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The Effects of a Low-Glycemic Index Diabetes Management Program on Weight, Body Mass Index, Triglycerides, Cholesterol and Hemoglobin A1C Values

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THE EFFECTS OF A LOW-GLYCEMIC INDEX DIABETES MANAGEMENT PROGRAM ON WEIGHT, BODY MASS INDEX, TRIGLYCERIDES, CHOLESTEROL AND HEMOGLOBIN A1C VALUES

by

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ABSTRACT

The purpose of this study was to evaluate effects of a low-glycemic index diet on weight, body mass index (BMI), triglycerides, cholesterol levels, and hemoglobin A1c (HbA1c) following participation in a 12-hour outpatient diabetes self-management education (DSME) program. This DSME program is unique as it focuses on a low-glycemic index diet rather than the traditional carbohydrate consistent diet to control blood glucose levels. Health outcomes obtained post participation were compared to baseline data. Participants were 283 individuals with type 2 diabetes including 94 (33%) men and 189 (67%) women, with a mean baseline HbA1c of 8.7 ±2.2%. Statistically significant improvements were seen in mean BMI (-0.7±2.0 kg/m^2, $p<0.05$), HbA1c (-1.1±1.9%, $p<0.05$), and total cholesterol (-12.3±37.3 mg/dL, $p<0.05$). No statistically significant differences in changes between men and women were found for the outcomes measured. Although males showed improvements in HDL cholesterol (+1.7±8.1 mg/dL, $p = 0.052$), results were not statistically significant, unlike the significant improvements for the female group (+1.6±10.1 mg/dL, $p<0.05$). Traditionally, a carbohydrate consistent diet has been supported as the primary diet for diabetes management. This research shows a low-glycemic index diet can also be beneficial. Future research should include long-term randomized control trials to compare the two approaches to diabetes management. The effects of the low-glycemic index diet on medication use and quality of life also should be explored.

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CHAPTER 1

INTRODUCTION

According to the American Diabetes Association (ADA), diabetes is characterized by hyperglycemia triggered by an abnormal surge in insulin and/or a defect in insulin action (2014). The development of diabetes can be caused by autoimmune damage to pancreatic *B*-cells, promoting an insulin deficiency and defects in tissue insulin sensitivity. Often, diminishing insulin secretion and insulin resistance can occur simultaneously in the same individual, and it can be unclear which defect is the primary cause of hyperglycemia (ADA, 2014).

Two general etiopathogenetic groups, Type 1 and Type 2 diabetes, categorize the majority of diabetes cases (ADA, 2014). Individuals diagnosed with type 1 diabetes have the inability to secrete insulin (ADA, 2014). On the other hand, individuals with both insulin resistance and insufficient compensatory insulin secretory response are categorized as having type 2 diabetes (ADA, 2014).

Statement of the Problem

The evidence highlighting the prevalence and incidence of diabetes is astounding. The 2017 National Diabetes Statistic Report indicates that of the 30.3 million people who have diabetes, 23.1 million have been formally diagnosed by a physician (Centers for Disease Control and Prevention, 2017). According to the Centers for Disease Control and Prevention's (CDC) 2016 Diabetes Data and Statistics report, Louisiana has the 5th

highest diabetes rate in the United States, with 11.8% of adults having a diagnosis of diabetes. If not managed properly, diabetes can lead to a number of complications. Common long-term complications from chronic hyperglycemia of diabetes include retinopathy, nephropathy, peripheral neuropathy, and autonomic neuropathy (ADA, 2014). Individuals with diabetes also have an increased risk for atherosclerotic cardiovascular, peripheral arterial, and cerebrovascular disease, as well as hypertension and lipoprotein metabolism abnormalities (ADA, 2014). These complications generally are associated with reduced life expectancy and decreased quality of life (ADA, 2014).

Numerous healthcare programs and services are available for individuals with diabetes to help manage their condition (Bianconi, Pope, Erickson, & Hood, 2016; Evert, Boucher, & Cypress, 2013; Franz, Boucher, & Evert, 2014; Franz, MacLeod, & Evert, 2017; Hall, Strong, & Krebs, 2016; Marincic, Hardin, & Salazae, 2017; Pastors & Franz, 2012). BRG Fit! is a 12-hour outpatient diabetes management program offered at Baton Rouge General (BRG) Medical Center in Baton Rouge, Louisiana. The program focuses on using a low-glycemic index diet to control blood glucose levels, and is accredited by the American Association of Diabetes Educators (AADE) and the ADA. Participants can either enroll themselves in the program or their physician can refer them. Referral is not limited to BRG physicians. Physicians refer patients with newly diagnosed diabetes and those with a previous diagnosis of diabetes. This program offers three, 3-hour group sessions, which focus on disease management, nutrition, and chronic complications associated with diabetes. All three group sessions are offered once a month, so participants begin the program as they are referred. A Registered Nurse (RN) leads the disease management and chronic complications group session, while a Registered

Dietitian (RD) leads the nutrition session. The instructors and learning materials are consistent for all participants. All participants are provided a hard copy of the program learning materials to take home and review, even if they are not able to fully complete all 12 hours of the program. The program also offers one 1-hour individual counseling session with the RN, and two 1-hour individual counseling sessions with the RD. Group sessions and individual counseling sessions are scheduled according to the participant's personal schedule. Depending on the insurance policies of participants, coverage and participation for these sessions vary. BRG Fit! does not offer exercise classes, but physical activity goals are set during the individual counseling sessions with the RD. An annual follow-up is provided following participation in the 12-hour program. However, some patients are seen more often seen more than others. The number of follow-up sessions between the initial visit and the annual follow-up session is typically dependent on an individuals' needs, compliance, insurance coverage, and ability to pay. On the initial visit, demographics, height, weight, and waist circumference are measured and recorded by either the RD or RN. Participants provide records of their most recent blood chemistry panels including triglycerides, hemoglobin A1c, total cholesterol, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol for the RN and RD to review.

The BRG Fit! is a unique program that recommends a low-glycemic index diet in an attempt to reduce the body's insulin response and control blood glucose levels. BRG Fit! recommends 8-12 cups of water per day, with water being the primary beverage. Sugar sweetened beverages, artificial sweeteners, sugar substitutes, and juices are avoided. Protein, fat, and fiber are recommended as the focus of each meal and snack.

BRG Fit! promotes animal based protein sources from poultry, pork, beef, seafood, cheese, and whole eggs, while breaded and/or fried meats are avoided. According to BRG Fit!, fats such as olive oil, coconut oil, nut oils, nuts, nut butters, and seeds are recommended to properly absorb fat-soluble vitamins. Butter is recommended over margarine, and vegetable oil, soybean oil, and canola oil are avoided. Fresh or frozen whole fruits and vegetables, milk, yogurt, and legumes are considered nutrient-dense carbohydrates and are allowed. All grains, added sugars, and starches are avoided in an attempt to control blood glucose levels. The following grains are to be avoided: any variety of rice and wheat, corn, quinoa, oats, popcorn, grits, potatoes, and others. BRG Fit! also promotes reading ingredient lists, and suggests that a food product should not be consumed if the ingredient list is long or if the participant cannot pronounce or identify an ingredient (Baton Rouge General Medical Center, 2015).

Current research focusing on low-glycemic approaches to diabetes management is limited. One study found individuals with type 2 diabetes improved glycemic control and lost more weight after participation in a randomized online low-carbohydrate, ketogenic diet program designed to compare results to those who were randomly assigned to a traditional, low-fat diabetic diet recommended by the ADA (Saslow, Mason, & Kim, 2017). Another recent study found a 6-month diet of less than 130 grams of carbohydrates per day reduced HbA1c and Body Mass Index (BMI) more than when compared to a calorie restricted diet. However, a one-year follow-up study showed the benefits of the low-carbohydrate diet on BMI and HbA1c did not persist in comparison with the calorie-restricted diet (Santo et al., 2017). Additional research is necessary to evaluate the effects of a low-glycemic diet in improving glycemic control. The BRG Fit!

diabetes management program has been in existence since 2012. Though health care providers have seen success, the program has not been formally evaluated.

Purpose of the Study

The purpose of this study was to identify differences in weight, BMI, triglycerides, cholesterol levels, and hemoglobin A1c values following participation in a 12-hour outpatient diabetes management program focused on using a low-glycemic index diet to control blood glucose levels. Health outcomes obtained one year following program participation were compared to baseline data obtained prior to beginning the program. Results were compared between male and female participants.

Hypotheses

Three hypotheses were tested:

1. There will be no significant difference in BMI and weight from baseline and measures obtained at the 1-year follow-up.

2. There will be no significant difference in hemoglobin A1c values, cholesterol levels, and triglyceride levels from baseline and measures obtained at the 1-year follow-up.

3. There will be no significant difference in the change in hemoglobin A1c values, cholesterol levels, and triglyceride levels from baseline to measures obtained at the1-year follow-up between males and females.

