/dl, SE = 21.70) and a higher mean value in the IE group (n = 24) than in the GE group (n = 46).

Table 4
Post-Program Comparisons for HbA1c (%), TC (mg/dl), HDL (mg/dl), LDL (mg/dl), and TG (mg/dl) between Education Groups

<table>
<thead>
<tr>
<th></th>
<th>IE (n = 64)</th>
<th>GE (n = 72)</th>
<th>P-value</th>
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<tbody>
<tr>
<td>HbA1c, %</td>
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<tr>
<td>n</td>
<td>38</td>
<td>58</td>
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<tr>
<td>Min</td>
<td>5.50</td>
<td>5.20</td>
<td>0.011</td>
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<tr>
<td>Max</td>
<td>12.95</td>
<td>9.06</td>
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</tr>
<tr>
<td>m</td>
<td>7.66</td>
<td>6.87</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>1.95</td>
<td>1.01</td>
<td></td>
</tr>
<tr>
<td>TC, mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>24</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>117.00</td>
<td>86.00</td>
<td>0.007</td>
</tr>
<tr>
<td>Max</td>
<td>255.00</td>
<td>222.00</td>
<td></td>
</tr>
<tr>
<td>m</td>
<td>188.83</td>
<td>167.52</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>33.44</td>
<td>28.47</td>
<td></td>
</tr>
<tr>
<td>HDL, mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>24</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>22.00</td>
<td>23.00</td>
<td>0.262</td>
</tr>
<tr>
<td>Max</td>
<td>66.00</td>
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<td>m</td>
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<tr>
<td>SD</td>
<td>12.57</td>
<td>12.68</td>
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</tr>
<tr>
<td>LDL, mg/dl</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>24</td>
<td>45</td>
<td></td>
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<tr>
<td>Min</td>
<td>48.00</td>
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<td>Max</td>
<td>186.25</td>
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<td>m</td>
<td>107.51</td>
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<tr>
<td>SD</td>
<td>33.04</td>
<td>24.21</td>
<td></td>
</tr>
<tr>
<td>TG, mg/dl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>24</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td>58.00</td>
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<td>0.034</td>
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<tr>
<td>Max</td>
<td>542.75</td>
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<td></td>
</tr>
<tr>
<td>m</td>
<td>194.91</td>
<td>148.05</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>106.48</td>
<td>73.64</td>
<td></td>
</tr>
</tbody>
</table>

Note. Decimal numbers are rounded to the nearest tenth. Abbreviations: IE, individual education; GE, group education; HbA1c, hemoglobin A1c; TC, total cholesterol; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; TG, triglycerides; m, mean; SD, standard deviation.

a,b Not all laboratory values were obtainable for each patient; thus the numbers presented do not equal the total number of patients in each group.

P-values delineate the degree of difference between the IE and GE groups for each variable. P-values are considered significant at p = 0.01.
Clinically, post-program laboratory values for the two groups differed in regards to reaching established goals. As for HbA1c, the IE group’s mean value remained above 7% by 0.66%, while the GE participants’ mean value met the target of less than 7% (Buse et al., 2007) at 6.87%, a 0.13% difference. As for TC, both groups’ mean values were under the recommended <200 mg/dl target (Solano & Goldberg, 2006; Buse et al., 2007) by 11.17 mg/dl for IE and 32.48 mg/dl for GE. Again, HDL cholesterol could not be compared clinically. Mean LDL exceeded the <100 mg/dl target (Solano & Goldberg, 2006; Buse et al., 2007) by 7.51 mg/dl in the IE group but averaged below that target in the GE group by 9.64 mg/dl. Lastly, TG exceeded the <150 mg/dl goal (Solano & Goldberg, 2006; Buse et al., 2007) in the IE group by 44.91 mg/dl but measured less than the goal value in the GE group by 1.95 mg/dl.

**Pre-to Post-Program Between-Group Changes**

Lastly, pre- to post-program change scores for each dependent variable (Table 5) were calculated and compared between the two groups using MANOVA. Data used to calculate the change scores were taken from records of patients who had both pre- and post-program laboratory values available for each variable. Therefore, change score calculations did not include data from all the patient records that were included in the pre- and post-program comparisons. As Box’s M test was not significant (p = 0.151), which indicated that the variance-covariance homogeneity assumption was met, the MANOVA results from Wilk’s Lambda were used. These values (Wilks’ Lambda = 0.901, F(5, 33) = 0.722, p = 0.612, partial $\eta^2 = 0.099$) indicated that no significant differences existed between groups in degree of change for any of the dependent variables pre- to post-program. Due to the insignificant result from MANOVA, further t-tests were unnecessary.
Table 5
Pre- to Post-Program Change Score Comparisons for HbA1c (%), TC (mg/dl), HDL (mg/dl), LDL (mg/dl), and TG (mg/dl) between Education Groups

<table>
<thead>
<tr>
<th></th>
<th>IE (n = 64)</th>
<th></th>
<th>GE (n = 72)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Complete</td>
<td>Change Score</td>
<td>Complete</td>
<td>Change Score</td>
</tr>
<tr>
<td></td>
<td>Records</td>
<td>m ± SD</td>
<td>Records</td>
<td>m ± SD</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>26</td>
<td>-1.39 ± 2.70</td>
<td>50</td>
<td>-1.53 ± 1.83</td>
</tr>
<tr>
<td>TC, mg/dl</td>
<td>16</td>
<td>-5.86 ± 40.36</td>
<td>34</td>
<td>-5.18 ± 26.74</td>
</tr>
<tr>
<td>HDL, mg/dl</td>
<td>16</td>
<td>0.00 ± 8.70</td>
<td>34</td>
<td>+2.04 ± 8.69</td>
</tr>
<tr>
<td>LDL, mg/dl</td>
<td>15</td>
<td>-9.30 ± 9.30</td>
<td>31</td>
<td>-4.90 ± 24.83</td>
</tr>
<tr>
<td>TG, mg/dl</td>
<td>16</td>
<td>+18.13 ± 116.00</td>
<td>34</td>
<td>-24.51 ± 62.81</td>
</tr>
</tbody>
</table>

