Implementation of a Mediterranean Diet in Type II Diabetic Patients

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Abstract

Type II Diabetes Mellitus has detrimental effects on the human body. A1C levels reflect the attachment of glucose to hemoglobin-the protein in red blood cells that carries oxygen. Elevated A1C levels are an indicator of how controlled diabetes is. Uncontrolled diabetes not only affects glucose levels, but has detrimental repercussions in other organs of the body, causing peripheral vascular disease, risk of developing dementia, periodontal or gum disease, skin infections, neuropathy in lower and upper extremities, renal damage, erectile dysfunction, decreased blood flow, and cardiac conditions among others.

A diet low in calories positively affects glucose levels in the body. Type II Diabetes can be easily controlled when lifestyle modifications are included in the plan of care. Among those modifications, diet is an effective intervention for the management of this condition. Establishing a diet among the patients that have an elevated A1C is the plan of care and ultimate goal for this project. The Mediterranean diet has demonstrated decreased blood glucose levels, improved weight control and enhanced quality of life.

Keywords: A1C, Type II diabetes, diet low in calories, glucose, Mediterranean diet.

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Problem Statement

Type II Diabetes, one of the most debilitating and chronic diseases, has become for a large amount of the population, an unmanageable disease affecting both adults and children. Current projections indicate that the number of individuals with diabetes will more than double from 2005 to 2050 (Miller et al., 2012). Compelling evidence from epidemiologic studies indicates that the current worldwide diabetes epidemic is due in large part to changes in diet and lifestyle. Excess adiposity is the most important risk factor for diabetes (Schulze & Hu, 2005). Maintaining a healthy body weight and avoiding weight gain during adulthood is the cornerstone of diabetes prevention (Schulze & Hu, 2005).

A more effective way to explain the problem is to define how diabetes affects the adult population and the impact toward society in general. The American Diabetes Association (ADA) has been actively involved in the development and dissemination of diabetes care standards, guidelines, and related documents for over 25 years. The ADA's clinical practice recommendations are viewed as important resources for health care professionals caring for people with diabetes (ADA, 2018). One quarter to one-half of insured patients have an A1C > 6.0% and many patients are not assessed by primary care providers according to ADA guidelines. There are also delays in intensifying treatment, and suboptimal glycemic control. This lack of control can lead to clinical complications, such as a 40% increase in the risk of microvascular events for each 1% increase in A1C above goal, and a 38% increase in the risk of macro vascular events for 1% in A1C above goal (Rowley & Bezold, 2012). There are also increased economic burdens to the health care system in general.

The prevalence of Type II diabetes for all age-groups worldwide was estimated to be 2.8% in 2000 and 4.4% in 2030. The total number of people with Type II diabetes is projected to rise from 171 million in 2000 to 366 million in 2030. The prevalence of diabetes is higher in men than women, but there are more women with diabetes than men (Wild et al., 2004).

In the U.S. the annual projection for adults diagnosed with diabetes incidence will increase from about eight cases per 1,000 in 2008 to about 15 in 2050. Assuming low incidence and relatively high diabetes mortality, total diabetes prevalence (diagnosed and undiagnosed cases) is projected to increase from 14% in 2010 to 21 % of the U.S. adult population by 2050 (Boyle et al., 2010). An estimated 30.3 million people in the U.S. or 9.4th percentile of the population has diabetes, with about one in four people unaware they have the disease. An estimated 84.1 million Americans aged 18 years or older have pre-diabetes (NIH, 2017) and it may affect between 21% and 33% of the total Unites States population by 2050. The prevalence of diabetes in the U.S. is substantial, managing the condition in an effective matter is mandatory (Rowley & Bezold, 2012).

In Arizona approximately 682,071 people or 12.5% of the adult population have Type II diabetes. Of these, an estimated 172,000 have diabetes but are unaware, increasing their related health risks. In addition, 1,796,000 people in Arizona or 37.5% of the adult population have pre-diabetes with blood glucose levels higher than normal but not yet high enough to be diagnosed as diabetic. Every year an estimated 34,000 people in Arizona are diagnosed with diabetes. Diabetes and pre-diabetes cost an estimated $6.4 billion in Arizona annually (ADA, 2014).

Purpose and Rationale

In every primary care setting there is a large percentage of patients that have been diagnosed with Type II diabetes (Renders et al., 2001). As previously mentioned, this problem

has been rising. Diet modification as an intervention that helps decrease hemoglobin A1C levels should be encouraged to any patient that has poor glycemic control. Diabetes self-management education (DSME) is an essential component of care for all people with the condition and is necessary to improve patient outcomes and dietary quality (Miller et al., 2012). Prospective cohort studies and randomized controlled trials have demonstrated that Type II diabetes can be prevented largely through moderate diet and lifestyle modifications (Schulze & Hu, 2005). Implementing a diet plan with an emphasis on low calorie foods in a primary care setting could benefit those patients that have an elevated hemoglobin A1C > 6 %.

Background and Significance

Type II Diabetic Patients

Patients with Type II diabetes mellitus are required to perform multiple self-care behaviors to achieve and maintain optimal glycemic control (HbA1C), reducing the risks from complications and premature mortality (Toobert, Hampson & Glasgow, 2000). Patients with diabetes and low socioeconomic status are more likely to have suboptimal A1C, often due to non-compliance to recommended self-care activities than their higher socio-economic counterparts (Brown et al., 2004). The most important self-care behavior for glycemic control is medication adherence (Osborn, Mayberry & Kim, 2016), but lack of resources and poor compliance on medication regimen places this population at higher risk to acquire elevated levels of A1C and comorbidities related to an uncontrolled glycemic management (cardiovascular disease, renal failure, etc.).

Gupta, Agarwal and Byadgi (2014) conducted a study on the effects of dietary interventions and lifestyle modifications in type two diabetes mellitus patients in India. Significant improvement was observed in clinical signs and symptoms along with plasma

glucose and glycosylated hemoglobin (A1C) in patients after these interventions (diet change and lifestyle modifications).

Low Calorie Diet and Medication

Shiau, So and Dent (2018) conducted a study to examine the outcomes of a low-calorie diet and weight management program in Type II diabetic patients. Observed that at six months those patients achieved an approximate 16% weight loss. Thirty percent of patients were no longer prescribed diabetes medications; and had an insulin discontinuation or decrease of 86.5%. Jung and colleagues (2014) conducted a study on the beneficial effects of Korean traditional diets in hypertensive and type two diabetic patients, concluding that Korean traditional diets (KTD) in contrast to contemporary diets in Korea (control group) for 12 weeks improved blood pressure, glycemic control, and cardiovascular risk factors. At the end of the study the KTD group had significantly lower anthropometric indicators, including body weight, BMI, body fat mass, body fat (%), waist-hip ratio, waist circumference and significantly better hemoglobin A1C and heart rate than the control group.

Medicare provides a medical nutrition therapy, which is an educational plan available to Medicare patients diagnosed with diabetes or renal disease. An initial nutrition and lifestyle assessment is performed followed by nutrition counseling (what foods to eat and how to follow an individualized diabetic meal plan) and lifestyle factors that affect their diabetes. Follow up visits are available to verify patient's progress in diet and its management (CMS, 2017). This educational plan has to be prescribed by the health care provider.

In addition, the Community Preventive Services Task Force (organization created by the U.S. Department of Health and Human Services) created a fact sheet offering strategies for providers to adopt and implement in the local community. The recommendations include

administering a combined diet and physical activity program to prevent Type II diabetes for high risk individuals (USPSTF, 2017).

Hemoglobin A1C Levels

Glucose and hemoglobin A1C provide complementary information and both are used to assess an individual's glycemic status. The concentration of glucose in the blood indicates the subject's glycaemia at the time of blood sampling. However, blood glucose concentrations are modified by numerous factors, ranging from food ingestion and exercise to stress and medication. In contrast, the concentration of A1C in the blood reflects the average glucose over the preceding eight to twelve weeks. A1C has several attributes which render it valuable in assessing diabetes. These include, but are not limited to the following: the patient does not need to be fasting, blood can be sampled any time of the day, the sample is stable, and there is very little biological variability. These factors in conjunction with the veracity that A1C predicts the development of microvascular and macro vascular complications of diabetes have led to the widespread adoption of hemoglobin A1C as integral to the management of patients with diabetes. Guidelines from several prominent clinical organizations recommend that A1C be measured at regular intervals in all patients with Type II diabetes (Sacks, 2012).

Diet modifications are important because they contribute to the reduction in hemoglobin A1C levels and affect weight management in patients with Type II diabetes. According to Ma et al. (2008), dietary management is the cornerstone of care for diabetes, and carbohydrate intake has the greatest influence on blood glucose. The study compares different diets and its benefits among diabetic patients (Low glycemic index vs. ADA diet). The studies review the benefits of diet change and its effect on the reduction of hemoglobin A1C levels. Recommendations vary regarding which regimen is better, but most suggest that lifestyle modifications and diet have a

strong beneficial impact on the disease. Another randomized control study which focused on a low-fat vegan diet and its benefits for Type II diabetic patients concluded that a low-fat vegan diet improved glycemic and lipid control better than an ADA diet (Barnard et al., 2006).

Internal Evidence

Healthcare providers in a primary care clinic in southern Arizona currently follow the Comprehensive Type II Diabetes Management Algorithm (Nathan et al., 2009) and recommend lifestyle modifications to manage the disease, but a specific diet low in calories is not formally prescribed.

PICOT Question

This inquiry has led to the clinically relevant PICOT question, "In diabetic patients Type II with a hemoglobin A1C > 6.0% (P), how does the combination of a low calorie diet and medication regimen (I) compared to a medication regimen only (C) affect their hemoglobin A1C levels (O) over a two-month period (T)?"

Search Strategy

An exhaustive search of the literature was conducted using the following databases: Cumulative Index of Nursing and Allied Health Literature (CINAHL), PubMed, and ProQuest. Keywords included: *effects of diet, diabetic patients, how to reduce, hemoglobin, impact of diet, diabetes type 2, low calorie diet, a1c, hemoglobin a1c, diet, how diet affects, medication management, adult, medication.* The initial search in CINAHL produced 1,488 results, the words used were *diabetes*, *diet* and *hemoglobin* (Appendix A). The searched in PubMed yielded 2200 results on the first search, the terms used were *diabetes type 2, hemoglobin a1c, diet* and *adult.* (Appendix B). When ProQuest was searched using the words *diabetes type 2, hemoglobin a1c* and *adults*, 6,754 results showed in the database (Appendix C). By making the search more

specific to the terms related to the PICOT question and by combining them to include all the components, the final search included all the terms related to the PICOT question, resulting in a final yield of 97 studies in CINAHL (Appendix A), 85 studies in PubMed (Appendix B) and 1386 in ProQuest (Appendix C). An additional search strategy was performed using Cumulative Index of Nursing and Allied Health Literature (CINAHL). Keywords included: *diabetes type two, diet, Hispanic, Latino, hemoglobin A1C.* The initial search produced 3, 398 results (Appendix D). By making the search more defined the final yield resulted in 76 studies with the latest terms.

Studies published prior to 2012 were eliminated as part of the exclusion criteria, with a single exception of one study because of its statistical relevance. Andrews et al. (2011) is a multicenter parallel group randomized control with a large sample size (n-593) and statistically significant (A1C levels $p<0.005$ after 12 months of treatment). Those involving children, adolescents, type one diabetes and adults in an intensive care unit, were also excluded.

After appraising 38 studies ten have been chosen for inclusion in this literature review. The included studies comprise the relationship between diabetes type two, elevated hemoglobin A1C, diets low in calories, adults, medication regimen and the effects of diet in the management of diabetes type two (Appendix E). After an exhaustive additional search for studies that parallel the goals of the proposed project, three more studies were found and added to the original ten previously chosen to guide the project.

Critical Appraisal and Evidence Synthesis

Ten studies included in the literature review were subjected to rapid critical appraisal and found to sufficiently address the elements of the PICOT question. Melnyk and Fineout-Overholt's (2015) hierarchy of evidence rating system was used to evaluate the level of evidence

of each study, Andrews et al. (2011) a multicenter parallel group randomized controlled study provided level II evidence. Coppell et al. (2017) a mixed methods non-randomized quantitative and qualitative pilot study provided level III evidence. Johansen et al. (2017) a randomized clinical trial provided level II evidence. Jung et al. (2014) a randomized controlled trial provided level II evidence. Rock et al. (2014) a randomized controlled trial provided level II evidence. Sylvetsk et al. (2017) a multicenter randomized controlled clinical trial provided level II evidence and Wolever et al. (2017) a randomized controlled trial provided level II evidence.

For the multicenter randomized controlled trial (RCT), mean HbA1C concentrations were significantly lower at six and 12 months in patients who received either study intervention than in those who received usual care, effect sizes were 0.3 SDs, and the lower 95% Cl values were roughly equivalent to the specified target difference of -0.5% (Andrews et al., 2011). One was a mixed-methods non-randomized quantitative and qualitative study, and five were randomized control trials. Of the three remaining studies one consisted on a trial clinical prospective and interventional study (level IV evidence), the second one consisted on a weighted linear regression with the use of cross-sectional data (level V evidence), and the last one was a retrospective cohort study (level IV evidence). Additionally, three studies had been added to the original ten. The first study (Cubillos, et al., 2017) consists of a clinical pilot (level III evidence), which was conducted in two phases (a formative and a clinical pilot).