Justification

Numerous healthcare programs and services are available for people with diabetes to learn how to manage their condition (Bianconi et al., 2016; Evert et al., 2013; Franz et al., 2014; Franz et al., 2017; Hall et al., 2016; Marincic et al., 2017; Pastors & Franz, 2012). Significant components of many programs are nutrition education and counseling provided by Registered Dietitians (RDs). Registered Dietitians have been trained to teach diabetic patients how to use different dietary strategies and physical activity to control their blood glucose levels and therefore manage their disease state (Mitchell et al., 2017). According to a 2017 systemic review of randomized control trials, adults counseled by RDs have shown improvement in diet quality; diabetes outcomes, such as blood glucose and hemoglobin A1c values; and weight loss outcomes, such as changes in weight and waist circumference (Mitchell et al., 2017). However, evidence specifically surrounding outcomes of low-glycemic interventions in the outpatient setting is limited.

The aim of this study was to evaluate the anthropometric and biochemical outcomes of patients who have participated in BRG Fit!, a 12-hour outpatient diabetes management program focused on a low-glycemic index diet. The results of this study will provide great benefit to Baton Rouge General Medical Center. If results are positive, BRG could use these results to attract more patients and increase business by demonstrating program success in managing diabetes. Positive program outcomes may be used to attract additional referrals and patient participation, thereby increasing revenue. Additional program participants may assist BRG in receiving additional reimbursement for services and offering the hospital opportunities to enhance the medical services provided. Positive research results would also enable the program manager and staff an opportunity to demonstrate a viable transition in patients from inpatient care to outpatient care services, thereby enhancing the continuity of care and promoting better disease management and prevention. In addition, positive results may provide evidence that a low-glycemic diet can be an effective strategy for diabetes management. This evidence also could be used in the development of future standardized diabetes management strategies. Negative outcomes also may be beneficial for BRG, as they can provide insight into where improvement and development is needed. The results of this study will provide insight for peers, health professionals, and future nutrition-related program planning.

CHAPTER 2

REVIEW OF LITERATURE

According to the American Diabetes Association (ADA), diabetes is defined as a group of metabolic diseases specifically classified by hyperglycemia, which results from either failure in insulin secretion or insulin action (ADA, 2014). Occasionally, insulin secretion and insulin action defects can occur in the same individual (ADA, 2014). The number of people with diabetes is steadily increasing among both genders and all age and ethnicity population groups (ADA, 2014).

Prevalence of Diabetes

The 2017 National Diabetes Statistic Report indicates of the 30.3 million people who have diabetes, 23.1 million have been formally diagnosed with diabetes by a physician (Centers for Disease Control and Prevention, 2017). Since 1958, the prevalence of diabetes among US citizens has significantly increased. Nearly 60 years ago, 1.58 million people or 0.93% of the U.S. population were diagnosed with diabetes (Centers for Disease Control & Prevention, 2017). Over a span of nearly 60 years the prevalence of diabetes has increased roughly ten-fold.

The prevalence of diabetes is increasing worldwide, and it is especially prevalent in the United States. According to the Centers for Disease Control (CDC) and Prevention, diabetes affects people of all ages, ethnicities, socioeconomic levels and genders and is also widespread across all geographical regions. The percentage of adults with diabetes is shown to increase as a part of the aging process, with 25.2% of those aged 65 years or older being diagnosed with diabetes (Centers for Disease Control and Prevention, 2017). The highest prevalence of diabetes for both men (14.9%) and women (15.3%) is seen in American Indians/Alaskan Natives (Centers for Disease Control and Prevention, 2017). Overall, prevalence is higher among American Indians/Alaskan Natives (15.1%), non-Hispanic blacks (12.7%), and people of Hispanic ethnicity (12.1%) than among non-Hispanic whites (7.4%) and Asians (8.0%) (Centers for Disease Control and Prevention, 2017). Prevalence also varied significantly by level of education, which is often an indicator of socioeconomic class (Centers for Disease Control and Prevention, 2017). The highest prevalence was seen in those with less than a high school education (12.6%) compared to those with a high school education (9.5%) and those with more than a high school education (7.2%) (Centers for Disease Control and Prevention, 2017).

Individuals living in the Southern and Appalachian regions of the United States tended to have the highest prevalence of diagnosed diabetes (Centers for Disease Control and Prevention, 2017). According to the CDC's 2016 Diabetes Data and Statistics report, Louisiana has the 5th highest diabetes rate in the United States, with 11.8% of the adult population having a diagnosis of diabetes. However, the ADA reported the prevalence of diabetes among adults living in Louisiana is actually higher than 11.8%. According to the ADA, 13.9% or 521,294 Louisiana residents had diabetes in 2015 (ADA, 2015).

Diagnostic Criteria for Diabetes

Indicators for determining increased risk for diabetes development or pre-diabetes include a fasting plasma glucose (FPG) from 100 mg/dL to 125 mg/dL, a 2-hour postprandial glucose (PG) test in the oral glucose tolerance test (OGTT) from 140 mg/dL to 199 mg/dL, or Hemoglobin A1c (HbA1c) of 5.7-6.4% (Cefalu, Bakris, & Blonde, 2017). An OGTT uses a glucose load containing the equivalent of 75 grams of anhydrous glucose dissolved in water. For FPG, fasting is defined as no caloric intake for at least eight hours prior to testing. Criteria for diagnosing diabetes include HbA1c values $\geq$ 6.5%, FPG $\geq$ 126 mg/dL, 2-hour PG test > 200 mg/dL during an OGTT, or a random plasma glucose $\geq$ 200 mg/dL in patients exhibiting classic symptoms of hyperglycemia or hyperglycemic crisis. Classic symptoms characterizing hyperglycemia include polyuria, polydipsia, weight loss, polyphagia, and blurred vision (ADA, 2019).

Complications of Diabetes

The effects of chronic hyperglycemia of diabetes have been associated with long-term damage, dysfunction, and failure of varying organs (Cefalu et al., 2017). The organs most commonly affected by chronic hyperglycemia are the eyes, kidneys, nerves, heart, and blood vessels. Long-term consequences of diabetes commonly include retinopathy causing possible loss of vision; nephropathy resulting in renal failure; peripheral neuropathy increasing risk for foot ulcers, amputations and Charcot joints; and autonomic neuropathy with gastrointestinal, genitourinary, and cardiovascular symptoms. Increased incidence of atherosclerotic cardiovascular, peripheral arterial and cerebral disease is commonly seen in individuals with diabetes. Individuals with diabetes also commonly have hypertension and defects in lipoprotein metabolism. Moreover, chronic hyperglycemia is also associated with growth impairment and susceptibility to certain infections. Hyperglycemia with ketoacidosis and non-ketotic hyperosmolar syndrome are acute consequences of uncontrolled diabetes that can be fatal. Therefore, all individuals with diabetes should receive nutrition education and develop glucose monitoring skills to learn how to properly manage diabetes in order to reduce the risk of developing complications (Cefalu et al., 2017).

Effectiveness of Nutrition Therapy in Diabetes Management

As the prevalence of diabetes continues to rise, effective dietary strategies are a necessary component of diabetes management programs (Hall, Strong, & Krebs, 2016). Three central components of diabetes management include weight loss or weight maintenance, improving glycemic control, and prevention or reduction in risk associated with uncontrolled diabetes (Hall et al., 2016). Dietary strategies such as carbohydrate counting and timing of meals with medications have traditionally been used as the best practices for assisting individuals with diabetes to obtain optimum blood glucose control (Hall et al., 2016).

Current research provides evidence that nutrition therapy for diabetes is effective in improving overall glycemic control and other metabolic outcomes (Franz et al., 2017). Hemoglobin A1c (HbA1c) is widely used to assess overall glycemic control because it demonstrates how effective the individuals were in controlling their blood glucose levels over a three month period of time (Franz et al., 2014). Nutrition therapy provided by RDs has been successful in decreasing HbA1c levels by an average of 1% to 2% depending on the type and extent of diabetes and initial HbA1c levels (Academy of

Nutrition and Dietetics, 2015; Evert et al., 2013; Franz et al., 2010; Pastors & Franz, 2012). For instance, individuals with newly diagnosed diabetes and an initial HbA1c level of roughly 9% experienced a reduction of about 2% following nutrition therapy intervention, while newly diagnosed individuals with roughly 6.6% HbA1c levels experienced a 0.4% decrease (Andrews et al., 2011; UK Prospective Diabetes Study, 1990). Both results prove to be significant and clinically momentous. Patients diagnosed with diabetes for greater than nine years experienced about a 5% decrease in HbA1c levels following use of nutrition therapy intervention (Coppell et al., 2010). A reduction in HbA1c levels has been demonstrated to be more cost-effective than using additional medications (Coppell et al., 2010). Medical nutrition therapy that has focused on modifying insulin doses based on carbohydrate intake in patients with type 1 diabetes resulted in about a 1% decrease in HbA1c levels, and enhanced quality of life without increasing hypoglycemia or cardiovascular risks (DAFNE Study Group, 2002). Additional research has supported these results by demonstrating similar findings as well as other beneficial outcomes, which include weight loss, decreased blood pressure, improved lipid profiles, decreased need for medication, and decreased risk for development of diabetes-related complications (Pastors & Franz, 2012).