Note. Decimal numbers are rounded to the nearest tenth. The change score calculation used only values from patients whose records contained complete pre- and post-program data, unlike the mean calculated for each pre- and post-program variable. N = the number of records with complete pre- and post-program information available for each variable. A “+” sign before the mean indicates that the average degree of change moved in an upward direction, or rose in value; while a “–” sign before the mean indicates a decrease, or downward change in direction of the value. Abbreviations: IE, individual education; GE, group education; HbA1c, hemoglobin A1c; TC, total cholesterol; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; TG, triglycerides; m, mean; SD, standard deviation.

However, a comparison of both groups’ pre- to post-program values as a whole (Table 6) does highlight some important clinical changes. In terms of HbA1c, both groups began above and made progress toward the goal of <7% (Buse et al., 2007) although only the GE group ended with an average value in accordance with the target, at 0.13% below the <7% goal. Mean pre- to post-program decreases were 1.17% for the IE group and 1.65% for the GE group. As for TC, both groups began and ended the program with mean values within the target limit of <200 mg/dl (Solano & Goldberg, 2006; Buse et al., 2007); the decrease was slightly more noticeable in the IE group (-5.47 mg/dl) than in the GE group (-0.33 mg/dl). HDL was shown to decrease very slightly in the IE group (-0.56 mg/dl) and increase slightly in the GE group (+2.72 mg/dl); these results were not compared to clinical targets. LDL decreased in the IE group from pre- to post-program (-13.96 mg/dl) but remained above the target value of <100 mg/dl (Solano & Goldberg,
at both points of measure, while it increased slightly in the GE group (+1.83 mg/dl) but still remained under the target value at both pre- and post-program. Lastly, TG in the IE group measured above the <150 mg/dl target (Solano & Goldberg, 2006; Buse et al., 2007) both pre- and post-program and actually increased during that time frame (+25.99 mg/dl), while TG in the GE group decreased by 26.83 mg/dl from a level above the target to a value that was below the target by 1.95 mg/dl.

Table 6
Pre- and Post-Program Comparisons for HbA1c (%), TC (mg/dl), HDL (mg/dl), LDL (mg/dl), and TG (mg/dl) between Education Groups

<table>
<thead>
<tr>
<th></th>
<th>IE (n = 64)a</th>
<th>GE (n = 64)b</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-Program</td>
<td>Post-Program</td>
</tr>
<tr>
<td></td>
<td>m ± SD</td>
<td>m ± SD</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>8.83 ± 2.56</td>
<td>7.66 ± 1.95</td>
</tr>
<tr>
<td>TC, mg/dl</td>
<td>194.30 ± 43.32</td>
<td>188.83 ± 33.44</td>
</tr>
<tr>
<td>HDL, mg/dl</td>
<td>44.27 ± 13.19</td>
<td>43.71 ± 12.57</td>
</tr>
<tr>
<td>LDL, mg/dl</td>
<td>121.47 ± 38.07</td>
<td>107.51 ± 33.04</td>
</tr>
<tr>
<td>TG, mg/dl</td>
<td>168.92 ± 87.48</td>
<td>194.91 ± 106.48</td>
</tr>
</tbody>
</table>

Note. Decimal numbers are rounded to the nearest tenth. Abbreviations: IE, individual education; GE, group education; HbA1c, hemoglobin A1c; TC, total cholesterol; HDL, high-density lipoprotein cholesterol; LDL, low-density lipoprotein cholesterol; TG, triglycerides; m, mean; SD, standard deviation.

a,b Not all laboratory values were obtainable for each patient; thus the numbers presented do not equal the total number of patients in each group.
P-values comparing change scores between groups were not calculated for each variable, as the MANOVA result did not demonstrate a significant difference between groups in degree of change.
Chapter 5: Discussion

Question One: Was there a significant difference in the average degree of reduction in HbA1c levels between patients with T2DM who attended an individual education session versus patients with T2DM who completed an individual session and all group education classes from pre- to post-program?

A statistically significant difference in reduction of HbA1c levels was not found between groups in this study, contrary to the original hypothesis. However, clinical differences were nonetheless noted between groups post-program (Table 4) and within groups from pre- to post-program (Table 6), observations that seem to support the purported pattern of a dose-response relationship between hours of diabetes education received and degree of change in DM-related laboratory values (Norris et al., 2002; Duncan et al., 2011). Whereas pre-program HbA1c concentrations were quite similar between the two groups with only a 0.30% mean difference (Table 3), post-program levels demonstrated a difference of 0.79% between groups (Table 4), which was a notable clinical difference in relation to the recommended target goal of <7% (Buse et al., 2007): Mean post-program HbA1c in the IE group declined from its pre-program value of 8.83% but remained above the <7% target at 7.66% (Table 6), while mean HbA1c in the GE group decreased from a pre-program value of 8.52% and was reduced below the <7% target value to 6.87% (Table 6).

