Mediterranean Diet in Self-Management of Type II Diabetes

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Abstract

Type II Diabetes Mellitus (T2DM) is a chronic metabolic disorder, the prevalence of the disease has been increasing rapidly, becoming a worldwide epidemic. Risk factors of T2DM are obesity, physical inactivity, and sedentary lifestyle. Uncontrolled T2DM is associated with co-morbid diseases, increasing the health care cost and mortality rate which creates the need for better management of the disease. The purpose of this quasi-experimental study was to improve diatebes self-management by implementing use of the Mediterranean diet and motivation interviewing. The study sample included eight participants with a diagnosis of T2DM with a glycosylated hemoglobin of greater than seven percent. The quality improvement project was conducted from November 2018 to March 2019 in a primary care clinic. Pre and post-surveys on Mediterranean diet intake and glycosylated hemoglobin results were obtained in the project. After 3 months of compliance with the Mediterranean diet, a reduction in glycosylated hemoglobin was achieved which fosters a decrease in the comorbid diseases of coronary artery disease, stroke, hypertension, and hyperlipidemia. Improved management of type II diabetes mellitus enhances individual well-being and quality of life, and reduces health care costs.

Keywords: Mediterranean diet, type II diabetes, motivational interviewing, quasi-experimental, self-efficacy.

Mediterranean Diet in Self-Management of Type II Diabetes

Type II diabetes mellitus (T2DM) is the most common form of diabetes. It is mainly caused by central obesity, metabolic syndrome, sedentary lifestyle, and lack of exercise (Schauer, 2014). Type II diabetes is characterized by high glucose in the bloodstream because the cells are unable to respond to insulin, does not produce enough insulin, and body resistant to insulin (Wing et al., 2010). According to the Center for Disease Control and Prevention (CDC), T2DM remains the seventh leading cause of death in the United States. African Americans, Hispanics, Native Americans, and Asians are at a higher risk to develop T2DM than Caucasians (2017). People with T2DM have a five times higher risk of heart attack than non-diabetic person (American Diabetes Association [ADA], 2016). Diabetes is the leading cause of disability in the United States due to related comorbid diseases and complications (CDC, 2017). The proposed evidence-based practice project (EBP) focuses on decreasing the prevalence of T2DM and related co-morbid diseases through improved self-management using the Mediterranean diet.

Background and Significance

Approximately 1.5 million people are diagnosed with diabetes each year (ADA, 2016). There are more than 30 million Americans who have diabetes and 90 to 95 percent are diagnosed with T2DM which accounts for one in every ten persons (CDC, 2017). According to CDC statistics, more than 84.1 million people are suffering from prediabetes each year. The rising prevalence of T2DM is a major health concern because it is the leading cause of chronic kidney disease, stroke, coronary artery disease and amputation disorders (Schauer, 2014). Evidence-based interventions need to be utilized that involve patients in their daily treatment plan to manage this epidemic. Interventions for diabetes management include diabetic self-management,

Mediterranean diet planning, self-efficacy, self-motivation, and exercise for better management of diabetes and prevention or slowing the progression of related complications (Bains, 2011).

Economic

According to the CDC (2017), the cost to treat patients with T2DM has increased from $170 billion in 2008 to $249 billion in 2016. Emergency Department (ED) visits and inpatient hospitalizations are common with uncontrolled diabetes, hyperglycemia, and diabetic ketoacidosis (DKA), which are often due to noncompliance with prescribed treatments (Araia, 2014). The annual cost of care for T2DM patients varies from $3,100 to $12,042, with one or more comorbid diseases (Huber, 2014). Better self-management of T2DM will decrease the associated health care costs related to co-morbid diseases and financial burden to individuals and society (CDC, 2017).

Local Issue

Obesity and T2DM are common local problems, obesity is the major cause of T2DM (ADA, 2018; CDC, 2016; Thompson, 2015). Obesity is ranked high in Kansas and Missouri, almost one in every three adults in Missouri are not only overweight but also obese (Thompson, 2015). Missouri is one of the fifth highest states that has a high rate of obesity since 2013 (Thompson, 2015). The increased rate of obesity in Missouri has increased the prevalence of T2DM as well; the state of Missouri has a diabetes rate of 16.3 percent every year (Thompson, 2015). According to the American Diabetes Association (ADA), there are more than 539,600 adults in Missouri who have T2DM (2018). Statistics show that the costs of diabetic medical expenses in Missouri were $5.9 billion in 2017 (ADA, 2018).

Diversity Considerations

The population estimate for Lee's Summit residents is 95,782 based on census reporter (2016). According to the 2016 census, 80.2% of the Lee's Summit residents spoke English as their primary language, 15.3% were Spanish speaking, and 5% spoke other languages. Lee's Summit population includes 72.2% white or non-Hispanic, 8.9% African Americans, 8% Asians and 12% Hispanic. The average annual household income in Lee's summit is $80,237 (Census reporter, 2016). Language barriers can be an issue during the implementation of this project as three are 20% of Lee's Summit residents who do not speak English as their primary language (Census reporter, 2016). The student investigator used the translator phone device to overcome the language barrier.

Problem and Purpose

Currently, there are many different types of treatment for T2DM (Inzucchi, 2012). Success rates in self-management of T2DM are low and related co-morbid disease rates are high due to uncontrolled diabetes. The EBP project was selected to improve the self-management in patients with T2DM on adherence to the Mediterranean diet, improve the quality of care, and lower the health care costs. Patients with T2DM can benefit from lifestyle intervention of the Mediterranean diet (Schauer, 2014). Evidence based interventions are needed to manage this epidemic. Health care providers need to collaborate with patients in their daily treatment plan to enhance their decision-making skills regarding self-management, self-efficacy, and self-motivation to better manage their diabetes, obesity, and prevent or slow the progression of related complications (Bains, 2011).

Purpose Statement

The primary purpose of this proposed quasi-experimental project was to explore if the adherence to Mediterranean diet (MD) in T2DM patients reduces glycosylated hemoglobin

(HgbA1c). Adherence to MD also reduces healthcare costs of diabetes and related co-morbid diseases. The Mediterranean diet can improve overall health, reduce the risk of coronary artery disease, and decrease mortality through better self-management of T2DM, weight loss, and blood pressure (CDC, 2017; ADA, 2017).

Facilitators and Barriers

The main project facilitators included UMKC instructors, student investigator, advanced practice registered nurse and workforce development. Potential barriers to the project included the recruitment goal of 25 participants, self-motivation, literacy level, limited resources on foods, poor dietary habits and the cost of the post HgbA1c lab draw (Schauer, 2014). The student investigator was able to overcome the barriers of low self-esteem, lack of motivation and lack of adherence by providing motivational intervening (MI), texting, and emailing for social support.

The economic considerations included creating a brochure on the Mediterranean diet and providing glucose monitoring machines to patients in need. For the sustainability and to facilitate change of practice, the project results were shared with the participating clinic to create a vision (Kotter, 1995).

Review of the Evidence

The synthesis of evidence review supports a reduction in HgbA1c through the intervention of self-management of T2DMwith the Mediterranean diet (Wing et al. 2008). Studies in adults with T2DM and related co-morbid diseases were included in order to expand the available literature and for better management of diabetes.

Inquiry

The inquiry for the evidence review and proposed project is, in adults aged 25 years and older diagnosed with T2DM with a glycosylated hemoglobin (HgbA1c) greater than 7percent, do

lifestyle modifications, including Mediterranean diet adherence, reduce HgbA1c in three months from November 2018 to March 2019 at a primary care clinic?

Search Strategies

The project employed various methods to identify literature on the term T2DM and effects of lifestyle modifications on the management of T2DM. Databases used for the literature search included Ovid Medicine, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Evidence Based Medicine, Index Medicus (MEDLINE), PubMed and Cochrane. A literature search utilized the keywords of type II diabetes, lifestyle modifications, Mediterranean diet, self-management, self-efficacy, motivational interviewing, adherence to diet, and self-reporting regarding daily blood glucose checks. Studies published within five to ten years that addressed the keywords were included and studies that are not available in English, performed outside the United States, or full text were excluded.

The literature search revealed 80 studies by the search strategy that meet the PICOTS criteria; There were only 20 studies that met the inclusion criteria and were selected for the EBP. Using Melnyk and Fineout-Overholt's *Rating System for the Hierarchy of Evidence for an Interventional Inquiry* (p. 11, 2015, adapted), the level of evidence of each article was rated according to study design (see Appendix I, Rating System). During the literature review, seven of the study designs were systemic reviews of RTCs with level I evidence, and three of the studies were meta-analysis design with level II evidence. Two studies were prospective, non-randomized controlled trials or level III evidence. Three of the studies were quasi-experimental with level III evidence, and four were cross-sectional studies with level IV evidence (see Appendix C, evidence table).

Synthesis of Evidence

The literature supports that the Mediterranean diet is successful in the self-management of T2DM (Inzucchi, 2012; Wing et al. 2008; Schauer, 2014). Several studies indicate that adherence to a Mediterranean diet improves the glycemic control for T2DM, reduces blood pressure, results in weight loss, and reduces the risk of coronary artery disease and heart attacks (Inzucchi, 2012). Key evidence topics include lifestyle modification for type II diabetes management, Mediterranean diet, Mediterranean Diet and type II diabetes management, adherence to Mediterranean diet, motivational interviewing, and self- management**.** Key terms related to the EBP project were used in the evidence review (see Appendix C for the definition of the key terms).