A recent retrospective chart review examined the outcomes of a diabetes self-management education and medical nutrition therapy program (Marincic et al., 2017). The program consisted of 8.5 hours of group classes, and 1.5 hours of individualized counseling with an RD. The duration of this program was approximately four months. This program focused on traditional carbohydrate counting and heart healthy eating methods. From baseline, significant weight loss (-1.6 kg±3.9, p=0.001) was observed.

Significant HbA1c reduction (-1.92%±2.25%, p=0.001) was observed from baseline, with 72% of patients reaching HbA1c goals. Triglycerides were reduced, and HDL cholesterol increased from baseline (Marincic et al., 2017). Another recent retrospective study evaluated the effectiveness of a diabetes education program in improving HbA1c values in 162 United States Military veterans (Bianconi et al., 2016). HbA1c values were significantly lower following program participation compared to baseline. However, no significant differences were found in the participants' HbA1c values based on the number of classes attended or BMI at baseline (Bianconi et al., 2016). It is well accepted that outpatient diabetes intervention is an effective strategy in improving glycemic control (Academy of Nutrition and Dietetics, 2015; Andrews et al., 2011; Bianconi et al., 2016; Coppell et al., 2010; DAFNE Study Group, 2002; Evert et al., 2013; Franz et al., 2010; Hall et al., 2016; Marincic et al., 2107; Pastors & Franz, 2012; UK Prospective Diabetes Study, 1990).

Nutrition Therapy Interventions

Nutrition therapy interventions traditionally used by registered dietitians include carbohydrate counting, individualized meal plans, calorie and fat intake reduction, insulin-to-carbohydrate ratios, exchange lists, physical activity, and behavioral strategies (Franz et al., 2014). Based on the ADA recommendations, individuals with diabetes should receive individualized nutrition therapy provided by a competent registered dietitian, who is able to provide diabetes medical nutrition therapy (Evert et al., 2013). In turn, the patient will be better able to reach treatment goals and glycemic control. One study compared the effects of four diabetes self-management education (DSME) programs (Dirlam, Pope, Erickson, & Fontenot, 2017). The four programs compared were: a DSME program taught by a RD; a multidisciplinary DSME course; a single-session diabetes education course taught by an RD that involved peer teaching; and individualized MNT taught by an RD. All four groups were successful in decreasing HbA1c ($\bar{x}$ =− 1.87±0.49%) and no method was significantly more effective than another. All four methods were also effective in lowering LDL cholesterol ($\bar{x}$ =25±15 mg/dL), although the DSME program led by an RD had the most significant improvement, with a mean decrease of 49±79 mg/dL. None of the methods were successful in producing a significant body weight change. The results suggest that any form of diabetes education can be effective in decreasing HbA1c and LDL (Dirlam et al., 2017). In another recent study, the effects of a single individual diabetes education session were compared to the effects of a group program on HbA1c and lipids in individuals with type 2 diabetes (Haque, Hoster, & Mistry, 2017). There were no significant differences between the groups for HbA1c or lipid values. However, clinically significant differences were noted from pre- to post- intervention in HbA1c and lipid values in participants completing the group program (Haque et al., 2017). Additional evidence also shows multiple counseling sessions with an RD and yearly follow-up visits are important for optimum medical management and health outcomes (Evert et al., 2013; Franz et al., 2014; Pastors & Franz, 2012).

Prevalence of Nutrition Therapy

Nutrition therapy for diabetes is effective in improving overall glycemic control and other metabolic outcomes (Franz et al., 2014). However, nationally representative data suggest that only half of individuals with diabetes ever receive diabetes education, and less visit a registered dietitian (Ali et al., 2013). Additionally, one study including over 18,000 individuals with diabetes found only 9.1% of participants received at least one nutrition therapy session over the course of nine years (Robbins, Thatcher, Webb, & Valdmanis, 2008). Diabetes care components necessary for improved outcomes include diabetes self-management, on-going support, and nutrition therapy (Franz et al., 2014).

Weight Loss Intervention and Glycemic Control

Achieving and maintaining a healthy body weight is a primary strategy for improving glycemic control (Bantle et al., 2008). Weight loss interventions for individuals newly diagnosed with diabetes have been shown to be specifically beneficial in improving glycemic control (Esposito et al., 2009; Feldstein et al., 2008).

However, the benefit of weight loss intervention among diabetics is controversial (Franz, 2013). According to the Academy of Nutrition and Dietetics, only half of weight loss studies in individuals with type 2 diabetes produced reduction in HbA1c levels one year post-intervention (Franz et al., 2010). Weight loss intervention studies lasting one year or longer among individuals with type 2 diabetes showed weight loss ranged from 1.9 kg to 8.4 kg (Evert et al., 2013). The Mediterranean-style diet and the intensive life style intervention in the Look AHEAD (Action for Health in Diabetes) trial were two interventions that resulted in the largest amount of weight loss after one year in newly diagnosed individuals. Individuals following a Mediterranean-style diet had a weight loss of 6.2 kg to 8.4 kg while participants in the Look AHEAD trial had a weight loss from baseline of 6% in the intervention group and 3.5% in the control group (Esposito et al., 2009; Pi-Sunyer et al., 2007). A weight loss of > 6 kg (approximately 7-8.5% of initial body weight), regular physical activity, and frequent contact with RDs appear important for consistent beneficial effects of weight loss interventions (Franz et al., 2007). Half of the intervention groups studied by the ADA reduced HbA1c levels at one year, while the other half did not incur any significant changes in HbA1c levels (Evert et al., 2013). Lipid panels and blood pressure outcomes from the weight loss interventions varied (Evert et al., 2013).

Most of the ADA reviewed weight loss interventions produced a weight loss ranging from 1.9 kg to 4.8 kg in overweight or obese individuals with type 2 diabetes following one year of intervention; however, this weight loss was less than 5% of baseline weight (Evert et al., 2013). Despite the fact that patients did not achieve the expected weight loss goal, the patients did show improvements in HbA1c levels, lipid panels, and blood pressures; but, improvements did not provide consistent results (Evert et al., 2013). Interestingly, research suggests weight loss may be more challenging for individuals with diabetes (Franz et al., 2007). According to a systemic review of 80 studies including 26,000 participants, the average weight loss is reported to be about 7.5 kg or 8% of baseline weight (Franz et al., 2007).

Consequently, weight loss intervention with the goal of improved glycemic control may be most beneficial for individuals with prediabetes or those newly diagnosed (Franz et al., 2014). Regular visits with a registered dietitian, consistent physical activity, and a 7-8.5% loss of initial body weight seem to be crucial for positive effects on glycemic control, lipids, and blood pressure (Franz, 2013). Nutrition therapy goals are not limited strictly to weight loss. Nutrient-dense intake, regular physical activity, and supportive behavioral changes are recommended for individuals with type 2 diabetes (Franz et al., 2014).

Low-Glycemic Diet in Diabetes Management

Over the years, researchers have used a number of different diet regimens with varying macronutrient percentage combinations to assess the effectiveness in controlling blood glucose levels and/or promoting weight loss among individuals with diabetes. At this time, there is considerable debate regarding the one diet regimen that is most effective (Franz et al., 2010; Franz et al., 2014; Hall et al., 2016; MacLeod, Franz, & Handu, 2017; Oza-Frank, Cheng, Narayan, & Gregg, 2009). According to one study, the majority of individuals with diabetes in the U.S. consume approximately 45% of total energy intake from carbohydrates, 35-40% from fat, and the remainder from protein (Oza-Frank et al., 2009). Positive results have been shown with an emphasis on total energy intake rather the energy source (Franz et al., 2010). However, the changes each individual with diabetes is willing and able to make have been found to alter total energy intake, which makes individualization crucial (Franz et al., 2010). Individualization goes beyond determining specific energy needs. Diet individualization is important for diabetic patients to reach metabolic goals while staying true to their personal preferences, culture, tradition, religion, and health benefits to promote compliance with disease management (Franz et al., 2010).

A considerable amount of debate surrounds the various types of carbohydrates, particularly the function of the glycemic index (GI) and glycemic load (GL) (Franz et al., 2014). The GL is based on portion sizes. The GI is a ranking system to measure the level at which a carbohydrate containing food raises the blood glucose level. This ranking system uses white bread with a GI of 100 to compare all other carbohydrate containing foods' impact on the blood glucose level. However, a recent study evaluating the reliability of the GI for white bread following ingestion by healthy adults found considerable influence based on the participant's age, BMI, serum triglycerides, insulin index, and HbA1c, among other factors (Matthan, Ausman, Meng, Tighiouart, & Lichtenstein, 2016). In order to determine the GI of a food, individuals consume 50 grams of the carbohydrate food being tested and a control food (Academy of Nutrition and Dietetics, 2017). The control food contains the same amount of carbohydrate as the test food. Blood glucose samples are collected prior to carbohydrate consumption, and then at regular intervals following consumption. The blood glucose changes throughout the test are plotted as a curve. The GI characterizes the qualified area below the glucose curve (Academy of Nutrition and Dietetics, 2017). The general public often receives misinformation, which sometimes defines GI as measuring how quickly blood glucose levels increase following consumption of a specific carbohydrate-containing food (Franz et al., 2014). This piece of misinformation suggests that high-GI foods cause a rapid, high glucose peak, and low-GI food causes a more steady and continued glucose reaction (Franz et al., 2014). The GL compares the potential of foods containing the same amount of carbohydrate to raise blood glucose levels, and is used to describe the quality and quantity of carbohydrate in a food serving, meal or diet (Academy of Nutrition and Dietetics, 2017).

