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Higher Fat Low Carbohydrate Diet to Improve Health Related Quality of Life

For Overweight or Obese Diabetics in a Primary Care Clinic

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Abstract

Diabetes and obesity are chronic diseases that affect individuals worldwide. The American Diabetes Association (ADA) and the American Heart Association (AHA) have developed guidelines for management of diabetes and obesity. The DNP student examined the use of the Higher Fat Low Carbohydrate (HFLC) diet, which conflicts with these frequently used guidelines. The literature on a HFLC diet suggests positive effects for type 2 diabetics, including weight loss, improved HA1c, lower BMI and no detrimental impact on metabolic markers such as cholesterol, triglycerides, or low and high density lipoproteins. The purpose of this project was to provide type 2 diabetics who are overweight or obese with a HFLC dietary educational tool and assess health related quality of life (HRQOL). Using a qualitative approach follow up included a monthly phone call for 2 months after the education with questions on the participant's experience following the HFLC diet in order to evaluate and modify the tool. A pre and post project survey was also used to examine HRQOL. The project survey results showed decreased experiences of being overwhelmed related to the diabetes diagnosis, not knowing if mood or feelings were related to diabetes, and worrying about low blood sugar or other complications. Although HA1c and BMI were not assessed in this project, future work should examine these outcomes for patients following a HFLC diet.

Keywords: higher fat-low carbohydrate diet, BMI, HA1c, metabolic biomarkers, health related quality of life, diabetes, obesity

Introduction

Problem

Diabetes and obesity combined can have serious health consequences if not diagnosed and managed. Poor dietary choices and lack of compliance with a recommended diet are major contributing factors. A novel treatment approach used is a lifestyle modification using a structured, supervised high fat low carbohydrate (HFLC) diet. With 21 million adults diagnosed with diabetes and 78.6 million diagnosed with obesity, the time has come to reevaluate the dietary guidelines recommended by the ADA and AHA (Feinman, Pogozelski, Astrup, Bernstein, Fine, & Westman, 2014). Working with diabetic overweight people who struggle to make healthy diet choices may decrease risk of and potentially prevent them from becoming obese in addition to helping obese people be classified in the overweight category.

Purpose and Summary of Plan

The purpose of this DNP project was to use a dietary educational tool to help type 2 diabetics not only learn about the positive impacts of the HFLC diet, but also promote improved Health related quality of life (HRQOL). The proposed project was implemented at a small family practice in St Augustine, Florida. Currently, 36% of Floridians are at a healthy weight (Florida Health, 2015). In 2013, the state of Florida joined with the American Medical Association (AMA) and the Centers for Disease Control and Prevention (CDC) to develop the Healthiest Weight Florida Initiative to help Floridians decrease their unhealthy weight by 5%. This DNP project was focused on innovative and alternative dietary choices to help participants get better control of their diabetes and promote weight loss, which is a component of the Healthiest Weight Florida Initiative. Offering an alternate dietary option was anticipated to improve health related quality of life (HRQOL) and may allow for greater weight loss and glycemic control.

The DNP project used a dietary educational tool to help type 2 diabetics not only learn about the positive impacts of the HFLC diet, but also promote improved HRQOL. The high obesity rates for the state of Florida and the potential negative sequelae as a consequence indicated that this DNP project was needed to help improve patient health outcomes and the quality of care.

Background

Being overweight is defined by the Centers for Disease Control and Prevention (CDC, 2014) as having a body mass index (BMI) of 25-29.9 kg/m² and obesity is defined as 30 kg/m² or above. BMI is calculated from a person's weight and height (kg/m²) and it is one of the best methods for assessing for being overweight or obesity. According to the Journal of American Medicine (JAMA) more than one-third of adults are obese. In 2008, the estimated medical cost of obesity in the U.S. was \$147 billion and \$1,429 higher for people who were obese than those of normal weight. The most common health consequences as a result of being overweight or obese include dyslipidemia, hypertension, and type 2 diabetes.

Diabetes mellitus type 2 is defined by the American Diabetes Association (ADA, 2015) as the body's inability to use blood glucose for energy resulting in frequent hyperglycemia. In 2012, 892,000 new diabetes cases were diagnosed in adults age 45-64 years old. Diabetes was the seventh leading cause of death in the U.S. in 2010 (CDC, 2014). Over the next twenty years obesity is expected to contribute to millions of cases of preventable chronic diseases such as diabetes type 2, heart disease, and cancer and cost an estimated 34 billion dollars in medical expenses. It is also estimated that by 2030 almost 60% of Florida's population will be obese. The Healthiest Weight Florida initiative works closely with the business community, hospitals, non-governmental organizations, non-profit agencies, and federal, state and local government agencies to improve the early identification of Floridians at risk for becoming obese.

Health related quality of life (HRQOL) can be negatively impacted by both diabetes and obesity. Obese diabetic women may experience limitations in daily life due to physical and emotional problems (Svenningsson, Marklund, Attvall, & Gedda, 2011). Obese diabetic males can experience reduced physical fitness and vitality. Hispanics reported impairment of the functioning in general health (Hu, Wallace, & Tesh, 2010). Quality of life (QOL) is often overlooked by providers because the main focus is on treatment of the physical illness. Primary care settings provide the ideal opportunity to identify and educate adult individuals with obesity and diabetes type 2 about their condition and individualize their treatment, promoting self-management and helping to address any HRQOL issues.

Diabetes and obesity have emerged as significant health problems (Yamada et al., 2014). Finding the right diet to help manage weight loss and improve glycosylated hemoglobin (HA1c), a reflection of longer term blood sugar control, without deterioration of high density lipoproteins (HDL), low density lipoproteins (LDL), triglycerides, and cholesterol remains a challenge for providers. In addition, the quality of life (QOL) of individuals with diabetes and obesity can be negatively impacted because of altered body composition, inability to participate in social events because of food restrictions, or emotional distress related to the overall disease process. Current guidelines for prevention of diabetes from the American Diabetes Association (ADA, 2015) recommend 45-60 grams of carbohydrates at each meal and 15-20 grams of carbohydrate servings with each snack. To prevent obesity, the American Heart Association (AHA, 2015) recommends low-fat dairy products and keeping saturated fats to no more than five to six percent of total calories for the adult American population. Recently alternative dietary interventions have been proposed yet no practice guidelines for a higher fat low-carbohydrate (HFLC) diet were found on accredited websites such as the National Guidelines Clearinghouse, American Diabetes Association, or the American Heart Association for the treatment of

diabetes or obesity. The project addressed the emerging research which supports the potential positive health impact of the HFLC diet.