Lifestyle Modification for Type II Diabetes Management

Lifestyle modifications are defined as healthy eating habits, as well as physical activity and maintenance of the healthy eating habits for months or years (CDC, 2016; Inzucchi, 2012; Wing et al. 2008; Schauer, 2014). Lifestyle modifications play an important role in better management of type 2 diabetes, reducing BMI, and controlling hypertension (ADA, 2017). A study done by Gupta, Agarwal, and Byadgi (2014) was an RTC with level I evidence to assess the clinical effects of dietary interventions and lifestyle modifications on T2DM patients. The study consisted of N= 56 patients in a primary care office in Bandara. The results revealed that with the implementation of lifestyle modification interventions, 64.29% of participants had a normal systolic blood pressure reading of <130mmHg and diastolic reading between 80-90mmHg (Gupta et al., 2014). Also, participants had a weight loss of 14.29% of their total weight, and the mean score of plasma glucose was 332.76 pre and 140.06 post 3 months. The four-year randomized study results showed that lifestyle interventions ILI had the greatest impact on weight loss in comparison to DSE (p<0.001*)* (Wing et al., 2008). The research found that

lifestyle modifications have a strong impact on the management of T2DM (Gosby et al., 2016; Gupta et al., 2014; Wing et al. 2008).

Mediterranean Diet and type II Diabetes Management

The studies revealed that lifestyle modification associated with the use of the Mediterranean diet is effective in lowering the HgbA1c, weight reduction, and improvement in self-management of T2DM (Gosby et al., 2016; Gupta et al., 2014; Wing et al. 2008). Buckland, Bach, Serra-Majem (2008) conducted a systemic review on the correlation of obesity and Mediterranean diet (MD). Study results showed that MD diet compared with other controlled diets had a greater reduction in HGBA1c with a mean difference of 0.30 to 0.46*,* confidence interval of 95% and *(p*=0.004*).* Body mass index decreased by 0.29kg/m2 and cholesterol and triglyceride levels decreased by 0.14mmol. MD also showed a positive correction with high density lipoprotein which was increased by 0.06mmol (Buckland et al., 2008; Esposito et al., 2015).

Different dietary approaches and lifestyle modification of Mediterranean diet aid in glycemic control, lipids, and weight loss (Olubukola, Patrick, and Jonathan, 2013). There was total of *N*= 20 RCTs that included total of 3073 participants in the intervention that lasted for six months that compared the low carbohydrate diet, low fat diet, high fiber diet, vegetarian diet, vegan diet, low glycemic diet, Mediterranean diet, and high protein diet (Olubukola, Patrick, and Jonathan, 2013; Schwinshackl, 2016). The study results showed reduction in glycated hemoglobin by *0.12% (p=0.03)* in low carbohydrate diet, 0.14% *(p*=0.007*),* low glycemic diet, 0.46% *(p*=<0.00001), Mediterranean diet, and 0.28% (*p*=<0.00001) in high protein diet with adherence to MD *(p*=<0.0001) (Olubukola, 2013; Schwinshackl).

Mediterranean Diet

The Mediterranean diet (MD) is a Middle Eastern diet. MD gained popularity around the world in 1995. The Mediterranean offers “a cuisine rich in colors, aromas and memories, which support the taste and the spirit of those who live in harmony with nature” (Altomare et al, 2013. p.74). The MD consists of eating fresh vegetables such as legumes, green beans, fresh fruits rich in vitamin A and C consist of carrots, cantaloupe, orange, and strawberries that must be strictly seasonal and fresh. The MD emphasizes eating a moderate amount of lean meat and moderate amounts of red wine. In healthcare, MD is the most acceptable diet among health care professionals (Hofmeister, 2015). Mediterranean diet improves the overall health of coronary artery disease (CAD), diabetes mellitus (DM), and obesity and decreases the incidence of Parkinson disease (Sofi, Macchi, Abbate, Gensini, and Casini, 2013).

In studies with a total sample size of 214 participants who were 50 to 71years and had high adherence to MD, a 22% reduction in cardiovascular mortality in men and 29% in women was found after the MD intervention (Sofi et al., 2013; Tapsell, 2014). During the meta-analysis, the adherence to MD reduced the incidence of T2DM by 20%, colorectal cancer by 25%, and cardiovascular mortality by 22% (Sofi et al., 2013; Tapsell, 2014).

Adherence to Mediterranean Diet

Adherence to MD is a key in the self-management of diabetes and the key to prevention of T2DM (Muñoz, 2009; Díez-espino,2011). A randomized controlled trial designed by Downer (2016) was designed to predict the short term and long term adherence with interventions promoting the Mediterranean diet. Study results showed that 54% of participants complied at one year follow up and 58% participants complied at four year follow up had lower cardiovascular risk factors and lower waist circumference(Díez-espino,2011). A large RCT study done by Díez-espino, Buil-cosiales, Serrano-martínez, Toledo, Salas-salvadó, Martínez-gonzález (2011)

showed that long-term adherence to MD fostered control of the progression of type II diabetes and resulted in better self-management of type II diabetes (p=<0.001).

Adherence to MD decreases the prevalence of obesity management and self-perceived mental and physical health (Muñoz, Fíto, Marrugat, Covas, Schröder, 2009). A random sample of 3910 men and 4285 women were selected for a cross-sectional study. The adherence to MD was examined using a validated food frequency questionnaire (FFQ). Study results showed that adherence to MD lowered the BMI by 7% (p=<.0001). However, the adherence to MD did not show any direct relationship in improvement of physical mental health (Muñoz, 2009).

Motivational Interviewing

Motivational interviewing (MI) strategies help in self-management, self-efficacy, adherence to lifestyle modifications and adherence to the Mediterranean diet for better management of diabetes (Chlebowy et al., 2014). A randomized controlled had N=36 participants in usual care (UC) and N=26 in MI to determine the effects of motivational interviewing (MI) on treatment adherence to diabetes. MI participants received a maximum of six MI sessions over 3 months, where sessions lasted 45 minutes to an hour and occurred every two weeks during *3*-months periods. Results revealed that MI increased the adherence to physical activity levels by 66.7% compared to 38.8%, and decreased glucose levels *(*p=0.043) and body mass index of *(*p=0.046*)*.

A randomized controlled traits study performed by Heinrich, Candel, and Nicolaas (2010) studied the effects and evaluation of MI-based counseling strategies on diabetes patients with N=584. During the study, participants received a five-and-a-half-hour session from a trained MI nurse to educate, demonstrates, role play and discussions. MI mainly focused on self-management behavior, self-monitoring of blood glucose, and self-motivation for better

management of the disease process. The results showed that 77.3% had an HgbA1c level below 7%, 41% had a BMI of <28, and 41.2% had a BMI of >30 in the participants.

Motivational Interviewing is the success key in problem solving skills and in adherence to any treatment for chronic disease (Lakerveld, et al., 2013). In a research study by Lakerveld et al. (2013), there were six face to face 30-minute counseling sessions, followed by 3-monthly telephone session on MI and problem-solving treatment. The study results showed that 536 (86.2%) completed the six month follow up and 502 (81.2%) completed 12 month follow up, and all the participants established self-management techniques for T2DM.

According to Anderson et al. (2017), supportive phone calls on a regular basis to the patients who are implementing lifestyle modifications have been associated with better outcomes of weight loss and better management of T2DM.

Self- Management

Self-management education teaches problem-solving skills. Self-management is aligned with self-efficacy, and it increases one's confidence and motivation to conduct a behavior or adhere to a plan to reach desired goals (Bodenheimer, 2012). Self-management with chronic disease in primary care decrease the progression of chronic disease, reduces the cost of chronic disease, improves motivation and self-efficacy, and soon will become a part of integral high quality primary care (Bodenheimer, 2012; Burridge, Foster, Donald, Zhang, Russell, & Jackson 2017).

Theory

The Health Believe Model (HBM) is the first theory of health behavior and remains the most widely used theory in the nursing profession (Butts & Rich, 2016). HBM was developed in 1950 by a group of psychologists who worked for the U.S. Public Health Services (Butts & Rich,

2016; Tavakoli, Dini-Talatappeh, Rahmati-Najarkolaei, & Gholami-Fesharaki, 2016). The main focus of this theory is to address problem behavior that impacts health concerns (Tavakoli et al., 2016). According to Butts and Rich (2016), the HBM guiding principle is based on four critical areas: the severity of the problem, one's susceptibility to that illness, the benefit of taking preventive measures, and barriers facing during taking prevention measures. The HBM model is the best model to use in self-management for chronic disease, adherence to lifestyle modifications, and for compliance to implemented interventions (Tavakoli et al., 2016). This model was used in the quasi-experimental study. Nonadherence to the lifestyle modification or any other prescribed treatment plan for T2DM are the main issues that contribute to T2DM complications, therefore using health belief model helped participants with better adherence to MD(Tavakoli et al., 2016). The literature review revealed that the HBM theory is widely used for self-management skills in chronic disease processes, and appraisal identified that 15 studies used HBM out of 22 (See appendix D, theory model).

Methods

The primary Institutional Review Board (IRB) for this project was the University of Missouri Kansas City. The doctoral project was categorized as Not Human Subjects Research, Evidence-Based Quality Improvement project (EBQI). The project involved noninvasive interventions during implementation that are routinely utilized with T2DM patients, and the project was designed to improve self-care. A site agreement was completed in the Missouri Clinic.

Ethical Considerations

The four Belmont ethical principles were considered and followed during this EBQI project. The participants were selected on the basis of inclusion and exclusion criteria. The

project focus was to maximize the benefits and minimize the potential side effects. The ethical consideration included keeping patient identity and data secure and confidential. Patients had voluntary or autonomous decisions to sign an informed consent to participate in the study. The informed consent included the possible benefits and risks associated with the study. The student investigator had no conflict of interest. Subjects participated on a volunteer basis and they reserved the right to leave the project at any time at their own self-determination. Participants were informed that their demographic, personal information and interventional data will remain confidential. The student investigator maintained the confidentiality of patients during selecting, sampling, implementing, gathering data, and during conducting results. The student investigator avoided using participant names during this study and identifying information during presenting results.

Funding

Costs related to the project included the development of a brochure on the Mediterranean diet, patient education, blood glucose monitoring machines and small incentives to participants at the end of the study. (See Appendix A, cost table). The funding for this proposed project was covered through personal findings. The student investigator applied for a grant provided from the UMKC graduate school which distributes yearly graduate research grants.