Adherence to a Mediterranean diet increased from 5.7 to 7.9 for a difference of 2.3 (95% Cl, 1.0-3.5), p = .001. The second study -PREDIMED- (Estruch, et al., 2013) is a randomized controlled trial (level I evidence) where 7447 participants were enrolled. The study was conducted in Spain to demonstrate the relationship between a Mediterranean diet supplemented with extra-virgin olive oil or nuts and the reduction of major cardiovascular events. After the first

follow up year, mean scores of adherence to the Mediterranean diet were significantly higher in the two Mediterranean diet groups than in the control diet group ($p < 0.001$ for all yearly comparisons from year one to six of follow-up). The third article relates to the 14-Item Mediterranean Diet Assessment Tool utilized on the PREDIMED Trial (level III evidence). This is a cross-sectional assessment of all participants in the PREDIMED trial. The study showed that high consumption of nuts and low consumption of sweetened/carbonated beverages presented the strongest inverse associations with abdominal obesity. The 14-Item Tool was able to capture a strong monotonic inverse association between adherence to a good quality dietary pattern (Mediterranean diet) and obesity indexes in a population of adults at high cardiovascular risk (Martinez-Gonzalez, et al., 2012).

Some bias was present across studies, Andrews et al. (2011) reports to be an independent consultant for four pharmaceutical companies. Coppell et al. (2017) excluded patients that do not speak English. Darwiche et al. (2016) excluded patients from different ethnicities and Kollanoor-Samuel et al. (2016) also excluded patients from other ethnic groups. Two studies were financed by private industry. One study was financed by Jenny Craig, researchers controlled only a portion of the study data management, analysis and publication (Rock et al., 2014). Wolever and colleagues (2017) are partial owners of Glycemic Index Laboratories and is an independent consultant for various other laboratory companies.

The sample sizes were adequate except for Darwiche (2016) and Jung (2014), whose sample sizes were small. Additionally, there was a considerable degree of heterogeneity in the sample demographics consisting of different cultures, ages, and ethnicities with the exception of a few studies whose primary focus was on certain populations. The sample sizes were

homogeneous in that most of the samples consisted of patients older than 18 years of age with an elevated hemoglobin A1C, diabetic or pre-diabetic diagnosis and elevated BMI.

There was moderate homogeneity in the independent variables in terms that the majority focused on diet and physical activity. But there was more heterogeneity in the dependent variables. Some concentrated their attention only on A1C levels and weight, while others made emphasis on insulin resistance, blood pressure, BMI, health-related quality of life activities and glucose lowering medications among others. The majority of the studies used similar measurement tools, for example to obtain blood samples the participants went to a laboratory were standard technique was used to draw their blood. To measure their height and weight a standard scale was utilized, and to take their blood pressure standard technique was also used. Of the ten studies six demonstrated statistically significant positive associations between A1C levels and diet, specifically when pre-diabetic or diabetic patients follow a diet that focuses on decreasing hemoglobin A1C levels. Seven of the ten studies demonstrated statistically significant positive associations between weight loss and diet. Statistically significant results (A1C levels and weight) and quality measurement tools and instruments suggest strong validity and reliability across the studies (Appendix E).

Discussion

The studies reviewed suggest that the implementation of a diet low in calories, carbohydrates and/or fat improves A1C levels and assists with weight management (decreasing weight, reducing BMI levels, reducing A1C levels). The evidence reviewed suggests that when a diet low in calories is added into the plan of care of a diabetic patient his or her anthropometric measures significantly improve ($p<0.001$) (Coppell et al., 2017). Lifestyle modifications (aerobic training sessions) led to a substantial and parallel reduction in glucose lowering medication

(Johansen et al., 2017). The findings of another study suggest that diet alone (Korean traditional diet) had significant effects on body weight, BMI, body fat mass, body fat (%), A1C levels and heart rate. Resulting in favorable changes in glycemic control, body composition, and cardiovascular risk factors (Jung et al., 2014). Based on the evidence, providers could implement diet changes on pre-diabetic and diabetic patients that have poor glycemic control, elevated hemoglobin A1C and elevated BMI. The variety of diets presented in the studies (Appendix F) offer providers the option to choose the dietary plan that best fits the needs of their patients. Based on the evidence reviewed hemoglobin A1C and weight were consistent outcome measurements.

The findings of the randomized controlled trial (Estruch, et al., 2013) that took place in Navarra, Spain showed the prevalence of diabetes and current smoking were lower among participants with higher adherence to the Mediterranean diet (Martinez-Gonzalez, et al., 2012).

Utility of Evidence

The evidence presented by Cubillos, et al. (2017), Estruch, et al. (2013) and Martinez-Gonzalez, et al. (2012) supported the implementation of a diet program based on the Mediterranean diet that was culturally acceptable for Hispanic American patients who have been diagnosed with Type II diabetes.

After multiple meetings with the lead provider of the clinic, it was recommended to formally implement the Mediterranean diet for all those patients that had a hemoglobin A1C > 6 % for a period of eight weeks. The implementation of the Mediterranean diet for Type II diabetic patients at a clinic in Southern Arizona could decrease hemoglobin A1C levels, reduce weight and improve quality of life. The ethnicity of the patients who visit the clinic are mostly Hispanic,

implementing a diet that includes foods that are part of their daily eating habits increases diet adherence (Estruch at al., 2013).

Theoretical Models

An evidence based practice model and a nursing health promotion model were selected to guide the overall project process and the specific nursing intervention.

Evidence-based Process Model

The Rosswurm and Larrabee model (Rosswurm & Larrabee, 1999) is derived from theoretical and research literature related to evidence-based practice, research utilization, and change theory. The model guides practitioners through the entire process of changing to evidence-based practice, beginning with the assessment of the need for change and ending with the integration of an evidence-based protocol. The model is suitable to be used in primary care or other settings in addition to acute inpatient units. This model guided the implementation of the project (diet implementation to decrease hemoglobin A1C levels) by assisting the doctoral student to assess the need for change in practice, link the problem to interventions and outcomes, synthesize the best evidence, design the practice change, implement and evaluate change in practice and integrate and maintain change in practice (Appendix G).

The implementation of the intervention followed step four “Design-practice change” of the evidence-based model of Rosswurm & Larrabee, which consists of identifying the needed resources, the plan implementation process, and the definition of outcomes. Pender’s Health Promotion Model guided the proposed intervention encouraging the individual to modify his or her diet and to commit to a plan of action that will lead to a health promoting behavior (diet modification). The evidence enabled the writer to decide what outcome variables were measured for the project. The recommended outcomes were hemoglobin A1C levels, body weight and diet

adherence. At both the beginning and the end of the project the dependent variables (A1C, body weight and diet adherence) were measured to verify the feasibility of the intervention (diet modification).

Health Promotion Model

The Pender' Health Promotion Model (Khodaveisi, Omidi, Farokhy & Soltaninan, 2017) guided the intervention. The model presents a systematic way of understanding events, behaviors and situations. Within the model there are several concepts that allow the provider to understand at what stage the patient is and if he or she perceives the benefits, barriers, behavior-related affect (positive or negative), self-efficacy and situational influences on their current condition. It also assists the provider and patient to understand their prior related behaviors and personal factors (lack of exercise, diet high in calories and carbohydrates, genetics) and how these factors have a strong influence on their weight, A1C levels, and current medical condition (Type II diabetes) (Appendix H).

The model addresses significance of motivation which is modifiable through both actions and the perceived benefits of action. Applied to this project, patients can achieve motivation thru: weight loss, decrease in A1C levels and better management of their Type II diabetes. The model also includes the perceived barriers to action, in this project considerations could be: difficult with change (a new diet is challenging), perceived self-efficacy (I cannot do this), activity-related affect, (this makes me unhappy), interpersonal influences (I do not have support at home), and situational influences (I cannot take my lunch to work, I do not have time to do this).

Setting the Stage/Plan

The project plan to introduce a Mediterranean diet to the targeted patients required the buy-in and involvement of clinic stakeholders (providers, patients, administration, medical

assistants and phlebotomists). The proposed patient education materials, flyers and guidelines were introduced to the stakeholders, resulting in consensus for their use at the clinic.

Outcome Measurement Tool

The 14-Item Mediterranean Assessment Tool (Appendix I) was selected to measure patient's adherence for pre and post diet intervention and was used in a face-to-face interview with each participant. The 14-item tool was developed in a Spanish case-control study (PREDIMED) of myocardial infarction, where the best cut-off points for discriminating between cases and controls were selected for each food or food group (Martinez-Gonzalez et al., 2012). The tool was chosen because the questionnaire captured a strong monotonic inverse association between adherence to a good quality dietary pattern (Mediterranean diet) and obesity indexes in a population of adults at a high cardiovascular risk (Martinez-Gonzalez et al., 2012)

Validity and reliability. In the validation study (Martinez-Gonzalez et al., 2012), the score obtained with brief 14-item questionnaire correlated significantly with that obtained from the full-length 137-item (FFQ) score (Pearson correlation coefficient (r) = 0.52; intra-class correlation coefficient = 0.51). Significant inverse correlations of the 14-item tool with fasting glucose, total: HDL cholesterol ratio, triglycerides and the 10-y estimated coronary artery disease risk also supported the validity of this brief Mediterranean diet adherence screener (Martinez-Gonzalez et al., 2012). Permission to use the tool was obtained from the author.

Project Methods

The clinic provided a letter indicating permission to implement the project at the clinic. The Institutional Review Board (IRB) at Arizona State University approved the study on 7/20/2018 (Appendix J). The protection of human subjects was of relevant importance for the evidence-based practice project. Patient's privacy interests were protected and only their

provider, medical assistants, phlebotomy and doctoral student had access to their electronic medical record (EMR). Charts were reviewed to identify those patients that qualified for participation in the project. All the participants that qualified for the project had the same provider (Family Nurse Practitioner). The setting for the project took placed in a primary care clinic located in Southern Arizona.

Budget

The project was entirely funded by the doctoral student (one-liter bottle of olive oil, one pound of nuts and a $10.00 gift card from Sprouts was provided to each participant that agreed to participate in the project). The total cost of the project was $995.00.

Sample

Patients previously identified as Type II diabetics with an elevated hemoglobin A1C > 6.0 were recruited for the project during the months of September and October of 2018 during their scheduled appointments.

Informed consent. Patients were notified that their participation would involve two (20 minutes) educational sessions at the clinic following their usual scheduled appointments and two (5-15 minutes) phone conversations to review their progress (date and time was determined by each participant). The study also entailed a completion of a pre and post-questionnaire (14-Item Mediterranean Assessment tool) and a demographics questionnaire (26 questions-five minutes to complete) (Appendix K) on visit one which was repeated on follow up visit two (14 questions to complete) during their usual scheduled appointment. Participants were notified that data would be taken from their medical record (weight and hemoglobin A1C) for study use to measure outcome of diet. The pre and post study questionnaire was used to determine if the information

modified their diet. Participants were also notified that the study needed to be completed within two months and each session and questionnaire would be individually linked.

Individuals were aware that their participation in the study was voluntary and that each participant needed to be 18 years or older to be eligible. They were also notified that they would not incur a penalty if they chose not to participate or to withdraw from the study at any time. The intervention was free to each participant, and routinely collected lab results at the time of the visit were used. Educational materials were developed in two languages (English and Spanish), and were translated by the doctoral student.

Benefits for participation included increased knowledge of the Mediterranean diet, potential weight loss, and potential decrease on hemoglobin A1C level. Participants received a bottle of olive oil (visit one), a bag of nuts (almonds or walnuts) and a $10.00 Sprouts gift card (visit two) upon completion of the study.

Intervention

The measurement outcomes were: hemoglobin A1C, weight and diet adherence. Each participant received the following educational materials: 14-Item Mediterranean questionnaire, dietary goal (Appendix L), informational flyer (Appendix M) and Mediterranean diet guidelines (Appendix N). During the months of September through the first week of December, data was collected (consents of participation, questionnaires, pre and post weight and hemoglobin A1C) by the medical assistants and doctoral student. During the months of January through March 2019, data was entered into SPSS.

The first week of the project recruitment took place at the clinic. Informational flyers were posted in the waiting room for all patients to see. Interested and eligible participants were contacted by phone or in person (at site) by the DNP student. As required, written informed

consent (Appendix O) was obtained from those eligible individuals. Measurements were taken by the medical assistants and phlebotomists (weight and hemoglobin A1C) and were recorded on each individual's electronic medical record. The 14-Item Mediterranean Diet Assessment Tool was provided by the DNP student while an overview of the program and the timeline of the intervention (Appendix P) was explained to each individual who agreed to participate in the project. Two sessions in person as well as two phone calls were part of the intervention, with the ultimate goal to educate each participant on the guidelines of the Mediterranean diet and to review each participant's dietary goals. Educative materials were provided in session one as well as a one-liter bottle of olive oil and a $10.00 gift card from Sprouts. During the second on site visit, guidelines and goals were reviewed with each participant. Weight, hemoglobin A1C and 14-Item Mediterranean Diet Assessment Tool were also recorded on all participants. Each individual received a one pound of nuts (almonds or walnuts) during visit two. Outcomes of the intervention (hemoglobin A1C, weight and results of the 14-Item Mediterranean Diet Assessment Tool) were reviewed with each individual during their follow up appointment at the clinic.