Review of the Literature

The literature was rated using the John Hopkins research evidence appraisal (The John Hopkins University, n.d.). A comprehensive search of the literature for the effects of HFLC diets on body mass index (BMI), nutrition therapy, and diabetes included UpToDate, Current Index to Nursing and Allied Health Literature (CINAHL), and PubMed of the National Library of Medicine. CINAHL was also used specifically to search the keywords “quality of life and diabetes and diet”. The following Medical Subject Headings (MeSH) were used to search in the PubMed database: high fat low carbohydrate and lower BMI; diabetes and quality of life. The same MeSH terms were used to search UpToDate. In addition, two systematic reviews were used to assist in the initial search of the literature. The Agency for Healthcare Research and Quality online site was explored for national guidelines with two applicable guidelines being found. Personal communication with an expert dietician on HFLC diets directed the DNP student to an online blog from which four research articles were obtained. Inclusion criteria included full text articles, written in the English language, and published within the past fifteen years. The articles that were obtained and chosen for review reflect the highest existing level of evidence available.

Findings from the review of the literature related to the HFLC diet showed the unknown risks of consuming higher fats over time and the possibility of a negative effect on health. Another finding was that individuals with type 2 diabetes had lower health related quality of life (HRQOL). Several benefits, which included weight loss, improvements in glycosylated hemoglobin (HA1c), and lipid markers were found when the literature regarding higher fat low-carbohydrate (HFLC) diet therapy was examined. Discussion of the studies follows.

Health Related Quality of Life (HRQOL)

Svenningsson, Marklund, Attvall and Gedda (2011) reported macrovascular and microvascular complications of obesity as major causes of decreased health related quality of life (HRQOL). An added stressor may be the potential inability to cope with self-care in daily life increasing the psychological distress brought on by disease burden. Hu, Wallace, and Tesh (2010) examined the relationships among age, body mass index, physical activity, nutritional health and quality of life in adult diabetic Hispanics. The authors found that the participants perceived their health to be fair or poor and were least satisfied with their functioning. Hu et al. (2010) found nutritional health as a strong predictor of decreased HRQOL. Although obesity was not found to be a strong predictor for decreased HRQOL, other studies that have shown obesity is negatively associated with HRQOL in the general US population. Jelsness-Jorgensen, Ribu, Bernklev and Moum (2011) found that women had significantly reduced HRQOL compared to men, but did not explore the possibilities of why there was a difference. The study did not report significant findings in the relationship between elevated BMI and reduced HRQOL. However, the authors did acknowledge the potential contribution of obesity. All of the studies recommended further research examining HRQOL related to the disease burden of diabetes.

In summary, the evidence discussed points to a higher fat low-carbohydrate (HFLC) diet as a potential healthy alternative for obese diabetic patients. Currently there is no evidence that a higher fat diet affects metabolic markers such high-density lipoprotein (HDL), low-density lipoprotein (LDL), cholesterol and triglycerides in a negative way, which is a common concern related to the HFLC diet. Concerns about the efficacy and safety of carbohydrate restriction are long term and conjectural rather data driven (Feinman et al., 2014).

Weight loss, BMI, and Higher Fat Low-Carbohydrate Diet

Volek et al. (2004) examined the comparison of a very low-carbohydrate ketogenic (VLCK) and low-fat diet in 50 randomized healthy subjects aged 18-55 years old with a body mass index (BMI) $> 25 \text{ kg/m}^2$. After 50 days for men and 30 days for women the subjects were asked to switch to the opposite diet. Reductions in BMI were significantly greater with the VLCK diet than the LF diet up to 10 kilograms (kgs) in men and 7 kgs in women. The participants that started with the VLCK diet, in fact, gained some weight when they switched to the LF diet. The authors concluded that low-carbohydrate diets can be a healthy alternative for general health beyond weight regulation. In addition, loss of fat in the trunk region with the VLCK diet was an important finding in that upper body fat storage carries a greater health risk than fat stored in other regions of the body.

In a randomized controlled trial of a dietary intervention, Samaha and colleagues (2003) demonstrated that severely obese subjects with a high prevalence of diabetes or the metabolic syndrome lost more weight during six months on a carbohydrate-restricted diet than on a calorie and fat-restricted diet. This study included a high proportion of black subjects who had a smaller overall weight loss of 5 kilograms (kgs) compared to the 13 kgs lost by white subjects. Future studies are needed to explore effective incorporation of culturally sensitive dietary counseling to help achieve greater weight loss in the black population. Similar findings demonstrated a greater weight loss of 9.7 kgs at the six month mark in a controlled trail that involved 63 obese men and women (Foster, 2003).

Volek et al (2009) conducted a 12-week study comparing a carbohydrate-restricted diet (CRD) with a low-fat diet (LF) in 40 subjects. The weight loss of the subjects consuming the CRD was nearly twice the amount of the LF control (10.1 kg vv. 5.2 kg). The authors also report that the subjects consuming the CRD consumed a greater fat intake, yet the whole body fat was decreased significantly in the CRD intervention group. Bazzano and colleagues (2014) conducted a 12-month randomized parallel-group trial with 75 of 148 men and women consuming a low-carbohydrate diet compared to those consuming a low-fat high carbohydrate diet finding that greater weight loss was achieved among

black and white obese adults consuming a low-carbohydrate diet with a mean difference is change of -3.5 kgs. Based on this finding, restricting carbohydrates may be an option for obese white and black adults who are seeking weight loss and reduction in cardiovascular risk factors. Saslow et al. (2014) conducted a RCT over three months comparing a medium carbohydrate, low fat, calorie restricted, carbohydrate-counting diet suggested by the American Diabetes Association (ADA) to a low-carbohydrate, high fat, non-calorie restricted diet. Sixteen of the thirty-four participants consuming the low-carbohydrate diet lost 5.5 kg versus 2.6 kg lost in the medium carbohydrate group. Unwin and Unwin (2014) conducted an eight month pilot study implementing a low carbohydrate higher fat diet to 18 type 2 diabetes and pre-diabetes patients in a suburban general practice. Much of literature therefore supports a higher fat low-carbohydrate diet for weight loss and the above studies demonstrate successful health outcomes for those using the HFLC diet.

