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Nutritional Management for Diagnosed Type 2 Diabetic Patients within a Primary Care Setting

Author
Waas, Roshani

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Doctor of Nursing Practice

by

Roshani Waas

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ABSTRACT OF THE DISSERTATION

Nutritional Management for Diagnosed Type 2 Diabetic Patients within a Primary Care Setting

by

Roshani Waas

Doctor of Nursing Practice

University of California, Los Angeles, 2022

Professor Dorothy Wiley, Chair

Objectives: To standardize health education about low carbohydrate diets, portion size control, and nutritional label literacy in an outpatient setting to increase patient's knowledge and facilitate behavior change as a means to better manage Type 2 Diabetes Mellitus.

Background: Type 2 diabetes mellitus (T2DM) is a growing public health concern that affects nearly 29 million and now is the seventh leading cause of death in U.S. residents; 10% of U.S. residents were T2DM-affected in 2017, as many as 33% may be affected by 2025. Standardization of nutritional education for diabetes management can improve health outcomes

and achieve glycemic control. Nutritional interventions focused on calorie reduction, and minimal carbohydrate intake are recognized to be the basis of treatment.

Methods*:* Participants (n=14) received standardized evidence-based nutrition education intervention focused on a low carbohydrate diet, portion size control, and nutrition label literacy within a primary care setting. Participants had an eight-week follow up visit with the same provider to reinforce subject matter and collect data. The primary outcome of the intervention was HgbA1c, and secondary outcomes were knowledge retention, improved BMI, and improved TTM stage of change which were measured at the baseline and eight-week follow-up visit. Patient satisfaction were also measured at eight-week follow up.

Results*:* Of the 14 participants, nine showed lower HgbA1c at the post-intervention visit, one showed no change, and four showed a higher measurement; with mean and median measures of 7.53% (SD 0.90) and 7.2%, respectively. Changes in knowledge score between the pre and post intervention visits were positive, meaning participants either scored the same or higher of up to six points increase on their post-intervention score. Specifically, the mean of the pre- and post-intervention knowledge scores were 5.7 (SD 1.48) and 7.3 (SD 2.02), respectively, and the difference in knowledge across individuals was 1.64 (SD=1.5). No statistical significance in pre and post intervention for BMI. Overall, positive feedback was received on the patient satisfaction survey.

Conclusions and Implications: Implementing a standardized, low-cost approach to include nutritional education focusing on portion size control, nutrition label literacy, and low carbohydrate in primary care may help achieve glycemic control. Focusing on preventive care may sustain potential return of investment through limited expenditures on specialty care services.

The dissertation of Roshani Waas is approved.

Sarah E. Choi

Anna Gawlinski

Eunice Lee

Dorothy Wiley, Committee Chair

University of California, Los Angeles

2022

This dissertation is dedicated to my parents who cultivated a passion for higher education, a life devoted to continuous scholarship, and an aspiration to improve the health for others. To my mother, Sharmaine Waas who instilled in me the power of knowledge and endless learning. Your unwavering support and resilient spirit always inspire me to be better. In memory of my father, Paul Waas who inspired this DNP project and fostered my curiosity to combine both nutrition and health. You are the motivation of my scholarly project and instilled in me the value to utilize food as medicine.

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VITA

CURRICULUM VITAE

Roshani Waas, DNP(C), MSN, RN, FNP-BC

EDUCATION

Doctor of Nursing Practice (DNP)	University of California, Los Angeles	2020 – present [Anticipate 2022]
Master of Science in Nursing (MSN)	University of Pennsylvania, Philadelphia, PA *Major Concentration: Family Health Nurse Practitioner; Minor: Women's Health*	2015-2018
Bachelor of Science in Nursing (BSN)	University of Pennsylvania, Philadelphia, PA *Cum Laude*	2015 - 2016
Bachelor of Science (BS)	University of California, San Diego, CA *Major Concentration: Biology; Minor: Public Health*	2008-2013

PROFESSIONAL EXPERIENCES

2020-Present	Nurse Practitioner	Facey Medical Group-Family Medicine, Los Angeles, CA
2018-Present	Nurse Practitioner	Planned Parenthood, Los Angeles CA
2018- Present	Clinical Preceptor	Planned Parenthood, Los Angeles CA

ADMINISTRATIVE POSITIONS

2017-2018	Data Analyst	Philadelphia Department of Public Health, Philadelphia PA
2015-2018	Research Analyst	University of Pennsylvania School of Nursing, Philadelphia PA *Step Up to Prevention HPV/Cervical Cancer Study*
2016-2018	Research Analyst	University of Pennsylvania School of Nursing, Philadelphia, PA *Can fNIRS detect brain differences that affect HIV risk behavior in young women?*
2012-2013	Consultant	Chancellor's Advisory Committee on the Status of Women. Office of Vice Chancellor of Equity, Diversity, and Inclusion. University of California, San Diego

CERTIFICATION

Family Nurse Practitioner (FNP-BC)	American Nurses Credentialling Center	Issued: 04/2018 Exp: 04/2023

LICENSURE

California	Registered Nurse Family Nurse Practitioner Nurse Practitioner Furnishing License	Exp: 10/2023
Drug Enforcement Administration	DEA	Exp: 10/2022

HONORS AND SPECIAL AWARDS

2019	Longevity Service Award	Planned Parenthood Federation of America (National)
2017	Hearst Foundation Academic Scholarship	University of Pennsylvania
2016	Honors – Graduated *Cum Laude* GPA 3.5/4.0	University of Pennsylvania
2016	Ruth Colket Academic Scholarship	University of Pennsylvania
2016	Nursing Excellence Award/Scholarship	University of Pennsylvania

PUBLICATIONS

1 Teitelman, A. M., Kim, S. K., **Waas, R**., DeSenna, A., Duncan, R.(2018) Development of the NowIKnow Mobile Application to Promote Completion of HPV Vaccine Series Among Young Adult Women. *Journal of Obstetric, Gynecological and Neonatal Nursing.* Volume 47, Issue 6, Pages 844–852 https://doi.org/10.1016/j.jogn.2018.06.001

NATIONAL CONFERENCE PRESENTATIONS

1 Teitelman, A., Kim, S. K., Chittams J., Anglin, O., DeSenna, A., Teising, S., **Waas, R**., Reyes. J., Nichols, G. A technology enhanced intervention increases uptake of HPV vaccine among young women ages 18-26. [oral presentation] 21st Biennial International Council on Women's Health Issues Congress - Nov. 6-9, 2016 - Baltimore, MD.

2 Teitelman, A., **Waas, R**., Kim, S.K., DeSenna, A., Anglin, O., Teising, S., Reyes. J., Duncan, R. Development and acceptability of a mobile application for promoting adherence to the Human Papilloma Virus (HPV) vaccine. [Poster presentation] 21st Biennial International Council on Women's Health Issues Congress - Nov. 6-9, 2016 - Baltimore, MD.

PROFESSIONAL MEMBERSHIPS

2018-Present	American Nurses Association, Member
2020-Present	California Association for Nurse Practitioners, Member

CHAPTER ONE: INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a growing public health concern that affects nearly 29 million and now is the seventh leading cause of death in U.S. residents (Diabetes Care, 2021). Some estimates suggest that T2DM-affected adults show a 1.8-fold higher risk for myocardial infarction-related death than unaffected adults (Diabetes Care, 2021). While nearly 10% of U.S. residents were T2DM-affected in 2017, as many as 33% may be affected by 2025 (Centers for Disease Control and Prevention {CDC}, 2017; Boyle et al., 2010; as cited in Ahmed, 2020). The management of T2DM and its comorbidities in primary care settings has caused exorbitant health care expenditures. Currently, 25% of healthcare costs are spent on diabetes management, ultimately costing $237 billion each year on direct medical expenses related to diabetes (Ma et al., 2020).

Nonetheless, diabetes management is a persistent problem in primary-care health settings. Specifically, a systematic review of qualitative research suggests that clinicians may have unrealistic expectations about the daily experiences of their T2DM-affected patients relative to the challenges of self-care management (Rushforth et al., 2016). These may be further affected by a limited appreciation of the socio-economic limitations and cultural beliefs that affect self-care and adherence to recommended behavior change as a treatment for early T2DM (Rushforth et al., 2016).

Last, limited health literacy alone is associated with a higher risk for death and may significantly influence patient self-care behaviors in low-income clinical care settings (Fan et al., 2021). A quantitative predictive study of glycemic control showed that health literacy is positively associated with diabetic knowledge in T2DM-affected adults (Bains & Egede, 2011).

Thus, focusing on health literacy skills that are important to glycemic control can improve T2DM outcomes for affected adults.