Outcomes/Project Results

The sample consisted of 27 participants (adult males and females). 23 participants had their weight measured post intervention. Of the 27 participants, 14 completed the diet adherence questionnaire. The hemoglobin A1C value was collected on 12 participants post intervention due to medical insurance denial of coverage for the test. A paired sample *t*-test was used, also called a dependent *t* test, which compares the means of two scores from related samples. Comparing a pre-test and a post-test score for a group of participants requires a paired-samples *t* test according to Cronk (2014).

A paired-samples *t* test was calculated to compare the mean pre-adherence score to the mean post-adherence score. The mean on the pre-adherence was 4.29 (*sd* = 1.54), and the mean on the post-adherence was 7.21 (*sd* = 1.31). A significant increase from pre-adherence to post-adherence was found ($t(13) = -7.346$, $p < .001$).

These results suggest that educating patients on a specific intervention (Mediterranean diet) and following up after implementing the intervention had a positive effect in diet adherence (Mediterranean diet).

It is relevant to report that the results pertinent to weight loss were not statistically significant. A paired-sample *t* test was calculated to compare the mean pre-weight score to the mean post-weight score. The mean on the pre-weight was 204.20 (*sd* = 73.58), and the mean on the post-weight was 203.93 (*sd* = 73.59). No significant difference from pre-weight to post-weight was found ($t(22) = .171$, $p > .05$).

These results suggest that a diet intervention performed in eight weeks does not reflect a significant weight loss among participants. For future research a longer intervention is needed to verify the effectiveness of the Mediterranean diet in weight loss.

The result of the scores of the hemoglobin A1C value were also not significant. A paired-sample t test was calculated to compare the mean pre-hemoglobin A1C score to the mean post-hemoglobin A1C score. The mean on the pre-A1C was 7.00 (*sd* = 1.32), and the mean on the post-A1C was 6.82 (*sd* = 1.44). No significant difference from pre-A1C to post-A1C was found ($t(11) = .815$, $p > .05$).

These results also suggest that a longer intervention is needed (> 3-4 months) to allow time for changes in hemoglobin A1C and weight management. Due to lack of insurance's

approval 15 participants were not able to measure their levels of hemoglobin A1C, which affected the tests results.

Discussion

The clinic has a high percentage of Type II diabetic patients that have poorly controlled diabetes presenting with symptoms including: elevated A1C levels, poor compliance, elevated BMI, and comorbidities related to diabetes.

Implications

If the clinic's stakeholders decide to implement educational measures to teach each Type II diabetic patient the benefits of a diet (Mediterranean diet) and lifestyle modifications, hyperglycemia will improve as well as weight management. Providers will be able to measure the tangible benefits that a change of diet implies to a diabetic patient (A1C levels and weight). A1C and weight should continue to be measured every three months to verify patient's improvement. Compliance among patients may improve when they experience the benefits of losing weight, being able to exercise, and enhancement of their quality of life. The project outcomes were the reduction on A1C levels, weight loss and diet adherence. The strengths of the project were the educational sessions that each participant received (educational flyers, dietary goals and Mediterranean guidelines). Diet adherence increased and the majority of the participants verbalized an understanding of how a change in lifestyle is needed to improve their hemoglobin A1C and weight control.

Sustainability

Sustainability will require the ongoing support from stakeholders and the need for future partnerships with diabetes educators for continuous education. Currently the clinic has a diabetic educator that provides monthly educative classes to every diabetic patient that agrees to assist on

the first Wednesday of the month. The classes focus on diet management and medication usage. To sustain this project, will be important to educate staff members (providers and medical assistants) as staff champions to implement the intervention (Mediterranean diet) in a weekly basis and sustain it for at least six months to accurately measure outcomes (weight, hemoglobin A1C and diet adherence).

Future research should focus on the benefits that the Mediterranean diet provides to Type II diabetic patients and how this dietary change can improve their weight and hemoglobin A1C levels. One provider is interested in continuing the intervention with her diabetic patients. The educational materials were given to the office manager and providers for the future implementation of the project. Actual outcomes might change within time (three to four months) post intervention.

Project Limitations and Barriers

The limitations of the project are related to the time of the intervention (eight-weeks). At least three to four months are needed to verify the significance of the evidence-based practice project. Unforeseen barriers included insurance approval, collecting data during three holidays (Halloween, Day of the Dead and Thanksgiving) that characteristically include high calorie traditional Mexican and American foods that have elevated content of carbohydrates. Participants admitted that following a diet during the holiday season was challenging.

Conclusion

The project confirmed that the establishment of educational programs oriented to modify lifestyle (diet) are effective in a primary care setting. As a future family nurse practitioner and doctoral student, the writer learned that implementing an intervention in a primary care setting is challenging and requires constant effort not only from the primary investigator but from the staff in general. Motivation, encouragement and evidence-based practice interventions are mandatory to sustain a project that modifies patient's behaviors.

To obtain better results the writer would extend the intervention to three to four months instead of eight weeks and will choose a different season of the year where the participants tend to be more receptive and motivated to lose weight and change their eating habits.

The entirety of the DNP 712 classes prepared the doctoral student to implement this project from beginning to end. Phase I (approval from IRB, site, and instruments) was primarily challenging because continuous correction needed to be done in order for the project to start, but the implementation phase was very encouraging as the excitement of the staff and the participants towards the intervention was evident.

This evidence-based project allowed the writer to become more independent in a foreign setting and to learn how to motivate and implement an intervention that required a change in behavior from each participant. Educating patients on a weekly basis not only allowed the writer to establish appropriate rapport with the participants, but after the second session the student and patients felt more comfortable with each other, enabling the student to grew as an educator and future practitioner through this experience.

As a result, the participants acquired knowledge of the Mediterranean diet and its benefits. Even though their hemoglobin A1C and weight did not show significant difference,

their diet adherence motivated them to continue with a lifestyle change that in the long term will modify their outcomes. The clinic kept all the educative materials and in the near future plans to continue with the project. The awareness that the project brought to the clinic regarding the elevated incidence of Type II diabetes among their clients will benefit their practice.

The following DNP essentials that were met by the DNP student are: systems thinking, health organizations, and the advanced practice nurse (APN) leader. This project allowed the student to practice policies and procedures in meeting the health needs of the patient populations with whom the writer practiced. It also allowed the student to create an intervention and strategies that will sustain changes in an organization for the near future (Zaccagnini & White, 2014).

Information systems technology and patient care for the improvement and transformation of health care was another essential that was covered during the implementation phase of this project. Computer literacy and competency were essential for the execution of this project. The student needed to constantly access the electronic medical record of each participant for information retrieval. The use of statistical software (SPSS) was mandatory for data entry, statistical information and testing.

Interprofessional collaboration for improving patient and population health was another DNP essential covered by the doctoral student. Constant communication and exchange of information was a daily practice during the execution of the project and the continuous interaction between the doctoral student and the stakeholders was necessary for the success of the project and the provision of care towards the participants.

As a result of this implementation the student and the staff developed a collaborative relationship that benefited not only their patients, but the DNP student, as valuable lessons were learned from this intervention.

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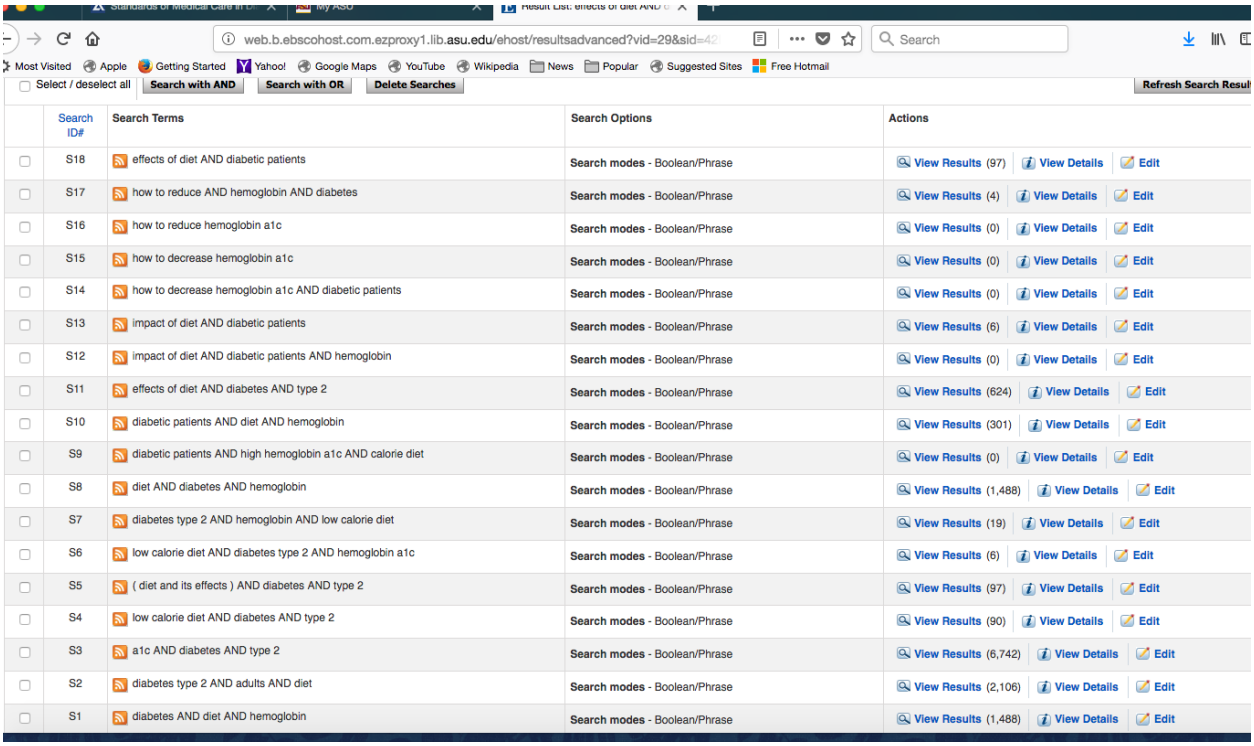
Appendix A

Figure 1.1. Screenshot of Database Searched, Cumulative Index to Nursing and Allied Health Literature (CINAHL)



web.b.ebscohost.com.ezproxy1.lib.asu.edu/ehost/resultsadvanced?vid=29&sid=42

Search

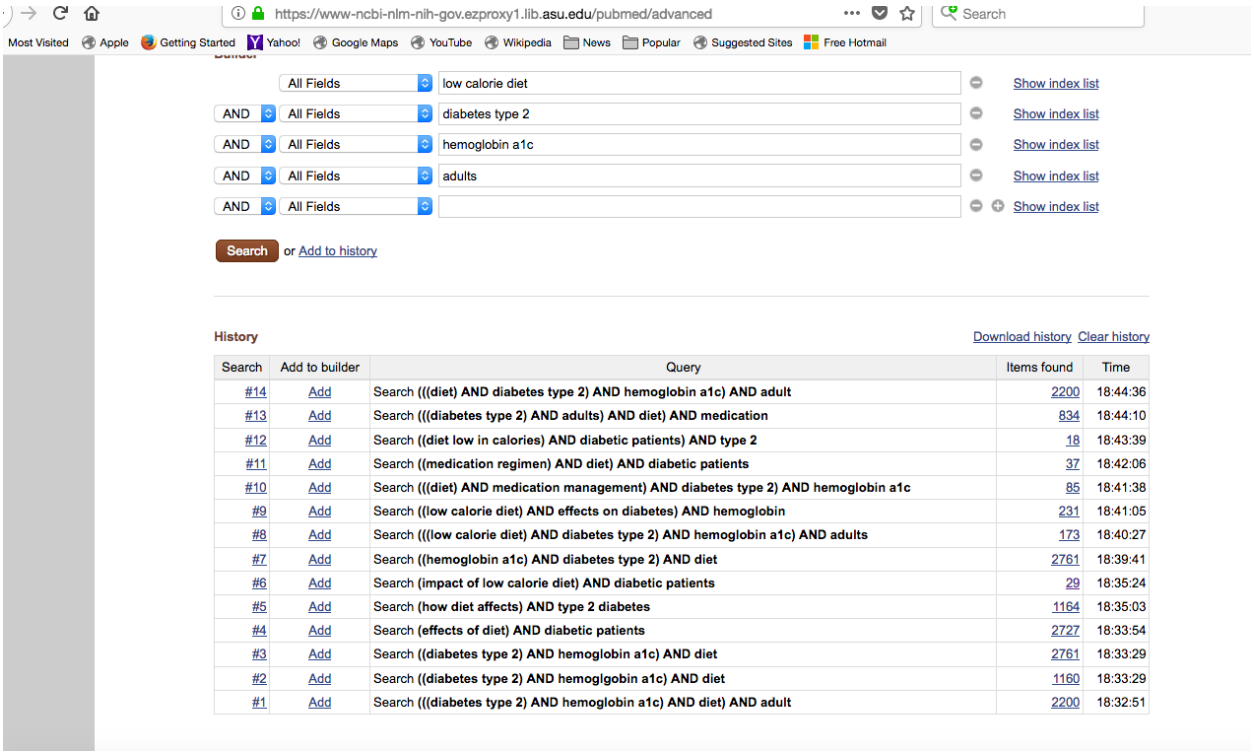
Most Visited | Apple | Getting Started | Yahoo! | Google Maps | YouTube | Wikipedia | News | Popular | Suggested Sites | Free Hotmail