A review of studies comparing the glucose reactions of low-GI and high-GI foods showed glucose peaked at about 30 minutes despite being labeled a high-GI, medium-GI, or low-GI food (Brand-Miller, Stockmann, Atkinson, Petocz, & Denyer, 2009). Because of the insignificant difference in peak glucose values of low- and high-GI foods, researchers decided that high-GI foods do not cause a more rapid peak in blood glucose nor do low-GI foods cause a more steady or continued glucose reaction (Brand-Miller et al., 2009).

A systemic review found a modest difference in glycemic control and cardiovascular risk when comparing low- and high-glycemic foods (Wheeler et al., 2010). This review suggests adherence to a lower-GI diet may produce a modest increase in glycemic control; however, some studies failed to acknowledge fiber (Wheeler et al., 2010). One study found an inverse association between GI and the risk for coronary heart disease in men. However, the participants were consuming large quantities of high-fat milk. The researchers concluded that the type of fat replaced by the carbohydrate has a strong influence on coronary heart disease risk in this specific population, and the role of dietary fiber was also cited as an influence (Simila, Kontto, Mannisto, Valsta, & Virtamo, 2013). Another review included a total of 15 studies; 12 were less than three months in duration and three were one year. Of the studies lasting one year, one reported the low-GI and control groups experienced no difference in GI (Wheeler et al., 2010), and the remaining two reported that low-GI and control groups had no difference in HbA1c values (MacLeod et al., 2017; Franz, et al., 2010). There is also the question of individual irregularity of GI responses following carbohydrate consumption. It appears the majority of individuals with diabetes consume a medium-GI diet. Research remains inconclusive in determining if reduction in baseline GI consumption will produce improved glycemic control (Wheeler et al., 2010). A 2017 study showed that following a high dietary fiber, low-glycemic index diet for six months significantly improved participants' fasting plasma glucose and HbA1c levels (Cai, Wang, & Wang, 2017). Another study examined the effects of consuming a low-glycemic index and low-glycemic load diet as part of a hypo-caloric diet in type 2 diabetics (Argiana, Kanellos, & Makrilakis, 2015). After 12 weeks, body weight, BMI, and waist circumference were significantly reduced in both the control and intervention groups. Blood pressure, fasting blood glucose, HbA1c, and insulin were reduced significantly only in the intervention group. However, at the end point, there were no significant differences between the two groups (Argiana et al., 2015). As part of a randomized control trial, dietary recalls from 238 Latino adults with type 2 diabetes were analyzed for glycemic index and glycemic load (Wang, Gellar, & Nathanson, 2015). Increases in glycemic index from baseline were associated with increases in HbA1c levels and waist circumference, but not with fasting blood glucose, blood lipid levels, or BMI (Wang et al., 2015). Independent of weight loss, two studies reported no significant effect on HbA1c levels in adults with type 2 diabetes (Turner-McGrievy, Jenkins, & Barnard, 2011; Wolever, Gibbs, & Mehlin, 2008).

Fiber recommendations for individuals with diabetes do not differ from those for the general public (U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2015). However, diets containing greater than 50 grams of fiber per day reportedly resulted in improved glycemic control in individuals with diabetes, while more common fiber consumption, roughly 24 grams per day, was not able to produce the same beneficial effect (Evert et al., 2013). Making half of all grains consumed whole grains remains one of the dietary recommendations for the general public and individuals with diabetes; however, whole grain consumption has not been shown to improve glycemic control (Evert et al., 2013). On the other hand, reduced incidence of type 2 diabetes has been associated with whole grain consumption in multiple cohort studies (ADA, 2012).

Carbohydrate Restriction

Postprandial glycemia is predominantly altered by available insulin and the amount of carbohydrates rather than the type of carbohydrates consumed (Cefalu et al., 2017; Evert et al., 2013; Franz et al., 2010). Therefore, the recommended approach for improving glycemic control is monitoring carbohydrate intake (Cefalu et al., 2017). This can be accomplished by counting carbohydrates or experienced approximation (Evert et al., 2013). Of course, carbohydrate intake from fruits, vegetables, whole grains, legumes, and dairy products should be emphasized over those containing added sugar, fat, or sodium (Evert et al., 2013).

Comprehensive examination of the effects of low-carbohydrate diets on diabetes management is increasing as controversy continues to surround the search for an ideal diet to improve glycemic control (Tay, Luscombe-Marsh, & Thompson, 2015). A randomized control trial compared the effects of a very-low carbohydrate, high-unsaturated fat, low-saturated fat diet with a high-carbohydrate, low-fat diet on glycemic control and cardiovascular risk factors after one year (Tay et al., 2015). Both diets produced significant weight loss and reduced HbA1c and fasting glucose. The low-carbohydrate diet, which was high in unsaturated fat and low in saturated fat, showed greater improvements in the lipid profiles, blood glucose stability, and reductions in diabetes medication requirements, suggesting an effective strategy for the optimization of diabetes management (Tay et al., 2015). Additionally, a recent study demonstrated carbohydrate restriction produced significant HbA1c (8.9-8.25) and daily insulin use (64.4 to 44.2 units /day) reductions (Krebs, Parry, Strong, & Cresswell, 2016). When compared to traditional carbohydrate counting methods, no significant reductions in body weight (83.2 to 78.0 kg) were shown (Krebs et al., 2016). Another study of the effects of a low-carbohydrate diet found that blood glucose control improved (HbA1c average 51 to 40 mmol/mol), and only two of 19 participants remained with an abnormal HbA1c at the end of the study period. Average body weight was reduced from 100.2 kg to 91.0 kg, and average waist circumference decreased from 120.2 cm to 105.6 cm. Significant improvements in blood pressure and cholesterol were also observed (Unwin & Unwin, 2014). One study found that individuals with type 2 diabetes improved glycemic control and lost more weight after being randomized to an online low-carbohydrate, ketogenic diet program when compared to a traditional, low-fat diabetic diet recommended by the ADA (Saslow et al., 2017). Additionally, another recent study found a 6-month diet providing less than 130 grams of carbohydrates per day reduced HbA1c and BMI more than a calorie restricted diet. However, a one-year follow-up showed the benefits of the low-carbohydrate diet on BMI and HbA1c did not persist in comparison with the calorie-restricted diet (Santo et al., 2017). Additional research is necessary to determine if a carbohydrate restricted diet can be effective in improving glycemic control, and to evaluate the effects in an outpatient setting.

Non-Nutritive Sweeteners

The use and consumption of non-nutritive sweeteners (NNS) has continued to be a controversial topic among both consumers and professionals (AHA and ADA, 2012). NNS are commonly referred to as non-caloric, low-calorie, or artificial sweeteners, and contain a greater concentration of intense sweet-taste than standard sweeteners, such as sucrose, while providing little to no energy (AHA and ADA, 2012). Both the ADA and the American Heart Association (AHA) state that consumers can use NNS approved by the U.S. Food and Drug Administration (FDA) without a concern for safety (AHA and ADA, 2012). The FDA enforces a thorough approval process consisting of widespread studies that rigorously evaluate a product's safety prior to use by consumers. With a plethora of misinformation circling the Internet, social media, and other news media, it is important for health care professionals to thoroughly evaluate the safety and consumption of NNS in order to assist in providing consumers with the proper recommendations regarding this controversial topic (AHA and ADA, 2012).

In a 2010 review of recent literature, The Academy of Nutrition and Dietetics (AND) concluded that, generally, NNS do not have the ability to impact the glycemic response or lipid levels in individuals with diabetes. The possible effects of NNS intake seen in the research are likely attributed to the carbohydrate substitute of NNS rather than a direct result. AND also recommends individuals with diabetes use NNS as a means to manage their weight and better control blood glucose levels while also reducing sugar, fat, and carbohydrate intake (Academy of Nutrition and Dietetics Evidence Analysis Library, 2010).

Recent publications have revealed the adverse effect NNS can have on blood glucose levels following a weeklong consumption of sucralose and saccharin (Klein, 2013; Pepino, Tiemann, Patterson, & Wice, 2013; Suez, Korem, & Zeeevi, 2014). The research conducted by Pepino et al. showed increased insulin and C-peptide levels, and a decrease in insulin sensitivity following sucralose exposure. However, it is important to note the test population included a large percentage of obese individuals, with the average BMI being 42 kg/m^2 (Pepino et al., 2013). In only seven subjects, Suez et al. studied the effects of saccharin intake after one week. Four of the seven subjects experienced a significant increase in blood glucose levels. A fecal sample was taken from the individuals experiencing the increase in glucose concentrations. Their feces were transplanted to mice. Following the transplant, the mice also experienced an increase in blood glucose levels. These results suggest NNS intake may impact the intestinal microbiome, thus impairing glucose tolerance (Suez et al., 2014).

GLP-1 concentrations have been studied. One study examined the effects of sucralose and acesulfame-K exposure, and found an increase in GLP-1 concentrations following exposure (Brown, Brown, Onken, & Beitz, 2012). A second study also demonstrated an increase in GLP-1 concentration following sucralose consumption (Temizkan et al., 2015).