Setting and Participants

The proposed project was implemented in a Missouri primary clinic. The primary care clinic provides care to individuals across the lifespan. Inclusion and exclusion criteria followed closely during the selection of the participants. Inclusion criteria included patients aged 25 and older, HgbA1c greater than seven percent, diagnosis of type II diabetes, and an office visit

appointment during Nvember1, 2018 through March 1, 2019. Exclusion criteria included patients younger than 25 years of age, and patients who are already on insulin therapy.

EBP Intervention

Selected participants received information on adherence to Mediterranean diet as the primary intervention. Mediterranean diet consists of eating fresh vegetables such as legumes, green beans, fruits rich in vitamin A and C consisting of carrots, cantaloupe, oranges, and strawberries that must be strictly seasonal and fresh (Bodenheimer, 2012; Burridge et al., 2017). The MD emphasizes eating a moderate amount of lean meat, and a moderate amount of red wine. In healthcare, MD has gained its importance due to prevention of many diseases and is the most acceptable diet among health care professionals (Hofmeister, 2015). The MD helps control the T2DM, blood pressure, helps with weight loss, and lowers the risk of cardiovascular disease (Bodenheimer, 2012; Burridge et al., 2017; Hofmeister, 2015). The participants had an option to keep a daily food journal for their daily intake along with their optional daily blood sugar log (see Appendix F for Project Timeline Flow Chart).

Recruitment

The recruitment was through convenience sampling, starting in October 2018 following IRB approval (See Appendix G, intervention flow chart). The clinic electronic medical record system (EMR) was utilized to identify potential subjects. The student investigator conducted a phone call to potential subjects for recruitment (See Appendix K: Recruitment material sheet). The student investigator was able to recruit 22 participants for the study by the end of November 2018.

Informed Consent

There was no signed consent necessary for this study; however, participants were informed, and a verbal agreement was obtained from the participants. The participants made an autonomous decision regarding agreement to participate in the study. Obtaining the verbal agreement before participation is professional and ethical.

Assessments and Intervention

Participants had an initial one on one meeting to discuss the expectations of the project, education on MD, specifics of the Mediterranean diet, goal-setting for specific lifestyle behaviors, and resources. Patients were given handouts on the Mediterranean diet and selected foods choices. Evidence based education approaches included motivational interviewing (see Appendix J: Handout on Mediterranean Diet). Participants had an option to keep a record of daily blood glucose reading and daily food intake.

The student investigator met participants every two weeks with a total of six meetings. Each weekly meeting lasted from three to four hours. Participants were required to attend each meeting either face to face, via video conference email, or text messaging; however, if participants could not attend the meeting due to emergency reasons, the student investigator provided the session over the phone. During each meeting, the student investigator reviewed the blood glucose logs and food journal. Motivation interviewing was provided during meetings to increase self-motivation and self-efficacy. The student investigator sent weekly emails and text messages to the participants during the project period from December 2018 through March 2019 for support in the adherence to MD.

The student investigator used an open-ended communication style with participants to discuss concerns regarding financial situations, emotional stress, or barriers or limitations to the interventions. The student investigator provided the glucometer machines to patients who lacked

a home monitor. The project site primary care clinic strictly follows the American Association of Diabetes (ADA) guidelines on HgbA1c and performs Hgb A1c every three months on the patients whose Hgb A1c is abnormal. After three months of the intervention, the student investigator was able to obtain the HgbA1c results on the eight participants who followed their MD diet through the three months (see Appendix G for the EBP intervention table).

Change Process, EBP Model

Behavior health theories have been used as change models in chronic health disease management and are widely used in health care (Appelbaum et al., 2012). The EBP project of T2DM management with MD will use Kotter and Cohen's Model of Change. Kotten and Cohen's model incorporates eight essential steps step process for better self-management and transformation: 1. Establishing a sense of 2. Powerful collation 3. Creating vision 4. communication 5. Empowering others to see the created vision 6. Planning short-term goals 7. build on the change, and 8. institutionalize the change (Kotter, 2012). A review of this model indicated support of this model but no evidence against the model (See Appendix E for logic model). The selected EBP model was developed by the Johns Hopkins Nursing Evidence-Based Practice Model (JHNPEBP). The JHNEBP model provides a structure that incorporates all aspects of EBP and an action plan that will be useful for developing the project (Appelbaum et al., 2012; Kotter, 2012).

Sustainability of this project relies on the support from the clinic facilitator, clinic staff, clear communication between the student investigator and facilitator, and the success of the project. The primary care clinic facilitators' interest on the Mediterranean diet with T2DM management will promote the project sustainability. Positive results of the study in decreasing the HgbA1c and better self-management of T2DM enhance sustainability for future patients.

Study Design

The study utilized a quasi-experimental design, one cohort. This study included pre and post evaluation of glycosylated hemoglobin HgbA1c and MD intake. Interventions of this study included the lifestyle modification intervention of Mediterranean diet along with motivational interviewing. The quality improvement project was based on implementation of the evidence from published studies and guidelines.

Validity

For promoting internal validity, it is important to consider the current evidence, the significance of the problem, the feasibility of the study, and the proposed setting (Leech, Barrett, & Morgan, 2014). The internal validity of the project was strengthened by using the evidence-based intervention of Mediterranean diet for T2DM management. The study did not control for confounding variables which can be a possible threat to internal validity. The external validity of the project was fostered by the diverse demographics at a primary care clinic of Missouri. The external validity was improved through the use of inclusion criteria during recruitment and the reliable evidence-based intervention to strengthen findings (Leech, Barrett, & Morgan, 2014).

Outcome Measures

Primary outcome measures included adherence to Mediterranean diet intake and a glycosylated hemoglobin HgbA1c. These measures were intended to align with the outcomes of improved diet, blood glucose, and glycosylated hemoglobin. The participants had an option to keep a daily food intake journal and blood glucose monitoring log. Patients were requested to bring their blood glucose log either to their every other week meetings or to send it through emails.

Measurement Instruments

There were five outcome measures utilized for this project (See Appendix H). Data was collected through the EMR, clinic visits, and journal logs from participants. Blood glucose monitoring, HgbA1c, readmissions, mortality rates, and costs are commonly published outcomes measures for studies on the lifestyle modification of Mediterranean diet with T2DM (See Appendix L: Data Collection Sheet; Bodenheimer, 2012; Burridge et al., 2017). Studies show that often participants fail to self-report dietary adherence or daily glucose monitoring results due to embarrassment (Leech, Barrett, & Morgan, 2014). Therefore, data obtained from the EMR will be considered a reliable and valid method of measurement (See Appendix L: Data Collection Sheet) (Bodenheimer, 2012; Burridge et al., 2017; Leech, Barrett, & Morgan, 2014). Participant lack of adherence to the implemented intervention protocol presented a limitation on the reliability and validity of the findings. Demographic data such as age, race, and gender were collected and were reported for the sample (see Appendix N).

Quality of Data

The anticipated sample size of the project was 25 participants. Calculation of the sample size using Gpower analysis indicated a sample size of 30 participants for a medium effect of 0.5, power of 0.8, and alpha of 0.5 with a paired t-test. There were potential threats to the quality of the project data including self-reporting data on the Mediterranean diet and self-reporting data on daily blood sugar monitoring.

The other potential threats could be low self-efficacy, low level of motivation, low education level, biases, or any other missing data. Inaccurate self-reporting data or low data on self-reporting can affect the validity and reliability of the findings. The student investigator planned to resolve some of these potential threats by providing motivational interviewing every other week, email reminders, and text messaging to increase their motivation level and to

improve self-efficacy and self-reporting. The results are compared to similar intervention studies (Bodenheimer, 2012; Burridge et al., 2017; Leech, Barrett, & Morgan, 2014).

Analysis Plan

The project sample size was insufficient to analyze by the planned paired t-test. The data was analyzed by descriptive statistics to show the demographics of the eight participants, daily intake of the MD, and HgbA1c (see Appendix L; Appendix M for adherence to Mediterranean diet; Appendix N; Appendix O).

Results

Setting and Participants

This quasi-experimental project was implemented at a primary care clinic in November of 2018. Recruitment for the project occurred in mid-October through the end of November 2018. Participants were screened by inclusion and exclusion criteria. There was a total of 22 participants in the project by the end of November. The three-month intervention period was from December 2018 through March 2019. By the end of three month of period, there were only eight participants. The other 14 participants who did not complete the project provided various reasons with noncompliance to diet such as the holiday season, relocating, losing insurance coverage, and unable to afford fresh vegetables and fruits.

Intervention Course

Participants had an initial one on one meetings during the recruiting process, participants gave verbal consent to participate in the study, and possible benefits and side effects of the study were discussed with the participant. Patients were provided handouts on the information of the Mediterranean diet and selected foods choices. Specifics on the Mediterranean diet were discussed along with a goal-setting for specific lifestyle behaviors, and resources.

After initial one on one meetings, participants had every other week meetings for a total of 6 meetings. Every other week face to face meetings were mandatory for participants; however, some changes were made due to participant scheduling and flexibility. Participants could attend every other week meetings either face to face, texting, emailing, or voice calling as feasible for their schedule. The student investigator emailed all the participants every week for continuous support and motivation. The student investigator met participants every two weeks for a total of six meetings, and the last meeting was on March 3, 2019. Each weekly meeting lasted from three to four hours. During every other week meetings, motivational interviewing skills were discussed with participants. Motivation interviewing skills were designed to increase self-motivation and self-efficacy.

Using personal funds, the student investigator provided the glucometer machines to the patients who lacked a home glucose monitor. After three months, the student investigator was able to obtain the HgbA1c results on the eight participants who followed their MD diet (see Appendix G for the EBP intervention table).