Although the GE group displayed a larger degree of reduction in HbA1c level than the IE group, both groups' mean values did decrease by greater than one percentage point, a reduction that is believed to lower the risk of micro- and macrovascular complications to some degree (Stratton, Adler, & Neil, 2000). Further analysis of data from the UKPDS trial demonstrated that a 1% reduction in HbA1c over 10 years was associated with risk reductions of 14% for
myocardial infarction, 37% for microvascular complications, and 21% for diabetes-related death (Stratton et al., 2000). Therefore, both groups in this study did appear to have obtained some benefit from their respective quantities of education; and if post-program HbA1c levels are sustained in the long term, participants in both groups might expect percentages of risk reduction for vascular complications that are similar to those in the UKPDS trial (Stratton et al., 2000).

However, the greater change seen in the GE group should not be minimized, as this group attained a mean post-program value in accordance with the <7% clinical target as recommended in the diabetes standards of care (Buse et al., 2007). Based upon evidence presented by Norris et al. (2002) that correlated a decrease in HbA1c levels with an increase in hours of diabetes education received, this result would be expected, especially since diabetes education programs that emphasized lifestyle interventions were the main focus of the meta-analysis. In the same meta-analysis, even patients who had received any quantity of diabetes education still displayed a greater overall reduction in HbA1c than patients in the control groups who had received usual care from their providers (Norris et al., 2002). Additionally, as implied from the parallel relationship between decreased HbA1c and reduced risk for vascular complications as demonstrated in the UKPDS trial (Stratton et al., 2000), the lowering of HbA1c to the clinically significant level of <7% (Buse et al., 2007) would likely heighten the health benefits received from completing the program, contrasting with a smaller projected degree of risk reduction that would be expected for participants who failed to complete the program.

Furthermore, due to the presence of such a clinically significant change between groups, the positive impact of quality diabetes education upon HbA1c values (Norris et al., 2002) is supported by this study. Though other factors may have affected the outcomes, such as medication dosage, it appears likely that program completion and overall patient compliance to
the educational recommendations are related, thus resulting in the changes noted. A comparable observation was reported by Duncan et al. (2011), who found that increases in compliance behaviors, such as adherence to medication regimen and follow-up with providers, corresponded with a higher number of hours of diabetes education. Although it is unknown as to what factors may have directly influenced compliance in this study, it is highly possible that the group class format encouraged success through the social connection with peers, a relaxed and interactive classroom atmosphere, and the opportunity to invite family members to classes for additional support. Those in the IE group, who did not attend these classes, could not have reaped the benefits from them. One important ramification from this finding is the potential for savings in healthcare costs, especially for patients who completed the program, as increased compliance to educational recommendations is associated with fewer inpatient hospital costs and thus a lower overall healthcare cost average long-term in patients with T2DM (Duncan et al., 2011).

**Question Two: Was there a significant difference in the average degree of reduction in lipid levels between patients with T2DM who attended an individual education session versus patients with T2DM who completed an individual session and all group education classes from pre- to post-program?**

As with HbA1c, no statistically significant differences were found between groups in lipid values pre- to post-program, although several other statistical and clinical differences do deserve mention. Beginning with TC, mean pre-program values in both groups (Table 3) were below the target value of <200 mg/dl (Solano & Goldberg, 2006; Buse et al., 2007), which is desirable; however, the mean difference of 26.45 mg/dl between the two groups was statistically significant, with the higher value residing in the IE group. Post-program, both groups’ mean values were still below the <200 mg/dl mark (Table 4); the mean difference of 21.31 mg/dl
between groups was again statistically significant, with a higher value present in the IE group. However, mean change within groups was fairly similar statistically and clinically, with a 5.47 mg/dl reduction in the IE group and a less than 0.5 mg/dl decrease in the GE group (Table 6). These constancies are likely explained by the rise and fall of LDL and TG within groups.

HDL values similarly remained fairly constant, with no statistically significant differences between groups present at pre- or post-program. Within groups, a slight decrease of 0.56 mg/dl was noted in the IE group and a slight increase of 2.72 mg/dl in the GE group from pre- to post-program (Table 6). Although analysis by gender was not performed, it should be noted that a statistically significant improvement in HDL did not occur for either education group as a whole; therefore, significant improvements within groups by gender are unlikely. However, it is possible that separate analyses by gender might have provided further clarification as to whether or not female patients within the two groups had achieved or not achieved the recommended HDL goal of >50 mg/dl (Solano & Goldberg, 2006; Buse et al., 2007) pre- and/or post-program, seeing as the means for both groups at pre- and post-program measured >40 mg/dl.

LDL data, in contrast, presented unique results. While the 32.94 mg/dl pre-program difference between groups was statistically significant (Table 3), the post-program difference of 17.15 mg/dl was not, although it was quite close (Table 4). Within groups, both pre- and post-program values in the IE group measured above the target value of <100 mg/dl (Solano & Goldberg, 2006; Buse et al., 2007), but a decrease of 13.96 mg/dl from pre- to post-program did occur (Table 6). In contrast, pre- and post-program GE group values measured less than the <100 mg/dl target, but a very slight increase of 1.83 mg/dl was noted from pre- to post-program (Table 6). From the data available, it appears that patients in the individual group may have benefitted
slightly from their initial appointments by a small LDL reduction, although their mean pre-
program LDL value was higher than that of the GE group, and they did not reach the target goal of <100 mg/dl.