Fats

Individuals with diabetes have an increased risk for atherosclerotic cardiovascular, peripheral arterial, and cerebrovascular disease, as well as hypertension and lipoprotein metabolism abnormalities (ADA, 2014). The type of fat versus the amount of fat consumed is more important when focusing on metabolic goals and cardiovascular disease risk (Evert et al., 2013). Unsaturated fats are recommended over saturated or trans fats for individuals with diabetes as well as the general public (Evert et al., 2013). Limiting fat intake will also help individuals achieve weight goals (Evert et al., 2013). When monounsaturated fats were consumed in place of carbohydrates and/or saturated fats, improved glycemic control and/or lipid profiles were observed. Consumption of foods rich in monounsaturated fats is commonly associated with the Mediterranean-style diet. Although the general public and individuals with diabetes are advised to increase long-chain omega-3 fatty acid consumption, supplementation with omega-3 fatty acids is not recommended for individuals with diabetes as a means for treatment or prevention of cardiovascular issues (Evert et al., 2013). A systemic review of seven randomized controlled trials suggested omega-3 supplementation failed to improve glycemic control or consistently affect serum cardiovascular risk markers (Wheeler et al., 2010). The results of a large six-year study of individuals with diabetes found one gram of omega-3 supplementation per day compared to placebo was unable to reduce the rate of cardiovascular events, death from arrhythmia, or all-cause death (Bosch et al., 2012).

Total fat, particularly saturated fat, has negative effects on insulin sensitivity in individuals with diabetes. Research suggests continued intake of diets high in total fat were associated with increased rates of insulin resistance (Estadella et al., 2013; Riserus, 2008). Improved insulin sensitivity has been achieved through reduction in saturated fat intake; however, research including individuals with diabetes is limited (Lee et al., 2006). As individuals with diabetes work towards controlling carbohydrate intake, fat intake commonly increased (Davis et al., 2009). Thus, monitoring long-term saturated fat intake becomes increasingly necessary due to the effects on insulin resistance (Davis et al., 2009).

Researchers conducting a parallel design, randomized control trial in 141 participants with type 2 diabetes found a low-glycemic load diet enriched with canola oil significantly improved HbA1c values and reduced cardiovascular disease risk factors when compared to the control group (Jenkins, Kendall, & Vuksan, 2014). Multiple studies have reported no significant effect of differing amounts of unsaturated and saturated fatty acids on HbA1c or glucose levels in adults with type 1 and type 2 diabetes (Delahanty, Nathan, & Lachin, 2008; Strychar, Cohn, & Renier, 2009; Wolever et al., 2008). One reported no significant effect on exogenous insulin doses in adults with type 1 diabetes (Strychar et al., 2009), and one reported no significant effect on endogenous insulin levels in adults with type 2 diabetes (Wolever et al., 2008).

Dietary Patterns and Diabetes Management

Dietary patterns are defined as combinations of various foods or food groups that describe associations between nutrition and disease (Cefalu et al., 2017). Diabetes can be managed by a variety of dietary patterns (Cefalu et al., 2017). Therefore, it is important to explore diet in terms of dietary patterns and food choices as opposed to studying single nutrients (Jones-McLean, Shatenstein, & Whiting, 2010). Evert et al. reviewed studies focused on eating patterns of individuals with diabetes to determine the effect of dietary patterns on diabetes nutrition goals (Evert et al., 2013). The following dietary patterns were reviewed: Dietary Approaches to Stop Hypertension (DASH); low-fat; low-carbohydrate; vegetarian; and Mediterranean. The research revealed multiple dietary patterns may lead to improved glycemic control or cardiovascular risk, and no one dietary pattern is ideal for all individuals with diabetes (Wheeler et al., 2010).

DASH Dietary Pattern

The DASH diet promotes consumption of fruits, vegetables, low-fat dairy products, whole grains, poultry, fish, and nuts, while limiting saturated fat, red meat, added sugars, and sodium (Evert et al., 2013). The DASH diet is commonly recommended for the general public, as it has been shown to improve blood pressure and cardiovascular risk factors in individuals without diabetes (Appel et al., 1997; Sacks et al., 2001; U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2015). Research highlighting the effects of the DASH diet on outcomes in individuals with diabetes is limited; however, the DASH diet has shown an improvement in glycemic control, blood pressure, and cardiovascular risk factors in individuals with diabetes (Azadbakht et al., 2011). The DASH diet also has been associated with lower risk of mortality (Park et al., 2016).

Low-Fat Dietary Pattern

The low-fat diet is characterized by a total fat intake less than 30% of total energy intake and less than 10% from saturated fat, while including fruits, vegetables, starches, lean protein, low-fat dairy products (Evert et al., 2013). The Look AHEAD trial evaluated a calorie restricted, low-fat diet that produced significant weight loss (Pi-Sunyer et al., 2007). However, multiple researchers suggest reduced fat intake was unable to consistently improve glycemic control or cardiovascular disease risk factors (Brehm et al., 2009; Davis et al., 2009; Guldbrand et al., 2012; Kodama et al., 2009; Papakonstantinou et al., 2010; Wheeler et al., 2010). When calorie restriction and weight loss occur, it appears the benefit from a low-fat diet is greater (Pi-Sunyer et al., 2007).

Vegetarian Dietary Pattern

Limiting animal products may reduce risk of chronic disease due to decreased saturated fat and cholesterol intake, and increased fruit, vegetable, whole grain, nut, soy, fiber, and phytochemical consumption (Evert et al., 2013). Of the six vegetarian and low-fat vegan diet studies reviewed, glycemic control or cardiovascular disease risk was not consistently improved in individuals with diabetes unless calorie restriction and weight loss occurred (Barnard et al., 2006; Barnard et al., 2009; Kahleova et al., 2011; Nicholson et al., 1999; Tonstad, Butler, Yan, & Fraser, 2009; Turner-McGrievy et al., 2008). Weight loss with the vegetarian diet has occurred in most studies (Barnard et al., 2006;

Nicholson et al., 1999; Tonstad et al., 2009; Kahleova et al., 2011). One study showed that a vegetarian diet reduced subfascial fat and intramuscular fat more than a traditional hypocaloric diabetic diet in individuals with type 2 diabetes (Kahleova et al., 2017).

Mediterranean Dietary Pattern

The Mediterranean diet focuses on increased local, seasonal plant-based food intake, and limiting processed foods. The fat source of choice for this diet regimen is olive oil. Additional fats from dairy products are limited, while the consumption of eggs is no more than four per week. In addition, red meat is excluded from the diet, but wine is consumed with meals (Evert et al., 2013). Improvement of cardiovascular risk factors has been reported in multiple studies following the implementation of the Mediterranean diet in individuals with diabetes (Elhayany, Lustman, Abel, Attal- Singer, & Vinker, 2010; Esposito et al., 2009; Franz et al., 2010; Wheeler et al., 2010). One study reported a reduced rate of cardiovascular events and stroke when diets included nuts or olive oil (Estruch et al., 2013). Improved glycemic control was observed in individuals following a calorie controlled, Mediterranean diet (Wheeler et al., 2010). However, most research studies were conducted in the Mediterranean region, which warrants the need for additional research to determine the ability to generalize findings to other populations (Evert et al., 2013). In a randomized trial of 215 adults with newly diagnosed type 2 diabetes, the Mediterranean-style eating pattern resulted in a greater reduction of HbA1c levels, higher rate of diabetes remission, and delayed need for diabetes medication compared to the low-fat diet. The Mediterranean diet was composed of less than 50% of energy from carbohydrates and greater than 30% from fat, mainly from olive oil, while the low-fat diet was defined as less than 30% of energy from fat, and rich in whole grains

(Esposito, Maiorino, & Petrizzo, 2014). Additionally, the Mediterranean diet has been shown to reduce inflammatory activity in newly diagnosed type 2 diabetes, and demonstrated that ongoing inflammatory activity is associated with the need to initiate anti-glycemic medication (Maiorino, Bellastella, & Petrizzo, 2016).

Summary

Given the prevalence of diabetes and the severity of complications associated with uncontrolled blood glucose levels, individuals with diabetes should receive diabetes medical nutrition therapy in addition to regular physical activity and if necessary, appropriate medication(s) (Academy of Nutrition and Dietetics, 2015; Cefalu et al., 2017; Evert et al., 2013; Franz et al., 2017). Medical nutrition therapy for diabetes management is effective in improving blood glucose control by using appropriate dietary strategies (Academy of Nutrition and Dietetics, 2015; Cefalu et al., 2017; Evert et al., 2013; Franz et al., 2017). In addition, weight loss generally occurs with patient compliance and enhances patient health outcomes (Bantle et al., 2008; Evert et al., 2013; Esposito et al., 2009; Franz et al., 2010; Franz et al. 2013; Pi-Sunyer et al., 2007). Even though experts may not agree on the ideal diet regimen to control blood glucose levels, they do concur different diet patterns have been shown to improve glycemic control and reduce the risk of cardiovascular complications (Cefalu et al., 2017; Evert et al., 2013; Strychar, 2009). Individualized nutrition therapy goals should be goals the individual is willing and able to achieve (Cefalu et al., 2017; Evert et al., 2013; Wolever et al., 2008). Overall, the goal of diabetes medical nutrition therapy is to improve weight, glucose, lipid, and blood pressure.