Pathophysiology

Although early diabetes is reversible with consistent, disciplined adherence to a low fat, low carbohydrate, lean protein, calorie-controlled diet, and routine weekly exercise, T2DM that requires exogenous insulin is a permanent, progressive disease (Freeman & Pennings, 2021). The underlying cause of diabetes is insulin resistance, a defected biological response to balancing endogenous insulin production (Freeman & Pennings, 2021). Increased levels of endogenous insulin follow weight gain targeting the liver, muscle, and adipose tissue. Increased weight leads to more insulin resistance, causing a damaging cycle until the body can no longer effectively produce insulin leading to greater insulin resistance, resulting in hyperglycemia. The consequence of insulin resistance is T2DM and is thought to develop 10 to 15 years before biomarkers confirm hyperglycemia (Freeman & Pennings, 2021).

Nutritional Interventions

Nutritional interventions focused on calorie reduction and minimal carbohydrate intake are recognized to be the basis of treatment (Freeman & Pennings, 2021). National American Diabetes Association (ADA) standard of care recommendations includes nutritional and physical exercise guidance for managing all T2DM-affected adults and children (Diabetes Care, 2021). The Diabetes Self-Management Education and Support Toolkit underscores the importance of incorporating healthy-eating education into diabetes care (Centers for Disease Control and Prevention {CDC}, 2017; as cited in Fain, 2017). Nearly half of T2DM patients do not achieve glycemic control through medication-focused approaches alone (Polonsky & Henry, 2016).

Making dietary changes is an intricate, challenging process that requires consistent, daily decision-making (Breland et al., 2013; Cheng et al., 2016).

Multiple factors such as limited resources, social and economic barriers, cost, transportation, communication difficulties, frustration, empowerment level, baseline diabetes knowledge, and duration of diabetes of the patient impede this form of management (Cheng et al., 2016). These barriers are witnessed in the clinic where the quality improvement initiative has been implemented. These barriers lead to inconsistent and non-standardized nutritional education for patients with T2DM in the project clinic setting. Health literacy impacts diabetes knowledge and directly affects self-management (Polonsky & Henry, 2016). Improving patients' health literacy can promote awareness of how daily dietary choices influence health status and disease progression. Thus, these data suggest that focused education to increase diabetes health literacy to improve measurable outcomes may increase adherence to lifestyle change.

This quality improvement (QI) project aims to implement a standardized, evidence-based nutrition education intervention to improve adherence to a low-carbohydrate diet, portion-size control, and nutrition-label literacy to improve T2DM knowledge and biomarkers: hemoglobin A1c (HgbA1c), and body mass index (BMI). The QI project will also assess patient satisfaction to evaluate the feasibility and acceptability of this approach in a primary care setting.

Problem Statement

Approximately 10.5% of the U.S population were diagnosed with diabetes in 2018; cases are projected to increase by 54% by 2030 (Diabetes Care, 2021). The total annual expenditure for medical care of T2DM may reach $622 billion by 2030 (Ma et al., 2020). Some studies have shown that practicing a healthy diet, achieving weight loss, and consistent physical activity can

improve glucose control and decrease cardiovascular risk factors (Ahmed, 2020; Morris et al., 2019; Snorgard et al., 2017; Tay et al., 2015). With a 12% national increase in the prevalence of T2DM among adults' projects poorly for quality and quantity of life over the next 20 or more years, effective changes are needed to improve adherence to nutritional guidelines for T2DM-affected adults (CDC, 2020).

This Doctor of Nursing Practice (DNP) quality improvement project is imperative to address a care gap by providing added, standardized nutritional education that focuses on three tasks (portion size control, low carbohydrate foods, and nutrition label literacy) in a primary care setting. This project supports T2DM patients in achieving glycemic control and potentially reducing the morbidity and mortality associated with diabetes through better nutrition literacy. The DNP project provides standardized, evidence based T2DM nutritional education in a pragmatic, achievable approach to improving health outcomes. Most providers possess the skills and knowledge to educate patients about low-carbohydrate diets and regular physical activity (Breland et al., 2013). However, providers may have limited time and skills to personalize their intervention to individual levels of readiness for change (Breland et al., 2013; Tseng et al., 2017). T2DM patients may be labeled as non-compliant or poorly controlled. Poor compliance may reflect a patient's lack of knowledge or resources and limited motivation for change or goal setting. Labeling patients blame the patient without recognizing the intricacies involved in long-term behavior change (Rahimi et al., 2019; Tseng et al., 2017; Melnyk & Fineout-Overholt, 2019). This DNP project standardizes health education about low carbohydrate diets, portion size control, and nutritional label literacy to increase patient's knowledge and facilitate a behavior change as a means to better manage T2DM (Rahimi et al., 2019; Tseng et al., 2017; Melnyk & Fineout-Overholt, 2019).

Clinical Question

In adults (18 years and older) with T2DM (P), is standardized, evidence-based nutrition education intervention (low carbohydrate diet, portion control, and nutrition label literacy) (I) added to the standard of care, compared to current practice alone of diabetic education that was non-standardized and dependent on individual clinicians' time and skills (C) more effective in improving T2DM outcomes (hemoglobin A1c (HgbA1c), body mass index (BMI), and knowledge retention) (O) within eight weeks (T)?

CHAPTER TWO: THEORETICAL FRAMEWORK

The Trans Theoretical Model of Change (TTM) has been applied to many health behaviors to facilitate health transformations and assess patients' readiness for lifestyle modifications (Tseng et al., 2017). This model states that the readiness for behavior change is a unique adaptation specific to the individual (Butts & Rich, 2017). Some individuals may be open to behavioral change, others are already making behavioral changes, and few are not apt to change. In the context of lifestyle modifications, this theory for behavioral adjustment plays an essential role in assessing a patient's readiness for change. The stages of change paradigm are a critical factor in the TTM, illustrating that individuals are at various stages of behavioral modification, which needs assessment to initiate lifestyle transformations.

The stages for the TTM include pre-contemplation, where there is negligible desire or acknowledgment of the need for change (Holmen et al., 2016). With contemplation, thoughts of changing but no action are generally undertaken (Rahimi et al., 2019). When individuals arrange for change, preparation is realized, and new behaviors are assimilated (Rahimi et al., 2019). Last, maintenance is emblematic of the continued practice of healthier behaviors (Rahimi et al., 2019).

Application of TTM on Diabetic Education

The ability to practice dietary self-management consistently requires knowledge and comprehension of simple how-to's that may decrease the progression of their disease: low carbohydrate nutrition sources, portion size control, and nutritional-label literacy (Holmen et al., 2016). Possibly, poor HgbA1c is emblematic of pre-contemplation (Holmen et al., 2016). T2DM-affected adults with low health literacy show a lower stage of change and are more likely to evidence pre-contemplation (Tseng et al., 2017). TTM may improve the identification of hesitancy for change; alternatively, hesitancy may underscore knowledge deficits for T2DM dietary control (Tseng et al., 2017). Through applying the TTM, the clinician can identify the current stage of change the patient is in and improve health literacy to increase diabetes knowledge, subsequently helping progress the patient on the continuum towards action.

Motivational interviewing was applied at the initial visit through a knowledge assessment survey to identify patients' current stage of change and health literacy. Understanding the patient's readiness for change provided helpful information on the present stage and address any barriers to initiating diabetic lifestyle choices (Tseng et al., 2017). Nutritional education aimed at glycemic control may facilitate conversion from the lower stage of change to active stages of change (Tseng et al., 2017). For many people, the TTM illustrates that behavior change is complex and requires continued education and guidance to transition from being unaware of a need for change to considering a change, ultimately making changes, and sustaining them (Butts & Rich, 2017).

CHAPTER THREE: REVIEW OF LITERATURE

A thorough literature review was conducted to understand nutritional management among T2DM patients. Google Scholar and PubMed databases were employed for the literature search. The search terms employed to find relevant articles specific to the project's target population included: adults, 18 years and older (only); T2DM, diabetic, overweight, or obese. Search terms for the intervention include nutritional management, nutritional education, low carbohydrate, diet, or lifestyle intervention. Search terms specific to the intended setting included: primary care or outpatient setting. Last, another term employed in the search was Transtheoretical Model for Change.

The search was limited to articles published between 2015 and 2021. This search generated many reports; articles were included if they specified lifestyle or nutritional intervention, outpatient/primary care setting, T2DM, and adults in the article title. Refining the search helps eliminate a significant number of research papers. Abstracts were then reviewed based on the collection of articles drawn from the search to determine their applicability to the DNP QI project topic.

Articles were eliminated if the abstract did not note the intervention focused on nutritional education within an outpatient setting. This helped narrow the search, and the full text of the selected articles was assessed to determine relevance to the topic of study and the article's validity and reliability. Five papers were chosen due to their specificity to nutritional education of T2DM patients within a primary care setting; two articles were selected due to the focus of TTM among T2DM patients (see Table of Evidence). Based on the literature search conducted, several themes were identified- influence of lifestyle intervention on T2DM care, application of nutritional education program, and TTM for change in T2DM patients.