Lastly, TG values did not demonstrate a statistically significant pre-program difference between groups (Table 3), although the post-program difference was more pronounced but still insignificant (Table 4). Clinically, however, within-group changes do stand out. From pre- to post-program, mean TG in the IE group increased by 25.99 mg/dl; both pre- and post-program values were above the recommended target of <150 mg/dl (Table 6) (Solano & Goldberg, 2006; Buse et al., 2007). Unlike the trend in the IE group, mean TG value in the GE group began above the <150 mg/dl mark at pre-program but decreased by 26.83 mg/dl to just under the <150 mg/dl goal at 148.05 mg/dl (Table 6). As the GE group’s pre-program value was higher than the IE group’s (Table 3), the clinically significant reduction in the GE group suggests that benefits of the diabetes education were more pronounced in that group.

In comparison to the limited literature on the subject of lipid values as outcome results from DSME (Liu et al., 2014; Tshiananga et al., 2012; Davis et al., 2010), results from this study seem to suggest a partial departure from the assumed pattern of beneficial changes in these measures. While the previously mentioned studies (Liu et al., 2014; Tshiananga et al., 2012; Davis et al., 2010) generally indicated statistically significant improvements in one or more parameters after an education program, either within the same group or as opposed to a control group, the GE group, who had attended the entire DSME program, did not demonstrate clinically significant changes in TC, HDL, or LDL from pre- to post-program or statistically significant changes when compared to the IE group, although TG did improve clinically but not significantly in comparison to that of the IE group.
Yet in comparison to the standards recommended for reducing the risk of CVD (Solano & Goldberg, 2006; Buse et al., 2007), the GE group certainly demonstrated a more noticeable improvement overall. As shown in Table 6, the GE group’s lipid values generally trended in a more protective direction than did those of the IE group, as evidenced by an upward trend in HDL, a nearly stationary LDL that remained within the target limit (Solano & Goldberg, 2006; Buse et al., 2007), and a clinically significant decrease in TG to below the target limit (Solano & Goldberg, 2006; Buse et al., 2007). In contrast, the IE group evidenced a decrease in HDL, an LDL that remained above the target limit (Solano & Goldberg, 2006; Buse et al., 2007) although it did decrease, and a TG count that increased even farther above the target limit (Solano & Goldberg, 2006; Buse et al., 2007). Although a statistically significant difference in TC was obvious between the groups, the general trend toward improvement in the GE group versus the mixed results in the IE group implies that the GE group likely reduced their risk of CVD to a degree, while the IE group probably did not. These findings further support the PSJMC DSMT program’s effectiveness as a whole and suggest that completion may be associated with risk-reducing improvements in lipid profiles.
Chapter 6: Conclusions

Summary and Conclusions

Although the study results did not statistically support the original hypothesis, they nonetheless provided valuable insight into the topic of DSME program completion in several ways. First, the analysis of HbA1c changes both between and within groups provides evidence that the PSJMC DSMT program does play a role in the lowering of this laboratory measure, even to the point of clinical significance (Buse et al., 2007). Between groups, the values do trend in the direction anticipated of them—namely, that participants in the IE group would, by nature of not having completed the full program and likely demonstrating less compliance as a whole, display a higher average HbA1c value than that of participants in the GE group. Within groups, the reduction in the GE group to a level considered clinically significant may be an added benefit for those patients who completed the entire educational program. Also, patients in the IE group who attended only the initial individual session still appeared to benefit by a greater than 1% reduction in this value. While statistical significance is important, the clinical significance of these changes should not be overlooked, as they are substantial for both groups in this study and have the potential to improve health outcomes through the reduction of vascular complications (Skyler et al., 2009).

Second, in regards to lipid values, the large amount of missing data makes it difficult to draw definitive conclusions from this study. However, it does appear that both groups may have derived a very slight benefit from the education in different ways. In the IE group, the one noticeable benefit was the slight reduction in LDL, the type of lipoprotein that has been implicated in increasing the risk of CVD (Gropper & Smith, 2013). However, opposing that reduction were a concomitant rise in TG, of which increased concentrations also may play a role...
in the development of CVD (Do et al., 2013), and a slight decrease in the cardio-protective HDL (Gropper & Smith, 2013). This group’s TC did decrease slightly overall, which may imply at least a minimal amount of improvement after one educational session. As for the GE group, potential benefits include the slight increase in HDL and the clinically significant decrease in TG, both of which may assist with reducing the risk of CVD (Do et al., 2013; Gropper & Smith, 2013). It should be noted that LDL did increase very slightly but was still under the clinical threshold both pre- and post-program in this group.

Third, although the disease process and exact time of diagnosis were not collected due to the fact that they were not uniformly available in the charts, many patients’ chart notes included references to the fact that they were fairly newly diagnosed, such that this was likely true of the majority of patients in the DSMT program as a whole. These findings indicate that DSME/DSMT programs may provide substantial clinical benefits for recently diagnosed patients.

Fourth, while the purpose of the study was not to compare the relative availability of laboratory values between groups, it was nevertheless observed that participants in the IE group generally tended to have fewer laboratory values available than participants in the GE group, both pre- and post-program as well as for complete pre- to post-program sets. This phenomenon occurred even after the primary care providers of all patients with missing laboratory values were contacted, which suggests that barriers that prevent compliance to full program attendance may also be at work in regards to these patients’ follow-up with their providers. These findings align with Duncan and colleagues’ correlation between frequency of HbA1c and lipid testing and number of episodes of diabetes education (Duncan et al., 2011).
In conclusion, the results from this study present a comparative picture of patients’ laboratory responses based on grouping by educational extremes in the newly restructured PSJMC DSMT program during the past year. As the program continues to grow, more data will be available in the coming years to confirm or deny the present findings and to determine the program’s success in the long term.