CHAPTER 3

METHODS

The aim of this retrospective chart review was to evaluate the effectiveness of the BRG Fit! program by assessing the outcomes of patients who have participated in the 12-hour outpatient diabetes management program focused on a low-glycemic index diet. The outcomes evaluated included changes in weight, BMI, triglycerides, cholesterol, and HbA1c values following participation in the program. The health outcomes one year following program participation were compared to baseline data of participants who met the study eligibility requirements.

Subjects

The subjects of this retrospective chart review consisted of individuals who participated in the 12-hours of the outpatient diabetes management program of Baton Rouge General Medical Center in Baton Rouge, Louisiana. Retrospective data from participants with type 2 diabetes were included. Study eligibility requirements included: participation in the BRG Fit! program; not pregnant; and at least 18 years of age. Participants with normal BMI (<25 kg/m^2) and HbA1c (<6.5%) values were excluded. A total of 25 participants were excluded because they did not have type 2 diabetes; this included 12 participants with pre-diabetes, 1 with gestational diabetes, 10 with type 1 diabetes, and 2 with other conditions. Participants also were excluded from the study if pre-/postintervention data were not available. Post-intervention data were obtained annually following participation in the program.

Instruments

Researchers obtained anthropometric, biochemical, and demographic data from a password protected, electronic document containing de-identified data. Demographics obtained included age, gender, and self-reported race/ethnicity. Biochemical tests were ordered by the referring physician and reviewed by the RD and RN of the program. Trained healthcare professionals collected biochemical and anthropometric data. Pre-intervention data were collected at the initial visit at the start of the program. Participants provided post-intervention data, which were collected at an annual follow-up appointment scheduled for one-year following participation in the program. All data were recorded in the electronic medical record by either the RN or RD of the program. Then, data were provided to the researchers. The data collection tool is provided in Appendix A.

Data Collection

The Human Use Committee at Louisiana Tech University along with the Institutional Review Board at Baton Rouge General Medical Center approved this study before data collection was initiated (Appendix B). Upon approval from both parties involved, de-identified data of all individuals who participated in the program between January 2015 and April 2018 were delivered electronically to the researcher in a password protected document accessible only by the researcher. All participants with type 2 diabetes who met all inclusion criteria were selected for this study.

Data Analysis

Microsoft Excel, version 14, was used for data analyses. The primary purpose of the data analysis was to assess the change in anthropometric and biochemical outcomes in relation to diabetes management following program participation. Baseline data were compared to data collected at one-year follow-up post program participation using paired sample t-tests for continuous variables. T-tests also were used to test for differences in the changes in outcomes based on gender. Statistical significance was defined as a p-value <0.05.

CHAPTER 4

RESULTS

The purpose of this study was to identify differences in weight, BMI, triglycerides, cholesterol levels, and hemoglobin A1c values following participation in a 12-hour outpatient diabetes management program focused on using a low-glycemic index diet to control blood glucose levels. Health outcomes obtained one year following program participation were compared to baseline data obtained prior to beginning the program. Results were compared between male and female participants.

A total of 414 participants participated in the program between January 2015 and April 2018, and 283 of those were included in this study. Participants were excluded for failing to provide baseline or follow-up data, which excluded 106 participants. A total of 25 participants were excluded because they did not have type 2 diabetes; this included 12 participants with pre-diabetes, 1 with gestational diabetes, 10 with type 1 diabetes, and 2 with other conditions.

Participants included 94 (33%) men and 189 (67%) women of several different racial backgrounds (64% African American), with a mean baseline HbA1c of 8.7% ±2.2. The average age of participants was 58 ± 11.2 years, with no significant difference between male and females. The demographics of the participants are further outlined in Table 1.

Table 1

Low-Glycemic Index Diabetes Management Program Participant Demographics

Variables	Total (n 283) N(%)	Male (n 94) N(%)	Female (n 189) N(%)
Age (years)			
18-29	5 (2)	1 (1)	4 (2)
30-49	57 (20)	22 (23)	35 (18)
50-64	137 (48)	47 (50)	90 (48)
65+	84 (30)	24(26)	60 (32)
Race/ethnicity			
African American	180 (64)	48 (51)	132 (70)
Caucasian	95 (34)	43 (46)	52 (28)
Hispanic	7 (2)	3 (3)	4 (2)
Asian	1(0)	0 (0)	1(0)

Table 2 summarizes baseline data. The total group's mean baseline health parameters were 228.1 lbs.±57.3 for weight; 37.5kg/m^2 ±8.5 for BMI; 8.7% ±2.2 for HbA1c; 182.3 mg/dL ±47.8 for total cholesterol; 48.5 mg/dL ±14.7 for HDL cholesterol; 102.9 mg/dL±40.1 for LDL cholesterol; and 169.3mg/dL±137.7 for triglycerides. Except for HbA1c and total cholesterol, there were statistically significant differences in the baseline health outcomes measured based on gender. Table 2 also provides a breakdown of baseline data based on gender.

Clinical data collected following program participation are shown in Table 3. The total group's mean follow-up data were 223.6lbs. ±55.2 for weight; 36.8kg/m^2±8.2 for BMI; 7.6% ±1.9 for HbA1c; 170.0mg/dL ±42.5 for total cholesterol; 50.1mg/dL ±15.2 for HDL cholesterol; 93.5mg/dL ±36.0 for LDL cholesterol; and 146.1mg/dL ±111.4 for triglycerides. Follow-up data based on gender are also shown in Table 3.

Table 2

Clinical Baseline Data For Program Participants

Variables	Total Mean±SD	Males Mean±SD	Females Mean±SD	*p*value
Weight (lbs)	228.1±57.3	241.3±54.6	221.5±57.6	0.005
BMI (kg/m^2)	37.5±8.5	35.5±7.4	38.5±8.8	0.003
Triglycerides (mg/dL)	169.3±137.7	218.7±200.5	144.7±82.0	0.001
Total Cholesterol (mg/dL)	182.3±47.8	175.1±48.0	185.8±47.4	0.076
HDL Cholesterol (mg/dL)	48.5±14.7	41.6±12.4	51.9±14.5	<0.001
LDL Cholesterol (mg/dL)	102.9±40.1	94.7±35.3	107.1±41.8	0.01
HbA1c (%)	8.7 ±2.2	8.8±2.1	8.7±2.3	0.776

$P < 0.05$

Table 3

Clinical Follow-Up Data For Program Participants

Variables	Total Mean±SD	Males Mean±SD	Females Mean±SD
Weight (lbs)	223.6±55.2	236.7±53.3	217.0±55.2
BMI (kg/m^2)	36.8±8.2	34.8±7.2	37.7±8.6
Triglycerides (mg/dL)	146.1±111.4	175.2±162.0	131.6±70.4
Total Cholesterol (mg/dL)	170.0±42.5	160.7±40.3	174.7±42.9
HDL Cholesterol (mg/dL)	50.1±15.2	43.3±12.7	53.5±15.3
LDL Cholesterol (mg/dL)	93.5±36.0	85.9±31.1	97.3±37.7
HbA1c (%)	7.6 ±1.9	7.8±2.2	7.5±1.8

Three hypotheses were tested in this study. Hypothesis one stated there would be no significant difference in BMI, and weight between baseline data and the annual follow-up data of those with type 2 diabetes. The null hypothesis was rejected. Significant improvements were seen in participants' weight and BMI following program participation, and are outlined in Table 4. Mean weight of the total group was significantly reduced by 4.5 lbs. (± 11.9, $p<0.05$). Mean BMI was also significantly reduced by 0.7 kg/m^2 (±2.0, $p<0.05$) following program participation.

The second null hypothesis was there would be no significant difference in HbA1c values, cholesterol levels, and triglyceride levels between baseline data and the annual follow-up data of those with type 2 diabetes. This null hypothesis was rejected as well. Significant improvements were seen in participants' HbA1c, cholesterol and triglyceride levels following program participation, and are outlined in Table 4. Significant reductions were seen in mean HbA1c (-1.1% ±1.9, $p<0.05$), total cholesterol (-12.2 mg/dL ±37.3, $p<0.05$), HDL cholesterol (+1.6 mg/dL ±9.5, $p<0.05$), LDL cholesterol (-9.5 mg/dL ±30.7, $p<0.05$), and triglyceride levels (-23.2 mg/dL ±123.0, $p<0.05$) for the total group with an improvement of following program participation.

Table 4

Changes In Outcome Measures Following Participation In A Low-Glycemic Index Focused Diabetes Management Program In Participants

Variables	Difference±SD	*p*value
Weight (lbs)	-4.5±11.9	<0.001
BMI (kg/m^2)	-0.7±2.0	<0.001
Triglycerides (mg/dL)	-23.2±123.0	0.002
Total Cholesterol (mg/dL)	-12.2±37.3	<0.001
HDL Cholesterol (mg/dL)	+1.6±9.5	0.005
LDL Cholesterol (mg/dL)	-9.5±30.7	<0.001
HbA1c (%)	-1.1±1.9	<0.001

$P < 0.05$

The third hypothesis was there would be no significant difference in the change in hemoglobin A1c values, cholesterol levels, and triglyceride levels from baseline to the end of the program between males and females. This hypothesis was accepted. Changes in outcome measures following program participation based on gender are further outlined in Table 5.