Hemoglobin A1c (HA1c)

HA1c is a long term biomarker specific to diabetes. In a comparative randomized trial performed over six months, 22 participants consumed either a conventional calorie restricted diet or a higher fat low-carbohydrate diet (HFLC) (Yamada et al., 2014). The participants received either a conventional calorie restricted diet or low-carbohydrate diet. The authors compared the effects of the two dietary interventions on glycemic control and metabolic markers. The results showed a significant decrease of HA1c (%) from 7.6 to 7.0 in the HFLC diet group compared with 7.7 to 7.5 in the calorie restricted group. Although, the sample size was small the authors found that a non-calorie restricted, low-carbohydrate diet was effective in lowering HA1c and recommend it as a safe dietary alternative for type 2 diabetics. Similarly, Saslow et al. (2014) found a mean decrease in HA1c (%) of 0.6 in subjects consuming a low carbohydrate diet compared to a mean decrease of 0.0 in the medium carbohydrate group. Unwin et al. (2014) showed improved blood glucose control with a one percent decrease in HA1c in the eighteen subjects consuming a HFLC diet. Seven patients were able to

discontinue Metformin completely. Samaha et al. (2003) found seven of forty-three subjects consuming a HFLC diet had dose decreases in oral hypoglycemic agents or insulin. These studies highlight the potential positive effects of a HFLC diet on diabetic markers such as H_{A1c}. One gap in the selected literature was whether the high fat or full fat component of the diet provided more satiety than a diet comprised of higher carbohydrates.

Metabolic Markers

It would be expected that a diet not constricting the intake of fats would have damaging effects on triglycerides, cholesterol, high-density lipoproteins (HDL) or low-density lipoproteins (LDL). Yet multiple studies, (Bazzano et al., Samaha et al., 2003; Unwin & Unwin, 2014; Volek et al. 2009; Yamada et al., 2014) show higher fat low-carbohydrate (HFLC) diets can provide a more comprehensive improvement in the clinical risk factors associated with MetS [metabolic syndrome] than a low fat diet (LFD) at reduced caloric intake. Samaha et al. (2003) found that the participants consuming a HFLC experienced improvements in insulin sensitivity and greater reductions in triglycerides, with a mean decrease of 20%. There was an increase in high-density lipoproteins (HDL) of 11 mg/dL over a 12 month period and a decrease in triglycerides of 17 mg/dL in subjects consuming a HFLC diet (Foster et al., 2003). Yamada et al. (2014) found a 58.2 point decrease in triglyceride levels in the HFLC diet group yet no statistically significant alterations in HDL or LDL of either group in a comparison trial. Bazzano et al. (2014) found a reduction in cardiovascular risks in their 12 month trial finding an increase in HDLs of 7 mg/dL, a decrease in triglycerides of 14.1 mg/dL, and cholesterol. Although, all the studies showed a positive effect on metabolic markers, the literature recommended that future studies needed to have continued focus on HFLC diets and the effects on metabolic markers. The scientific evidence for all the articles was rated “good quality” in the results were “fairly” consistent and “fairly” definitive. The recommendations made in the studies were similar

and suggested continued future evaluation of the outcomes of a HFLC diet on metabolic markers, but potential as a viable healthy alternative diet therapy for obese and diabetic patients.

The clinical guideline, *Dietary Guidelines for Americans, 2010*, recommends a decrease in solid fats, an increase in fat-free or low-fat milk, and control over calorie intake (AHRQ, 2010). The HFLC diet recommends the opposite of the clinical guideline making the implementation of this diet a controversial therapy for obese and diabetic patients. Providers are urged to examine the recent research and consider the HFLC diet as a healthy option. Feinman and colleagues (2014) developed a 12-point review which emphasizes the need for a reevaluation of the dietary recommendations due to the following: general failure to decrease the epidemic of diabetes under current guidelines, failure of low-fat diets to reduce obesity and improve cardiovascular risks, and the continued success of low carbohydrate diets for improving features of diabetes and metabolic syndrome. Importantly, Wu et al. (2010) identified a gap between providers and the standards for diabetes care. Thus, empowering self-management combined with collaborative care may foster patient-centered practices and help to close the gap. The feasibility of translating the recommendations into primary care practices warrants further study. Although the initial start-up time to implement the dietary intervention may be labor intensive, most patients can return to regularly routine follow-up after four months (Unwin & Unwin, 2014).

Theoretical Framework

The causal theory (Issel, 2014) and Ausubel's theory of meaningful learning (1978) provided the underpinnings guiding this project. The risk for diabetes among adults of the American population is indicated by the number of patients diagnosed and treated for diabetes type 2 and resulting from poor dietary compliance, self-mismanagement of medication, and the lack of knowledge about diabetes and alternate diets such as the HFLC diet (Issel, 2014).

The causal theory has four key elements to be considered when developing a causal theory: existing factors, causes, mediating factors and moderating factors. The ideal population would have, but not limited to, existing factors that include a diagnosis of diabetes type 2 with or without obesity and receipt of treatment for diabetes for at least 2-3 years. The causal factors would include lack of knowledge about the disease, medications and/or healthy food choices and possible predisposition to develop diabetes. The mediating factors for this population include quality of healthcare including disease education, dietary options, and medication management. Moderating factors include knowledge about diabetes treatment and family and provider support for self-care. The patients have to be willing to perform their own self-care or have the ability to practice self-care such as identifying healthy food choices, identification of diabetes medications and their proper use, and other disease related self-care issues.

Concepts from Ausubel's Theory of Meaningful Learning (1978) provided the foundation to actualize the project. Ausubel's key concept is developing cognitive structure by using our existing knowledge to help learn something new. Ausubel proposed 17 tenets for understanding. Three of these basic rules guided this project. First, meaningful learning rather than rote learning is the focus of Ausubel's theory. In order for meaningful learning to take place in the cognitive structure, the new information must have a relation to previously learned content and will lead to forming a connection between the new information and the existing information (Hannum, 2005). This process helped to drive the intervention because the participants had some knowledge about diabetes and some knowledge about how diabetes is treated. The participants may not have a clear understanding of their disease and best practice treatment but at least there will be an opportunity to form a connection between the new and existing information within the cognitive structure.

Second, Ausubel's theory discusses the material that is provided be potentially meaningful. If the educational tool that is provided in the intervention is not meaningful to the participants, then the

new material will not be incorporated into the cognitive structure. Last, another one of Ausubel's tenets applicable for this intervention was practice in learning. Learning that takes place over time rather than bunched together will produce stronger cognitive learning and memory retention. Practiced learning gives the participant the opportunity to compare and contrast the new information and strengthen the relationship between the new and existing information. A diabetes specific educational tool gave the participant an opportunity to take in the new information and processed it for an agreed upon timeframe. The follow-up phone calls that took place allowed the participant to discuss what has worked and what has not worked and adjustments were made to better suit the participants needs.

Theory guides practice. The complexity of diabetes and obesity lends itself to multi-theory approach. The causal theory helps to identify the existing factors, causes, medicating factors and moderating factors of diabetes and obesity. Educating participants on new diet options to help manage their diabetes and weight loss potentially can engender enough curiosity to allow meaningful and intrinsic learning to take place, which is drawn from Ausubel's theory. The education that was initially provided was built on and modified during the following few months based on project findings allowing the information to be sifted through and assimilated as needed.