Limitations of the Study

As has been implied, several limitations exist within this study. Availability of patient laboratory values was a prominent one, especially in the IE group. This occurred because many of these patients did not have regular follow-up visits with their physicians and/or the physicians did not order an analysis of the specific variables in this study at the time blood work was performed. As this factor was out of the control of the PI and the CDE, the actual effect of either type of education may never be fully known. Future, larger studies may attempt to ascertain program efficacy with more confidence.

Second, differences in the availability of patient data for the pre- and post-program calculations versus the data available for change score calculations may have contributed to discrepancies regarding the actual efficacy of the program. As it was originally anticipated that more data would be available than the data that were actually present, the proposed plan of analysis was kept for pre- and post-program comparisons in an attempt to maintain adequate statistical power. Unfortunately, the general lack of data resulted in very few values available for the change score calculations, which require a complete set of pre- and post-program values. As a result, averaging the small number of scores resulted in high variability with large standard deviations. Again, larger studies may display better results from this procedure.
Third, medication usage information was not collected for pharmacotherapy agents. The extent to which patients were prescribed these medications, especially those for lipid control, as well as the extent to which the medications influenced the study results is unknown.

Fourth, previous diabetes-related knowledge within patient groups is relatively unknown. Patients’ “yes” responses to the question of having received previous diabetes education were marked by uncertainty, and the question itself did not address knowledge obtained by the patient through means other than that of formal diabetes education delivered by a healthcare professional. It is very possible that knowledge obtained through other means assisted the movement of laboratory values in a favorable direction.

Fifth, it is possible that the significant difference in demographic information (i.e., age and BMI) between the two groups may have influenced the end results. Although it appears that BMI has not been studied in correlation to HbA1c levels in established T2DM, there may be a relationship that research has yet to uncover which could have affected the IE group participants’ success. As post-program BMI was generally unavailable in patient records, that relationship could be explored in future studies.

**Implications**

This study’s results demonstrate that the PSJMC DSMT program does effectively assist with the improvement of HbA1c and lipids in a clinically significant manner in participants who complete the entire program. It may also be implied that participants who attend even the initial educational session may derive some clinical benefit from the introductory material covered in the session. As such, the CDE can continue to use the current schedule and materials for the individual appointments and classes and refine them as needed. All patients should continue to
be encouraged to attend classes if at all possible in order to receive the full benefits of the education.

In addition to providing the PSJMC DSMT program with outcomes data, these findings also contribute to the body of research specifically surrounding AADE-accredited DSME programs. This research supports the effectiveness of the organization’s program accreditation standards in their ability to produce positive changes in patients with DM and may serve as an example for other programs in regards to methods of creating and presenting educational curricula.

**Future Research**

Based on these findings, further studies may be performed to quantify the clinical results of dropping out of versus completing a DSME program on a larger scale, both at PSJMC and nationwide. Additional comparisons could be made regarding number of educational sessions attended and degree of effectiveness to determine the success rates of participants who drop out of programs at varying points in time. When more definitive data is obtained on this topic, efforts could focus upon developing other educational materials and strategies to address the barriers that seem to hinder many past, current, or prospective participants.

Furthermore, cost analysis research continues to be needed in this field (Boren et al., 2009), and accredited programs such as this may serve as a ready supply of information, upon which more detailed studies and organization-wide policies may build. Further cost-effectiveness studies may also provide continuing support for current service reimbursement policies.

Last, a method of addressing barriers in communication with providers and the process of obtaining laboratory values in a timely manner is needed. As technology continues to improve,
so may the ease of obtaining necessary information. This topic should certainly be one of those focused upon by information technology specialists in the coming years.
References


doi:10.5888/pcd9.120074


doi:http://dx.doi.org/10.1590/S0034-89102009005000001


Appendix A: Eastern Michigan University Human Subjects Review Committee
Approval Letter

RESEARCH @ EMU

UHSRC Determination: EXEMPT

DATE: February 13, 2015

TO: Devon Hoster
Department of Health Sciences/Dietetics and Human Nutrition
Eastern Michigan University

Re: UHSRC: # 707522-1
Category: Exempt category 4
Approval Date: February 13, 2015

Title: Thesis Proposal: Effectiveness of Individual versus Group Diabetes Education on Hemoglobin A1c (HbA1c) and Lipids in Type 2 Diabetes Mellitus

Your research project, entitled Thesis Proposal: Effectiveness of Individual versus Group Diabetes Education on Hemoglobin A1c (HbA1c) and Lipids in Type 2 Diabetes Mellitus, has been determined Exempt in accordance with federal regulation 45 CFR 46.102. UHSRC policy states that you, as the Principal Investigator, are responsible for protecting the rights and welfare of your research subjects and conducting your research as described in your protocol.

Renewals: Exempt protocols do not need to be renewed. When the project is completed, please submit the Human Subjects Study Completion Form (access through IRBNet on the UHSRC website).

Modifications: You may make minor changes (e.g., study staff changes, sample size changes, contact information changes, etc.) without submitting for review. However, if you plan to make changes that alter study design or any study instruments, you must submit a Human Subjects Approval Request Form and obtain approval prior to implementation. The form is available through IRBNet on the UHSRC website.