Table 5

Changes In Outcome Measures Following Participation In A Low-Glycemic Index Focused Diabetes Management Program Based on Gender

Variables	Males	Females	
	Difference±SD	Difference±SD	*p*value
Weight (lbs)	-4.7 ±11.6	-4.4±12.0	0.859
BMI (kg/m^2)	-0.7±1.8	-0.72±2.2	0.807
Triglycerides (mg/dL)	-43.5±192.0	-13.1±64.5	0.138
Total Cholesterol (mg/dL	-14.4±44.3	-11.1±33.3	0.533
HDL Cholesterol (mg/dL)	+1.7±8.1	+1.6±10.1	0.956
LDL Cholesterol (mg/dL)	-8.8±32.9	-9.8±29.6	0.809
HbA1c (%)	-1.0±2.0	-1.1±1.9	0.607

$P < 0.05$

Significant outcomes were observed in both male and female groups. For the female group, significant improvements were seen in all health parameters evaluated in this study. Although the male group produced improvements in HDL cholesterol, results were not significant. HDL cholesterol was improved by 1.7mg/dL ±8.1 ($p = 0.052$) following program participation. The female group produced significant HDL cholesterol outcomes with an improvement of 1.6 mg/dL ±10.1 ($p<0.05$) following program participation.

CHAPTER 5

DISCUSSION

The purpose of this study was to identify differences in weight, BMI, triglycerides, cholesterol levels, and hemoglobin A1c values following participation in a 12-hour outpatient diabetes management program focused on using a low-glycemic index diet to control blood glucose levels. Health outcomes obtained one year following program participation were compared to baseline data obtained prior to beginning the program. Results were compared between male and female participants.

This was a retrospective study designed to evaluate the effectiveness of the BRG Fit! diabetes management program. The diet component of this program is different from that of most diabetes management programs; BRG Fit! emphasizes a low-glycemic index diet rather than the traditional carbohydrate consistent diet. Baseline data collected at the beginning of the program was compared with follow-up data collected following program completion. This study was not a randomized controlled trial; results were not compared to a control or typical ADA diet group, and therefore the results of this study should be interpreted cautiously.

Individuals with diabetes constantly make decisions involving self-management, including dietary choices, regular blood glucose testing, and medication administration; ultimately effecting the progression and management of this chronic disease. DSME programs provide individuals with diabetes a foundation for properly navigating these decisions, and activities and have been shown to improve health outcomes (Brunisholz, Briot, & Hamilton, 2014; Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012; Weaver, Hemmelgarn, & Rabi, 2014). DSME programs have been shown to improve HbA1c by as much as 1% in people with type 2 diabetes (Siminerio, Ruppert, Huber, & Toledo, 2014; Tshianang et al., 2012; Welch, Zagarins, Feinberg, & Garb, 2011). It is the position of the ADA that all individuals with diabetes receive DSME at diagnosis and as needed thereafter (ADA, 2019). Studies evaluating DSME programs that use a low-glycemic index diet are limited.

In the current study, weight, HbA1c, and BMI were significantly improved compared to baseline data. Participants achieved a mean weight loss of 4.5 lbs. or 1.8%. This accounted for a reduction of 0.7 kg/m^2 in BMI. Previous studies using similar diet plans reported comparable findings. One study found a ketogenic diet (≤20 grams of carbohydrates and no calorie restriction) was associated with a 2.4 kg/m^2 reduction in BMI compared to a 2.7 kg/m^2 reduction with a low-fat diet (<30% energy from fat, 10% from saturated fat, <300mg of cholesterol, and a 500-1000 calorie deficit) after 48 weeks in individuals with type 2 diabetes (Mayer et al, 2014). A low-carbohydrate, high-fat diet plan similar to the paleo diet was to be associated with an average weight loss of 19.4 lbs. following three months of diet compliance from individuals with two or more features associated with metabolic syndrome (Unwin, Cuthbertson, Feinman, & Sprung, 2015). More recently a diet plan referred to as the ketogenic diet or KETO has gained popularity and has demonstrated a mean body mass reduction of 19.8 lbs. or 7.2% from baseline after 10 weeks in individuals with type 2 diabetes (McKenzie et al., 2017). A randomized clinical trial found a nutritional ketosis diet produced a 12.1 lbs. compared to

5.7 lbs. weight loss with a typical ADA “create your plate” diet following 32-weeks of online intervention in overweight or obese individuals with type 2 diabetes or pre-diabetes (Saslow et al., 2014). An additional randomized controlled trial by Tay et al., (2015) achieved similar mean weight loss after 52 weeks; individuals with type 2 diabetes achieved an average weight loss of 21.56 lbs. while on a very-low carbohydrate, high-unsaturated fat diet (14% energy as carbohydrates and less than <10% of saturated fat per day) compared to 22.22 lbs. with a high carbohydrate low-fat diet (53% energy as carbohydrates and less than <10% of saturated fat per day). This current study was associated with less weight loss than previous studies presented here; however, the weight loss achieved was significant.

Collectively, these studies support the premise that weight loss is facilitated by calorie control. The recommended approach to sustainable, long-term weight loss is to eliminate 500 Calories from an individual’s total daily caloric consumption to promote 1-2 lb. weight loss per week. Incorporating 30-60 minutes of cardio and resistance training exercise per day will enhance weight loss and preserve lean muscle mass (ADA, 2019). Moreover, the CDC indicates a weight loss of as little as 5 - 10 percent of total body weight has been associated with improvements in blood pressure, blood cholesterol, and blood sugars (CDC, 2018). The BRG Fit! program is accredited by the AADE and ADA, which requires the development of program and service goals, as well as documentation of at least one clinical outcome measure to evaluate the effectiveness of the educational intervention. BRG Fit! focuses on individualizing behavior goals for participants while working together with the RN and RD of the program. However, BRG Fit! also encourages a weight loss of 5% initial body weight and achieving an HbA1c of less than 7%, which aligns with national guidelines (ADA, 2019).

Participants in this study achieved a 1.1% mean decrease in HbA1c. Previous studies found similar results. One study found a low-carbohydrate diet with ≤20 grams of carbohydrates and no calorie restriction was associated with decrease in HbA1c of 0.7% compared to a 0.2% increase on the low-fat diet with <30% energy from fat, 10% from saturated fat, <300mg of cholesterol, and a 500-1000 Calorie deficit after 48 weeks in individuals with type 2 diabetes (Mayer et al., 2014). A low-carbohydrate, high-fat diet plan similar to the paleo diet was associated with a reduction in HbA1c of 3.1% following three months of diet compliance from individuals with two or more features associated with metabolic syndrome (Unwin et al., 2015). A 10-week program promoting adequate carbohydrate restriction to achieve nutritional ketosis achieved a 1.0% reduction in HbA1c from baseline in individuals with type 2 diabetes (McKenzie et al., 2017). A randomized clinical trial studying overweight or obese individuals with type 2 diabetes or pre-diabetes found HbA1c to be unchanged in the traditional ADA diet, while HbA1c was decreased by 0.6% in the nutritional ketosis group (Saslow et al., 2014). An additional randomized controlled trial comparing outcomes of a 52 week very-low carbohydrate, high-unsaturated fat diet with 14% energy as carbohydrates and less than <10% of saturated fat per day and a high carbohydrate low-fat diet with 53% energy as carbohydrates and less than <10% of saturated fat per day showed both groups achieved a 1.0% reduction in HbA1c (Tay et al., 2015). The improvements in HbA1c of this study are very similar to or greater than that of previous studies.

In this current study, significant improvements also were achieved in total cholesterol (-12.3 mg/dL), HDL cholesterol (+1.6mg/dL), LDL cholesterol (-9.4 mg/dL), and triglyceride levels (-23.2 mg/dL) compared to baseline. Previous studies examining similar diet programs in adults with type 2 diabetes produced similar results. One study also showed that a low-carbohydrate, high-fat dietary intervention similar to the paleo diet was associated with an average reduction in total cholesterol of 11.6 mg/dL in individuals with two or more features associated with metabolic syndrome (Unwin et al., 2015). An additional randomized controlled trial compared the effects of a very-low-carbohydrate, high-unsaturated fat diet and a high carbohydrate low-fat diet following 52 weeks of diet compliance. Both groups achieved similar reductions in LDL cholesterol (-3.87 mg/dL with a very-low-carbohydrate, high-unsaturated fat diet vs -7.73 mg/dL with a high carbohydrate low-fat diet). Compared with the high carbohydrate diet group, the low-carbohydrate diet group achieved greater mean reductions triglycerides (-35.43 mg/dL vs -17.71mg/dL), and greater mean increases in HDL cholesterol (3.87 mg/dL vs 2.32 mg/dL) (Tay et al., 2015). These results could be attributed to overall improvement in dietary and lifestyle choices including reducing refined carbohydrate consumption and sugar, and not solely attributed to the specific carbohydrate to fat ratio of the diet itself. In this current study, no statistically significant differences were found in the change in baseline outcome measures to the end of the program between males and females. However, it is important to not that there were statistically significant differences in the baseline health outcomes measured based on gender, except for HbA1c and total cholesterol. The males in this current study exhibited significantly improved cholesterol, weight, BMI, and HbA1c levels. Although the male group produced triglycerides improvements, the results were not significant. The female group produced significant improvements in follow-up weight, BMI, HbA1c, cholesterol, and triglyceride levels compared to baseline. The results show that participants following a low-glycemic index diet gained a variety of health benefits including lower HbA1c, body weight, BMI, cholesterol, and triglyceride levels.