Select / deselect all | Search with AND | Search with OR | Delete Searches | Refresh Search Result

Search ID#	Search Terms	Search Options	Actions
S18	effects of diet AND diabetic patients	Search modes - Boolean/Phrase	View Results (97) | View Details | Edit
S17	how to reduce AND hemoglobin AND diabetes	Search modes - Boolean/Phrase	View Results (4) | View Details | Edit
S16	how to reduce hemoglobin a1c	Search modes - Boolean/Phrase	View Results (0) | View Details | Edit
S15	how to decrease hemoglobin a1c	Search modes - Boolean/Phrase	View Results (0) | View Details | Edit
S14	how to decrease hemoglobin a1c AND diabetic patients	Search modes - Boolean/Phrase	View Results (0) | View Details | Edit
S13	impact of diet AND diabetic patients	Search modes - Boolean/Phrase	View Results (6) | View Details | Edit
S12	impact of diet AND diabetic patients AND hemoglobin	Search modes - Boolean/Phrase	View Results (0) | View Details | Edit
S11	effects of diet AND diabetes AND type 2	Search modes - Boolean/Phrase	View Results (624) | View Details | Edit
S10	diabetic patients AND diet AND hemoglobin	Search modes - Boolean/Phrase	View Results (301) | View Details | Edit
S9	diabetic patients AND high hemoglobin a1c AND calorie diet	Search modes - Boolean/Phrase	View Results (0) | View Details | Edit
S8	diet AND diabetes AND hemoglobin	Search modes - Boolean/Phrase	View Results (1,488) | View Details | Edit
S7	diabetes type 2 AND hemoglobin AND low calorie diet	Search modes - Boolean/Phrase	View Results (19) | View Details | Edit
S6	low calorie diet AND diabetes type 2 AND hemoglobin a1c	Search modes - Boolean/Phrase	View Results (6) | View Details | Edit
S5	(diet and its effects) AND diabetes AND type 2	Search modes - Boolean/Phrase	View Results (97) | View Details | Edit
S4	low calorie diet AND diabetes AND type 2	Search modes - Boolean/Phrase	View Results (90) | View Details | Edit
S3	a1c AND diabetes AND type 2	Search modes - Boolean/Phrase	View Results (6,742) | View Details | Edit
S2	diabetes type 2 AND adults AND diet	Search modes - Boolean/Phrase	View Results (2,106) | View Details | Edit
S1	diabetes AND diet AND hemoglobin	Search modes - Boolean/Phrase	View Results (1,488) | View Details | Edit

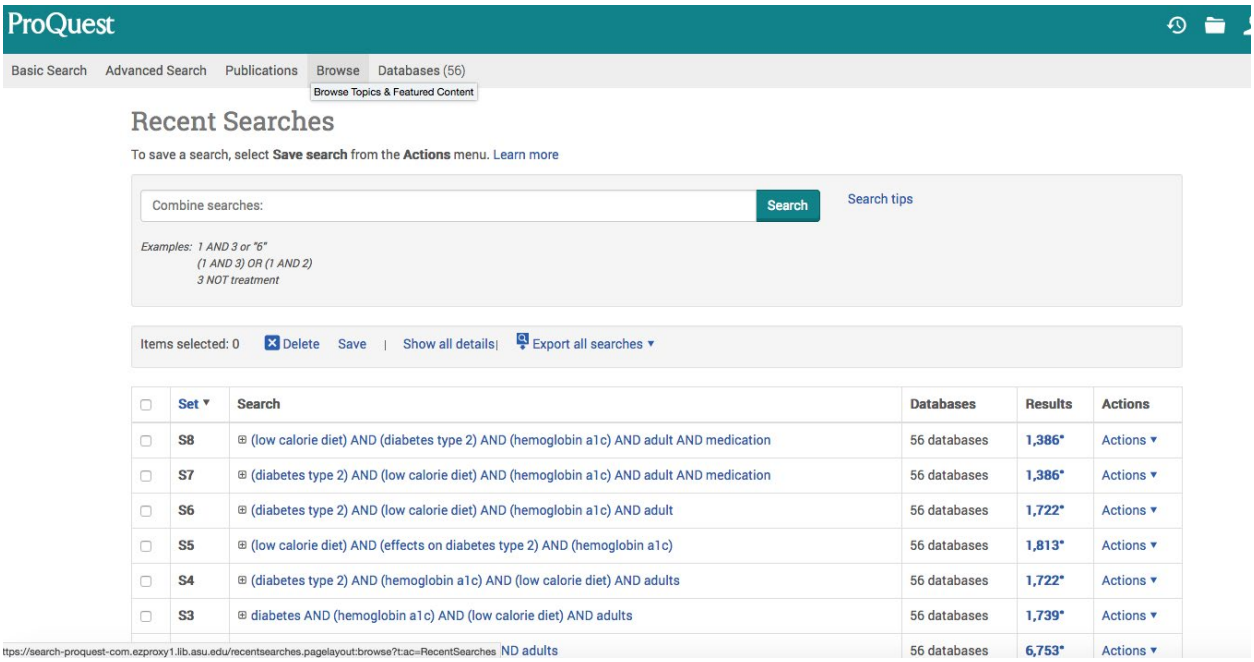
Appendix B

Figure 1.1. Screenshot of Database Searched, PubMed



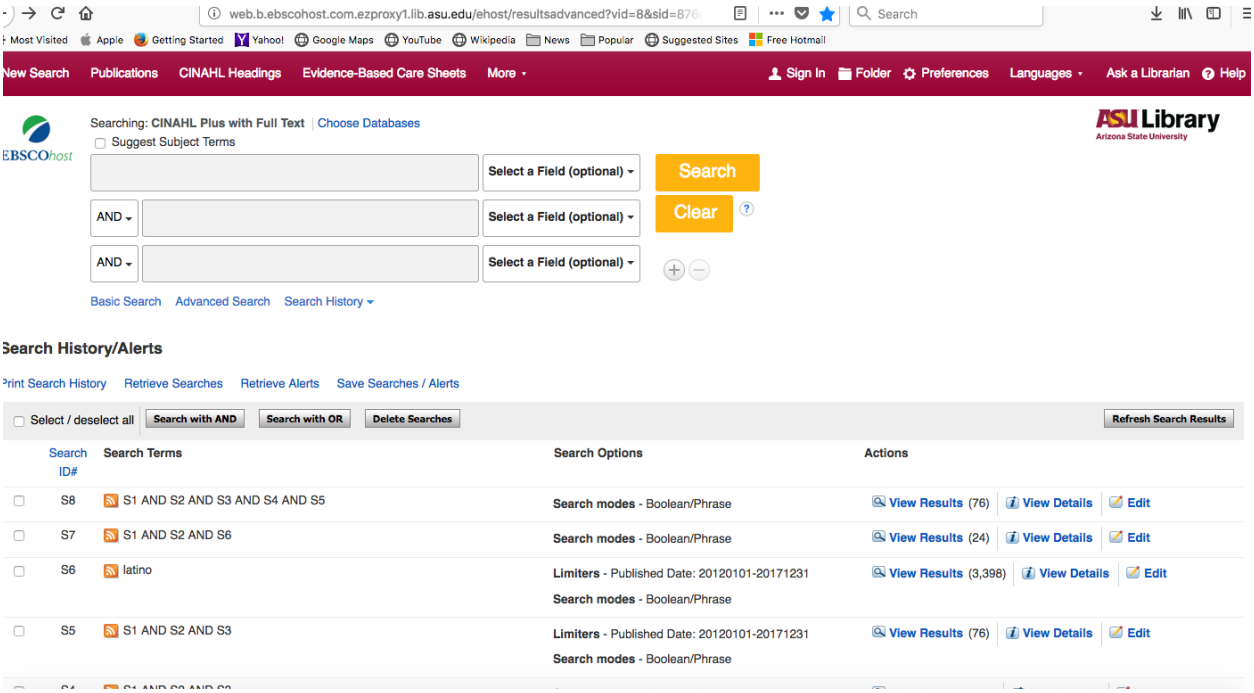
Appendix C

Figure 1.1. Screenshot of Database Searched, ProQuest Dissertation



Appendix D

Figure 1.1. Screenshot of Database Searched, CINAHL



Appendix E Quantitative Studies

Table 1

Evaluation Table

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Andrews et al. (2011) Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: The Early ACTID randomized controlled trial. **Country:** England **Funding**: Diabetes UK and the UK Department of Health **Bias**: RCA (honoraria from GSK, NN, SA and Lilly). CMD (Consulter fees from GSK and Medtronic).	Physiologic Model explaining the benefits of diet and physical activity to improve outcomes on diabetic patients.	**Design**: Multicenter parallel-group, randomized controlled. **Purpose**: To evaluate the effectiveness of increase physical activity and diet intervention.	N-8 studies n- 593 CG- 99 IG1- 248 IG2- 246 At 6 months: n- 587 CG- 97 IG1- 247 IG2- 243 At 12 months n- 579 CG- 93 IG1- 246 IG2- 240 **Demographics**: Males and females > 30 years old. **Setting:** Southwest England **Inclusion**:	IV1- Diet IV2 – physical activity DV1- A1C DV2 – Body weight DV3-insulin resistance DV4- BP **Time frame of the intervention**: 6 and 12 months	**IV 1-Diabetes UK dietary guidelines**. DV1- performed in laboratory using standard technique. DV2- “measured according to standard procedure” DV3-measured by homeostasis model assessment. DV4- not stated on the study.	Descriptive statistics, multivariable linear regression with Bonferroni correction.	**At 6 months**: DV1- A1C -0.28% (-0.46 to -0.10) p< 0.0049 **At 12 months:** DV1-A1C -0.26%(-0.44 to -0.08) p< 0.005	**Level II,** **Strengths** Community-based recruitment, the targeting of newly diagnosed individuals, the matching of contact time for the two study interventions and the use of motivation-based lifestyle programs without direct supervision that could be transferred into primary care at little cost. **Weaknesses** The additional activity program did not further improve outcomes, further research is needed

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			Older than 30 years old, newly diagnosed with type 2 diabetes. **Exclusion**: Older than 80 years, Ha1c > 10%, BP > 180/100, LDL cholesterol > 4mmol/I., BMI < 25, weight > 180 kg, use of weight loss drugs, taking a sulphonylurea at the maximum dose, unstable angina, an MI within the previous 3 months, unable to increase physical activity, and pregnancy or planning to become pregnant. **Attrition**: 14 (2.4%).					to clarify whether different programs or intensities of physical activity, longer interventions, or intervention at an earlier or later stage of diabetes will have benefits additive to those of dietary modification. **Conclusions**: The study clearly reflects the benefits of diet implementation on diabetic patients and its impact on their hemoglobin A1C (decrease). **Feasibility:** Recommended to use in practice due to the effectiveness of a lifestyle-based program among diabetic patients.

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Coppell et al. (2017) The effectiveness of a primary care nursing led dietary intervention for pre-diabetes: A mixed methods pilot study. **Country**: New Zealand **Funding**: The New Zealand Ministry of Health, a Hawke's Bay Medical Research Foundation grant in aid and a New Zealand Society for the Study of Diabetes research award. **Bias:** Selection bias (Excluded patients that do not speak English)	Physiologic Model that explains the benefits of dietary implementation in pre-diabetic patients.	**Design**: Mixed methods Non-randomized quantitative pilot study and qualitative. **Purpose**: To evaluate the effectiveness of a structured pre-diabetes dietary intervention led by primary care nurses.	n- 133 IG-67 CG-66 **Demographics**: Aged < 70 years English speakers Males and females **Setting**: Primary care setting, community settings. **Inclusion**: Non pregnant adults Aged < 70 years with newly diagnosed pre-diabetes with an A1C 6.1-6.9. BMI > 25, not prescribed Metformin. **Exclusion**: Non English speakers, Pregnancy, adults > 70 years of age, BMI < 25.	IV- diet intervention DV1- weight DV2- A1C **Time frame of the intervention**: 6 months.	**IV1- Diet Diabetes and Healthy Food Choices-New Zealand.** DV1- standard practice for weight measurement (weighing scales, shoes were removed, and patients were wearing only one layer of light clothing) nurses took duplicate measures to verify accuracy of information. DV2- A1C levels were collected at the laboratory by the nurse.	Chi-squared and Fisher's Exact tests. Linear regression models.	**At 6 months:** DV1- Weight-(SD) 95.6 (23.8), ratio 0.97 (0.95, 0.98) p< 0.001 DV2- A1C-(SD) 42.0 (3.6), ratio 0.96 (0.92, 1.00) p 0.096 (not significant)	**Level III** **Strengths:** Although mean weight loss was relatively small, it is clinically meaningful, as in the decrease for each kilogram the risk of progressing to diabetes was reduced by 16%. **Weaknesses:** The less than expected mean weight loss and insignificant change in HbA1c may reflect insufficient intensity of the intervention as both nurses and patients recommended additional sessions or monthly phone check-ins.