Problems: All major deviations from the reviewed protocol, unanticipated problems, adverse events, subject complaints, or other problems that may increase the risk to human subjects or change the category of review must be reported to the UHSRC via an Event Report form, available through IRBNet on the UHSRC website.

Follow-up: If your Exempt project is not completed and closed after three years, the UHSRC office will contact you regarding the status of the project.

Please use the UHSRC number listed above on any forms submitted that relate to this project, or on any correspondence with the UHSRC office.

Good luck in your research. If we can be of further assistance, please contact us at 734-487-3090 or via e-mail at human.subjects@emich.edu. Thank you for your cooperation.

Sincerely,

Jayne Yatczak PhD, OTRL
Chair
College of Health and Human Services Human Subjects Review Committee
Appendix B: Eastern Michigan University Human Subjects Review Committee
Continuing Approval Letter

RESEARCH @ EMU

UHSRC Determination: EXEMPT

DATE: July 21, 2015

TO: Devon Hoster
Eastern Michigan University

Re: UHSRC: # 707522-2
Category: Exempt category 4
Approval Date: July 21, 2015

Title: Thesis Proposal: Effectiveness of Individual versus Group Diabetes Education on Hemoglobin A1c (HbA1c) and Lipids in Type 2 Diabetes Mellitus

Your amendment request for research project, entitled Thesis Proposal: Effectiveness of Individual versus Group Diabetes Education on Hemoglobin A1c (HbA1c) and Lipids in Type 2 Diabetes Mellitus, has been determined to maintain an Exempt status in accordance with federal regulation 45 CFR 46.102. UHSRC policy states that you, as the Principal Investigator, are responsible for protecting the rights and welfare of your research subjects and conducting your research as described in your protocol.

Renewals: Exempt protocols do not need to be renewed. When the project is completed, please submit the Human Subjects Study Completion Form (access through IRBNet on the UHSRC website).

Modifications: You may make minor changes (e.g., study staff changes, sample size changes, contact information changes, etc.) without submitting for review. However, if you plan to make changes that alter study design or any study instruments, you must submit a Human Subjects Approval Request Form and obtain approval prior to implementation. The form is available through IRBNet on the UHSRC website.

Problems: All major deviations from the reviewed protocol, unanticipated problems, adverse events, subject complaints, or other problems that may increase the risk to human subjects or change the category of review must be reported to the UHSRC via an Event Report form, available through IRBNet on the UHSRC website.

Follow-up: If your Exempt project is not completed and closed after three years, the UHSRC office will contact you regarding the status of the project.

Please use the UHSRC number listed above on any forms submitted that relate to this project, or on any correspondence with the UHSRC office.

Good luck in your research. If we can be of further assistance, please contact us at 734-487-3090 or via e-mail at human.subjects@emich.edu. Thank you for your cooperation.

Sincerely,

April Nelson, MS
Research Compliance Administrator
University Human Subjects Review Committee
Appendix C: PSJMC Institutional Review Board Approval Letter

CERTIFICATE OF APPROVAL
(EXEMPTION)

March 31, 2015
Devon Hoster
333 N. Madison
Joliet, IL 60435

Dear Ms. Hoster,
IRB # 00005323

TITLE OF STUDY: Effectiveness of Individual versus Group Diabetes Education on Hemoglobin A1c (HbA1c) and Lipids in Type 2 Diabetes Mellitus

This letter is to officially notify you of the approval of exemption of this study by the Presence Saint Joseph Medical Center Institutional Review Board for the Protection of Human Subjects. It is the Board’s opinion there are adequate safeguards for the rights and welfare of the participants in this study. This study is in compliance with this institution’s Federal Wide Assurance 00005323 and DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Date of Exemption: March 31, 2015
Items reviewed:
- Initial Application
- Certificate of HIPAA
- Protocol
- Exempt Approval Letter from UHSRC
- CV & GCP

Date of Next Review: September 24, 2015

You are authorized to conduct this study.

Please refer to IRB meeting minutes and/or your IRB review request letter located in the IRB binder: 4th floor, East tower, Room 078.

This study should be conducted in full accordance with all applicable sections of the IRB Guidelines and you should notify the IRB immediately of any proposed changes. As the Principle Investigator, you should report any unanticipated problems involving risk to the participants or others to the Board. Please notify us when your study has been completed.

If you have any questions, please contact Lorrie Holland, IRB Coordinator, at 815.741.7693.

Respectfully,

Joshua Tepper, MD
PSJMC IRB Chairperson/Designee
cc: Clinical Research Operations

This is to certify that the information contained herein is true and correct as reflected in the records of the Presence Saint Joseph Medical Center Institutional Review Board (PSJMC). WE CERTIFY THAT PSJMC IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION 9 (ICH) GUIDELINES

333 North Madison Street . Joliet, Illinois 60435 . 815.726.7133 . presencehealth.org

Sponsored by the Franciscan Sisters of the Sacred Heart, the Servants of the Holy Heart of Mary, the Sisters of the Holy Family of Nazareth, the Sisters of Mercy of the Americas and the Sisters of the Resurrection
Appendix D: DSMT Initial Visit Form

Initial Patient Self-Assessment (Version 2)

Demographics:
Name: ________________________________
Address: ________________________________
E-mail: ________________________________
Phone Number: ________________________________
Gender: ________________________________
Primary Language: ________________________________
Date of Birth: ________________________________

Occupation:
☐ Clerical ☐ Skilled Labor ☐ Student ☐ Retired
☐ Homemaker ☐ Professional/Managerial ☐ Other Labor ☐ Disabled
☐ Sales ☐ Unemployed ☐ Other