Lifestyle Interventions for T2DM Patients in Outpatient Setting

In the randomized control trial (RCT), a low carbohydrate, low energy diet for T2DM patients, Morris et al. (2019) evaluated the use of a low-carbohydrate diet that provided fewer than 26% of daily calories for T2DM-affected adults. A DIAMOND (Dietary Approaches to the Management of Type 2 Diabetes Mellitus) nutritional intervention was incorporated over 12 weeks among a sample size of 33 participants measuring participants pre- and post-HgbA1c and weight. The intervention group found an overall mean reduction of HgbA1c of 16.3 mmol/mol (SD 13.3) compared to 0.7 mmol/mol (SD 4.5) for the control group, with an adjusted difference of -15.7 mmol/mol (-24.1 to -7.3, $p< 0.001$). The study found it feasible to implement a low carb, low energy dietary intervention within a primary care clinic ($p<0.001$). The limitation of the study included a small sample size; the study invited 422 patients via letters; however, only 60 (15%) responded, 48 were screened, and 33 were eligible for enrollment. The study's strength concerning the DNP QI project demonstrated the feasibility of employing a low carbohydrate, low-calorie dietary intervention within a primary care setting. In addition, the intervention was conducted over 12 weeks, a comparable timeline to the DNP QI project time frame. This study is relevant to the DNP topic and intervention in its multi-faceted approach of a low carbohydrate diet and portion size guidelines.

Tay et al. (2015) conducted an RCT in Australia to compare low carbohydrate, high fat (LC) and high carbohydrate, low fat (HC) diets for T2DM patients in an outpatient research clinic. This RCT randomly assigned 115 obese adults with T2DM and HgbA1c >7.0 % to a hypocaloric or a high carbohydrate diet. The study design was measured using HgbA1c, fasting blood glucose, diabetes medication, blood pressure, weight, and lipid panel, comparing results at

baseline and 52 weeks of study implementation. The study concluded that both diets noted significant weight loss and HgbA1c improvement (LC diet -1.0% to HC diet -1.0%). However, the low carbohydrate diet noted a more significant improvement of lipid profile, non-fasting blood glucose (LC diet: -1.3 mmol/L; HC diet -1.5 mmol/L; $p = 0.09$) and minimized use of diabetic medications (LC diet: -0.5; HC diet: -0.2; $p = 0.02$). The most notable aspect of the study was that participants were followed for 52 weeks to determine the long-term effects of holistic lifestyle modifications and utilized a large sample size (Tay et al., 2015). The study found a notable decrease in diabetic medications among the low carbohydrate group (95% CI [-0.05, -0.2]; $p = 0.02$). One study executed a highly controlled caloric intake over 52 weeks that provided fewer than 1500 kilocalories daily, using a low carbohydrate diet (Tay et al., 2015). While both the 12- and 52-week interventions achieved lower HbA1c, a safe, rapid transition to improved glycemic control is preferable to a one-year transition (Morris et al., 2019).

Snorgard et al. conducted a systematic review and meta-analysis to examine nutritional therapy in self-management education of T2DM patients (2017). The study aimed to compare low carbohydrate diets to high carbohydrates. Research databases including EMBASE, MEDLINE, and Cochrane review from 2004-2014 assessing outcomes of HgbA1c, weight, and lipid panel identified 10 RCTs consisting of 1376 participants. A low carbohydrate diet showed a 0.34% decrease in HgbA1c (3.7 mmol/mol) in comparison to a high carbohydrate diet 0.06% (0.7 mmol/mol) over 12 months. The study found a significant correlation between a low carbohydrate intake and a greater glucose-lowering effect ($R=-0.85$, $p < 0.01$). Several factors could influence these results, such as medication therapy, baseline HgbA1c, and diet adherence; however, the research demonstrated that low carbohydrate intake could significantly influence

glycemic control for diabetic patients. The study findings help support the DNP QI project's nutritional guidance of a low carbohydrate dietary plan.

Nutritional Education Program

A notable lack of understanding of how diet influences diabetes progression is a significant challenge facing clinicians in T2DM management (Sami et al., 2017). Sami et al. (2017) conducted a systematic review to understand the effects of diet on T2DM using Embase database. A systematic review of 89 intervention studies concluded that diabetes education improves T2DM knowledge, including concepts of disease progression. Specific educational interventions focused on food-group choices, nutrition label reading, portion control, eating habits and attitudes, weight monitoring, and blood glucose monitoring skills maximized glycemic control (Sami et al., 2017). The systematic review found that education on food selection behaviors, specifically carbohydrate intake, is significantly associated with improving dietary knowledge, practices, and treatment compliance. The review concluded that education on diabetic counseling and assessing dietary attitudes could notably enhance patients' quality of life and ease the burden on family members. The study illustrated an unrelenting need for lifestyle interventions and increased demand for dietary awareness. This review also highlighted the ADA (2019) self-dietary management as the sole factor in mitigating complications and weaning off medications (Sami et al., 2019). The review had several limitations, including a lack of information on specific studies analyzed and limited generalizability of findings as studies analyzed were specific to Asia and Europe. A construct of this review pertinent to the DNP QI project is delineating how healthy dietary guidelines and improved food selections can be a salient element of comprehensive diabetes care.

Muchiri et al. (2021) conducted an RCT to evaluate the effects of a customized nutritional education program on HgbA1c in two community health centers. The study was conducted over one year with face-to-face monthly health education meetings (Muchiri et al., 2021). The sample size consisted of 40 participants total, with the intervention consisting of baseline diabetic education, dietary guidelines, meal planning, nutrition label overview, and healthy cooking tips. The study found a -0.63% (P = 0.16) reduction in HgbA1c at 12 months in the intervention group and decreased daily caloric intake of 5988 kj/d compared to the control group, 6946 kJ/d; p = 0.017. The intervention did not result in a significant decrease in BMI, blood pressure, or lipid profile. A limitation of the study included possible underreporting of food intake leading to no significant change among the intervention group for BMI. The findings apply to the DNP QI project in that results underscored a considerable knowledge deficit, poor dietary choices, and financial constraints among participants. Similar to the findings highlighted in Morris et al. (2019), practical dietary education from daily caloric intake, understanding nutrition labels, and portion control can positively impact glycemic control. This RCT incorporated nutritional education interventions such as diabetic pathophysiology, nutrition label overview, reduction in starchy foods, treatment goals, and meal balance that apply to the DNP QI project.

Transtheoretical Model for Change in T2DM Patients

Understanding individuals' stage for lifestyle modification using the TTM model is insightful to gauge one's intention for behavioral change. An RCT aimed to investigate the stage of change for dietary patterns and physical activity of T2DM patients using a mobile health intervention at an outpatient clinic in Norway (Holmen et al., 2016). The study consisted of 151

participants with an average HgbA1c of >7.1% (7.1%-12.4%). The study outcome was measured using the Health Education Impact Questionnaire (heiQ). The TTM stage of change assessment showed that 119 (79%) were in the pre-contemplation stage, and 31 (21%) were in the action stage. This data shows that higher scores on the heiQ, such as being in the action stage, were associated with higher self-monitoring rates and better-controlled HgbA1c (n=31, 58%). Those in the pre-contemplation stage reported lower self-monitoring heiQ scores (1.19 pre-contemplation stage compared to 13.4 action stage), meaning there is a need for lifestyle education and guidance to move towards the desired behavior change. Recognizing that T2DM patients fall in the pre-contemplation stage highlights a need for more advanced support to progress to a higher stage of change. This RCT study showed a significant correlation between the TTM stage of change and daily dietary habits (OR=2.5, 95% CI, 1.10-5.88). The study highlights that individuals in the pre-contemplation stage can benefit from focused professional nutritional guidance. Limitations of the study include volunteer bias as the study utilized a self-reporting questionnaire. The study findings are relevant to the DNP QI project in highlighting the need to understand individuals' current TTM stage of change to transition them to the action stage to achieve better self-management. If patients cannot progress to the action stage, there are still opportunities to educate them on how daily dietary habits influence their T2DM disease progression.

A cross-sectional survey of 232 T2DM participants in a single hospital assessed health knowledge and readiness for behavioral change to illustrate a relationship between the stage of change to health literacy (Tseng et al., 2017). A 10-item nutritional knowledge survey, HgbA1c, BMI, and demographic data were utilized. Newest Vital Sign (NVS) assessed health literacy by having participants review an ice cream nutrition label and complete a six-item questionnaire.

The study found that low health literacy rates were negatively associated with HgbA1c (95% CI -0.2995 [-0.2073, 0.0693] $p< 0.05$). The study demonstrated an indirect effect of individuals' stage of change on health literacy level and overall glycemic control (95% CI -0.0229 [-0.0648 to -0.0019]). Thus, those with higher dietary knowledge progressed into higher stages of change than those with lower health literacy; consequently, enhanced dietary knowledge improved overall glycemic control. Although the study findings are limited in generalizability and utilization of a non-probability sampling method, the results concluded an association between health literacy and readiness for change in dietary behaviors. The study underlines that higher health literacy is linked to better readiness of change, leading to improved HgbA1c, and applicable to the DNP QI project topic of interest. Both Holmen et al. (2016) and Tseng et al. (2017) found poor glycemic control associated with being in the pre-contemplation stage, while Tseng et al. (2017) underline how low health literacy impacts individuals' self-management motivation and brings attention to a need for dietary guidance.