Project Design and Methods

The Quality Improvement project design included a qualitative methods approach. The qualitative method implemented a single dietary intervention educational tool that was provided to the participant with follow up via phone call monthly for two months (see Appendix A). The qualitative approach addressed the proposed problem by following a fairly linear path as described in what follows (Polit & Beck, 2012). The identified problem of diabetes and obesity in adult Americans with a poorer quality of life has been documented in the previously discussed review of the literature. It was suggested that the higher fat low carbohydrate (HFLC) diet was a healthy alternative and could improve health related quality of life (HRQOL). Administering a single dietary educational

intervention with follow-up phone calls allowed the DNP student to evaluate and amend individual participant educational tools. The monthly follow up calls helped retain participation and helped in the further refinement of the educational tool. The qualitative method was used by administering a pre and post health related quality of life survey. This project focused on both quality improvement and program development and evaluation (Moran, Burson, & Conrad, 2014).

Goals, Objectives, and Expected Outcomes

Goals generally do not involve quantitative measurements but are statements about the health impact of the target audience whereas objectives include who, how, and when of the outcome evaluation (Issel, 2014). The identified goals included objectives, expected outcomes, and results. The goals ideally were relative to the individual not to the normal range for this project. Objective feedback was received from the staff and clients participating in the intervention to allow the organization to take action on the effectiveness of the HFLC diet. The outcome data is useful in comparing the American Diabetes Association (ADA) recommended diet with the HFLC diet. This data is useful to clients by allowing them the freedom to make the choice about which diet was more beneficial to them in terms of obtaining healthy outcomes (White & Dudley-Brown, 2012). The outcome data is also useful to the provider to help evaluate and improve the care they deliver. This type of data analysis is often called ‘outcomes management.’ If the outcomes are managed properly, then outcomes management and evidenced-based practice can become a complementary contribution to quality improvement. As stated previously, there is current evidence suggesting the HFLC diet as a healthy alternate. If combined with positive outcomes from the intervention, the HFLC diet can improve the quality of care provided to those with diabetes and obesity.

Implementation of the higher fat low carbohydrate diet (HFLC) required identified goals that had objectives and expected outcomes (see Appendix B). To address the health related quality of life (HRQOL) the goal was to improve quality of life with the HFLC diet. The objectives: 1) administered a

pre and post survey containing questions about HRQOL related to diabetes and 2) the pre survey was administered at the initial visit and the post survey was administered at the last visit. The expected outcomes was increased HRQOL post dietary intervention. A second goal was the offering of an alternative diet, HFLC, to type 2 diabetics. The objectives: 1) type 2 diabetics were provided with a dietary educational tool during their routine visit and 2) participants received phone calls monthly for two months to evaluate the educational tool. It was expected that 80% of participants will accept the educational tool and will have increased dietary compliance. It was also expected to have minor alterations to the dietary tool to help individualize care and maintain retention of at least 80% of original participant group. The anticipated time frame for the actualization of the project was two months and all expected outcomes aside from the pre and post survey were obtained by the end of the two month period.

Data Analysis

The higher fat low-carbohydrate (HFLC) diet is a novel diet that could be used as an alternative for the management of obesity and diabetes. The problem solution is intended to be patient-centered by ensuring that patient values guide the clinical decision through respect and responsiveness of individual preferences (IOM, 2001). The HFLC diet education that was provided as part of the translation of evidence was planned to be safe and an effective alternative to other diets suggested by the American Diabetes Association (ADA) and the American Heart Association (AHA). Despite the lack of national guidelines, the implementation of the proposed HFLC diet to individuals meeting inclusion criteria could lead to positive healthy outcomes. The intervention included specific structures for patients and specific structures for providers. Patients were expected to keep a food record and also document, if possible, what feeling or behavior caused them to stray from the prescribed diet.

The basic action plan followed the Plan-Do-Study-Act (PDSA) QI model framework developed by Walter Shewhart in the 1920s (Ransom, Joshi, Nash, & Ransom, 2008). This model helped to guide

the planning and performance improvement efforts for obesity and diabetes using the HFLC diet. The “Plan” of the project assessed the effectiveness of a HFLC diet to improve HRQOL. Data was collected and analyzed during this phase. Data collection began once the individual consented to participate in the project. Data included a pre and post HRQOL survey. The pre survey was obtained by the DNP student at the beginning of the initial visit. The “Do” for this project included educating staff on the components of a HFLC diet and then implement it on a small scale. The staff was given a 1-2 hour educational class regarding the planned steps of implementing the project, individual roles, and the educational tool that was given to the participants. The dietary educational tool was provided to all participants with a return verbal understanding as the goal. The DNP student and the registered dietician (RD) administered the educational tool.

All participants had follow-up phone calls monthly for two months to reevaluate the diet tool and made modifications as necessary. The DNP student and the RD were present to make the monthly follow-up phone calls. The patients were provided with a survey pre- and post-intervention regarding their quality of life related to their disease process (see Appendix C). The goal was to have improved health related quality of life (HRQOL) with less physical and psychological complications of obesity and diabetes. The “Study” of this project assessed the effect of the diet by analyzing the data and feedback from the collaborating staff and participants. The pre and post survey that measured quality of life was also measured for change. The “Act” of this project identified any remaining gaps in the process and made modifications as necessary. Potential barriers and threats, which will be discussed, were assessed and managed throughout the phases of implementation. Data analysis was completed by the DNP student and the RD assisted.

Setting and Resources

The DNP project took place in a small family practice clinic located in St. Augustine, Florida. The DNP student’s mentor, a registered dietician, provided the primary dietary education and resources

on the HFLC diet. In addition, Janine Dray, registered dietician (RD), joined the DNP student for all educational sessions to the staff and project participants. The clinic physician and nurse practitioner (NP) identified potential participants.

Description of the group, population or community

The project setting took place in a general family practice to ensure a more controlled sample of participants as compared with a sample of subjects with acute exacerbations of diabetes likely found in the hospital setting. The clinic identified 33.7% of its diabetic population are type 2 diabetics taking metformin. The participants were selected from the 33.7% to eliminate medication bias. The sample inclusion criteria are adults aged 30 years old and older with a BMI of 25.5 – 29.9 for overweight and 30 or greater for obese and are type 2 diabetics with a HA1c greater than 7%. Type 1 diabetics on insulin therapy were excluded because ketoacidosis has been reported during ketogenic low carbohydrate diets (Yamada et al., 2014). Individuals with cognitive impairment were also excluded due to the possibility of their inability to follow through with dietary compliance and food records. The targeted sample size was 20 participants. It was expected that some participants may drop out of the project with attrition due to a number of factors. Patients and the overall healthcare system were the primary stakeholders.