Outcome Data

There was a total of 22 participants. The majority of the participants were female (70%) and were morbidly obese, and 30% were male. The age of the participants ranged from 30 years to 67 years old. After the first month of completion of the Mediterranean diet, there were only 15 participants who followed with their every other week meeting, 60 % were female and 40 % male. The seven participants who did not follow their weekly meetings were withdrawn from the study after multiple attempts from the student investigator to call them. The main barriers reported by all the participants was the continuous struggle with diet choices and the holiday season. To encourage, motivate, and engage participants, the student investigator gave an

incentive to the participants who attended their every other week meeting. The incentive minimally improved the attendance to the meetings; however, attendance of participants decreased after the incentive was started but may have been related to other factors.

After the fourth motivational interviewing skills meeting at approximately two months of diet adherence, the participant attendance was decreasing during follow up calls. During the fifth meeting, there were only eight participants (see Appendix N for demographics). These eight participants were 75% female and 25% male contribution. The range of age for these participants was from 32 years to 65 years old. All of the eight participants had completed their daily blood glucose log and their daily food intake logs. The major perceived barrier from the participants was that they could not maintain self-control of their diet habits as indicated by 75% of all participants.

All eight participants post HgbA1c result had a reduction ranging from 0.5 to 1.0. The results of the pre and post survey on MD intake had an increase in the consumption of MD components (see Appendix N). There was a positive view in the relationship of adherence to MD and self-management as reported by participants in their exit interview. The secondary data also showed a reduction in BMI and reduction in blood pressure

Discussion

Successes

The most significant success was that the participants who adhered to the three months of diet adherence had a reduction in the post HgbA1c result. The other important success of the study was that participants who completed the study had overcome the barrier of poor eating habits during the three months of intervention. They were able to self-control their eating habits and master the Mediterranean diet intake, which overall improved their health. Although the data

was not collected as a primary outcome measure in the project, the blood pressure readings were better than pre-intervention, and there was a reduction in the body mass index. The participants reported their energy level as increased after being on the MD for three months.

Study Strengths

The study strengths include the continuous support from the office administration, office staff, preceptor, and continuous feedback from project site facilitator. The office staff was helpful in providing the student investigator with access to the electronic medical records (EMR) during the recruiting process so that student could gather pre-intervention data from participants and verify with the EMR (Chin et al., 2013).

Results Compared to Evidence in the Literature

Results of this project study were quite similar to the evidence in the literature. There is multiple evidence that supports adherence to MD in a correlation of reduction in a HgbA1c. The lifestyle modification of the Mediterranean diet is effective in lowering the HgbA1c, weight loss management and self-management of T2DM (Gosby et al., 2016; Gupta et al., 2014; Wing et al. 2008). Study results showed that MD diet compared with other controlled diets had a greater reduction in HGBA1c with a mean difference of 0.30 to 0.46, confidence interval of 95% and *(p*=0.004*)*. Body mass index decreased by 0.29kg/m2 and cholesterol and triglyceride levels decreased by 0.14mmol. MD also showed a positive correction in overall high energy level. (Buckland et al., 2008; Esposito et al., 2015).

Limitations

Internal Validity Effects

The potential elements that positively affected the internal validity include every other week follow up meetings according to the participant's schedule and flexibility via face to face,

texting, voice calls, or video calls. Weekly communication through emails for continuous social support and to address financial needs also strengthened the internal validity. During all follow-up voice calls, the student investigator used open-ended communication. During the project, only one student investigator was utilized and the same systemic approach was maintained during the pre and post data collection.

External Validity Effects

The participants of the study were diverse and represented various ethnic backgrounds, races, and ages which enhances external validity and generalization to other populations and sites. The external validity was improved through the use of inclusion criteria during recruitment and the reliable evidence-based intervention to strengthen findings (Leech, Barrett, & Morgan, 2014).

Sustainability of Effects

Sustainability of this project mainly relies on the support from the clinic facilitator, clinic staff, clear communication between the student investigator and facilitator, and the success of the project. The primary care clinic facilitator interest in the Mediterranean diet with T2DM management fosters the project sustainability. Positive results of the study with reduction in the post HgbA1c by an average of 0.5 to 1.0 within the 3 months of adherence to MD, increase in overall energy, reduction in BMI, lowered blood pressure readings reported by participants, self-efficacy, and better self-management of T2DM enhance sustainability for future patients.

Efforts to Minimize Limitations

Efforts to minimize the limitations were established by verbal consent to participants in the study and utilizing only one investigator to collect the data. Participants could withdraw from the project at any time. Every two weeks' follow-up using motivational interviewing and weekly

emails were performed by the one investigator to promote internal validity. Even though this method was labor intense, this process was utilized by the investigator to enhance the internal vitality.

Interpretation

Expected and Actual Outcomes

The anticipated results of the study were a reduction in HgbA1c and compliance with the Mediterranean diet. The study results were close to the expected results. The results of the study showed a reduction in a post HgbA1c by 0.5 to 1 compared to preHGbA1c results and an increase in the intake of Mediterranean diet compare to pre-survey on Mediterranean diet intake (See Appendix N). Results also indicated a reduction in BMI and reduction in BP, and participants reported an increase in an energy level and improvement in physical and mental health which were unexpected positives outcomes from the study. In the study, participants self-reported their adherence to MD on daily log journal which was a potential barrier to the study due to lack of honesty in self-reporting and self-reporting; however, the post HgbA1c results supported adherence to MD resulting in reduction in HgbA1c.

Intervention Effectiveness

Intervention effectiveness is difficult to ascertain as more than 63% of the participants were not able to complete the study. Only 36% of the participants completed the study. Of participants who were unable to complete, they reported nonadherence to MD due to inability to maintain self-control of eating habits and financially afford the components of MD diet. The student investigator provided follow up calls to participants every two weeks to promote self-motivation and provide skills on how to make healthy eating choices. The primary barrier to intervention effectiveness was the self-control of participants which comes within self,

Participants had to be mentally prepared to make a change in self-control. According to Al-Khawaldeh, self-control starts with oneself, and self has to be mentally prepared to make a change (Al-Khawaldeh et al, 2012).

Intervention Revision

Intervention revision that could improve the outcomes are an increased patient sample size, longer recruiting period, longer time of adherence to the Mediterranean diet, more incentives to participants, and greater resources for participants to receive fresh fruits and vegetables. An increase in sample size would strengthen the results of the study. A longer period of adherence to the Mediterranean diet will be helpful in the determination of complete reversal of T2DM and percentage of reduction of HgbA1c that could be achieved with a longer period of adherence. More incentives and resources to fresh fruits and vegetables could enhance motivation in participants to adhere to MD for a longer period which could result in an increased rate of completion with the study and favorable T2DM outcomes.

Expected and Actual Impact to Health

The expected impact of this study is that participants have better self-control in the management of T2DM with diet modifications which assist in lowering the progression of other co-morbid diseases and overall better quality of health. Participants in the project were able to achieve self-efficacy and self-motivation for better management of T2DM and a better quality of life.

System, Costs, and Policy

Mediterranean diet in the management of T2DM aids in control of the progression of the disease, prevents the related co-morbid disease, and helps lower health cost. The evidence in the literature revealed that adherence to the Mediterranean diet in T2DM is effective in lowering the

risk of heart attack by 30%, and stroke by 20%. A long period of adherence to Mediterranean diet reduces HgbA1c, BP, and BMI. Mediterranean diet could be a one and only diet for the management of multiple disease processes (Gosby et al., 2016; Gupta et al., 2014; Wing et al. 2008).

The cost of the project was estimated at $1900.00 for 25 participants in an outpatient setting. After implementing the project with 22 participants and with the rapid attrition by the end of the first month, the cost for the project was only $800.00 with eight participants who completed the study. The majority of the cost for the project involved providing glucometer machines to participants and monthly incentives to participants. Cost was covered from the student investigator's personal funding. The benefits of better management of T2DM, preventing related co-morbid disease, and better quality of life out-weighs the associated cost of implementing this project.

Conclusion

Adherence to Mediterranean diet lifestyle modifications was the single important tool by which adequate glycemic control was obtained in patients with T2DM and in patients who are on medication treatments but their HgbA1c who not controlled (Tapsell, 2014). In the synthesis of literature, current evidence indicates that the Mediterranean diet is the most effective diet in improving the glycated hemoglobin A1c, losing weight, reducing BMI, reducing the risk of cardiovascular diseases by 30%, and better management of blood pressure. The Mediterranean diet should be considered in the overall strategy for self-management of T2DM and related co-morbid diseases.

Practical Usefulness of Intervention

This intervention of adherence to MD in the management of T2DM in this project has practical usefulness that allowed patients to achieve greater self-efficacy and self-motivation in the management of disease progression with a low cost of implementation in a primary care setting. The American Diabetes Association guidelines and Standards of Medical Care in Diabetes reinforce lifestyle modifications as the first line treatment plan for T2DM management; however, there is a knowledge gap on which lifestyle modifications are the most effective. The lack of standard lifestyle modifications creates confusion among the patients. The Mediterranean diet consists of all the nutritional components of lifestyle modification for disease management.

Future Study

A future study or implementation of evidence could address the duration period of adherence to MD in reduction of HgbA1c to reverse T2DM completely. There is a lack of studies to confirm length of time that a person needs to be adherent to MD to completely resolve T2DM. Type II diabetes is a chronic disease, and uncontrolled T2DM significantly increases the risk for co-morbid diseases and negatively impacts the patient's quality of life. Better T2DM self-management will lead to improved patient quality of life and reduced health care costs related to T2DM and co-morbidities. Self-management of chronic conditions and disease management is a core concept of nurse practitioner practice.