Synthesis of Literature Review

This review suggests that standardized nutritional interventions improve care for T2DM-affected adults. Most evidence we reviewed reports that T2DM diet and exercise education in the outpatient setting is feasible. In 2017, ADA's national diabetes self-management and education standards recommended a healthy eating standard that included a low-carbohydrate diet and portion control (Fain et al., 2017). A low carbohydrate diet is associated with lower levels of HgbA1c (Morris et al., 2019, Snorgard et al., 2017; Tay et al., 2015). Overall, using a low carbohydrate diet requires education about daily dietary choices and their influence on blood sugar (Sami et al., 2019). Concentrating on food sources that collectively provide <40% of daily

calories from carbohydrates is essential to glucose control (CDC, 2021). For example, a recommended 1,800 daily caloric intake requires 800 calories from carbohydrates, approximately 200 grams per day (CDC, 2021).

Overall, evidence also supports the benefit of nutrition label education for T2DM (Muchiri et al., 2021; Sami et al., 2019; Tay et al., 2015). For instance, one systematic review of 17 qualitative studies, nine RCTs, and eight cohort studies showed nutrition label literacy improved chronic illnesses, such as cardiovascular conditions and T2DM, at statistically significant levels (Moore et al., 2018). Lastly, data show portion size dramatically increased in the last quarter of the 20th century among U.S. households and provided an additional 500 kCal/day to the average diet (Young & Nestle, 2002). Two RCTs and a systematic review show portion control and low-calorie diets will lower HgbA1c (Muchiri et al., 2021; Tay et al., 2015, Sami et al., 2019). Thus, together, these data support the combination of a low carbohydrate diet, portion size control, and nutrition label literacy to help achieve glycemic control.

CHAPTER FOUR: METHODS

Project Design

The study design is in the form of a quality improvement (QI) project, quasi-experimental, single group, pre and post-test design. The patient was the control, and changes in knowledge (pre-and post-intervention tests), HgbA1c, and BMI were measured. The quasi-experimental design examines data of patients with no randomization, or a control group involved (Heavey, 2010). The clinical question examined a single group of newly or currently diagnosed T2DM patients. A quasi-experimental design was selected because it can measure the association between an applied intervention and a health outcome (Melnyk & Fineout-Overholt, 2019). Utilizing a pre and post-test design ensures consistent variables are being evaluated before

and after the intervention implementation. This test design eliminates alternative variables for the proposed relationship and ensures the validity of the study results (Melnyk & Fineout-Overholt, 2019).

Sample and Setting

The setting of this quality improvement project is a community-based, privately-owned clinic that provides care to medically underserved adults and children located in the San Fernando Valley, California. Most patients receive publicly funded care through Medicaid (M. Gonzalez, personal communication, August 8, 2021). Currently, this clinic does not employ a nutritional specialist or Registered Dietician on staff. The staff comprises two primary care physicians (PCPs) and one physician assistant managing T2DM-affected adults. Patient education is non-standardized and dependent on individual clinicians' time and skills. Any additional nutrition resources available outside the clinic to each patient are unknown.

The visit setting was in the break room of the outpatient clinic during standard clinic hours and was approximately 45 minutes in length to deliver the standardized, evidence-based nutrition education intervention in its entirety. Family members and those preparing participants' food at home were encouraged to attend the education sessions to help reinforce critical concepts. At their initial visit, follow-up appointments were scheduled with the same DNP project lead, and reminders were sent to ensure retention at the eight-week mark.

There is a significant minority population within the San Fernando Valley, consisting of 42% Hispanic, 11% Asian, and 4.2% African American residents (U.S. Census Bureau, 2019). Of the San Fernando Valley residents, 82% are high school graduates with a mean annual household income of $71, 543. This clinic has diverse patient populations varying in cultural

identities, education levels, and socioeconomic backgrounds. According to a community needs assessment conducted by Dignity Health - Northridge Hospital, the clinic's partnering medical center, T2DM was listed as one of the six prioritized health needs affecting 9% of the population in 2015 (2019). The DNP QI project fulfills a clinical gap and area of need in this community.

Participants for the quality improvement project were recruited using the Electronic Medical Record (EMR), clinic flyers, and PCP referrals. Participants were self or provider referred to participate in the quality improvement project. T2DM-affected adults treated at the community-based clinic and identified from EMR data were invited to participate in two educational visits with the DNP-advanced practice nurse practitioner (APRN).

Eligibility

Adults, 18 to 70 years of age diagnosed with T2DM, show one or more HgbA1c measurements >6.5% over the last six months, report access to a mobile phone device, and agree to attend a follow-up visit scheduled eight weeks after the standardized, evidence-based nutrition education intervention were eligible to participate. Study participants were newly diagnosed T2DM patients or were already on glucose-lowering medications at the time of the study. Conversely, adults diagnosed with Type 1 Diabetes Mellitus or insulin dependent were excluded from participating in the project.

Intervention

Previously, patients received nutritional counseling from providers during routine or extended-office visits where acute and chronic health concerns were managed. Current practice at this clinic includes a two-page nutritional handout to limit carbohydrate intake and provide

suggested daily amounts of food from each food group. This patient handout was published in 2017 and printed on white paper using black ink. The brochure has a readability Flesch-Kincaid grade level of 6.3. The information provided includes many words that can be overwhelming for the patient to follow (see Appendix A).

The primary goal of this QI project was to determine if standardized, evidence-based nutrition education intervention focused on a low carbohydrate diet, portion size control, and nutrition label literacy can improve HgbA1c, BMI, knowledge retention, and patient satisfaction within a primary care setting. The standardized, evidence-based nutrition education intervention consisted of a single, one-on-one session with an eight-week follow-up visit to collect data, review food logs, and reinforce the subject matter introduced at the initial visit. In current practice, T2DM follow-up visits are scheduled every 8-12 weeks to re-evaluate HgbA1c levels (Forouhi et al., 2018). During the initial session, the DNP instructed patients on three key concepts. First, limiting carbohydrate intake to fewer than 40% of daily calories provides a low-carbohydrate diet. Second, limiting carbohydrate or starchy vegetable portions to one-quarter of each meal or one cup per serving (CDC, 2021). Third and last, improved nutrition label literacy for sources of carbohydrates and calories can limit simple sources of starch and sugar in favor of complex fiber, starch, and sugar foods (CDC, 2021). These three dietary practices effectively achieve glycemic control, as evident in the literature review (Morris et al., 2019, Muchiri et al., 2021; Snorgard et al., 2017; Tay et al., 2015).

To reinforce learning, debriefing interventions derived from simulation learning were implemented (Shinnick et al., 2011). After the hands-on activities, debriefing allows for guided reflection for the patient to communicate and teach-back key concepts. This allows patients to verbalize their thoughts and reasoning on the materials that were discussed. Thus, to assess and

reinforce active learning, the DNP-APRN practiced the teach-back method, where the patient will briefly verbalize key concepts gained from the educational session. This allowed the DNP-APRN to re-assess knowledge and reinforce essential concepts. Last, the DNP-APRN has challenged the patient to actively use these skills in the next 48 hours when preparing their meals or grocery shopping.

Study participants were asked to keep a daily food log with a printed food diary provided by the DNP (see Appendix I). The food logs help patients record their caloric intake and guide them with portion control. Food logs were reviewed at their follow-up visit with the DNP-APRN. Participants were also provided a laminated brochure on portion size control to keep on their refrigerator as a daily reinforcement (See Appendix B). Due to the standardized, evidence-based nutrition education intervention assessing nutritional management alone, during the study, medication adjustments for T2DM management were minimized. These data on medication adjustment were also collected. Some quality improvement metrics may be impacted if medication adjustment is required, and data may be confounded. For example, HgbA1c measurement over 12% requires medication adjustment by the PCP. The analysis was adjusted for medication changes over the course of the project through a stratified analysis. This evaluated the effect of the standardized, evidence-based nutrition education intervention in two groups of patients: participants requiring medication changes and those that do not.

Variables

The dependent variables for this project were HgbA1c (%, mmol/mol), BMI (kg/m^2), knowledge retention (%), and patient satisfaction. The project's independent variable was the standardized, evidence-based nutrition education intervention. Specifically, nutrition-based

education focused on three procedures described in the Literature Synthesis and Intervention: low carbohydrate diet plan, nutrition label literacy, and portion-size control using a standardized approach (CDC, 2021; U.S. Department of Agriculture, n.d.). Other covariates of interest include age, gender, number of years since the first diagnosis of T2DM, years of formal education (attending a school), primary household member preparing meals at home, number of T2DM medications currently prescribed, health insurance (private, Medicare, Medicaid, self-pay, charity care, other), number of minutes of weekly exercise.