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			Taking Metformin. Already discussed pre-diabetes management. **Attrition:** 24 (15.28%).					**Conclusions:** Even though there is no significant difference on the A1C level, there are significant improvements on anthropometric measures (weight $p< 0.05$). **Feasibility:** Recommended to use in practice.

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Cubillos et al. (2017) Feasibility and acceptability of a clinic-based Mediterranean style diet intervention to reduce cardiovascular risk for Hispanic Americans with Type 2 diabetes. **Country:** United States **Funding:** The research was supported by Grant No. P30DK093002 from the National Institute of Diabetes and Digestive and Kidney Diseases. University of North Carolina at Chapel Hill. Bias: Preferred patients that are of Hispanic descent.	Physiologic Model that explains the benefits of adherence diet to a Mediterranean style diet intervention.	**Pilot study** **Purpose:** To modify a previously tested Spanish language version of a Mediterranean style dietary intervention so that the dietary recommendations align with the cultural and social needs of Hispanic Americans with type 2 diabetes and evaluate the modified intervention's feasibility and acceptability.	n= 19 IG= 19 **Demographics:** Male, females, from Mexico, Central America and South America. Hispanic participants with diabetes type 2. Spanish language preference. **Setting:** The University of North Carolina, Chapel Hill. **Inclusion:** Diabetes type 2, cardiovascular disease, male, female, adult, Spanish speaking. **Exclusion:** Kidney disease, cancer, pregnancy or planning to become pregnant in the next 6 months, or a	IV- Mediterranean diet DV1- Diet adherence DV2- Weight DV3- A1C **Time frame of the intervention:** 2 months.	**IV1- Four counseling sessions.** **DV1-** 14-Item PREDIMED dietary screener. **DV2-**electronic scale (Scale-Tronix, Skaneateles Falls, New York) **DV3-** Assessed by the hospital clinical laboratory.	Descriptive statistics were used to describe baseline demographic and health characteristics, and 95% confidence intervals are reported for change in pre-post measures. Statistical analyses were performed with Stata software.	**At 2 months:** **DV1-(95% Cl, 1.0-3.5) p=.001** **DV2- Weight 0.0 (-0.5 to 0.5) p=.99** **DV3- A1C 0.3 (0.0 to 0.6) p=.07**	**Level III** The En Forma-Diabetes adapted dietary intervention proved to be feasible and acceptable to study participants. Overall, the retention and completion rates were high for all study components.

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			serious medical condition. **Attrition:** 2 (9.53%)					

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Darwiche et al. (2016) An Okinawan-based Nordic diet improves anthropometry, metabolic control, and health-related quality of life in Scandinavian patients with type 2 diabetes: A pilot trial **Country**: Sweden **Funding**: Grants from Hans-Gabriel and Alice Trolle Wachtmeister's Foundation for Medical Research, King Gustaf and Queen Victoria Free Maison's Foundation, Dir Albert Pahlsson's Foundation, Development Foundation of Region Skane, and Foundation of	Health Belief Model	**Design:** Trial clinical prospective study-prospective interventional study. **Purpose:** To evaluate the effectiveness of an Okinawan-Nordic diet in Scandinavian type 2 diabetic patients.	n- 28 IG- 28 **Demographics:** Scandinavian males and females with both parents inborn in Scandinavia. Aged between 18 and 70. **Setting:** Primary health care center in southern Sweden. **Inclusion**: Both parents inborn in Scandinavia. Ages 18-70-year-old. **Exclusion**: Not Scandinavian, severe food allergy, type 1 diabetes, major gastrointestinal surgery; severe heart, pulmonary, cardiovascular, malignant, or	IV- Okinawan-based Nordic diet DV1- BMI DV2- A1C DV3- health-related quality of life (physical functioning) **Time frame of the intervention**: 12 weeks	**IV1- Diet- Okinawan-based Nordic diet** DV1- Height was measured to the nearest centimeter, and weight to the nearest kilogram in subjects wearing light clothes, but not shoes, and BMI was calculated. DV2- Venous blood samples were taken in the morning between 07:45 and 0900 h after a 10-h fast. All samples consisted of whole blood drained into 6-mL serum separation tubes, plasma separation	A power analysis was performed. Linear mixed effect models with random intercept and unstructured covariance's for repeated measures within a patient.	**At 12 weeks**: DV1- BMI Mean 27.8, mean change -2.5, p< 0.001 DV2- A1C Mean 49.20, mean change -12.37, p< 0.001 DV3- Health related quality of life (physical functioning) Mean 86.5, mean change 10.8, p< 0.001	**Level IV** **Strengths:** A significant body weight reduction was seen after introduction of the new diet (Okinawan). **Weaknesses:** A significant increased in HDL cholesterol was observed. A limitation of the study was that no control group was included. **Conclusion:** The Okinawan diet seems to contribute to the improvement on A1C levels, blood pressure, weight and physical functioning but further research needs to be implemented.

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Skane University Hospital. **Bias**: Selection bias (Excluded patients from different ethnicities).			psychiatric diseases. Pts with severe liver insufficiency, INR > 1.1, or severe renal insufficiency. GFR < 30. **Attrition**: 2 (6.7 %).		tubes, and Microtainer tubes with EDTA (BD Biosciences, Franklin Lakes, NJ). Blood chemistries were analyzed continually during the study. DV3- RAND 36 Item Health Survey.			**Feasibility:** Recommended to use in practice.

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Estruch et al. (2013) Primary prevention of cardiovascular disease with a Mediterranean diet **Country:** Spain **Funding:** Supported by the official funding agency for biomedical research of the Spanish government, Instituto de Salud Carlos III. **Bias:** Dr. Estruch reports serving on the board of and receiving lecture fees from the Research Foundation on Wine and Nutrition, serving on the boards of the Beer and Health Foundation and the European	Pender's Health Promotion Model	**Design:** Parallel-group, multicenter, randomized trial. **Purpose:** Observational cohort studies and a secondary prevention trial have shown an inverse association between adherence to the Mediterranean diet and cardiovascular risk.	n-7, 447 IG1- 2543 IG2- 2454 CG- 2450 **Demographics:** Male and females, age range- 55-80-year-old **Setting:** Universidad Medica de Navarra, Spain. **Inclusion:** Males, females, with no cardiovascular disease at enrollment, who had either type 2 diabetes or at least three of the following major risk factors: smoking, hypertension, elevated low-density lipoprotein cholesterol levels, low high-density	IV- Mediterranean diet DV1- with EVOO DV2- with nuts **Time frame of the intervention:** 4.8 years.	**IV- Mediterranean diet.** **DV1-** 14-Item dietary screener to measure adherence to the Mediterranean diet. **DV2-** 14-Item dietary screener to measure adherence to the Mediterranean diet.	With the use of O'Brien Fleming stopping boundaries, the P values for stopping the trial at each yearly interim analysis. All primary analyses were performed on an intention-to-treat basis by two independent analysts. Cox regression models were used to adjust for sex, age, and baseline risk factors.	**At End Point:** **DV1- Primary end point: 8.1 (6.6-9.9) p=0.009** **DV2-Primary end point: 8.0 (6.4-9.9) p=0.02**	**Level I** **Strengths:** In this trial an energy unrestricted Mediterranean diet supplemented with either extra-virgin olive oil or nuts resulted in an absolute risk reduction of approximately 3 major cardiovascular events per 1000 person-years, for a relative risk reduction of approximately 30% among high risk persons who were initially free of cardiovascular disease.

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Foundation for Alcohol Research.			lipoprotein cholesterol levels, overweight or obesity, or a family history of premature coronary heart disease. **Exclusion:** Not specified. **Attrition:** **523 (7.0%)**					

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Johansen et al. (2017) Effect of an intensive lifestyle intervention on glycemic control in patients with type 2 diabetes. **Country**: Denmark **Funding**: TrygFonden. The Centre for Physical Activity Research. Centre for Inflammation and Metabolism, Danish Council for Strategic Research, Danish Diabetes Academy (supported by the Novo Nordisk Foundation) **Bias**: Novo Nordisk Foundation (pharmaceutical company) even though funders had no role in the	Pender's Health Promotion Model	**Design**: Randomized Clinical Trial **Purpose:** To evaluate the effectiveness of lifestyle intervention on glycemic control in patients with T2D.	n- 93 IG-62 CG-31 **Demographics**: Male and females (adults- age was not specified). Educational level (was not specified). **Setting**: Rigshospitalet, Copenhagen, Denmark. **Inclusion**: Adults with T2D diagnosed < 10 years, BMI of 25-40, taking 2 or fewer glucose-lowering medications. **Exclusion**: A1C > 9.0, insulin dependence, presence of one or more of the following complications: diabetic retinopathy,	IV1- Aerobic training sessions. IV2- Resistance training IV3- diet DV1- A1C DV2- glucose lowering medication **Time frame**: 12 months	Diet (consistent on 45-6-% carbohydrates, 15% to 20% protein, and 20% to 35% fat with < 7% saturated fat). implemented in the Region of Zealand and Denmark DV1- Measurements were performed in 1 laboratory and biochemical analysis were completed at the central laboratory using standard procedures. DV2-the study endocrinologist titrated the patient's glucose-lowering medication to	Repeated-measures analysis of covariance applied in mixed linear models.	DV1-A1C-Change (95% CL) -0.31(-0.45 to -0.16) p value .15 (not significant) DV2- glucose lowering medication-Change (95% Cl) -2.0 (-3.0 to -1.0) p<0.001	**Level II** **Strengths:** Lifestyle intervention led to a substantial and parallel reduction in glucose-lowering medication. **Weaknesses:** Only participants with DM2 diagnosed for < 10 years were included. Also the self-reported dietary intake in this study is subject to biases and limitations. **Conclusions:** The A1C changes were no significant as expected (p value= 0.15). **Feasibility:** Recommended to use in practice.

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design and conduct of the study.			macro albuminuria, nephropathy. **Attrition**: 5 (5.10%)		obtain prescribed treatment targets. Medical standardization was performed to assess the effect of the lifestyle intervention without amplifying the result due to poorly regulated A1C levels at baseline. Data collected at Rigshospitalet, Copenhagen, Denmark.			

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Jung et al. (2014) Beneficial effects of Korean traditional diets on hypertension and type 2 diabetic patients. **Country**: Republic of Korea **Funding**: Grants provided by the Ministry for Food, Agriculture, Forestry and Fisheries, Korean Food Foundation. **Bias**: No bias reported.	Physiologic Model	**Design**: RCT **Purpose**: To evaluate the efficacy of the KTD in controlling fasting plasma glucose, BP and CVD risk factors in hypertensive and T2D patients.	n-41 IG-21 CG-20 **Demographics**: Age: > 18 yrs. m/f- 54/46% **Setting**: Chonbuk National University Hospital **Inclusion**: Diagnosed with HTN and T2D. Taking oral meds for HTN, plasma glucose and lipids. **Exclusion**: DBP > 116 mmHg, or SBP>200. Hx of CV events; type 1 diabetes; uncontrolled T2D, Hx CA; retinopathy or neuroretinopathy; digestive or CNS disorders; renal and liver function;	IV- KTD DV1-Body weight DV2- BMI DV3- body fat mass DV4- body fat (%) DV5- waist hip-ratio DV6- A1C DV7 – HR **Time frame**: 3 X day for 12 weeks	DV1- measured using a digital scale while the subjects were wearing a light hospital gown. DV2- was calculated by weight (kg)/height (m)2 DV3- determined using a bioelectric impedance analyzer. DV4- determined using a bioelectric impedance analyzer. DV5- waist circumference was measured twice to the nearest 0.1 cm with a measuring tape at the midpoint	All stats were performed according to the pre-established protocol using SPSS version 18.0 Repeated measures mixed model analysis of variance was performed to determine the effects associated with time.	**At 12 weeks:** DV1 -2.3+-0.7 p<0.002 DV2 -0.83+-0.2 p< 0.002 DV3 -2.1+-0.5 p<0.001 DV4 -2.2+-0.6 p< 0.001 DV5 -0.03+-0.01 p 0.202 (not significant) DV6 –0.72+-0.1 p<0.003 DV7 -7.1+-1.8 p<0.002	**Level II** **Strengths:** The study proved the efficacy of the KTD diet for hypertensive and diabetic patients, resulting in favorable changes in glycemic control, body composition, HR and CVD risk factors. **Weaknesses:** Waist hip ratio was not significant (p 0.202), the control group was not provided a strict "controlled diet" per se nor monitored closely for their dietary intake as was done for the KTD group. **Conclusion:** The Korean diet improved glucose levels, weight,

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			dysproteinemia; nephritic syndrome; renal diseases; coagulopathy; HIV; Psych meds in last 2 months; gastric bypass surgeries; participants of clinical trials (last 2 months); ETOH hx; pregnant and/or breastfeeding. **Attrition**: 7 (14.6%)		between the lower border of the ribs and the upper border of pelvis. Hip circumference was measured at the largest extension of the buttocks. DV6- Blood samples were collected after 12 h fasting and were stored at -80C until further analysis. HbA1c by the Hitachi-7600 analyzer. DV7-vital signs were obtained using standard protocols.			BMI, blood pressure, heart rate, it could be an appropriate intervention for diabetic patients type 2. **Feasibility:** Recommended to use in practice.