Ethics and Human Subjects Protection

This project utilized surveys and feedback from project participants. There was minimal risk to the participants and the confidentiality of the personally identifiable information was maintained throughout the project and thereafter (Issel, 2014; Burns & Grove, 2003). Health Insurance Portability and Accountability Act (HIPPA) guidelines were maintained in addition to the DNP student having completed the CITI training course in human projects protection. HIPPA is a United States law designed to protect patients' medical records and health related information.

This project included the follow ethical elements: 1) protecting subjects' rights, 2) balancing the benefits and the risks in the project, 3) obtaining informed consent, 4) patient self-determination, and 5) preserve the subjects' privacy and confidentiality (Burns & Grove, 2003; Grgurich, 2012). All personal information obtained, such as pre and post surveys, was stored in a locked filing cabinet in the home of the project manager. Each participant was assigned a number that coincided with their surveys to eliminate a breach of subject confidentiality. In addition, the clinic physician requested each participant sign an informed consent form (see Appendix D). The project manager followed all research and clinical care policies of the Health Insurance Portability and Accountability Act (HIPPA).

Results

Outcomes

The health related quality of life (HRQOL) survey was administered pre and post dietary educational intervention. The Problem Areas in Diabetes Questionnaire (PAID, Joslin Diabetes Center, 1999) was a 20 question survey that was used. The PAID survey rated responses 0=not a problem to 4=serious problem. The answers to the 20 questions were added for the total and multiplied by 1.25 to generate a total score between 0-100. A score 40 or greater indicates a HRQOL disturbance and should be evaluated further. An individual with poor glycemic control and an extremely low score (0-10) would be indicative of denial.

The two participants that completed the project from start to finish had improvements in their HRQOL surveys. The male participant had a pre-survey score of 61.25, which included 9 circled scores of 4. In meeting with him the first time he was very motivated to change his dietary habits and stated, "I am sick of fast food but ordering good costs more." He reported he was looking forward to learning how to make better food choices. During our first follow-up call he reported he completely cut out drinking cola, which was a significant hurdle for him because he works the night shift and drinks that

instead of coffee. He has since switched to tea. He felt he was struggling with wanting more carbohydrates and asked for suggestions. Although, not measured in this project he did inform the DNP student that his blood sugar readings had decreased significantly. His educational tool was adjusted to help with his carbohydrate cravings. During the second follow up call he reported he was adjusting to the diet better and his cravings were decreased with the adjustments made from the previous phone call. He stated, "I don't crave sweets but do have the occasional bowl of ice cream. Just not every day like I used to." He reported that he has been making healthier choices when eating out to include salads and not double sizing the meals if opting for fast food. His post-survey was 1.25, which is a significant decrease. He had all zeros except for a one for the feeling of deprivation regarding food and meals question. During his final visit he reported he has started to have higher protein snacks for the night hours while he is working. He stated he fell back into old habits "a little" because of remodeling taking place in the house and not food prepping as he was in the past. He was very pleased with the changes he has made for himself and said, "the challenge of changing someone's opinion is the hardest." He plans to continue with this new lifestyle modification because he feels better, his blood sugars are under control and he has lost weight. He feels confident that he will continue to feel good and thanked the DNP student and RD for offering this project to him.

The female participant had a pre-survey score of 48.75. She had mostly 3s circled with two 4s. She was concerned about the tool because she had several food allergies and reported having kidney disease. The RD working with the DNP student had experience working on a renal floor and was very familiar with the dietary restrictions that the female participant spoke about. She was motivated to participate in the educational intervention because she has been worrying about future complications of her illness if she did not make a serious change in her lifestyle. She reported a high intake of fast food and stated, "we will take a son somewhere healthy for dinner then go get fast food for us [her and spouse]". During the first follow-up visit she reported feeling very satisfied and was not craving sweets. She did

not need any modifications to her dietary tool. During her second visit she reported that she had been out of town helping her daughter care for her newborn baby. She stated her blood sugars were dropping low secondary to not eating as much. Once she got into a routine at her daughter's house she was able to resume the suggested HFLC diet. She reported she really like the diet and was enjoying trying out new recipes with the different food choices on the educational tool. Encouragement and praise was given for not giving up on the dietary intervention and she stated "I really like it [diet] and it is something I think I would like to carry on with." Her post-survey score was 6.25. During the final visit she stated, "I feel well enough to make better decisions." She and her spouse had decided to move to North Carolina to be closer to her daughter and grandchildren. She contributes this decision was partly made after she had started the dietary intervention and was feeling better and healthier. She did acknowledge that with increased stress in her life her dietary choices are not as healthy. She is planning to continue this diet and make a lifestyle change because of her overall general health improving, satisfied with healthier meals and weight loss. She was grateful to be a participant in the capstone project and thanked the DNP student and RD for opportunity and life changing educational tool.

Facilitators and Barriers

Performing a gap analysis can help nurse leaders identify and close gaps between "real-world practice and desired service, quality, and patient outcomes" (Davis-Ajami et al., 2014, p. 17). In a best practice randomized control trial (RCT), good participant retention was used to compare a medium carbohydrate, low-fat, calorie restricted, carbohydrate counting diet with guidelines from the ADA with a low carbohydrate, high fat, non-calorie restricted diet in prediabetic or diabetic patients with a BMI > 25 over a three month period (Saslow et al., 2014). The participants had to be willing to consume either diet and have control over their food intake to be able to be compliant with the diet intervention. The researchers also included skills to support behavior change [diet] and maintenance. Potential barriers to this best practice strategy is finding providers willing to go against the recommendations of the ADA

and finding the time to teach the skills needed to maintain the diet change. Unwin and Unwin (2014) implemented a low carbohydrate higher fat diet in patients with a HA1c of 6.0%. The diets were tailored to suit the patient needs and time was spent concentrating on the positive outcomes such as weight loss and health gain. Potential barriers to this best practice implementation would include lack of time to do counseling for diet compliance and recommending a diet that goes against the suggested norm, despite improved biomarkers such as blood pressure, HA1c, and weight loss. In another RCT conducted by Yamada et al. (2014) patients received a conventional calorie-restricted diet or a low-carbohydrate diet and received dietary consultations every two months for six months. Potential barriers to this best practice strategy is dietary non-compliance and follow-up with the dietary consultant. The major barriers to implementing this diet will be finding providers willing to try this alternative diet because it goes against the recommendations of the ADA and the AHA. The *Dietary Guideline for Americans, 2010* actually recommends the opposite of the HFLC diet, which is another major barrier to implementation. Since this is a novel treatment intervention for diabetes and obesity most practices continue to follow the ADA and AHA recommendations as best practice.