Implementation, Data Collection, and Rationale

The project commenced in January 2022 and concluded in April 2022. Before the design started, the DNP lead met with Registered Dieticians, Diabetes Educators, APRNs, PCPs, and Clinical Pharmacists (PharmD) to review educational materials provided to study participants during the standardized, evidence-based nutrition education intervention.

HgbA1c is the most accurate biomarker of periodic hyperglycemia, and the successful reduction of HgbA1c is associated with improved glycemic control (Diabetes Care, 2021). This standardized, evidence-based nutrition education intervention measured fingerstick point-of-care HgbA1c at the baseline visit and eight weeks later at the follow-up visit. Although the study's primary goal was to improve glycemic control, it also measured secondary outcomes such as improved BMI, knowledge retention, and patient satisfaction to support or refute the study goals.

A pre-and post-intervention test for T2DM knowledge consisted of ten questions focused on the participant's knowledge about causes of diabetes, the body organ affected, signs of hyperglycemia, benefits of weight loss; healthy eating habits, food choices, and the importance of food labels to maximize nutrient-dense food sources; the importance of dietary fiber (CDC,

2010). Scores were estimated from each quiz and compared to calculate the difference. The greater the difference in pre-and post-intervention scores, the more knowledge attained. The knowledge assessment survey is publicly available: How to Prevent or Delay Type 2 Diabetes Mellitus in Your Community A Training Guide for Community Health Workers (CDC, 2010). A team of clinical experts, including a Registered Dietician, APRN, and clinical pharmacist, reviewed the adapted knowledge assessment for content validity.

Patient satisfaction scores provided an assessment of the feasibility of the standardized, evidence-based nutrition education intervention. Patient satisfaction was measured using a five-point Likert scale to assess the usefulness, organization, and relevance of low-carbohydrate diets, portion control, and nutrition-label literacy. The participant was the control where the pre-intervention baseline characteristics were compared to the measure at eight weeks following instruction.

Age, gender, the number of T2DM medications currently prescribed, and health insurance (private, Medicare, Medicaid, self-pay, charity care, other) were abstracted from the chart using a standardized form. The EMR did not contain individual or household income information; thus, receiving Medicaid health insurance stood as a proxy for low income.

Each participant completed a brief questionnaire. Variables include the number of years since the first diagnosis of T2DM, years of formal education (attending a school), primary household members preparing meals at home, and the number of minutes of weekly exercise. Last, the study participant identification key (IDKEY) files were completed at the first intervention visit to link the Participant_ID variable to identifying information. The IDKEY file was stored on a flash drive, password-protected, and in the medical office under lock and key.

Statistical Analysis

Descriptive, graphical, and tabular analyses were used to explore the data. A Student t-test (e.g., age) and chi-square tests (e.g., gender (Male/Female)) were used to examine associations between continuous and categorical variables, respectively. Skewness, kurtosis, and normality were evaluated using plots. The small sample size and the distribution suggested that the data were not normally distributed. For continuous variables with non-normal distributions, the Wilcoxon test was employed to evaluate the characteristic. The analysis aimed to evaluate the study results was a paired t-test, a form of change scores analysis. The paired-sample t-test is a statistical approach to compare two measurements taken from the same individual separated by time, estimating the average change in pre- and post-intervention outcomes variables of interest for the sample (Heavey, 2010). The paired t-test evaluated the association between the intervention and change in HgbA1c, BMI, knowledge (change), and patient satisfaction. Data analysis was conducted using Microsoft Excel, SAS Statistical software (Version 9.4), and R software (Version 4.0.5).

CHAPTER FIVE: RESULTS

A total of 26 participants were recruited to participate in the study project through provider referral or clinic flyer recruitment distributed at the clinic of project implementation. A total of 12 potential participants were excluded due to their inability to attend scheduled visits (5) or inability to be reached for scheduling (7). Thus, 14 (54%) participants met inclusion criteria: T2DM diagnosis by a primary care provider recorded in the EMR and verbal agreement to participate in the project.

Demographic Characteristics

Overall, the average age was 53.5 years, and participants ranged from 26 to 69 years of age. Half the sample was male. The majority of participants reported themselves as of Hispanic descent (8, 57%), while the remainder reported Asian (5, 36%) or Caucasian (1, 7%) race or ethnicity. Most reported being fluent English speakers, readers, and writers (11, 79%), while three reported Spanish as their primary language. Instruction and interviews were conducted in English or Spanish, with Spanish-language instruction performed by a clinic-certified language translator (Table 1). The educational background of the sample varied from third grade to master's graduate level. Nearly, 85% (12) of participants were married, and 57% (8) reported that they prepared their meals at home (Figure 5). All female participants prepared their meals at home, while most male participants (6/7) reported that a partner or family member prepared their meals.

Nearly 50% of the sample showed recent T2DM diagnosis, and half had been diagnosed for more than nine years. The range between T2DM diagnosis is 1-29 years, with a mean (SD) of 7.65 years and a median of 7 years, respectively. There was no association between the number of T2DM affected years and the current HgbA1c level (Figure 3). Other bivariate relationships that demonstrated no association include years of formal education and HgbA1c (Figure 4) and primary household members preparing meals at home and HgbA1c level (Figure 5).

Table 1: **Sociodemographic and Clinical Characteristics of the Participants at the Baseline Visit**

Sample Characteristics	Number	%
Sex		
Male	7	50
Female	7	50
Race		
Hispanic[1]	8	57

Asian[2]	5	35
Caucasian	1	7
Years since first T2DM diagnosis		
<5 years	7	50
>9 years	7	50
Education		
Less than high school	5	35
Highschool Degree	6	42
Bachelor's Degree	2	14
Master's Degree	1	7
Primary Household preparing meals		
Self	8	57
Partner/Spouse	4	28
Other[3]	2	14
Weekly Exercise (in minutes)		
<60 minutes	5	35
<90 minutes	4	28
>120 minutes	5	35
Primary Language		
English	11	78
Spanish	3	21
Current Medications		
Biguanide	13	92
Thiazolidinediones	1	7
Sulfonylurea	7	50
Dipeptidyl peptidase-4 inhibitor	1	7
Glucagon-like peptide-1 agonist	2	14
Characteristic	Mean (SD)	Median
HgbA1c (%)	8.29 (1.46)	7.4
BMI (kg/m2)	30.1 (9.22)	29.2
Systolic Blood Pressure (mmHg)	136 (17.17)	136
Diastolic Blood Pressure (mmHg)	79 (8.96)	77
[1] Mexican, El Salvadorean		

[2] Filipino, Japanese, India, Korean
[3] Parent, Child

Figure 1: Proportional Distribution of Self-Reported Race at the Baseline Visit

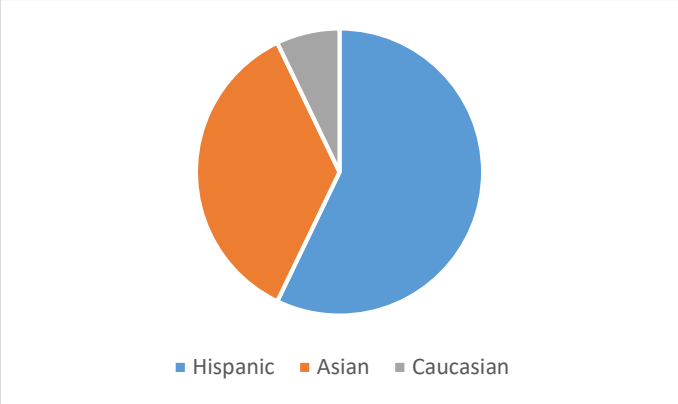


Figure 2: Association Between HgbA1c and Self-reported Race at the Baseline Visit

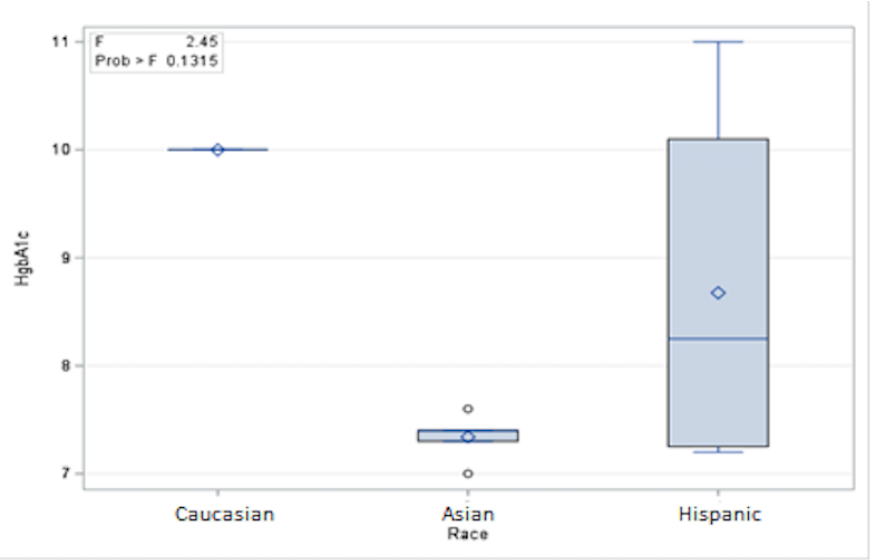


Figure 3: **Association Between Pre-Intervention HgbA1c and Years of T2DM Diagnosis at the Baseline Visit**