Education:
☐ Elementary School ☐ High School Degree ☐ College Degree
☐ Some High School ☐ Some College ☐ Post Graduate

Race/ Ethnicity:
☐ American Indian or Alaska Native ☐ Hispanic / Latino / Mexican
☐ Asian / Chinese/ Japanese / Korean ☐ White / Caucasian
☐ Black / African American ☐ Native Hawaiian or other Pacific Islander
☐ Other
Introduction

Have you ever been diagnosed, ever been told, or have you had problems with the following? (mark all that apply)

- High Blood Pressure
- High Cholesterol
- Kidney / Bladder problems
- Eye or vision problems
- Frequent nausea, vomiting, constipation, diarrhea
- Surgery in the last 5 years
- Heart Disease / Chest Pain
- Thyroid Disease
- Asthma
- Numbness/pain/tingling of hands/feet
- Depression or anxiety
- Drug allergies
- Stroke
- Problems with sexual function
- Shortness of Breath
- Other foot problems
- Other health problems

What is your height?

_________ feet _________ inches

What is your current weight?

________________________ lbs

In the past year have you?

- Lost more than 10 lbs
- Gained more than 10 lbs
- Stayed about the same

During what year were you diagnosed with diabetes?

________________________

Have you had diabetes education?

- Yes
- No

If yes, when (month and year)?

________________________

Do you have any physical limitations that may affect your ability to perform your self-care? (check all that apply)

- Hearing problems
- Problems with the use of your hands
- Problems with the use of your feet
- Vision loss (not corrected by glasses or contacts)

How do you learn best? (check all that apply)

- Listening
- Watching
- Hands On/Doing

Number of emergency room visits or 911 calls for your diabetes requiring assistance in the last three months:

________________________

Number of days missed from work, school or usual routine because of diabetes within the last 30 days:

________________________

Number of hospital admissions for diabetes within the last 3 months:

________________________
Having diabetes means that you need to make choices about food, physical activity, and when and how to take medicines. You may need blood tests and other exams to monitor your diabetes health status. You also need to do things to prevent problems related to your health, know how to cope with your diabetes, and make everyday management decisions.

The following questions are about the things you need to do to stay healthy with your diabetes. These questions ask about the things you do, how often you do them, how important they are to you and how sure you are about doing them.

Reducing Risks
Reducing risks means that you are taking steps to prevent or reduce problems related to diabetes. This includes having eyes checked by an eye doctor, having feet checked by a health care provider, seeing a dentist, getting flu and/or pneumonia vaccinations, having blood pressure checked, having cholesterol and triglycerides checked, and not smoking.

Check all of the following things that have happened in the past year.

<table>
<thead>
<tr>
<th>Had an eye exam (with drops in the eyes) by an eye doctor.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had feet checked by a health care provider.</td>
</tr>
<tr>
<td>Saw a dentist.</td>
</tr>
<tr>
<td>Had a flu and/or pneumonia vaccination.</td>
</tr>
<tr>
<td>Had blood pressure checked.</td>
</tr>
<tr>
<td>Had cholesterol and triglycerides checked.</td>
</tr>
<tr>
<td>Got help to stop smoking (only applicable for smokers)</td>
</tr>
<tr>
<td>Had an A1C test</td>
</tr>
</tbody>
</table>

How important do you feel it is to do the things listed above to help prevent or reduce problems related to diabetes, where 0 is not important at all and 10 is very important?

0  1  2  3  4  5  6  7  8  9  10

How often does life stress make it hard for you to perform diabetes self care, where 0 is not at all and 10 is very likely?

0  1  2  3  4  5  6  7  8  9  10

How often do you closely examine or look at your feet with your socks off?

☐ Daily  ☐ Several times a week  ☐ A few times a month
☐ Once in a while  ☐ Rarely or never

How sure are you that you can get the help you need to prevent or reduce problems related to diabetes, where 0 is not sure at all and 10 is very sure?

0  1  2  3  4  5  6  7  8  9  10
Result of my A1C test as given to me by the health care provider:

Are you able to become pregnant? If so, when was the last time you had counseling about what to do before getting pregnant (if female and able to get pregnant)
☐ Never ☐ Last 6 months ☐ Last year ☐ Over a year ago ☐ Do not know

**Being Active**

*Being active means you are taking part in doing things such as jogging, bicycling, golfing, gardening, or walking without stopping for at least 30 minutes most days of the week.*

During the past week, or last 7 days, how many days were you able to be active? (circle one)

1 2 3 4 5 6 7

How important is it to you to be active, where 0 is not important at all and 10 is very important?

0 1 2 3 4 5 6 7 8 9 10

How sure are you that you can be active, where 0 is not sure at all and 10 is very sure?

0 1 2 3 4 5 6 7 8 9 10

**Healthy Eating**

*Following an eating plan that is good for you includes: not eating too much, counting the amount of carbohydrates you eat, not eating too much fat, keeping an eye on and/or drinking less alcohol. It also means eating fruits, vegetables, whole grains, and beans and other foods with high fiber. Following an eating plan that is good for you may also include reaching goals for losing weight, and limiting the amount of protein and salt you eat.*

During the past week, or last 7 days, how many days were you able to follow a healthy eating plan? (circle one)

1 2 3 4 5 6 7

How sure are you that you can follow an eating plan that is good for you, where 0 is not sure at all and 10 is very sure? (circle one)

0 1 2 3 4 5 6 7 8 9 10

How important is it to you to follow an eating plan that is good for you, where 0 is not important at all and 10 is very important? (circle one)

0 1 2 3 4 5 6 7 8 9 10
Taking Medication

Taking medication means that you take medicines that have been prescribed by your healthcare provider to treat your diabetes or other health conditions. These may be pills, insulin, creams, or other medicines that you inject. For the next several questions, please answer for all the medicines that you take.