Dissemination

Dissemination of this project included a poster presentation at the Advanced Practice Nurse of Ozarks (APNO) conferences in November 2018. The student investigator will disseminate the results of this study at the APNO conference of 2019 and submit for publication in the *Journal of Nurse Practitioners.* The long-term outcome goal of this project is to disseminate findings of this study via publication, presentations, and educational classes to

patients and family members on the adherence to MD for better T2DM self-management. Adherence to Mediterranean diet showed reduction in the HgbA1c and better control of T2DM self-management which will lead to improved patient quality of life and reduction in the health care cost. Better self-management of T2DM will decrease the related co-morbid disease progression and the financial burden to individuals and society.

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Appendix A: Cost Analysis

Raj winder Kaur, DNP Student Investigator			
Line Item	**Expected Cost**	**Actual Cost**	**Notes**
Salary – Rajwinder Kaur /Student investigator	$0.00	$0.00	Student investigator
Printing Material for MD	$0.00	$0.00	Will be using UMKC library student printing fund money to print the handout on MD
Salary - Staff training time	$210.00	$0.00	Student investigator implemented the project by herself, and all the follow up appointments.
Supplies	$1639.00	$650.00	Blood glucose machine provided to 10 participates with 3 months supplies of lancets and strips. Education, pamphlet, Motivation interviewing, printing materials, papers.
Presentation materials	$150.00	$150.00	Poster x2, proposal poster and poster with results of the study.
Total	$1900.00	$ 800.00	

Appendix B: Definition of Terms

Autonomy - a patient's right to be fully informed and educated about a health care decision, and to make that decision without coercion from others (Bandura, 2010).

Life style modifications: Lifestyle modification is a weight management approach that teaches the skills necessary for weight loss, healthy eating habits and skills to decrease overall stress level (Rejeski et al., 2012).

Motivation interviewing: Motivational interviewing (MI) is a patient-centered method for enhancing intrinsic motivation to change health behavior by exploring and resolving ambivalence (Wall, 2014).

Mediterranean diet: The Mediterranean diet emphasize son eating primarily plant-based foods, such as fruits and vegetables, whole grains, legumes and nuts and healthy fats such as olive oil and canola oil (Hofmeister, 2015).

Self-management: Self-management is a key skill that help set the goals, manage the goals, develop motivation and concertation to overcome the barriers to reach the goal (Bodenheimer, 2012; Burridge, 2017).

Self-efficacy: the confidence or belief in one's ability to perform a behavior or task and is considered the central feature of motivation to produce change in behavior and health outcomes (Bandura, 2010).

Appendix C Evidence Synthesis table

Lifestyle modification for type II diabetes management.						
Wing (2010). Long-term effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus: Four-year results of the look-ahead trial.	Lifestyle modification intervention on weight and Type 2 Diabetes Mellitus	**Design** A systemic review, meta-analysis **Level** I **Variables** includes Weight, blood glucose, BMI, hemoglobin A1c	*N* # *5* *1* *4* *5* RTC Primary care	Weight measures, hemoglobin A1c measures, coronary artery disease measures (CAD) in Diabetic type II patients.	Treadmill fitness (p=<0.001), Hemoglobin A1c (p=<0.001), Systolic blood pressure (p=<.001), diastolic BP(p=0.01), Lipoprotein cholesterol (p=<0.001) Chi-squared, Fisher	**Strengths:** Long term life style modifications help loose, weight, increase self-confidence and help lower the CAD and type 2 diabetes risk. **Limitation:** Results of the studies will not be useful for the other studies of CAD due to group risk factors will translate into differences in the development of CVD.
Gupta (2014). Clinical assessment of dietary interventions and lifestyle modifications.	To assess the clinical effects of	**Design** Quasi-experimental **Evidenced Level** Level III	*N* # *56* Traits Age, sex,	Blood pressure, body weight, BMI, central obesity, plasma	Improvement was observed in clinical signs and symptoms along with plasma glucose and	**Strengths:** Almost 70% patients had normal systolic blood pressure after the intervention. **Limitations:**

Madhumeha (type- 2 Diabetes Mellitus).	dietary interventions and life style modifications in *Madhumeha (type 2 diabetes)* patients.	**Variables** blood sugar, HbA1c, type 2 diabetes, age, genetic, dietary interventions, life style modifications.	Primary care	glucose (FPG); 2-h plasma glucose (2-hPG) and glycosylated hemoglobin (HbA1c).	glycosylated hemoglobin (HbA1c) in *type 2 diabetes* patients after these interventions of life style modifications ($P < 0.001$).	Author used so many differentiate life style modifications.
Senior (2016). Meta-analysis of variance: an illustration comparing the effects of two dietary interventions on variability in weight.	Comparing the effects of the dietary interventions on the variability in weight.	**Design** A systemic review, meta-analysis **Evidence Level** Level I **Variables** Diet, low carbohydrate, nutrition, obesity, standard deviation, dietary interventions, life style modifications.	*N= 250, 7* groups. Primary care	Mean weight, BMI, central obesity, prediabetes, wait measurements.	low carbohydrate diets are effective in a large proportion of the population, and low carbohydrates diets reduce mean mass more effectively.	**Strengths:** MD consist of high protein diet and high protein diet predict success on weight loss regimes. **Limitations:** self-motivation, loss of appetite Self-reporting Self-efficacy
Mediterranean diet and type II diabetes						

management						
Olubukola (2013). Systematic review and meta-analysis of different dietary approaches to the management of type 2 diabetes.	Dietary changes, can prevent the progression of impaired glucose tolerance to diabetes.	**Design** Meta-analysis RTC with 9 studies **Evidenced Level** Level I **Variables** Type 2 diabetes, lipid profile, hgb A1c, weight loss.	*N # 3460* randomly assigned participants. *N # 3073* individual include in final analysis. Primary care setting	Glycated hemoglobin, Mediterranean diets, weight loss, HDL levels.	Glycated hemoglobin reductions of -0.12% (*P*=0.04), Mediterranean diets led to greater weight loss [-0.69kg (p=0.21) and -1.84kg (p<0.0001) and increase in HDL levels.	**Strengths:** Mediterranean, and high-protein diets reduced HgbA1c by 0.5 to 0.7 % compared with comparison or control diets. **Limitations:** None
Buckland (2015). Obesity and the Mediterranean diet: a systematic review of observational and intervention studies.	The purpose of this study is to review and analyze the effects of Mediterranean diet	**Design,** Cross sectional study **Evidence Level** IV 21 cohort studies in 8 groups. **Traits** # BMI, weight measures, wait circumferences	Sample: *N=320*, Female=*130*, Male sample= *100*	Mediterranean diet, body weight, total body weight loss,	Individuals with a high MD adherence were 27% (in women) and 29% (in men) less likely to become obese with (*p=<0.05*) in women and (*p=<0.04)* in males.	**Strengths:** MD showed weight loss in males and females along with decrease in cholesterol. **Limitations:** There is no consisting in the components of MD**.**

	(MD) on obesity.					
Esposito (2015). A journey into a Mediterranean diet and type 2 diabetes: a systematic review with meta-analyses.	Efficacy of a Mediterranean diet (MD) on the management of type 2 diabetes and prediabetes states.	**Design** Meta-analyses and randomized controlled trials **Evidenced Level** Level I **Variables** Mediterranean diet, type 2 diabetes, prediabetes, Hob A1c, blood glucose checks.	*N=395* RTC with history of type 2 diabetes and Pre-diabetes.	Mediterranean diet, HbA1c, total cholesterol, body weight	Mediterranean diet, as compared with those following a control diet, had a 49% of remission in prediabetes and better control on type 2 diabetes (95% CI 14% to 96%)	**Strengths:** Help in overall physical, and emotional health. High level of evidence study. **Limitations:** Consistency across the world on the definition of the Mediterranean diet varies.
Huo (2015). Effects of Mediterranean-style diet on glycemic control, weight loss, and cardiovascular risk factors among type 2 diabetes individuals: A Meta-analysis. .	Type 2 diabetes management, weight loss and cardiovascular risk management with Mediterr	**Design** Meta-analysis with RTC with 9 studies **Evidenced Level** Level I **Variables** Type 2 diabetes, blood sugars, daily walking,	*N # 1178* patients Trait: RTC	Glycemic control, BMI, body weight and waist circumference, Cardiovascular risk factors such as lipid profile and blood pressure.	Compared with control diets, Mediterranean diet. (MD) led to greater reductions in hemoglobin A1c with CI of 95%, fasting plasma glucose, with $P <$ of 0.24 to − 0.21with $P <$ 0.55 to − 0.04.	**Strengths:** Large data, more reliablitty. **Limitations:** Controlled trail

	anean diet (MD).	BMI, body weight and waist circumference				
Schwinshackl (2015). Adherence to a Mediterranean diet and risk of diabetes; A systematic review and meta-analysis.	Purpose of the study to find out if the adherence to Mediterranean diet reduce the risk of diabetes or reduce hob A1c	**Design** A systemic review, meta-analysis **Evidenced Level** Level I **Variables** Age, sex, Type 2 diabetes, hgbA1c, risk blood sugars.	*N=550* Total participants. There were *10* groups in totally study and *25-60* participants in each group with type 2 diabetes. Primary care setting	Mediterranean diet, randomized controlled trial, fasting plasma glucose.	Highest adherence to Mediterranean diet, has a CI of 95% compare to lower adherence to Mediterranean diet	**Strengths:** Better management of hgbA1c, and stress level. **Limitations:** No optimal strategies for the intervention on educating.
Mediterranean Diet						
Sofi (2013). Mediterranean diet and health.	Components of Mediterr	**Design Level:** Cohort studies	2 cohort studies *#N=136*	Mediterranean diet, Weight loss	Mediterranean diet with higher adherence had a	**Strengths:** Long term adherence can show decrease in the obesity, coronary