All of these studies evaluated unconventional diets that differ from the traditional diet for treatment of type 2 diabetes recommended by the ADA, and yet all were able to produce similar effects on health parameters. Low-carbohydrate and/or low-glycemic index diets typically recommend the consumption of lean meats, seafood, mono-unsaturated fats, poly-unsaturated fats, and vegetables, which leads to a diet high in B vitamins, healthy fats, antioxidants, and fiber. Collectively, these nutrients work together to promote increased satiety, better glucose control, and reduction in inflammation (ADA, 2019). Unfortunately, these diets can seem restrictive and may become monotonous. Also, there is concern for ketoacidosis (ADA, 2019). Additional research should be conducted to determine the safety of a low-carbohydrate diet for those with diabetes with close monitoring of blood glucose levels and the transition to a typical ADA diet consisting of 50% of energy from carbohydrates, 20% from protein, and 30% from fat. The results of this study provide additional support for the use of a low-glycemic index diet in improved health outcomes in individuals with type 2 diabetes. Traditionally, a carbohydrate consistent diet has been supported as the primary diet for diabetes management. Further studies should be conducted to compare results to a control group participating in a carbohydrate consistent diet program and consider a larger number of participants followed over a longer duration of time to determine whether positive health effects are sustained long-term.

The results of this study will provide great benefit to Baton Rouge General Medical Center. The positive results of this study demonstrate BRG's program success in managing diabetes. This success can be used to attract additional referrals and patient participation. Thereby increasing revenue and offering the hospital opportunities to enhance the medical services provided. These results also demonstrate the success of the BRG Fit's program manager and staff in providing a viable transition to patients from inpatient care to outpatient care services, thereby enhancing the continuity of care and better disease management and prevention.

This study's results also provide insight into where improvement and development is needed. For example, HDL cholesterol was significantly improved in the female population, but not in the male population. This study's results provide evidence that a low-glycemic diet can be an effective strategy for diabetes management. This evidence also could be used in the development of future standardized diabetes management strategies; however, further research is warranted.

This study has several limitations. Participants were educated on a low-glycemic index diet; however, detailed dietary intake was not measured. Medications at baseline or follow-up were not analyzed. Amount and frequency of dietary education varied between participants based on insurance coverage and participants' ability to attend group classes and one-on-one sessions. This study also had no control group with which to compare results. A larger randomized controlled trial with a multiple follow-ups over a longer duration is needed to better understand the effects of a low-glycemic index diet on glycemic control, weight and lipid levels.

APPENDIX A

A-1 DATA COLLECTION INSTRUMENT

A-1 DATA COLLECTION INSTRUMENT

De-Identified data was provided via a password-protected electronic document.

Gender	Age	Race	Type of diabetes	Weight (kg) Baseline	Weight (kg) Follow-up	BMI Baseline	BMI Follow-up	HbA1c (%) Baseline	HbA1c (%) Follow-up

Total cholesterol (mg/dL) Baseline	Total cholesterol (mg/dL) Follow-up	HDL cholesterol (mg/dL) Baseline	HDL cholesterol (mg/dL) Follow-up	LDL cholesterol (mg/dL) Baseline	LDL cholesterol (mg/dL) Follow-up	Triglycerides (mg/dL) Baseline	Triglycerides (mg/dL) Follow-up

APPENDIX B

B-1 LETTER OF APPROVAL FROM HUC

B-2 LETTER OF APPROVAL FROM BRG'S IRB

B-1 LETTER OF APPROVAL FROM HUC

LOUISIANA TECH UNIVERSITY

MEMORANDUM

OFFICE OF SPONSORED PROJECTS

TO: Ms. Morgan Williston and Dr. Catherine Fontenot

FROM: Dr. Richard Kordal, Director of Intellectual Property & Commercialization (OIPC)
rkordal@latech.edu RJK

SUBJECT: HUMAN USE COMMITTEE REVIEW

DATE: October 1, 2018

In order to facilitate your project, an EXPEDITED REVIEW has been done for your proposed study entitled:

"The Effects of a Low-glycemic Index Diabetes Management Program on Weight, Body Mass Index, Triglycerides, Cholesterol and Hemoglobin A1c Values"

HUC 19-015

The proposed study's revised procedures were found to provide reasonable and adequate safeguards against possible risks involving human subjects. The information to be collected may be personal in nature or implication. Therefore, diligent care needs to be taken to protect the privacy of the participants and to assure that the data are kept confidential. Informed consent is a critical part of the research process. The subjects must be informed that their participation is voluntary. It is important that consent materials be presented in a language understandable to every participant. If you have participants in your study whose first language is not English, be sure that informed consent materials are adequately explained or translated. Since your reviewed project appears to do no damage to the participants, the Human Use Committee grants approval of the involvement of human subjects as outlined.

Projects should be renewed annually. ***This approval was finalized on October 1, 2018 and this project will need to receive a continuation review by the IRB if the project continues beyond October 1, 2019.*** **ANY CHANGES** to your protocol procedures, including minor changes, should be reported immediately to the IRB for approval before implementation. Projects involving NIH funds require annual education training to be documented. For more information regarding this, contact the Office of Sponsored Projects.

You are requested to maintain written records of your procedures, data collected, and subjects involved. These records will need to be available upon request during the conduct of the study and retained by the university for three years after the conclusion of the study. If changes occur in recruiting of subjects, informed consent process or in your research protocol, or if unanticipated problems should arise it is the Researchers responsibility to notify the Office of Sponsored Projects or IRB in writing. The project should be discontinued until modifications can be reviewed and approved.

Please be aware that you are responsible for reporting any adverse events or unanticipated problems.

A MEMBER OF THE UNIVERSITY OF LOUISIANA SYSTEM

P.O. BOX 3092 • RUSTON, LA 71272 • TEL: (318) 257-5075 • FAX: (318) 257-5079

AN EQUAL OPPORTUNITY UNIVERSITY

B-2 LETTERS OF APPROVAL FROM BRG'S IRB

Baton Rouge General
A Community of Caring

IRB APPROVAL DOCUMENT

INSTITUTIONAL REVIEW BOARD
225-387-7112
FAX: 225-387-7912

3600 Florida Boulevard
Baton Rouge, LA 70806

Investigator: Morgan Williston

IRB Approval Date: 08/09/2018
Study Approval Expires: 08/08/2019
IRB Number: 2018-012
Submission Type: Initial
Type of Review: Expedited

SPONSOR: None
TITLE: THE EFFECTS OF A LOW-GLYCEMIC INDEX DIABETES MANAGEMENT PROGRAM ON WEIGHT, BODY MASS INDEX, WAIST CIRCUMFERENCE, CHOLESTEROL AND HEMOGLOBIN A1C VALUES

Approval Includes: M.W. Protocol (Protocol), Full Thesis Research Proposal (Protocol), citiCompletionReport4466269 (2).pdf (CITI Training), citiCompletionReport4466269.pdf (CITI Training), citiCompletionReport4466269 (4).pdf (CITI Training), citiCompletionReport4466269 (3).pdf (CITI Training), citiCompletionReport4466269 (1).pdf (CITI Training), Morgan Williston Resume (1).docx (CV/Biosketch), Mogan Williston- signed FCOI 2017.pdf (Other Documents), IRB Submission form- Effects of Low-G;ycemic Index Diabetes Management- Williston, Morgan- signed.pdf (Initial Application)

The study meets the following requirements for expedited review. (1) The study involves no more than minimal risk and (2) the only involvement of human subjects involves:

Expedited 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis.)

BRGMC FWA #00001821 **BRGMC IRB # IRB00005439** **IORG # IORG0004567**

1. The IRB complies with the requirements found in Part 56 of the Code of Federal Regulations and Part 46 of Federal Regulations
2. Re-Review of this proposal is necessary if:
   - Any significant alterations or additions are made to the protocol/proposal. Please note that some changes may be approved by expedited review; others require full board review.
   - You wish to continue beyond the continuing review date assigned to the study.
3. Use only the most current consent form bearing the IRB "APPROVED" STAMP. It is required that all IRB approved consent forms be retained in your files.
4. In addition to the study consent form, the Baton Rouge General may require execution of standard hospital and/or surgical consent forms for any invasive procedures

Please contact the HRPP Office at 225-387-7112 or irb@brgeneral.org, if you have any questions or concerns.

____

Emily Panepinto, CHRC

Manager Research Compliance
Baton Rouge General Medical
Center

Date Letter Generated: 08/13/2018

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