The two most common barriers cited in the literature include lack of time for education and providers not wanting to go against the dietary recommendations suggested by the ADA. However, they were not barriers for the DNP student for this project. The clinic allotted time for educational purposes and the providers at the clinic were willing to follow HFLC dietary recommendations. The providers at the project site clinic agreed that the HFLC diet is a healthy alternative to the recommended ADA diet. The office allows thirty minutes for each visit, which allowed enough time for dietary education. It was the goal that 20 participants would enroll voluntarily and complete the entire project from start to finish. Overall, there were minimal barriers to implementing this project.

The literature provided the groundwork for potential barriers, however lack of time or going against the suggested dietary ADA recommendations did not prove to be barriers for this project. The

clinic providers identified the participants that met inclusion criteria for the project. The identified participants included approximately 30 individuals, which was reduced to 17 with initial calls. Six individuals returned calls and made the initial appointment. Three individuals made the first visit and received the first follow-up call. Two participants completed the second follow up call and final visit. A small participant pool was expected but not as small as two participants. A small participant pool can be considered a potential barrier because it can be lacking in rich data feedback.

Another barrier that was encountered during the project implementation was ample, quiet space for follow-up phone calls. The project manager had not considered this aspect when developing the project and was planning to use a personal cell phone. However, due to possible HIPPA violation the clinic phone was used. The clinic providers and MA all share the same common space and making a call using the speaker phone was not ideal. The project manager made the calls not using the speaker phone option and consulted with the RD when applicable.

The clinic staff were excellent facilitators. The staff at the front of the house staff fielded calls was I not at the clinic and provided me with detailed messages. The back of the house staff provided encouragement and support throughout the entire project process. The clinic physician/owner was very involved with the project and hoped for positive outcomes. The amount of support from the clinic allowed for a smooth project implementation process.

Discussion

The HFLC DNP project highlighted the positive outcomes for the two participants that completed the project as evidenced by the improved pre to post survey scores. The participants were married, which could have contributed to the high motivation for life style change. Weight and blood sugar results were not included in this project but both participants reported improvements in blood sugar results and weight. Fear of future complications related to diabetes decreased for both

participants. Although, the male participant still reported some difficulty with feeling deprived of some foods and meals his score went from a 4 to 1. The small participant pool is considered a limitation of this project and future projects will aim for larger sample sizes. Having a dietary tool developed by a RD that uses the HFLC diet with diabetics on a daily basis was a strength of this project. Also, having a RD involved with all participant interactions and phone calls allowed for more advanced modifications of the dietary tool. Future recommendations would include a larger participant pool and pre and post biomarkers such as weight and HA1c. Overall, for the two participants, this project allowed for a positive lifestyle modification with improved HRQOL pre to post survey scores.

Conclusion

A higher fat low-carbohydrate (HFLC) diet can be a safe alternative to the recommended American Diabetes Association (ADA) diet as highlighted in literature reviewed above. The evidenced-based interventions suggests behavioral modifications, supervised medication regimens, and patient centered care of illness provide the best combination of care to manage a chronic illness such as diabetes. The causal theory and educational theory concepts from Ausubel were used as the theoretical framework to address diabetes and obesity with the HFLC diet. The diabetic client must be ready to make a change in order to assimilate new knowledge and empower them to take control of their illness and have better health related quality of life (HRQOL). The suggested implementation plan has the potential to grow from a small family practice to rural communities as long as there is access to healthy food options. The role of the DNP is to provide leadership using evidenced-based conceptual frameworks to translate the evidence into practice for improved client outcomes. Diabetes and obesity are chronic illnesses that put people at a higher risk for health disparities and inequalities. The DNP has to be an advocate for their clients by identifying disparities and work to develop quality improvement projects not only in smaller communities, but also at a federal level.

This DNP project focused on a diet intervention for type 2 diabetics that are overweight and/or obese in addition to the frequent health related quality of life (HRQOL) issues that diabetics may suffer from as a consequence. The end goal was to improve HRQOL by providing an alternate diet option such as the higher fat low carbohydrate (HFLC) diet. The results and recommendations from the project were provided to the clinic staff and the faculty at the University of Massachusetts, Amherst. In addition, the findings will be presented at the UMASS, Amherst, School of Nursing Scholarly Presentation Day. The HFLC diet is relatively novel and the findings should be disseminated more broadly. An abstract will be submitted to clinical practice journals focused on chronic disease management to be considered for publication and help to ensure a broader dissemination. Through local and national dissemination this HFLC diet quality improvement project can be further refined and disseminated to different health care settings that are interested in the alternate diet and HRQOL issues of diabetics.

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Appendix A

Sodium intake: When people cut their carbohydrate intake significantly, their kidneys increase excretion of sodium and water. So in addition to drinking plenty of fluid (a minimum of 2 liters of water daily), increasing sodium by 1000 to 2000 mg per day is often beneficial, particularly at carbohydrate intakes lower than 60 grams per day.

Magnesium and potassium: These electrolytes may also decline in the initial stage of a low-carb diet. I generally recommend taking 300-400 mg of magnesium daily. Potassium needs can be met by choosing high-potassium foods: avocado, Greek yogurt, fish, tomatoes, cooked greens, and cooked mushrooms.

Websites:

<http://www.lowcarbdietitian.com> (Franziska Spritzler RD – developer of this educational tool)

<http://www.peaceloveandlowcarb.com>

<http://www.breatheimhungry.com>

Sample Menu

Breakfast:

eggs and spinach cooked in butter, coconut oil, or olive oil
raspberries topped with greek yogurt and walnuts
water, coffee, or tea with cream or half-and-half

Lunch:

Caprese salad – mozzarella cheese, sliced tomato, olive oil and basil
¼ cup roasted almonds
Water

Dinner:

Steak, chicken, shrimp fajitas with grilled bell pepper, onion, and guacamole
Blackberries with whipped cream
Water, coffee, or tea with cream or half-and-half

Snacks (optional):

Cheese
Cucumbers or celery with cream cheese
¼ cup almonds, hazelnuts, macadamias, walnuts or pecans

The Healthy Low-Carb Plate

At each meal, fill your plate with the following:

Protein (1 serving)

(negligible net carbs unless noted)

Fat (1-4 Tbsp)

(negligible net carbs unless noted)

Meat/Poultry/Game/Fish (4-6 oz/120-180 gm)	Olive oil
Eggs (2-3)	Coconut oil
Cheese (3-4 oz/90-120 gm)	Butter
Plain Greek yogurt (1 cup: 7 grams carb)	Cream, sour cream
Nuts and nut butters (2 Tbsp: 3-4 grams net carb)	Cream cheese
	Avocado (1/2 medium: 1-2 grams net carb)