	anean diet and how it helps improve the overall health of CAD, DM, Obesity or decrease the incidence of Parkinson disease.	**Evidenced Level** IV Variables Fresh fruits, vegetables, olive oil, low fat foods, Obesity , DM,	*09* in first study and # *22000* people in the second study.	management, coronary artery disease management, smoking cessation, physical exercise.	59% reduction in the risk of CAD with CI of 95%, 16% reduction in the risk of dying from neoplastic cause, 25% reduction in the risk of Parkinson's disease and reduce risk of DM by of 35% with CI of 95%.	artery disease, DM and Parkinson disease. **Limitations:** None
Tapsell (2014). Foods and food components in the Mediterranean diet: supporting overall effects.	Food Components of Mediterranean diet supporting the overall effects.	Non-experimental, level VII (expert opinion). Variables, Mediterranean diet,	N/A	N/A	Dietary contributions to benefits were moderate alcohol consumption (23.5%), little meat (16.6%), high consumption of vegetables (16.2%), fruits and nuts (11.2%), and legumes (9.7%), and a high dietary monounsaturated	**Strengths:** Better education regarding food involved in Mediterranean diet **Limitation:** Evidence level 7

					fatty acid: saturated fatty acid as olive oil). Olive oil is a characteristic food of the Mediterranean diet.	
Hofmeister (2015). Correspondence: Mediterranean Diet.	The identify the meaning of Mediterranean diet.	Non-experimental, level VII (expert opinion).	N/A	N/A	Mediterranean diet includes fresh vegetables, fruits, legumes, mainly complex carbohydrates with low glycemic index, fish, olive oil, dairy products, etc. and little processed food, "red meat", sweets and sugary.	**Strengths:** Detailed information on Mediterranean diet and serving portion**.** **Limitation:** Evidence level 7
Adherence to Mediterranean diet						
Muñoz (2009). Adherence to the Mediterranean diet is associated with better mental and physical health.	The purpose of the study was to analyze the associati on	**Design:** RTC **Evidence:** II **Variables:** Age, BMI, Smoking, Education level, and	# N= 3910 men and # 4285 women	Quality assessment, Dietary assessment, Smoking cessation assessment.	Age adjusted linear regression analysis revealed a significant ($P < 0{\cdot}01$) direct association of the MDS with self-reported mental and	**Strengths:** Showed direct relationship between mental and physical health function directly associated with adherence to the Mediterranean diet.

	between adherence to the Mediterranean diet and self-perceived mental and physical health function.	chronic condition.			physical health in both sexes.	
Díez-espino (2011). Adherence to the Mediterranean diet in patients with type 2 diabetes mellitus and HbA1c level.	Analyzing the association between adherence of a Mediterranean diet (MD) in patients with type 2 diabetes mellitus and HbA1c	**Design:** Cross Sectional study **Evidence:** Level IV **Variables:**	Individuals participates in PREDIMED N # 383 with type 2 diabetes and N # 262 participants had data	Hgb A1c, Fasting glucose, Total Cholesterol, HDL cholesterol, LDL cholesterol, BMI, Waist circumference, Carbohydrase intake, Protein intake,	Study showed the great association between adherence to the MD and levels of HbA1c. However, the inverse association was not statistically significant at the $p < 0.05$ level. .	**Strengths:** Inverse association between adherence to the MD and levels of decrease in HgbA1c **Limitation** No convincing method for sampling.

	level.		availabl e on hgbA1c			
Downer (2016). Predictors of short- and long-term adherence with a Mediterranean-type diet intervention: the PREDIMED randomized trial.	To identify participa nt characte ristics at baseline and study features that predict short-term and long-term adherenc e with interven tions promoti ng the Mediterr anean-type diet	**Design:** A systemic review, meta-analysis **Evidence Level:** I **Variables:** Age, Sex, Mediterranea n diet.	*# N= 2543* RTC	Cardiovascula r risk factors, larger waist circumference , lower physical activity levels, lower total energy intake.	Independently predicted poorer adherence. Participants from PREDIMED recruiting centers with a higher total workload (measured as total number of persons-years of follow-up) achieved better adherence. No adverse events or side effects were reported.	**Strengths:** Large sample size, low attrition rate and better glycemic control. **Limitation:** Controlled trail Mixed results

Motivational interviewing						
Heinrich (2010). Effects evaluation of Motivation Interviewing based counselling strategy in diabetes care.	The purpose of the study was to evaluate impact of the motivation intervening in type 2 diabetes patients.	**Design** A systemic review, meta-analysis **Evidence** Level I	*# N=584* totally participants and only *524* filled the questionnaire	Blood glucose monitoring, Exercise, Self-management behavior. 51/2 educational hours. One on one visits for 3 and half hours every 2 weeks.	Study showed mixed results. according to study only 250 participants had better control on their diabetes and self-management behavior.	**Strengths:** Large sample size, randomized traits clinics, and primary care setting. **Limitation:** Mixed results found. More studies needed.
Pérula (2011). Effectiveness of Motivational Interviewing in improving lipid level in patients with dyslipidemia assisted by general practitioners: Dyslipidemia -EM study protocol.	The purpose of this study is to evaluate the effectiveness of motivational interviewing in improving lipid levels in	**Design** A systemic review, meta-analysis **Evidence** Level I	*N= 436* Total participants. *40 to 50* participants in each group, total of *8* to *10* groups. Primary care setting	Motivation Interviewing at 2 months, 4 moths, 6momths, 8months, 10 months and 12 months.	Study results showed that only 200 participants followed all 12 months MI. It showed that low education level participants had hard time following the program. Results showed some decrease in the lipid levels.	**Strengths:** Large sample, Educational, motivational interviewing can be helpful.

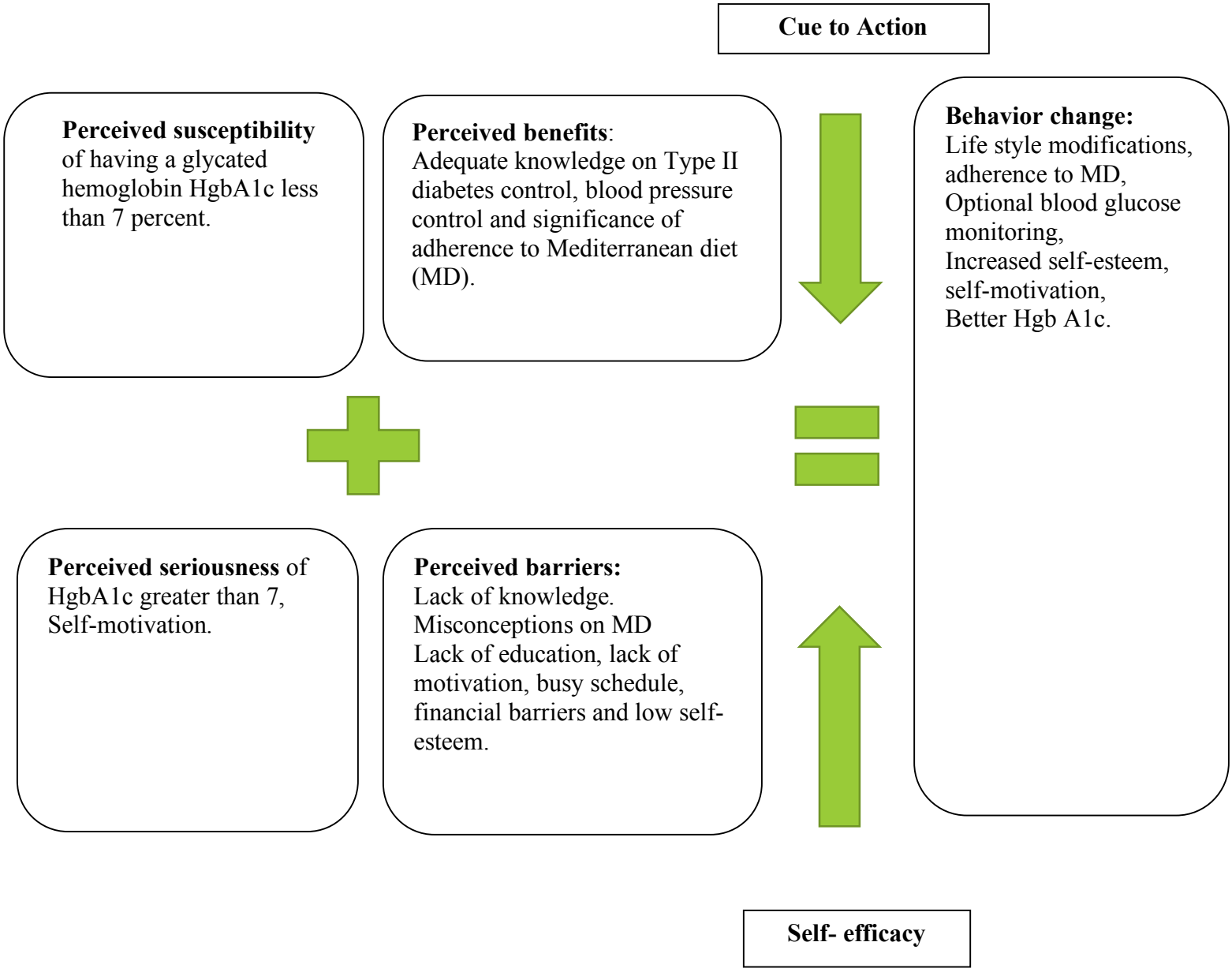
	patients with type 2 diabetes.					
Lakerveld (2013). Motivational interviewing and problem solving treatment to reduce type 2 diabetes and cardiovascular disease risk in real life: a randomized controlled trial.	The aim of the study is to assesses the effectiveness of the motivational interviewing in primary care to better manage type 2 diabetes.	**Design** A systemic review, meta-analysis **Evidence** Level I	*N= 622* total participants. *532* completed 6 months follow up. Primary care setting	Better management of type 2 diabetes, dietary behavior, smoking cessation, physical activity during 6 face to face 30 minutes counseling sessions followed by 3 months of telephone sessions.	Result showed an increase in fruit intake of 0.2 pieces of fruit per day and daily physical activity.	**Strengths:** Large sample size, high level evidence level. **Limitation:** Mixed results.
Diane Orr Chlebowy (2014). Motivational Interviewing to Improve Diabetes Outcomes in African Americans Adults with Diabetes.	The aim of the study is to determine the effects of motivational	**Design** A systemic review, meta-analysis **Evidence** Level I	*N =62* including *40* males and *22* females	Six motivation interviews over 3 months of period. Data based on self-reports, glucose monitoring, and	Results showed that out of 62 participants only 30 participants finished 3 months follow up. Results showed there were no significant difference in education,	**Strengths:** Motivation interweing improve overall health of diabetic patients. **Limitation:** MI did not increase the likelihood of adherence to glucose monitoring.