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Kollannoor-Samuel et al. (2016) Nutrition facts panel use is associated with higher diet quality and lower glycated hemoglobin concentrations in US adults with undiagnosed pre-diabetes. **Country**: United States **Funding**: No funding received **Bias**: Selection bias (Excluded pts from other ethnic groups, they were mostly Caucasian with higher socioeconomic status.	Health Belief Model	**Design**: Weighted linear regression with the use of cross-sectional data (study). **Purpose:** To compare the associations between components of food label use on the overall diet quality of individuals with pre-diabetes.	n- 2599 **Demographics**: Males and females Middle-aged, non-Hispanic whites, some college education, above-poverty-threshold family, born in the United States. **Setting:** Department of Chronic Disease Epidemiology, Yale School of Public Health, New Haven, CT. **Inclusion:** Diagnosed with pre-diabetes, Adults > 18 years of age, A1C > 5.7 and < 6.5, fasting plasma glucose > 100 and < 126, or 2-hour oral glucose tolerance test blood glucose > 140 and < 200. **Exclusion**:	IV- Food labels DV1- Diet quality DV2- A1C **Time frame of the intervention**: 5 years	DV1- assessed with the use of the Healthy Eating Index (HEI)-2010, diet-scoring metric. DV2- Blood samples were collected at NHANES Mobile Examination Centers. A1C concentrations were obtained with the use of the Tosoh A1c2.2	Descriptive statistical analyses were conducted in SAS 9.4 software.	DV1 p< 0.001 DV2 (for people that read both labels-health claims and nutrition facts panel) A1C 0.10 (0.03, 0.17) p 0.009	**Level V** **Strengths:** The study concluded that individuals who do not use the nutrition facts panel have poorer diet quality. The study was not affected by selection bias because the sample was selected independently of subject food label use, diet quality, or A1C concentration. **Weaknesses:** First study to examine the association between nutrition fact panel and health claims labels, together and separately. **Conclusion:** The use of both labels had a

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			Pregnant women, undiagnosed pre-diabetes, patients that self-reported diabetes/pre-diabetes, participants without 2 reliable 24-hour recalls, participants without responses to health-claim questions. **Attrition**: 55 (2.07%)					significant level (p 0.009) **Feasibility:** Recommended to use in practice.

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Martinez-Gonzalez et al. (2012) A 14-Item Mediterranean Diet Assessment Tool and Obesity Indexes among High-Risk Subjects: The PREDIMED Trial **Country**: Spain **Funding**: Biomedical Research of the Spanish Government, Patrimonio Comunal Olivarero and Ojiblanca from Spain (extra-virgin olive oil), the California Walnut Commission from Sacramento California (walnuts), Borges S. A. (almonds), and La Morella Nuts (hazelnurs) Spain. **Bias:**	Health Belief Model	**Design:** Cross sectional assessment of all participants in the "Prevencion con dieta Mediterranea" PREDIMED trial **Purpose:** Intervention using a dietary assessment tool	**Sample:** 7447 participants **Setting:** Spanish Primary Care Centers **Inclusion:** Women (60-80 years of age) Men (55-80 years of age) without prior cardiovascular disease but at high cardiovascular risk because they have Type II diabetes or at least three major cardiovascular factors **Exclusion:** Children, adults older than 80 years old	IV1- Diet adherence DV1-BMI DV2-Diabetes Type II DV3-Mediterranean Assessment Tool	DV1- BMI was measured by trained nurses who measured weight, height and waist circumference. DV2- Type II DM was measured on their primary care clinic. DV3-Mediterranean Assessment Tool-Dietitians assessed in a face-to-face interview with each participant.	All analysis were conducted with one-way ANOVA and chi-square tests.	Results: DV1-BMI $p < 0.001$ DV2- Type II DM $p < 0.010$ DV3- For a two-point increment in the 14-item score, the multivariable-adjusted differences in WHtR were 20.0066 (95% confidence interval, –0.0088 to 20.0049) for women and –0.0059 (–0.0079 to –0.0038) for men. The multivariable-adjusted odds ratio for a WHtR.0.6 in participants scoring $10 points versus #7 points was	**Level III** **Strengths:** Results suggest that closer adherence to a Mediterranean diet is associated with a lower prevalence of obesity, specifically abdominal obesity. **Weaknesses:** The main limitation relates to the cross-sectional nature of our analysis and the potentiality for reverse causality bias.

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Potential bias would be towards finding a higher adherence to a healthier Mediterranean diet among overweight or obese subjects.							0.68 (0.57 to 0.80) for women and 0.66 (0.54 to 0.80) for men. High consumption of nuts and low consumption of sweetened/carbonated beverages presented the strongest inverse associations with abdominal obesity.	

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Rock et al. (2014) Weight loss, glycemic control, and cardiovascular disease risk factors in response to differential diet composition in a weight loss program in type 2 diabetes: A randomized controlled diet. **Country**: United States of America **Funding:** Was provided through a clinical trial contract to the coordinating center (School of Medicine, UCSD). Jenny Craig provided program activities and materials including prepackaged foods. **Bias**: This study was supported by Jenny Craig by	Physiologic Model	**Design**: Randomized Controlled Trial **Purpose**: To evaluate the effectiveness of a weight loss program in weight loss, glycemic control and CVD risks in T2D patients.	n- 225 IG1- 73 IG2- 76 CG- 76 **Demographics**: Males and females (adults) Aged > 18 years **Settings**: University of California (San Diego) and University of Minnesota (Minneapolis) **Inclusion:** History of T2D, aged > 18 years, BMI 25-45, not pregnant or breastfeeding or planning to become pregnant in the next year, willing to participate in any of the study diet arms over a 1-year period, no eating disorders, food allergies or food intolerances,	IV1- high carbohydrate low fat diet plan IV2- lower carbohydrate, higher fat diet plan DV1- weight loss DV2- glycemic control markers DV3- triglyceride levels DV4- A1C **Time frame of the intervention**: One year.	DV1 Weight was measured at the clinic (it does not specify how it was measured) DV2 Fasting >6h blood samples were collected at each clinic visit and were measured with the Kodak Ektachem Analyzer system. DV3 Fasting >6h blood samples were collected at each clinic visit and were measured with the Kodak Ektachem Analyzer system. DV4 A1C was measured in washed erythrocytes	All analysis were conducted with SAS 9.3 statistical software.	**At 12 months:** DV1 weight- 101.9 (17.4) p 0.005 DV2 glycemic control markers- (glucose 141 (133-149) mg/dL, p= 0.023 (not significant) DV3 triglycerides 148 (134-163), p < 0.001 DV4 A1C 6.9% (6.6-7.1%) p= 0.001	**Level II** **Strengths:** Glycemic control and weight loss improved in DM2 patients. At 1 year, participants in the weight loss program intervention lost 8.2% of initial weight compared with a 2.5% weight loss in the control group. **Weaknesses:** Lack of information about adherence to the prescribed diets. The target was a free-living population, so variability in adherence is likely. Self-reported dietary data have well-recognized limitations in accuracy.

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agreement scientist at UCSD and the University of Minnesota have independence regarding data management, analysis and publication.			no history of bariatric surgery, willing to perform a step test for assessing cardiopulmonary fitness. **Exclusion**: Current involvement in another diet intervention study or weight loss program, weight loss > 10 lb in the past 3 months, having a psychiatric disorder, A1C > 11%, fasting triglyceride > 600 mg/dL and serum creatinine level > 1.4 (women) or 1.5 (men). **Attrition**: 2 (0.88%).		with ion exchange high-performance liquid chromatography.			**Conclusion:** Following a regimen with a diet plan low in calories is proven to improve A1C levels, weight loss and triglyceride levels. **Feasibility:** Recommended to use in practice.

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Shiau et al. (2018) Effects on diabetes medications, weight and glycated hemoglobin among adult patients with obesity and type 2 diabetes: 6 month observations from a full meal replacement, low-calorie diet weight management program. **Country:** Canada **Funding**: Ottawa Hospital Weight Management Clinic **Bias**: Excluded patients that were not registered on the registry. No other bias found.	Pender's Health Promotion Model	**Design**: Retrospective Cohort Study **Purpose**: To evaluate the effectiveness of a meal replacement supervised weight management program in patients with T2D.	N-5 n-317 IG1- 235 IG2- 82 **Demographics**: Pt who where registered at the local registry. Males and females **Setting**: Ottawa Hospital Weight Management Clinic in Ontario, Canada **Inclusion**: Pt who had T2D, taking medications, A1C > 6.5 or higher on 2 separate occasions. **Exclusion:** Non compliance in the behavioral program (taking < 50% of the meal replacements, attending fewer than 6 sessions in the program.	IV- Meal replacement DV1- weight DV2- A1C DV3- medication intake. **Time frame of the intervention**- 6 months	DV1 (not specified) DV2 (not specified) DV3 primary physician had the goal to reduce medication intake, specially (insulin, sulfonureas, thiazolidinedoines and/or meglitinides), which are medications that are attributed to increase weight. The study does not mention the reduction rate of the medications.	ANOVA Chi-square ANOVA using a mixed between-within subject analysis Linear regression.	**At 6 months:** DV1 weight For group who is taking weight gain medications: 16.7% (6.7), p<0.0001 Weight for group who is taking neutral medications: 16.8% (6.9) p<0.0001 DV2 A1C For group who is taking weight gain medications: 6.7% (1.6) p<0.0001 For group who is taking neutral medications: 5.8% (1.3) p<0.0001 DV3 medication intake At 6 months: Weight: 16% (6.7) p<0.0001	**Level: IV** **Strengths:** Full meal replacement-low calorie diet behavior programs can be regulated for strategic breaking of the cycle that patients are caught in with respect to their weight, allowing patients to achieve lower weights and subsequently "reset" themselves. **Weaknesses:** This is a retrospective cohort and the rationales for choices of initial diabetes medications cannot be elucidated. The analysis was restricted to weight and

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Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			Attrition: 0%				A1C: 6.6% (1.6) p<0.0001	glycemic control in patients with obesity and diabetes taking medications at 6 months. **Conclusion:** Weight gaining medications are a big barrier to loss weight and improve mobility. Meal replacement shakes could assist patients to lose weight, and improve A1C levels. **Feasibility:** Recommended to use in practice.

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Sylvetsky et al. (2017). A high-carbohydrate, high-fiber, low-fat diet results in weight loss among adults at high risk of type 2 diabetes. **Country:** United States **Funding:** Provided by the National Institute of Diabetes and Digestive and Kidney Diseases. **Bias:** Not reported.	Physiologic Model	**Design**: Multicenter, randomized controlled clinical trial. **Purpose**: To evaluate the association between diet and weight at baseline and to identify specific dietary factors that predicted weight loss among adults with high risk of diabetes type 2.	n- 2,924 IG1- 967 IG2- 979 CG- 978 **Demographics**: Male and females > 25 years of age. **Setting**: Information was collected through the years in multiple settings, it is not specified where the collection centers were located. **Inclusion**: Participants needed to be > 25 years of age, had a BMI > 24 (>22 for Asian Americans), and had elevated fasting plasma glucose concentrations (95-125 mg/dL or 5.3-6.9 mmol/L) and impaired glucose tolerance (140-199 mg/dL	IV1- Lifestyle (high-carbohydrate, high-fiber, low-fat diet) IV2 – Metformin DV1- Weight loss **Time frame of the intervention**: 3 years.	DV1- Does not mention how they measured the participant's weight.	Linear regression SAS version 9.3 was used for all analyses (SAS Institute).	**At 12 months**: DV1- Weight loss using low fat-carbohydrate intake diet (-1.14+-0.18 kg body weight/100 kcal carbohydrate, p< 0.0001) specifically, dietary fiber (-1.26 +- 0.28 kg/5g fiber, p<0.0001).	**Level II** **Strengths:** Weight loss after 1 year was associated with increases in carbohydrate intake, specifically dietary fiber, and decreases in total fat and saturated fat intake. **Weaknesses:** There is no measurement on participant's weight (it is not mention in the study) **Conclusion:** Given the widespread public perception that carbohydrates are detrimental in increasing diabetes risk and the increasing prominence of low-carbohydrate diets for weight loss, the current

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
			or 7.8-11.0 mmll/L) during an oral-glucose-tolerance test. **Exclusion**: Participants < 25 years of age, BMI < 24, no elevated fasting plasma glucose concentrations (<95) and impaired glucose tolerance (<140) during an oral-glucose-tolerance test. **Attrition**: 310 (9.6%)					findings are critical to the development of evidence-based recommendations for optimal dietary approaches to prevent diabetes. **Feasibility:** Recommended to use in practice.