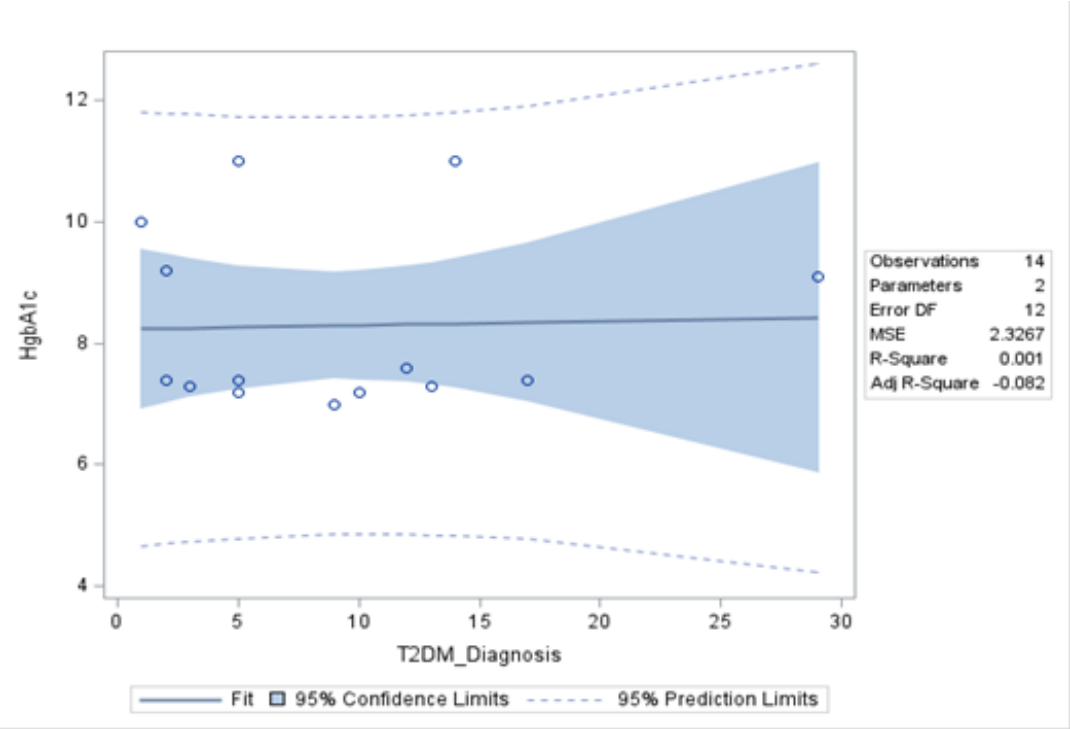


Figure 4: **Association Between HgbA1c and Self-reported Maximum Number of Years of Completed Formal Education**

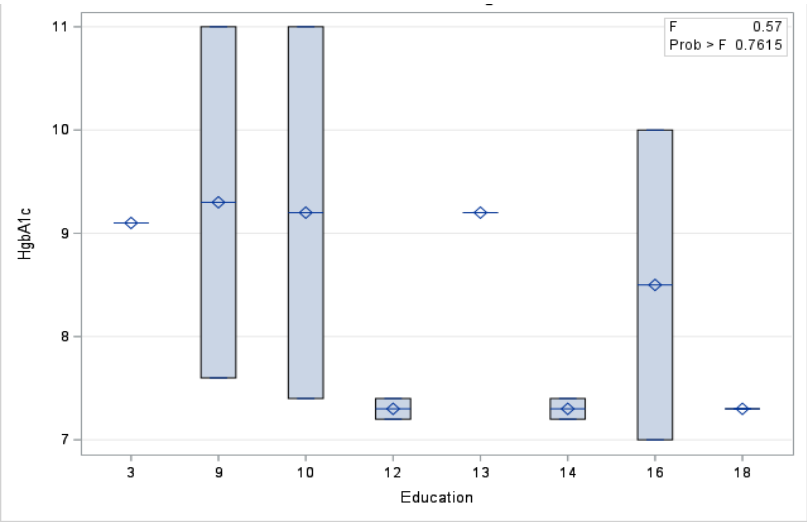
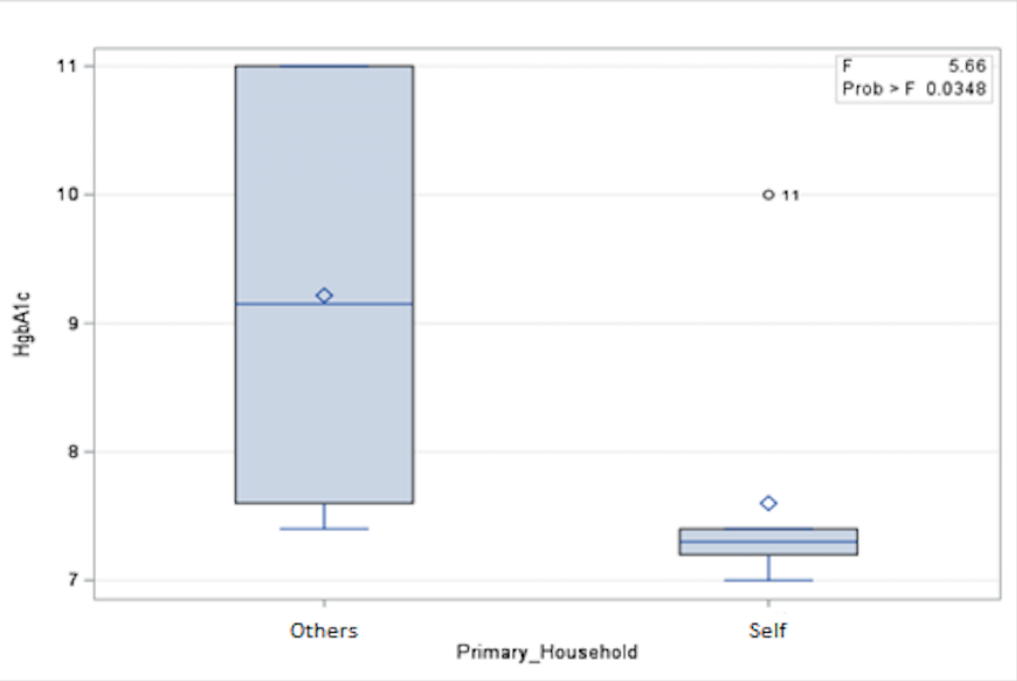


Figure 5: **Association Between HgbA1c and the Household Member Preparing Meals at Home**

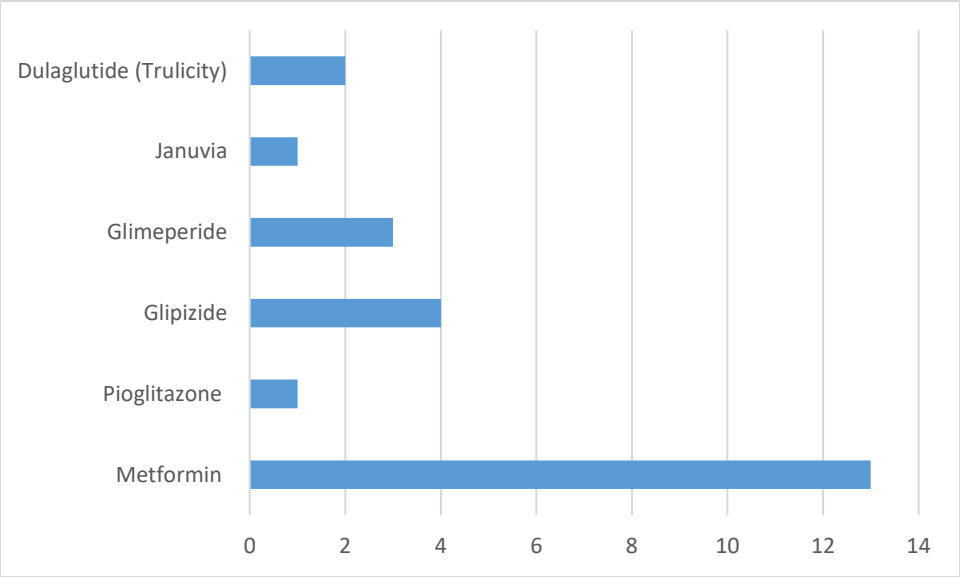


T2DM is associated with overweight and obesity, a sedentary lifestyle, and poor glucose metabolism associated with cardiovascular disease. On average, BMI was 30.1 kg/m2, ranging

from 21.5 to 58.4 kg/m2. Nonetheless, 43% of the sample showed BMI between 31.2 and 58.4 kg/m2. Participants reported their average baseline weekly exercise varied widely: <60 minutes (4, 28%), 61 to 90 minutes (5, 36%), or >120 minutes (5, 36%). More than half of the participants showed one or more comorbid conditions: 64% (9) showed hypertension, and 71% (10) were prescribed statin therapy to prevent or treat hyperlipidemia.