Nonstarchy Veggies

(1-3 cups)

Fruit and Starchy Veggies

(optional, based on tolerance)

	Net Carbs		Net Carbs
Artichoke (medium)	4 grams	Blackberries (1 cup)	6 grams
Artichoke hearts (1 cup)	5 grams	Blueberries (1 cup)	18 grams
Asparagus (1 cup)	3 grams	Raspberries (1 cup)	6 grams
Bell peppers (1 cup)	5 grams	Strawberries (1 cup, sliced)	9 grams
Broccoli (1 cup, steamed)	4 grams	Melon (1 cup, sliced)	14 grams
Brussels sprouts (1 cup)	6 grams	Apple (1 small)	17 grams
Cabbage (1 cup, raw)	2 grams	Butternut squash (1 cup)	17 grams
Cauliflower (1 cup, cooked)	4 grams	Carrots, raw (1 cup, chopped)	8 grams
Celery (1 large stalk)	1 gram	Spaghetti squash (1 cup)	8 grams
Cucumbers (1 cup, sliced)	3 grams	Turnips (1 cup, mashed)	7 grams
Green beans (1 cup)	5 grams		
Jicama (1 cup)	5 grams		
Kale (1 cup, cooked)	6 grams		

Lettuce (1 cup)	1 gram		
Mushrooms (1 cup, raw)	3 grams		
		Miscellaneous (Optional)	
Onions (½ cup, raw)	6 grams		Net Carbs
Radishes (10 medium)	2 grams		
Spinach, greens (1 cup, cooked)	3 grams	Chia seeds (2 Tbsp)	1 gram
		Flaxseed, ground (2 Tbsp)	1 gram
Tomatoes (1 medium)	2 grams	Shirataki noodles (1 package)	1 gram
Zucchini (1 cup, chopped, cooked)	4 grams		

Low-carb snacks (less than 5 grams net carbs per serving)

1-2 oz (30-60 grams) cheese (mozzarella, cheddar, Swiss, Monterey Jack, Muenster, etc.)

1-2 Tbsp nut butter on celery

¼ cup nuts (almonds, hazelnuts, macadamias, pecans)

10-15 black or green olive

The Well-Stocked Low-Carb Kitchen

Have these staples on hand so you can put together easy, healthy meals all week long. Feel free to leave out any foods you don't care for or have allergies or sensitivities to, of course. Ideally, choose organic and/or locally sourced items whenever possible.

FRIDGE AND FREEZER

Low-Carb Vegetables

Fresh

Lettuce: large leaves for wraps (place meat or other sandwich filling inside)

Bagged lettuce for salads

Kale and spinach for sautéing or casseroles

Zucchini, eggplant, mushrooms, and green beans for sautéing

Cabbage, eaten raw or cooked

Onions and garlic for flavor

Fresh berries

Extra veggies for spreads, dips, and salads: bell peppers, cauliflower, cucumber, jicama, tomatoes, and other low carb veggies.

Avocado: Great snack on its own, or make guacamole for dipping low-carb veggies. Pre-made

Guacamole is another great option.

Frozen

Bagged broccoli, spinach, cauliflower, stir-fry veggie blends (Great time saver because they're already washed, cut and prepared), berries (no sugar added)

Proteins and Fats

Fresh

Beef, pork, poultry, game

Eggs

Heavy cream

Half-and-half

Sour cream

Plain Greek yogurt

Cottage cheese

Cream cheese

Butter

Cheese: hard cheeses in blocks, slices, shredded, and individually wrapped portions for snacks

Nuts: almonds, Brazil nuts, hazelnuts, macadamias, peanuts, pecans, walnuts (keep in refrigerator or freezer)

Frozen

Fish or easy-to-peel shrimp

Ground beef or turkey patties

PANTRY

Canned or Jarred Items

Seafood: tuna, salmon, crab, shrimp, sardines, anchovies

Tomato products: canned tomatoes and tomato paste (look for lowest carb count – they vary greatly!)

Sauces: pasta sauce, pesto, and Alfredo sauce with no added sugar or thickeners

Low-carb veggies: artichoke hearts (moderate carbs), chipotle peppers, green beans, green chiles, greens, hearts of palm, okra, roasted red peppers, sauerkraut, sun-dried tomatoes (moderate carbs)

Nut butters (natural and unsweetened — most need refrigeration after opening)

Fats:

Extra virgin coconut oil

Extra virgin olive oil

Macadamia nut oil

Avocado oil

Condiments

Mustard (except sweetened mustards like honey mustard)

Cider and wine vinegars (use balsamic vinegar *very* sparingly)

Bottled hot sauces (such as Tabasco or Tapatio)

Salsa

Soy sauce

Mayonnaise (preferably made from olive oil rather than soybean oil)

Capers

Olives

Lemon or lime juice

Cooking and Baking Items

Salt (preferably unrefined Celtic sea salt or Himalayan crystal salt)

Whey protein powder

Herbs and spices (cinnamon, chili powder, basil, rosemary, etc.)

Natural vanilla extract

Broth or bouillon

Unsweetened cocoa powder

Erythritol and/or stevia (if using sugar substitutes)

Cocoa powder

Unsweetened chocolate

Dark chocolate (at least 85% cacao)

Almond flour

Coconut flour

Miscellaneous

Chia seeds

Flaxseeds

Appendix B

Goals, Objectives and Expected Outcomes

Goal 1: Improved quality of life (QOL) with a different dietary option.

Objective	Expected Outcome	Result
A short survey containing questions about QOL related to diabetes. The survey will be administered pre and post dietary educational tool.	Increased QOL post dietary educational tool.	
Assessment of survey application during routine visit. The pre survey will take place at first visit and post survey will take place during last visit	95% of the Townsend Clinic staff will agree that the survey can be administered at initial and final visits during the capstone project timeframe.	

Goal 2: Health care providers will benefit from the dietary educational tool by supplying it to type 2 diabetic patients that do not have contraindications.

Objective	Expected Outcome	Result
Health care providers will have an alternative option for lifestyle modification through the use of the dietary educational tool.	Clinic staff will use the use the educational tool 85% of the time to provide a dietary alternative to type 2 diabetics as evidenced by verbal declaration or documentation of provision of educational tool.	
The educational tool will be reviewed by Franziska Spritzler (registered dietician and Registered Diabetes Educator).	The approval rating for the education tool by Franziska will be 95%.	
The educational tool will be reviewed by the clinical staff at the Townsend Clinic.	The approval rating for the educational tool by the Townsend Clinic staff will be 95%.	
The educational tool will be reviewed by 1st and 2 nd committee members.	The approval rating for the educational tool by the committee members will be 95%.	