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Wolever et al. (2017) Effects of changing the amount and source of dietary carbohydrates on symptoms and dietary satisfaction over a 1-year period in subjects with type 2 diabetes: Canadian trial of carbohydrates in diabetes. **Country**: Canada **Funding**: Author obtained funding for the study. **Bias**: Author is partial owner of Glycemic Index Laboratories. Received consulting fees from McCain Foods, Bunge, and Temasek	Health Belief Model	**Design:** Randomized Control Trial **Purpose**: To evaluate if the long-term effects of changing the amount of carbohydrates on quality of life, symptoms and dietary satisfaction in T2D patients.	n-130 IG1- 41 IG2- 45 IG3- 44 **Demographics**: Males and females 35 to 75 years of age **Setting**: Department of Nutritional Services, Ontario Canada **Inclusion**: Men and no pregnant women with T2D (fasting plasma glucose >7.0 mmol/L or 2-hour plasma glucose after 75G oral glucose tolerance test > 11.1 mmol/L, whose diabetes was managed by diet alone. 35-75 years of age, had A1C < 13.0 and BMI 24 to 40, otherwise healthy.	IV1- High-Glycemic Index Diet IV2- Low glycemic index diet IV3- Low carbohydrate diet DV1- quality of life DV2- GI symptoms DV3- Dietary satisfaction **Time frame of the intervention**: 12 months	DV1- Quality of life The Quality of Life questionnaire was adapted from validated questionnaires and was filled out at baseline and at 12 months. The 5 domains of the questionnaire-general health (3 items), diabetes management self-efficacy (4 items), energy (5 items), emotional well-being (4 items) and physical functioning (13 items)- were scored as the weighted average of the scores on each item, with each item given equal weight.	Dietary intakes and quality of life scores were assessed using analysis of variance (ANOVA). The Spearman correlation coefficient was used to assess the correlation among variables.	DV1- Quality of life (no differences in QOL among the diet groups at baseline, and end of study) DV2- GI symptoms Flatulence associated with fiber intake (7.8+-1.4, p=0.019) DV3- Dietary satisfaction Low carbohydrate diet (p=0.0065) and greater enjoyment of eating (p=0.0003).	**Level II** **Strengths:** The study shows that diets containing 40% of energy from carbohydrate may be more satisfying to adults with type 2 diabetes than those containing 50% carbohydrate. **Weaknesses:** Their findings of dietary satisfaction need to be interpreted with caution because the intervention they used is different from usual dietary advice that requires clients to provide their own foods. Therefore, the findings may not necessarily apply to standard medical nutrition therapy. A1C levels increased over the

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Citation	Theory/ Conceptual Framework	Design/ Method	Sample/ Setting	Major Variables & Definitions	Measurement / Instrumentation	Data Analysis (stats used)	Findings/ Results	Level/Quality of Evidence; Decision for practice/ application to practice
Polytechnic; other authors did not report any relevant conflicts of interest.			**Exclusion**: Pregnant women, people older than 75 years of age, A1C > 13 %, BMI > 40. **Attrition:** 32 (20%)		DV2- GI symptoms The symptom questionnaire is the same as that used in our previous trial of acarbose in the treatment of diabetes. DV3- Dietary satisfaction The dietary satisfaction questionnaire was adapted from that used in the Diabetes Control and Complications Trial.			1-year period of the study, and there was no significant difference in A1C level change in the three diets (High-GI diet, Low GI diet and Low carbohydrate diet). **Conclusion:** According to the study hemoglobin A1C levels decreased less in those patients that gain less weight. Some variation is shown regarding the three diets presented on the study. **Feasibility:** Needs further evaluation.

Key: **A1C**- glycated hemoglobin; **BMI**- body mass index; **BP**- blood pressure; **CA**- cancer; **CNS**- central nervous system; **CV**- cardiovascular; **CG**- control group; **DV**-dependent variable; **GFR**- glomerular filtration rate; **HTN**- hypertension; **INR**- international normalized ratio; **IV**- independent variable; **IG**- intervention group; **N**-number of studies; **n**- number of participants; **RCA** – Randomized Control Trial; **T2D**- type two diabetes.

Appendix F

Table 1
Synthesis Table

Study Details										
Author	Andrews	Coppell	Darwiche	Johansen	Jung	Kollannoor	Rock	Shiau	Sylvetsky	Wolever
Year	2011	2017	2016	2017	2014	2016	2014	2018	2017	2017
Design	RC multicenter	Mixed methods non randomized Study	Trial clinical prospective Study	RCT	RCT	Weighted linear regression	RCT	Retrospective Cohort Study	Multicenter RCT	RCT
Level of Evidence	II	III	IV	II	II	V	II	IV	II	II
Number of subjects	593	133	28	93	41	2566	225	317	2924	130
Independent Variables										
Diet	X	X	X	X	X		X	X	X	X
Physical activity	X			X						
Food label						X				
Medication									X	
Dependent Variables										
A1C levels	↑	↓	↑	↓	↑	↑	↑	↑		±
Weight	↑	↑			↑		↑	↑	↑	
BMI			↓		↑					
Findings										
Risk or Harm if Implemented	None	None	None	None	None	None	None	None	None	None

↑ Independent variable showed a statistically significant positive association with dependent variable
↓ Independent variable showed a statistically significant negative association with dependent variable
±- Intervention showed no statistical difference

Table 2

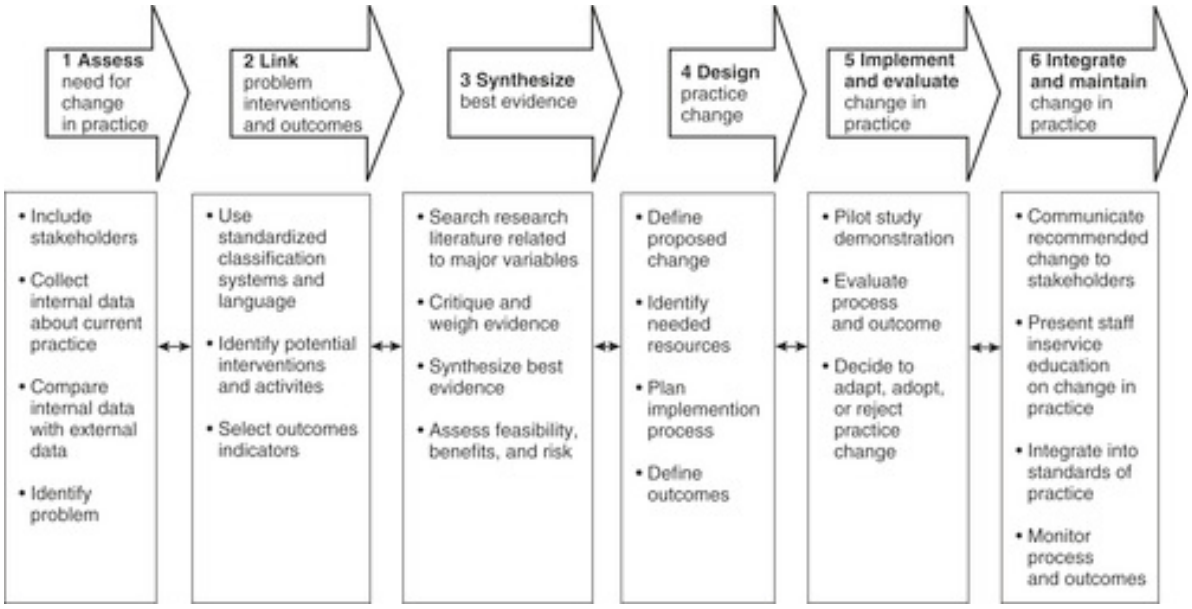
Synthesis Table

Study Details			
Author	Cubillos	Estruch	Martinez-Gonzalez
Year	2017	2013	2012
Design	Clinical pilot	Parallel group-multicenter randomized trial	Cross sectional assessment
Level of Evidence	III	I	III
Number of subjects	19	7447	7447
Independent Variables			
Diet	X	X	X
Physical activity			
Food label			
Medication			
Dependent Variables			
A1C levels	↓	±	↑
Weight	↓	↑	
BMI		↑	↑
Findings			
Risk or Harm if Implemented	None	None	None

↑ Independent variable showed a statistically significant positive association with dependent variable
↓ Independent variable showed a statistically significant negative association with dependent variable
±- Intervention showed no statistical difference

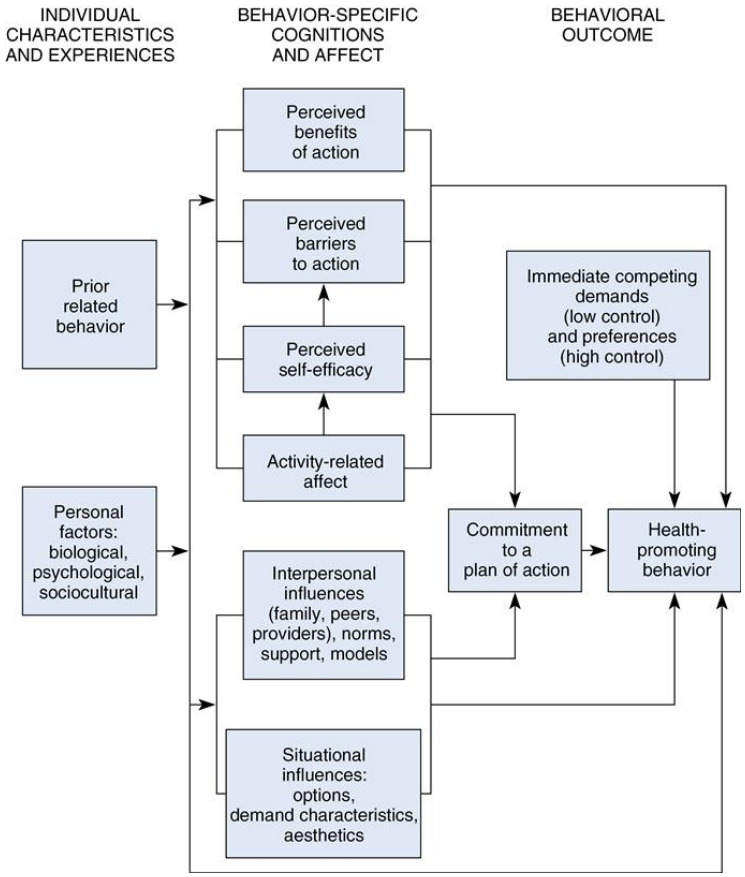
Appendix G

Figure 1.1 Diagram of Rosswurm & Larrabee Model



Appendix H

Figure 1.1 Diagram of Pender's Health Promotion Model



Appendix I

Table 1

Validated 14-Item Questionnaire of Mediterranean Diet Adherence

Questions	***Criteria for 1 point****
1. Do you use olive oil as a main culinary fat?	Yes
2. How much olive oil do you consume in a given day (including oil used for frying, salads, out-of-house meals, etc.)?	More than 4 tbsp.
3. How many vegetable servings do you consume per day? (200 g/7 oz. consider side dishes as half a serving)	More than 2 (more than 1 portion raw or as a salad)
4. How many fruits units (including natural fruit juices) do you consume per day?	More than 3
5. How many servings of red meat, hamburger, or meat products (ham, sausage, tec.) do you consume per day? (1 serving 100-150 g/5 oz.).	Less than 1
6. How many servings of butter, margarine or cream do you consume per day? (1 serving: 12g/0.4 oz.)	Less than 1
7. How many sweet or carbonated beverages do you drink per day?	Less than 1
8. How much wine do you drink per week?	More than 7 glasses
9. How many servings of legumes do you consume per week? (1 serving: 150g/5 oz.)	More than 3
10. How many servings of fish or shellfish do you consume per week? (1 serving 100-150 g / 5oz.of fish or 200 g/7 oz. of shellfish)	More than 3
11. How many times per week do you consume commercial sweets or pastries (not homemade), such as cakes, cookies, biscuits or custard?	Less than 3 custard?
12. How many servings of nuts (including peanuts) do you consume per week? (1 serving 30 g/1 oz.)	More than 3
13. Do you preferentially consume chicken, turkey, or rabbit meat instead of veal, pork, hamburger, or sausage?	Yes
14. How many times per week do you consume vegetables, pasta, rice, or other dishes seasoned with sofrito (sauce made with tomato and onion, leek, or garlic and simmered with olive oil)?	More than 2

**0 points if these criteria are not met. The score for adherence to the Mediterranean diet is based on the 14-Item PREDIMED dietary screener (0 indicates minimum adherence, 14 indicates maximum adherence).*

Permission to use the tool was obtained on 06/29/18 and provided by Dr. Miguel Angel Martinez-Gonzalez, MD, PhD, MPH from the University of Navarra Medical School in Navarra, Spain.