	intervening on regimen adherence and diabetes among African Americans.			accelerometer prints outs.	insurance coverage, or income between two groups.	
Self-Monitoring						
Bodenheimer (2012) Patient Self-management of chronic disease in primary care.	The aim of the study is to evaluate the self-management of chronic disease in primary care.	**Design** RTC **Evidence** Level II	N/ A	Self-management of chronic disease	Six of the 8 studies showed reduced costs including a self-management action plan.	**Strengths:** Increase in Self-monitoring is the long term management in the chronic disease**.** **Limitation:** Not enough trained personnel to makes a self-management courses available.
Burridge (2017). A qualitative follow-up study of diabetes patients' appraisal of an integrated diabetes service in primary care.	The purpose of this study is to explore the views of a new	**Design** RTC **Evidence** Level II	*N= 30* Randomized selection of the sample	Age, gender, years with diabetes and baseline HbA1c, Interviewing	Study results showed that managing significant lifestyle change such as food volume, exercise and nutrition, as well as multiple clinicians and	**Strengths:** High level of evidence and randomized controlled tracts**.** **Limitations:**

	model integrated care for type 2 diabetes patients.		Primary care setting		appointments, together with complex medical regimens are major imposts on patient and family time and flexibility, which can be easily managed through integrated care.	

Appendix D: Theory Application Diagram

The Health Belief Model



Appendix E: Logic Model

Logic Model for DNP Project					
Student: Rajwinder Kaur					
PICOTS: In adults 25 years and older diagnosed with Type II diabetes with a glycated hemoglobin (HGB) A1c greater than 7, do lifestyle modifications including Mediterranean diet adherence reduce Hgb A1c, within three months from December1st to March 1st at a primary care					
Inputs	**Intervention(s) Outputs** *Activities*	*Participation*	Outcomes -- Impact Short	Medium	Long
Evidence, sub-topics 1. Lifestyle modifications for type II diabetes management. 2. Mediterranean diet and type II diabetes management 3. Mediterranean diet 4. Adherence to Mediterranean diet 5. Motivational Interviewing 6. Self-Monitoring **Major Facilitators or Contributors** 1. Office staff-front desk	**EBP intervention which is supported by the evidence in the Input column (brief phrase)** One on one counseling regarding education on Mediterranean diet. Every 2-week group meeting for 45 minutes, motivation interviewing, reviewing, optional blood sugar logs and food log for 4 months. Brochure on Mediterranean diet. **Major steps of the intervention (brief phrases)**	**The Participants (Subjects)** Patients 25 years and older diagnosed with Type II diabetes **Site** Unknown at this time **Time Frame 10/2018-3/2019** **Consent or assent Needed** Yes **Other person(s) collecting data** Yes **Others directly involved in**	**(Completed during DNP Project)** **Outcome(s) to be measured** Glycated hemoglobin A1c, pre and post survey on Mediterranean diet **Measurement tool(s)** 1.Hgb A1c readings. 2. Pre and post survey on Mediterranean diet **Statistical analysis to be used** 1. Descriptive data and table	**(after student DNP)** **Outcomes to be measured** To better self-management of blood sugars, and to keep the sustainability of the project. The clinician education on promoting Mediterranean diet for better management of Type II diabetes.	**(after student DNP)** **Outcomes that are potentials**

2. Office manager 3. the 3 providers in clinic 4. statistician 5. grant funding **Major Barriers or Challenges** 1.Patient adherence 2.Provider adherence 3. Lack of motivation 4. Financial barriers 5. Low education level.	1. Pre assessment of HGB A1c 2. Clinician and staff briefing 3.One on one initial meeting. 4. Every 2 week meetings. 5. Mediterranean diet 6. Optional self-blood glucose monitoring, and food log 7. Weekly emails or texting. 8. After 4 months, rechecking HGB A1c, and post survey on MD intake	**consent or data collection** yes			

Appendix F: Project Timeline Flow Graphic

Type II diabetes Management with Mediterranean diet

Appendix G: Intervention Participant Flow Diagram

Step 1: October-November 2018: Identify potential subjects who have glycated hemoglobin A1c greater than 7 %, who meets the inclusion and exclusion criteria. A total participant who participated in the quality improvement project with a verbal informed consent, N= 22

Step 2: December 2018: Initial Visit. Discuss regarding the specifics of Mediterranean diet, handout on Mediterranean diet given to the participants. Pre hgbA1c date collected and pre survey on Mediterranean diet intake. The participants encouraged but not mandatory to keep a log of daily blood glucose reading, and daily food intake.

Step 3: December 2018 to March 2019: Motivational intervening every 2 weeks via face to face, text messaging, emails, or voice phone calls. Weekly emails remaindering for continues social support and to keep motivation and compliance to Mediterranean diet.

Step 4: April 2019: Total of 6 motivational interviewing, and 3 months of compliance to Mediterranean diet completed. Post data collection on post hgbA1c and post survey on Mediterranean diet intake collected.

Appendix H: Measurement Tools

Outcome	Instrument or Source	Validity	Reliability	Permission for Use
#1. Adherence to Mediterranean diet	Diary log	N/A	N/A	Developed by the student investigator will analysis the frequency to consider the adherence to Mediterranean diet
# 2. HgBA1c	Lab Draw	Valid in the Medical Community	Valid in the Medical Community	No

Appendix I: Hierarchy Table

Rating System for the Hierarchy of Evidence For an Interventional Inquiry (Modification by Dr. Lindholm for course N5613)	
Level I	Evidence from a systematic review or meta-analysis of all relevant RCTs. *Evidence-based clinical practice guidelines based on systematic reviews of RCTs).**
Level II	Evidence obtained from well-designed RCT. *Quantitative systematic review of well-designed controlled trial without randomization.*
Level III	Evidence obtained from well-designed controlled trial without randomization *(quasi-experimental).* *Quantitative systematic review of case-control, cohort, or correlational studies.*
Level IV	Evidence from well-designed case-control or cohort study *(or cross-sectional study)*
Level V	Evidence from systematic review of *quantitative* descriptive *(no relationships to examine)* or qualitative studies.
Level VI	Evidence from a single *quantitative* descriptive *(no relationships to examine in the study) or* qualitative study
Level VII	Evidence from the opinion of authorities and/or reports of expert committees

Melnyk, B.M. & Fineout-Overholt., E. (2015). *Evidence-based practice in nursing and healthcare.* Philadelphia Lippincott Williams & Wilkins.

**Italics, appropriate in this category, modification by LL 2017 based on opinions from experts to place SR at one level higher than single study design level.*

Appendix J: Handout on Mediterranean Diet

The Mediterranean diet consists of eating fresh vegetables, fruits, lean meat, sea food, poultry such as legumes, green beans, spinach, avocadoes, red potatoes, celery, eggplant, onions, tomatoes, carrots, asparagus, olives, fruits rich in vitamin A and C, cantaloupe, orange, strawberries, pears, that must be strictly fresh, lean meat of chicken, turkey, fish, seafood, poultry, eggs, cheese, yogurt, feta cheese, gouda cheese, olives oil, coconut oil, moderate amounts of red wine consist of one glass of red wine with dinner, using whole grains or complex grains, drinking plenty of water. Mediterranean diet improves the overall health of coronary artery disease (CAD), diabetes mellitus (DM), and obesity and decreases the incidence of Parkinson disease (Sofi, Macchi, Abbate, Gensini, and Casini, 2013).

1. Serving portion should include: at least 6 to 7 serving of fresh fruits and vegetables each day, each meal should include 2 servings of vegetables and a 1 cup serving a fresh fruit. Green leafy vegetables and fruits rich in vitamin C are preferred sources of vegetables and fruits.
2. Eating 1 serving of beans a day, or ½ cup of cooked beans.
3. Consuming a 1 to 2 serving of fish per week and one serving of poultry per week, avoiding the red meat use to once or twice a month.
4. Using an olive oil, or coconut oil for the cooking, avoid sunflower oil, peanut oil, or any soybean oils and cooking with garlic and herbs such as oregano, rosemary thyme, and basil, to season the food, limit to ½ to 1 teaspoon for each serving of meal and 1 to 2 cloves of garlic a day.
5. Eating a 4 to 5 serving of whole grains per day. Consume whole grain pasta, brown rice, avoid using the white flour bread.
6. Eating a handful of nuts every day, and using low fat milk products, feta cheese or gouda cheese is preferred, consume only 20 unsalted nuts.
7. Avoid the use of hard alcohol, may consume a 1 glass of red wine with dinner for women and 2 glass of red wine with dinner for men.

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Appendix K: Recruitment material, IRB Approval

The recruitment for this project will be through convenience sampling, there will be Inclusion and exclusion criteria to be followed closely during selection of 30 participants. Inclusion criteria will include patients aged 25 and older, HgbA1c greater than 7 percent, diagnosis of type II diabetes, blood pressure measurement of greater than 130mmHg systolic and greater than 80mmHg diastolic, BMI greater than 27, and an office visit appointment during October 1, 2018, through February 1, 2019. Exclusion criteria will include patients younger than 25 years of age, BMI of less than 27, and patients who are already on insulin therapy.