Assessment of educational tool application during routine visit. *office schedules appointments every 30 minutes	95% of the Townsend Clinic staff will agree that the tool can be administered during routine visit.	
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Goal 3: Type two diabetics will have an alternative dietary option.

Objective	Expected Outcomes	Result
Type 2 diabetics will be provided with a dietary educational tool during their routine visit.	80% of participants will accept the educational tool during their routine visit.	
Type 2 diabetics will receive monthly phone calls x 2 to evaluate educational tool.	Minor alterations will be made in educational tool. Retention of participants by providing individualized follow up care at least 80% of original participant group.	

Appendix C

Health Related Quality of Life (HRQOL) Survey

Problem Areas in Diabetes Questionnaire (PAID)

INSTRUCTIONS: Which of the following diabetes issues are currently a problem for you?

Circle the number that gives the best answer for you. Please provide an answer for each question. Please bring the completed form with you to your next consultation where it will form the basis for a dialogue about how you are coping with your diabetes.

Patient name: (For capstone project this will be a number and will not use patient name)

Completion date:

(0=Not a problem) (1=Minor problem) (2=Moderate problem) (3=somewhat serious problem) (4=Serious problem)

1. Not having clear and concrete goals for your diabetes care? 0 1 2 3 4
2. Feeling discouraged with your diabetes treatment plan? 0 1 2 3 4
3. Feeling scared when you think about living with diabetes? 0 1 2 3 4
4. Uncomfortable social situations related to your diabetes care (e.g., people telling you what to eat)? 0 1 2 3 4
5. Feelings of deprivation regarding food and meals? 0 1 2 3 4
6. Feeling depressed when you think about living with diabetes? 0 1 2 3 4
7. Not knowing if your mood or feelings are related to your diabetes? 0 1 2 3 4
8. Feeling overwhelmed by your diabetes? 0 1 2 3 4
9. Worrying about low blood sugar reactions? 0 1 2 3 4
10. Feeling angry when you think about living with diabetes? 0 1 2 3 4
11. Feeling constantly concerned about food and eating? 0 1 2 3 4
12. Worrying about the future and the possibility of serious complications? 0 1 2 3 4
13. Feelings of guilt or anxiety when you get off track with your diabetes management? 0 1 2 3 4
14. Not "accepting" your diabetes? 0 1 2 3 4
15. Feeling unsatisfied with your diabetes physician? 0 1 2 3 4
16. Feeling that diabetes is taking up too much of your mental and physical energy every day? 0 1 2 3 4
17. Feeling alone with your diabetes? 0 1 2 3 4
18. Feeling that your friends and family are not supportive of your diabetes management efforts? 0 1 2 3 4
19. Coping with complications of diabetes? 0 1 2 3 4
20. Feeling "burned out" by the constant effort needed to manage diabetes? 0 1 2 3 4

www.dawnstudy.com

PAID - © 1999 Joslin Diabetes Center

Problem Areas in Diabetes Questionnaire (PAID)

Ways to identify patient emotional distress

Diabetes can be demanding and cause emotional distress. It is vital that clinicians are able to identify diabetes-related emotional distress in their patients. Validated practical strategies are available to promote an open dialogue and help to flag when serious emotional distress exists.

One tool that has proven very helpful to healthcare professionals is the Problem Areas in Diabetes (PAID) scale, a simple, one-page questionnaire.

Why the PAID scale?

PAID has high acceptability and scientific validity as evidenced by more than 60 scientific papers and scientific research abstracts. The PAID measure of diabetes related emotional distress correlates with measures of related concepts such as depression, social support, health beliefs, and coping style, as well as predicts future blood glucose control of the patient. The questionnaire has proven to be sensitive to detect changes over time following educational and therapeutic interventions.

What is the PAID scale?

The PAID is a self-report pencil and paper questionnaire that contains 20 items that describe negative emotions related to diabetes (e.g. fear, anger, frustration) commonly experienced by patients with diabetes. Completion takes approximately five minutes.

Scoring of the questionnaire

Each question has five possible answers with a value from 0 to 4, with 0 representing “no problem” and 4 “a serious problem”. The scores are added up and multiplied by 1.25, generating a total score between 0 – 100. Patients scoring 40 or higher may be at the level of “emotional burnout” and warrant special attention. PAID scores in these patients may drop 10-15 points in response to educational and medical interventions. An extremely low score (0-10) combined with poor glycemic control may be indicative for denial.

How to use the PAID scale?

In a clinical setting, the PAID can be administered routinely (e.g. annual review) and/or ad hoc as a diagnostic tool. The patient can be asked to complete the questionnaire before consultation (waiting room) or at the beginning of the consultation. Together with the patient, the clinician can calculate the total score and invite the patient to elaborate on problem areas that stand out (high scores) and explore options for overcoming the identified issues. This may include referral to a mental health specialist.

Novo Nordisk 2006. Adapted from DAWN Interactive 2. Text by Frank Snoek and Garry Welch.

Appendix D

Diabetes, Diet, and Health Related Quality of Life Project Volunteer Consent Form

We are asking you to take part in quality project study on the effects of a higher fat low carbohydrate diet on diabetes and health related quality of life issues associated with you disease process.

The study will consist of several parts. The first part involves filling out a quality of life survey related to your diabetes. The second part involves an educational hand out with verbal instruction on the diet parameters. The third part will include monthly follow up calls or visits to the Townsend Clinic for two months for educational follow-up and reassessment of the dietary educational tool. The final part will include filling out a quality of life survey after following the dietary recommendations for two months.

We will guard your confidentiality. We protect all information about you and you're taking part in this project as much as we can. We have trained staff not to tell anyone outside the study any information about a participant. No reports about the surveys will contain your name or any name of the participants in the project.

We will use the results of the survey to plan for better health care services for everyone. We are asking all participants to fill out the survey pre and post dietary education. There are no risks in taking part, because a corresponding number will used instead of names. It takes about 10 minutes to finish.

Taking part is voluntary. If you choose not to fill out the survey, there will be no penalty and it will not affect any services or other benefits you might receive from the Townsend Clinic.

If you have any questions about your rights as a project participant, you may contact Breck Baker, DNP student from the University of Massachusetts, (904) 461-1901 ext. 208.

Consent statement:

I have read and understood the information above. The project manager has answered all the questions I had to my satisfaction. They gave me a copy of this form. I consent to take part in the diabetes, diet, health related quality of life project.

Signature: _____ Date: _____

Signature: _____ Date: _____