Appendix J

Figure 1.1 IRB Approval Letter

APPROVAL: EXPEDITED REVIEW

Lynda Root
CONHI: DNP
602/496-0810
Lynda.Root@asu.edu

Dear Lynda Root:

On 7/30/2018 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	DIET MODIFICATION IN TYPE II DIABETIC PATIENTS
Investigator:	Lynda Root
IRB ID:	STUDY00008541
Category of review:	(5) Data, documents, records, or specimens, (7)(a) Behavioral research
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• Informational_Flyer.pdf, Category: Recruitment Materials; • OPTUM_Approval.pdf, Category: Other (to reflect anything not captured above); • Consent Form, Category: Consent Form; • PRE_Mediterranean_Diet_Assessment_FINAL.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • CITI TRAINING, Category: Other (to reflect anything not captured above); • GOALS.pdf, Category: Participant materials (specific directions for them); • Mediterranean_diet_general_guidelines.pdf, Category: Participant materials (specific directions for them); • Mediterranean Diet Type II Diabetes, Category: IRB Protocol; • Scoring for questionnaire, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • HIPAA, Category: Other (to reflect anything not captured above); • Patient version-Questionnaire, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • CITI TRAINING, Category: Other (to reflect anything not captured above); • IRB clarification letter, Category: Other (to reflect anything not captured above); •POST_Mediterranean_Diet_Assessment_FINAL.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);

The IRB approved the protocol from 7/30/2018 to 7/29/2019 inclusive. Three weeks before 7/29/2019 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 7/29/2019 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol, you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Ana Maria Burger
Ana Maria Burger
Johannah Uriri-Glover
Lynda Root

Appendix K

Figure 1.1 Demographics Questionnaire

Demographics.
Instructions: Please answer the following information about yourself *(circle the correct answer)*

1. **Gender:** Male Female
2. **Age** _____ (***fill in years***)
3. **Ethnicity**: White Hispanic/Latino Asian Black/African American Other_____ (***write in***)
4. **Marital status**: Single Married Widowed Divorced Other
5. **Primarily language:** English Spanish Other_____(***write in***).
6. **Have you heard of a Mediterranean diet?** Yes No Not sure
7. **Have you tried a Mediterranean diet?** Yes No
8. **Do you prepare your own food?** Yes No Sometimes
9. **Who is the primary cook in your home (more than 50% of the time?)** Yourself Spouse/Partner Children Other_____(***write in***).
10. **Are you the primary grocery shopper in your home (more than 50% of the time?)** Yes No
11. **Are you the primary meal planner (more than 50% of the time?)** Yes No
12. **Which of the following categories best describe your employment status?** (***Please check below***)

Full time (40+ hours) _____ Part-time (30 or less) _____ Not Employed_____
Retired_____ Disabled_____

Appendix L

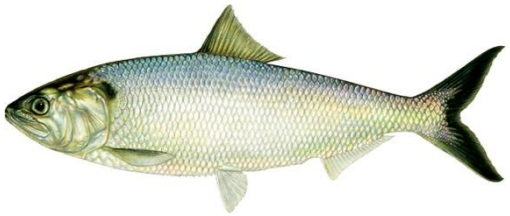
Figure 1.1 Dietary Goals

DIETARY GOALS
for session 1 and session 3

Session 1

Eat at least 3 portions of nuts every week

Eat at least 1 portions of fish every week



Eat at least 3 portions of natural dressing and/or mayonnaise every week, use healthy fats to fry, stew or bake

No more than 2 portions of red meat per day

Reduce consummation of processed meat

Choose margarine without trans fat

Session 3

Try to eat 4 or more portions of vegetables weekly

Choose whole grains options, at least 2 portions a day

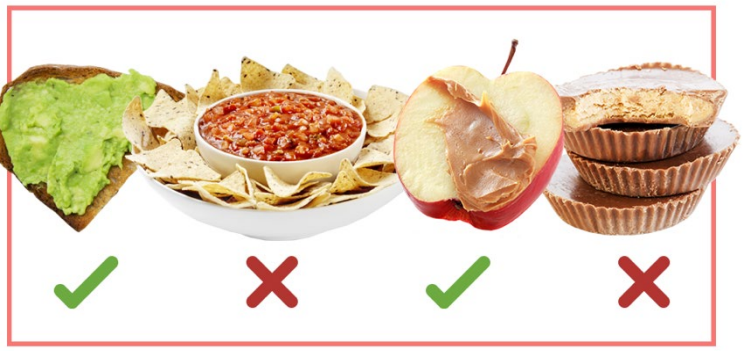
Choose healthy drinks

Careful with chips and cookies. Choose the ones made with vegetable oil

Eat legumes at least 3 times a week

Choose whole grains options for breakfast, at least 3 portions per week

Choose healthy options for snacks and desserts



No more than 2 portions of cold or frozen dessert per week

Try to eat 3 different fruits every day

- *Participants will be asked to select 2 achievable goals at each session. All potential goals for each session are listed.*

Appendix M

Figure 1.1 Informational Flyer

The benefits of a Mediterranean Diet may include reduction of A1c and weight loss

Patients 18 years or older with Type 2 Diabetes are invited to learn more about the proven health benefits of a Mediterranean diet!

Sessions will be given by an RN/Doctor of Practice Student.
Participation includes: 2 sessions on site (20 minutes each session) + 2 coaching phone calls (5-15 minutes each) over an 8-week period (September-November 2018)
Questionnaires and guidelines will be provided to each participant.

There is no cost to you and participation is voluntary. Each participant will receive a detailed information about the diet, a bottle of olive oil, a bag of nuts and a $10.00 Sprouts gift card upon completion.

This is for a research study at Arizona State University

For more information, contact:
Ana Maria Burger RN ASU DNP Student @ (520) 304-3392

Appendix N

Table 1
Mediterranean Diet General Guidelines

Recommended	
Olive oil	More than 4 tbsp./day
Tree nuts and peanuts	More than 3 servings per week
Fresh fruits	More than 3 servings per day
Vegetables	More than 2 servings per day
Fish (especially fatty fish), seafood	More than 3 servings per week
Legumes	More than 3 servings per week
Sofrito (mix of tomatoes, onion and garlic sauce)	More than 2 servings per week
White meat	Instead of red meat
Wine with meals (only for habitual drinkers)	7 glasses per week
Discouraged	
Soda drinks	Less than 1 drink/day
Commercial bakery goods, sweets, and pastries	Less than 3 servings/week
Spread fats	Less than 1 serving/day
Red and processed meats	Less than 1 serving/day
Each serving= 3 ounces	

MORE RECOMMENDATIONS:

- Cook at least twice a week with tomato, garlic and onion adding or not other aromatic herbs, and dress vegetables, pasta, rice and other dishes with tomato, garlic and onion adding or not aromatic herbs. This sauce is made by slowly simmering the minced ingredients with abundant olive oil.

- Two main meals per day should be eaten (seated at a table, lasting more than 20 minutes). For usual drinkers, the dietitian's advice was to use wine as the main source of alcohol (1-3 glasses of wine per day).

- Walnuts, hazelnuts and almonds are highly recommended. As stronger evidence supports that alpha-linolenic acid-rich walnuts might offer special advantages in cardiovascular prevention.

- Try to eliminate or limit the consumption of cream, butter, margarine, cold meat, pate, duck, carbonated and/or sugared beverages, pastries, industrial bakery products (such as cakes, donuts, or cookies), industrial desserts (puddings, custard), French fries or potato chips, and out-of-home pre-cooked cakes and sweets.

Appendix O

Figure 1.1 Informed Consent

Implementation of a Mediterranean Diet on Type 2 Diabetic Patients

To Whom It May Concern:

I am a doctoral student under the direction of Professor Lynda Root, DNP, RN in the Doctor of Nursing Practice Program at College of Nursing and Health Innovation at Arizona State University. I am conducting an evidence based project to introduce a Mediterranean diet with patients who have type 2 diabetes.

Your participation would involve - two (20 minutes) educational sessions at the clinic following your usual scheduled appointments; and two (5-15 minutes) phone conversations to review your progress (date and time to be determined with participants), completion of a pre and post-questionnaire and a demographics questionnaire (26 questions-five minutes to complete) on visit one, repeated on follow up visit two (14 questions to complete) during your usual scheduled appointment). Data will be taken from your medical record (weight and hemoglobin A1c) for study use to measure outcome of diet. The pre and post study questionnaire will be used to determine if the information has modified your diet. This study is to be completed within two months and each session and questionnaire will be individually linked.
Your participation in this study is voluntary. Participants need to be 18 years or older to be eligible to participate. There will be no penalty if you choose not to participate or to withdraw from the study at any time. There is no additional cost to the participant, routinely collected lab results at the time of the visit will be used. If you choose to participate, you have the right to skip any questions and to stop participation at any time.

Benefits to participation include increased knowledge on the Mediterranean diet, potential weight loss and potential decrease on hemoglobin A1c level. Participants will receive a bottle of olive oil (visit one), a bag of nuts (almonds or walnuts) and a $10.00 Sprouts gift card (visit two). There are no foreseeable risks to your participation.
Study results could be used in presentations, or publications, but your name will not be reported. Any reporting of results will be in aggregate form only. The pre and post assessments will be linked in a group form and not on an individual level.

If you agree to participate in this study, please return this signed consent and the pre-questionnaire in the attached envelope to the front desk at check out, attention to: Ana Maria Burger.
If you have any questions concerning the program, please contact the study team: Ana Maria Burger, DNP student at 520-304-3392 or at aburger2@asu.edu; or Dr. Lynda Root DNP, PMHCNS-BC at (602) 496-0810 or Lynda.Root@asu.edu

If you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.
By signing below, you are agreeing to participate in this study.

Name:

Signature: Date:

Appendix P

Table 1
Intervention Timeline

Week 0	Recruitment: ● *Informational Flyers* (Appendix M) were posted in the clinic waiting room. ● Eligible patients were identified (patients with diabetes type 2, adults > 18 years of age, male-female) by the physicians, nurse practitioners, medical assistants and/or receptionists. All established or new patients with a diagnosis of type 2 diabetes were given an *informational flyer*. ● Interested participants were contacted by phone and in person (at site) by DNP student.
Week 1 Session 1 First intervention	● Written informed consent (Appendix O) was obtained from eligible participants by DNP student. ● Weight was recorded by the medical assistant and documented in the patient's electronic medical record (EMR). ● Per routine visit protocol, the Hemoglobin A1c was drawn by the laboratory phlebotomist at the clinic and recorded in the patient's electronic medical record (EMR). Session one. DNP student: ● Provided an overview of the program explaining to the participants what the program entails including: number of sessions, diet guidelines and recommendations. ● Administered the *14-Item Mediterranean Diet Assessment Tool* (Appendix I) ● Reviewed the dietary content for session 1. Using the *Mediterranean Diet General Guidelines handout* (oils, dressing, nuts, fish and meats) (Appendix N). ● Reviewed *Diet Goals Handout* (Appendix L) (used for session one and three). ● A tailored action plan was developed by the DNP student and the participant by highlighting potential areas for dietary improvement as identified by the *Mediterranean Diet General Guidelines.* ● Assisted the patient to select from the *Diet Goals Handout* two achievable diet modification goals to work on before the next counseling session. At the conclusion of session 1, participants received a bottle of olive oil (medium size) and a Sprouts gift card with a value of $10.00 to buy fruits and vegetables.
Week 2	No activities this week.

Week 3 Session 2	● Phone call (approx. 5-15 minutes) to review content from session 1 and to identify progress on reaching goals were made. *(questions to ask: do you remember your goals? were you able to follow your goals? if not, how can I assist you to achieve your goals?)*
Week 4	No activities this week.
Week 5 Session 3	Session three. ● Each participant received counseling on the dietary content of the following foods: Beverages, desserts, fruits and vegetables, grains and beans (based on the *Mediterranean Diet General Guidelines*) ● Selected another two achievable goals. ● Administered the *14-Item Mediterranean Diet Assessment Tool* At the end of the session participants received a bag of nuts –medium size- (walnuts or almonds according to participant preference).
Week 6	No activities this week.
Week 7 Session 4	● Phone call (approx. 5-15 minutes) to review content from session 3 and to identify progress on reaching goals were made. *(questions to ask: do you remember your goals? were you able to follow your goals? if not, how can I assist you to achieve your goals?)*
Week 8	Beginning of post assessment sessions.
Post assessment	During their routine follow up visit with their provider: ● Weight was recorded by the medical assistant and documented in the patient's electronic medical record (EMR). ● Per routine visit protocol, the Hemoglobin A1c was drawn by the laboratory phlebotomist at the clinic and recorded in the patient's electronic medical record (EMR). ● Outcomes of the project were reviewed with each participant at the clinic (hemoglobin A1c, weight and results of Mediterranean Assessment Tool)