UMKC
Office of Research Services

UMKC
5319 Rockhill Road
Kansas City, MO 64110
TEL: (816) 235-5927
FAX: (816) 235-5602

NOT HUMAN SUBJECTS RESEARCH DETERMINATION

Principal Investigator: Dr. Lyla Lindholm
UMKC Health Sciences Building
Kansas City, MO 64108

Protocol Number: 18-211
Protocol Title: Mediterranean Diet in Self-Management of Type II Diabetes
Type of Review: Not Human Subjects Determination

Date of Determination: 09/20/2018

Dear Dr. Lindholm,

The above referenced study, and your participation as a principal investigator, was reviewed and determined to be Not Human Subjects Research (NHSR). As such, your activity falls outside the parameters of IRB review. You may conduct your study, without additional obligation to the IRB, as described in your application.

The NHSR Determination is based upon the following Federally provided definitions:

"Research" is defined by these regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

The regulations define a **"Human Subject"** as "a living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information."

All Human Subjects Research must be submitted to the IRB. If your study changes in such a way that it becomes Human Subjects Research, please contact the Research Compliance office immediately for the appropriate course of action.

Please contact the Research Compliance Office (email: umkcirb@umkc.edu; phone: (816)235-5927) if you have questions or require further information.

Thank you,

Cynthia Thompson
UMKC IRB Administrative Office

Appendix L: Data Collection Sheet

1. Data will be collected during the initial meeting with the participants.
2. Some of the data will be collected through using the EMAR of Truman Pavilion primary care center.
3. Data will be collected through every other week meeting with the participants.
4. Self-reporting via participants.
5. Data collection from daily food journal, blood pressure logs and blood sugar logs.

# of pt.	Age	DX of T2DM	HgbA1c >7	BP of >130/80	Attending every other week classes
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					

20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					

Appendix M: Pre and Post Questionnaire for adherence to Mediterranean diet

Question 1: How many days of the week do you have at least of 3 to 4 servings of fresh vegetables?

Answer: One Two Three Four Five - Seven

Question 2: How many days of the week do you have at least of 2 servings of fresh fruits?

Answer: One Two Three Four Five-Seven

Question 3: How many meals during a day do you have at least a serving of a protein?

Answer: One Two Three Four or More

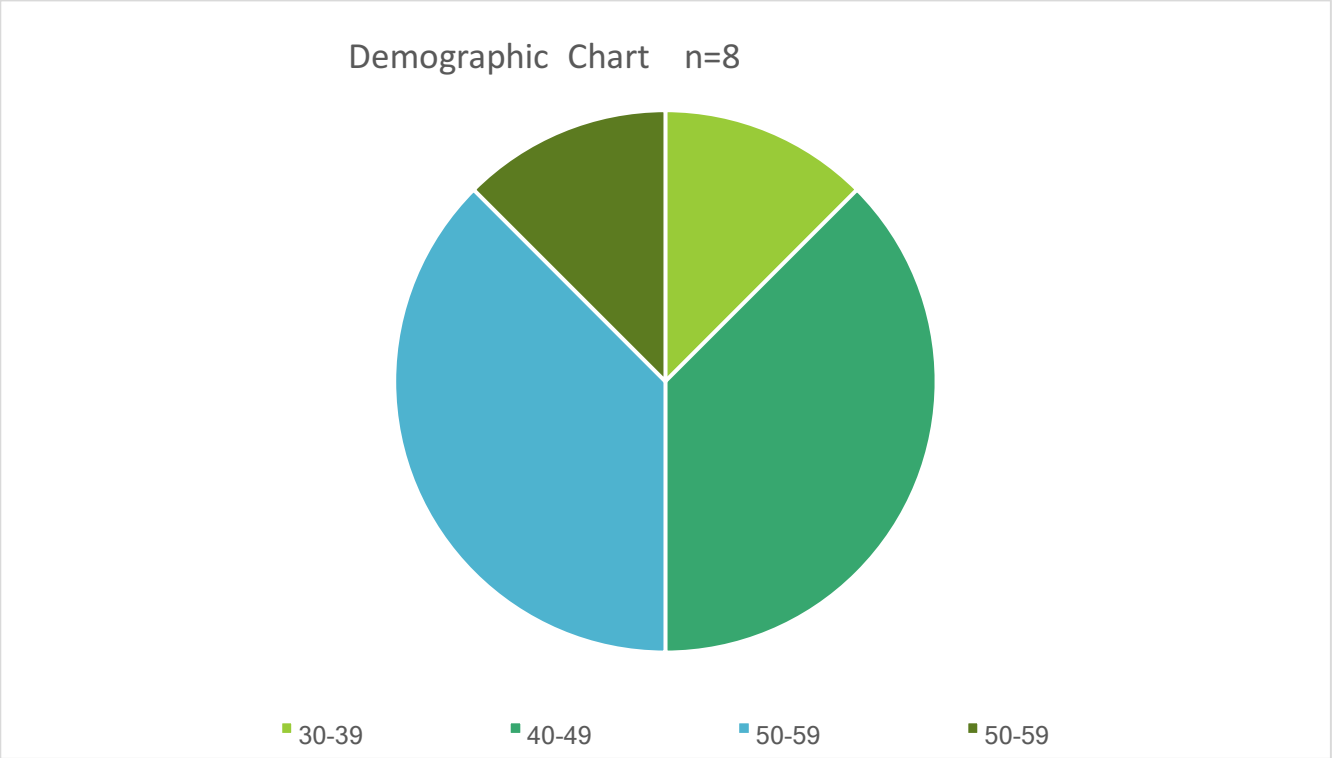
Question 4: How many days of the week do you use olive oil for cooking, or on salad dressing?

Answer: One Two Three Four or More

Appendix N: Descriptive data
Demographic Data

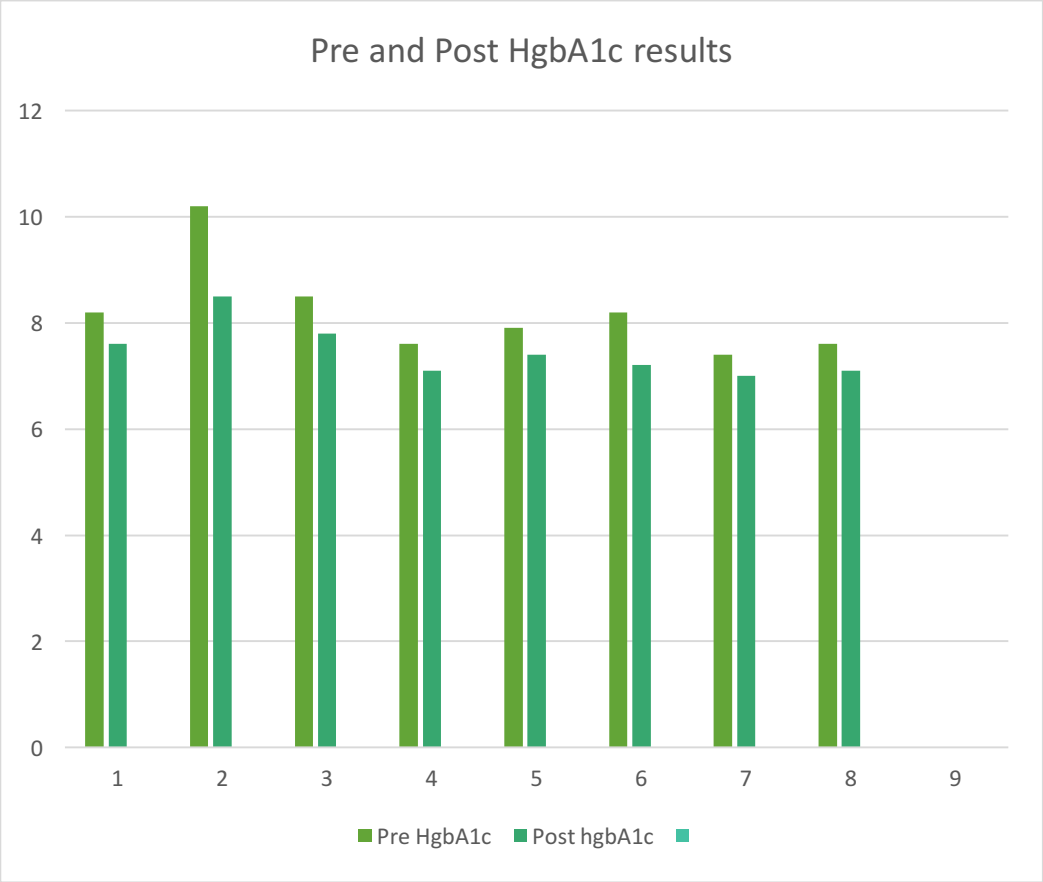
N=22
n=8

Age	Gender	Race
30- 39	F, F, F	Black, Asian, White
40-49	M	Hispanic
50-59	F,F,M	Asian, Asian, Hispanic
60-69	M	White



Pre and Post HgbA1c Results

Participants	Pre-Hgb A1c	Post-Hgb A1c	Decrease
1	8.2	7.6	0.6
2	10.2	8.5	1.7
3	8.5	7.8	0.7
4	7.6	7.1	0.5
5	7.9	7.4	0.5
6	8.2	7.2	1.0
7	7.4	7.0	0.4
8	7.6	7.1	0.5



Adherence to Mediterranean Diet

Pre Q1	Post Q1	Change	Pre Q2	Post Q2	Change	Pre Q3	Post Q3	Change	Pre Q4	Post Q4	Change
3	5	+2	2	4	+2	2	4	+2	1	3	+2
2	4	+2	2	4	+2	1	3	+2	1	3	+2
3	4	+1	2	3	+1	2	5	+2	1	2	+1
2	4	+2	2	3	+1	1	5	+4	2	4	+2
3	5	+2	3	3	0	2	4	+2	2	4	+2
3	3	0	2	3	+1	2	3	+1	2	4	+2
2	5	+3	3	4	+1	2	5	+3	1	4	+3
3	4	+1	2	4	+2	2	4	+2	1	2	+1