Do you take diabetes medication? Check all that apply
☐ Do not take medication
☐ Other injections for blood sugar
☐ Pills
☐ Insulin

Do you take any additional nutritional supplements? Check all that apply
☐ Vitamins
☐ Herbal supplements
☐ Other

Sometimes it can be a hard to remember to take all of your medicines. Over the past week, or last 7 days, how many days have you missed taking your diabetes medicines as recommended?

1 2 3 4 5 6 7

How important is it to you to take your medicines, where 0 is not important at all and 10 is very important?

0 1 2 3 4 5 6 7 8 9 10

How sure are you that you can take your medicines, where 0 is not sure at all and 10 is very sure?

0 1 2 3 4 5 6 7 8 9 10

Monitoring

Monitoring for people with diabetes means that they regularly check blood sugar. Monitoring also includes checking your blood pressure, cholesterol, and weight. For this set of questions, we will focus on blood sugar monitoring. Monitoring the level of your blood sugar means that you use a blood sugar meter to take a blood sugar reading. Monitoring may be done on your own or with the help of a healthcare provider.

During the past week, or last 7 days, how many days were you able to monitor your blood sugar at least once per day?

1 2 3 4 5 6 7

How important is it to you to monitor your blood sugar at least once per day, where 0 is not important at all and 10 is very important?

0 1 2 3 4 5 6 7 8 9 10

How sure are you that you can monitor your blood sugar at least once per day, where 0 is not sure at all and 10 is very sure?

0 1 2 3 4 5 6 7 8 9 10
How often do you have high blood sugar?
☐ Daily   ☐ Several times a week   ☐ A few times a month
☐ Once in a while   ☐ Rarely or never   ☐ Don’t know

How often do you have low blood sugar?
☐ Daily   ☐ Several times a week   ☐ A few times a month
☐ Once in a while   ☐ Rarely or never   ☐ Don’t know

Do you wear a bracelet or keep something with you to identify that you have diabetes?
☐ Yes   ☐ No

Do you use a meter to check your blood sugar? (check one)  ☐ Yes   ☐ No

How often do you usually check your blood sugar?
☐ 4 or more times a day   ☐ Once a day
☐ 3 times a day   ☐ Once a week or less
☐ 2 times a day   ☐ Rarely or never

Problem Solving

Problem solving means coming up with ways to make everyday and/or challenging decisions to stay healthy with your diabetes. When you make a decision about what to eat or how much to eat, choose which medicines to take, decide whether to take a walk, or determine how you’re going to make changes to your daily routine to help your diabetes, you are problem solving. For most situations this means figuring out the problem, finding a way to deal with it and thinking about what may prevent you from solving the problem.

Over the past week, or last 7 days, how many days have you done problem solving for everyday and/or challenging decisions?

☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5   ☐ 6   ☐ 7

How important is being able to problem solve when being faced with everyday and/or challenging decisions, where 0 is not important at all and 10 is very important?

0  ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5  ☐ 6  ☐ 7  ☐ 8  ☐ 9  ☐ 10

How sure are you that you can problem solve when faced with everyday and/or challenging decisions, where 0 is not sure at all and 10 is very sure?

0  ☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5  ☐ 6  ☐ 7  ☐ 8  ☐ 9  ☐ 10

When you are sick or can’t eat your usual foods how often do you do the following? (check all that apply)
☐ Replace usual food with carbohydrates or sugar   ☐ Drink more water
☐ Take diabetes medication   ☐ Check ketone level
Healthy Coping
Healthy coping is having ways to help yourself or knowing when and how to seek help when you are overwhelmed by your diabetes. Every person with diabetes has to deal with stress, strong emotions or family situations that can make it hard to manage their diabetes. How you feel and your quality of life can be affected by emotional and social problems.

Over the past week, or last 7 days, how many days were you able to cope in a healthy way when you faced stress, emotional or family problems?

1 2 3 4 5 6 7

How important is it to you to either help yourself or know when and how to seek help when you are faced with stress, emotional or family problems, where 0 is not important at all and 10 is very important?

0 1 2 3 4 5 6 7 8 9 10

How sure are you that you can help yourself or know when and how to seek help when faced with stress, emotional or family problems, where 0 is not sure at all and 10 is very sure?

0 1 2 3 4 5 6 7 8 9 10

How often do you feel depressed?

☐ A lot ☐ A little
☐ Some ☐ Not at all

How much does your diabetes interfere with sexual function?

☐ A lot ☐ Some ☐ A little ☐ Not at all

Goal Setting
Having diabetes means you may need to make changes. What changes, if any, would you like to make now?
☐ Activity ☐ Eating
☐ Medication taking ☐ Monitoring
☐ Problem solving for blood sugars and sick days ☐ Reducing risks of diabetes complications
☐ Living with diabetes ☐ None of the above

Culture
Do you have any cultural factors that may make it more difficult for you to control your diabetes?

☐ Yes ☐ No

If yes, please state what these are:
Do you have trouble paying for your medications or doctor visits?  □ Yes  □ No

If yes, please explain what kind of trouble


Do you have a support person at home?  □ Yes  □ No