All participants reported taking prescribed oral hypoglycemic agents. These included 92% (13) prescribed biguanide (Metformin), 7% (1) thiazolidinediones (Pioglitazone), 50% (7) sulfonylurea (Glipizide or Glimepiride), 7% (1) dipeptidyl peptidase-4 inhibitor (Januvia), or 14% (2) weekly-injectable glucagon-like peptide-1 agonist (Trulicity). Nearly 57% (8) were prescribed multiple hypoglycemic agents.

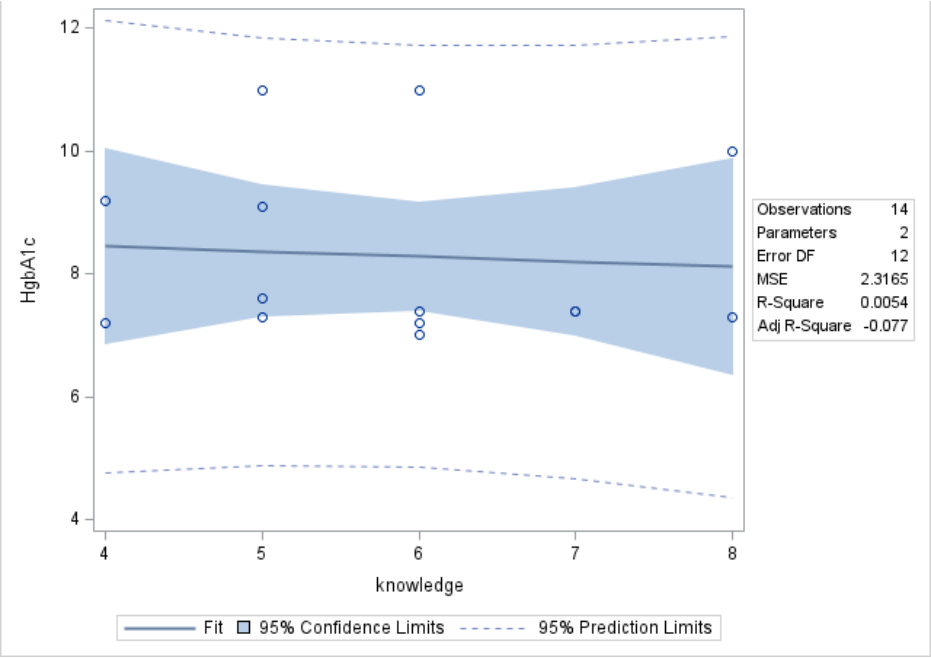
Figure 6: **Distribution of Oral and Injectable Hypoglycemic Agent Currently Prescribed**



T2DM Knowledge at Baseline Visit

All participants completed the pre-intervention assessment of T2DM about causes of diabetes, the body organ affected, signs of hyperglycemia, healthy eating habits, and food choices using a 10-item standardized questionnaire (CDC, 2010). Participants completed either English (11) or Spanish (3) questionnaires. There was no statistically significant association between HgbA1c level and Pre-Knowledge assessment scores (Figure 7).

Figure 7: **Fit Plot between HgbA1c and Pre-Knowledge Assessment**



Effects of Intervention on HgbA1c

At the pre-intervention visit, the average HgbA1c was 8.29% (SD 1.46), somewhat higher than the median level, 7.4%. While paired observations are available, the post-intervention HgbA1c mean and median measures were similar to the pre-intervention measures but more closely approximated, 7.53% (SD 0.90) and 7.2%, respectively. The pre- and post-intervention HgbA1c is presented in a table (Supplementary Table 1, Appendix C). Of the 14

participants, nine showed lower HgbA1c at the post-intervention visit, one showed no change, and four showed a higher measurement. Changes in HgbA1c levels between the pre- and post-intervention visits ranged from -3.0 to 5.0 units. The mean change in hemoglobin level in the sample was -0.76 units. This is the point estimate for the population mean (the mean effect of the intervention that we would expect in the relevant population), and a 95% confidence interval is (-1.45, -0.07). The data roughly meet the criteria for a paired t-test, which gives a p-value of 0.03. The nonparametric Wilcoxon test gives a p-value of 0.06. Thus, we have some evidence that the standardized, evidence-based nutrition education intervention may decrease HgbA1c levels. See the boxplots for a visualization of the distribution of pre- and post-intervention levels (see Appendix D) and the arrow plot for a visualization of the changes for each individual (Figure 9). Two participants reported that their primary care provider decreased one hypoglycemic medication between the pre- and post-intervention visits. Specifically, both decreased one oral hypoglycemic by half the daily prescribed dose.

Table 2: **Pre-Intervention and Post-Intervention Participant Characteristic**

	Mean	Standard Deviation	95% Confidence Interval	Minimum - Maximum	*p* (Paired t-Test)	*p* (Wilcoxon Test)
HgbA1c (%)						
Before	8.29	1.46	-	(7.0, 11)	-	-
After	7.53	0.90	-	(6.5, 9.6)	-	-
Difference	-0.76	1.19	(-3.1, 1.58)	-	0.03	0.06
BMI (kg/m^2)						
Before	30.1	9.2	-	(21.5, 58.4)	-	-
After	29.6	9.04	-	(22.3, 58.0)	-	-
Difference	-0.51	1.31	(-3.08, 2.06)	-	0.17	0.07
Knowledge Questionnaire						
Before	5.7	1.48	-	(3, 8)	-	-
After	7.3	2.02	-	(3, 10)	-	-
Difference	1.64	1.50	(-1.30, 4.58)	-	N/A	0.002

Figure 8: Comparison of Pre-Intervention and Post-Intervention HgbA1c at Eight Week Follow Up Visit

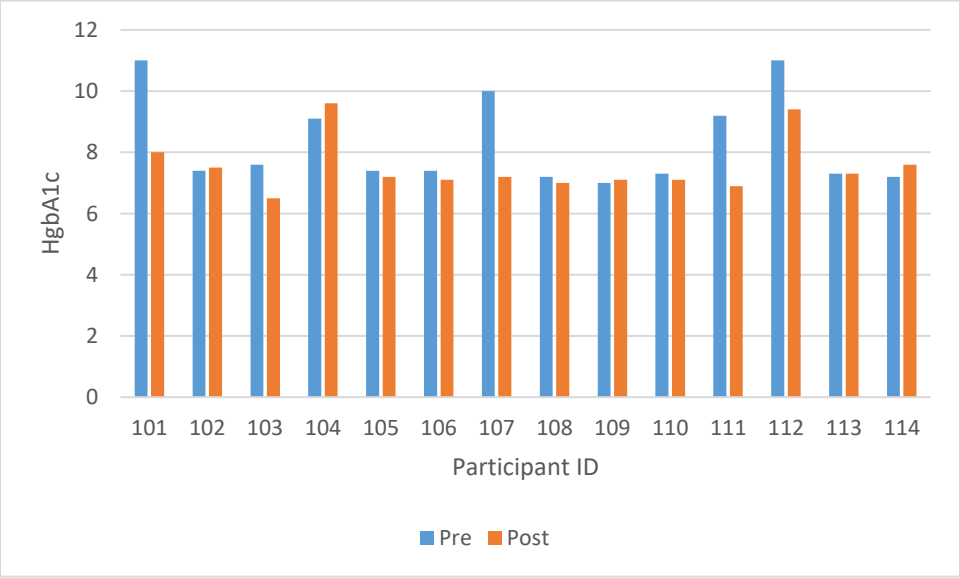
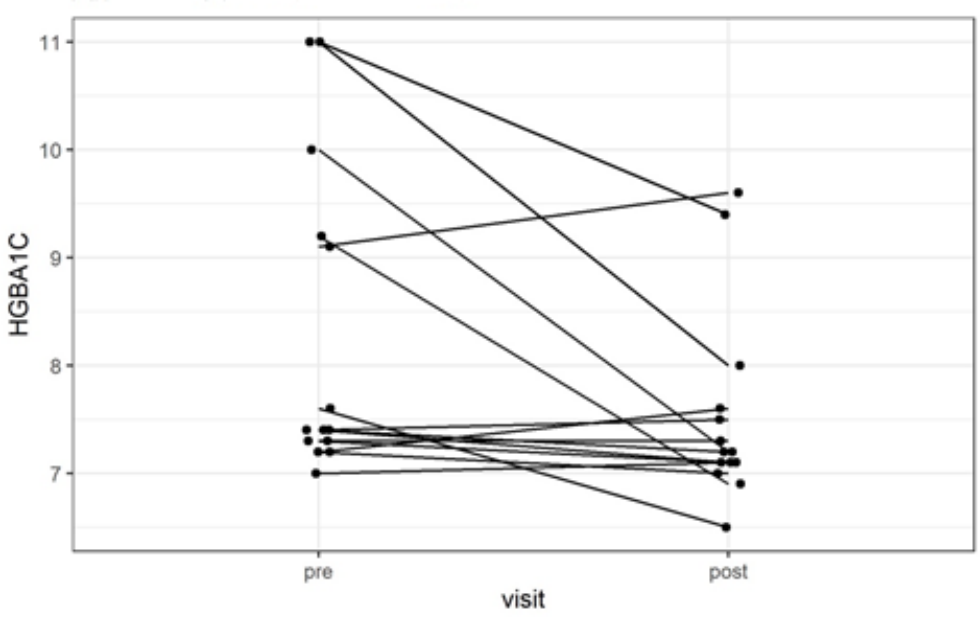


Figure 9: Arrow Plot of Pre-Intervention and Post-Intervention HgbA1c by Visit



Pre and Post Knowledge Assessment

All 14 participants completed the knowledge assessment fully. At the post-intervention visit, those with higher pre-intervention knowledge scores showed higher scores subsequently (Table 2). Changes in knowledge scores between the pre- and post-intervention visits were positive, ranging from 0 to 6 points (Figure 10). Specifically, the mean of the pre- and post-intervention knowledge scores were 5.7 (SD 1.48) and 7.3 (SD 2.02), respectively, and the difference in knowledge across individuals was 1.64 (SD=1.5). Scores were not normally distributed (Wilcoxon test, p=0.002, Figure 11).

Figure 10: Arrow Plot of BMI between Pre-Intervention and Post-Intervention Visit

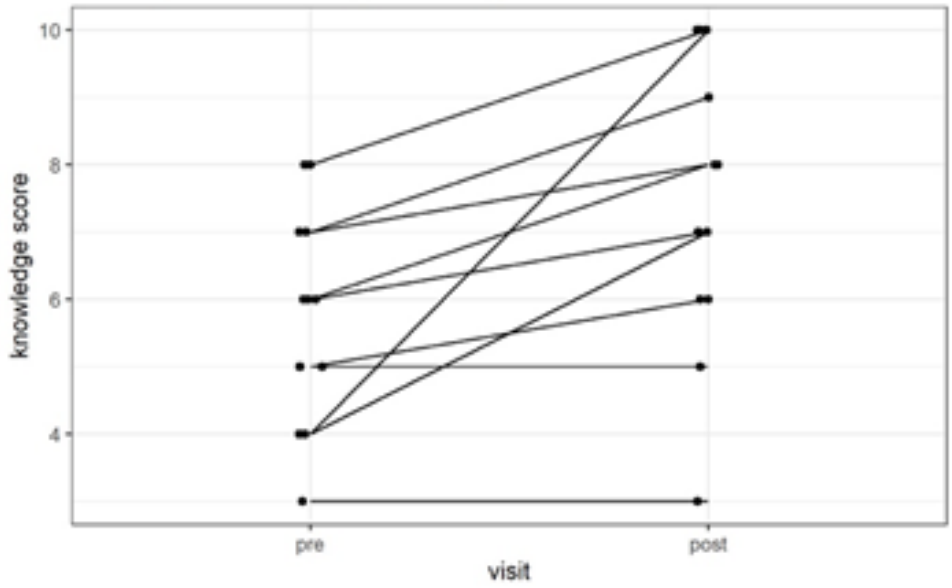
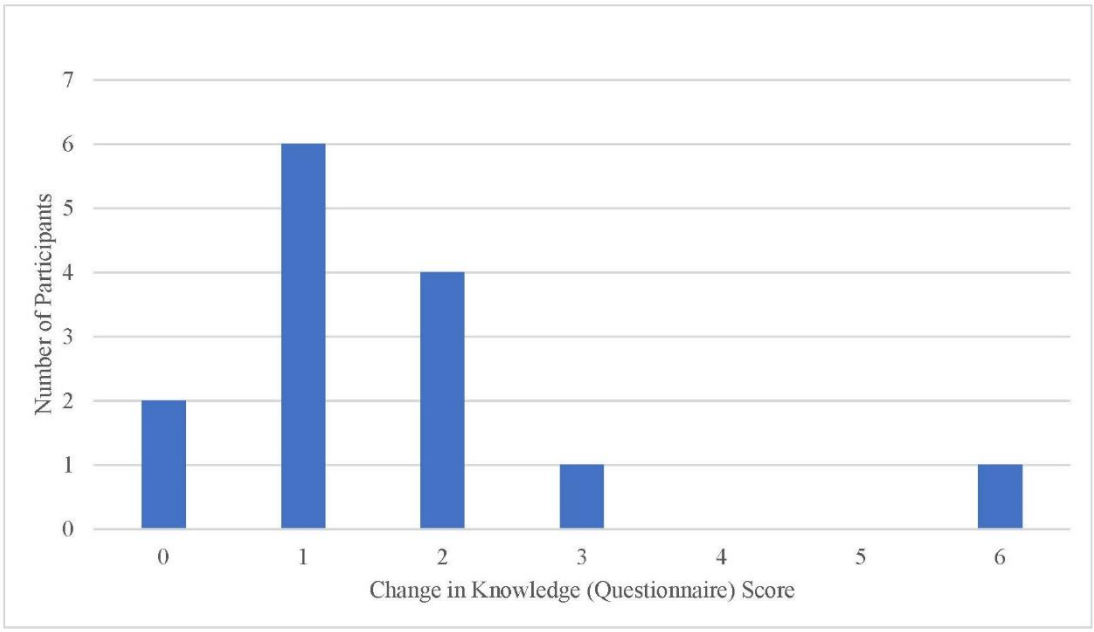


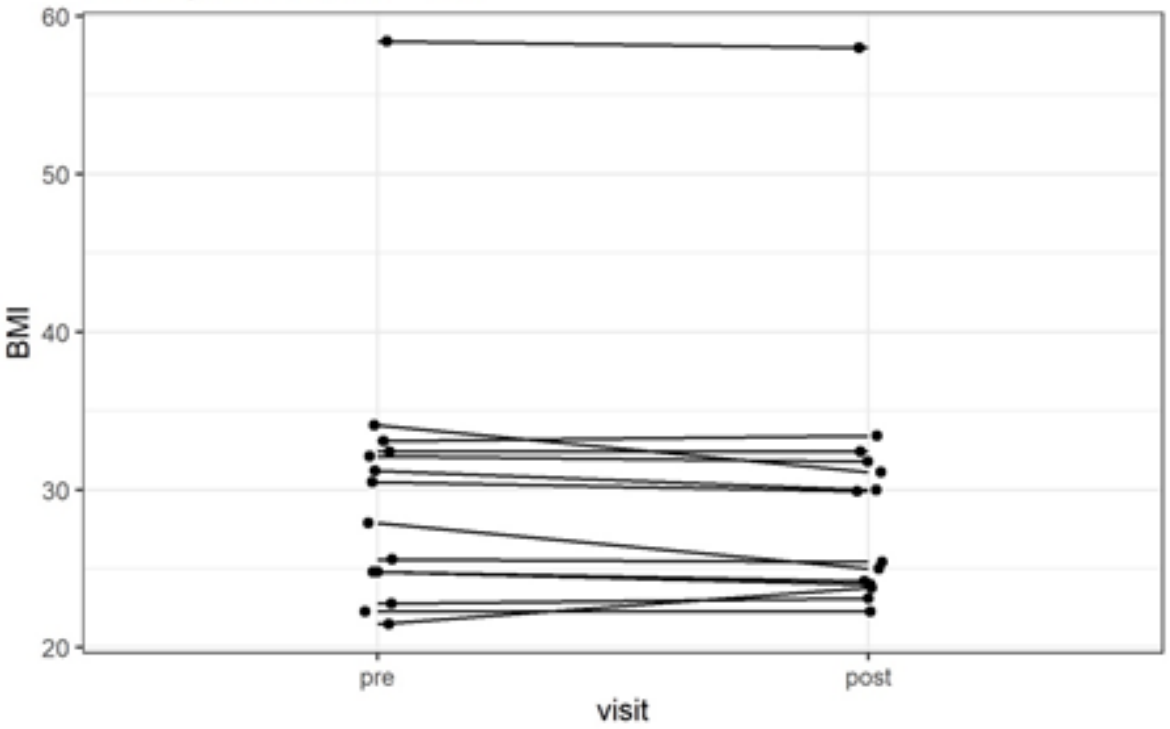
Figure 11: Distribution of Knowledge Questionnaire Score Differences Over Eight Weeks of Observation for 14 Adults with Type 2 Diabetes Mellitus Participating in an Educational Intervention



Effects of the Intervention on Body Mass Index

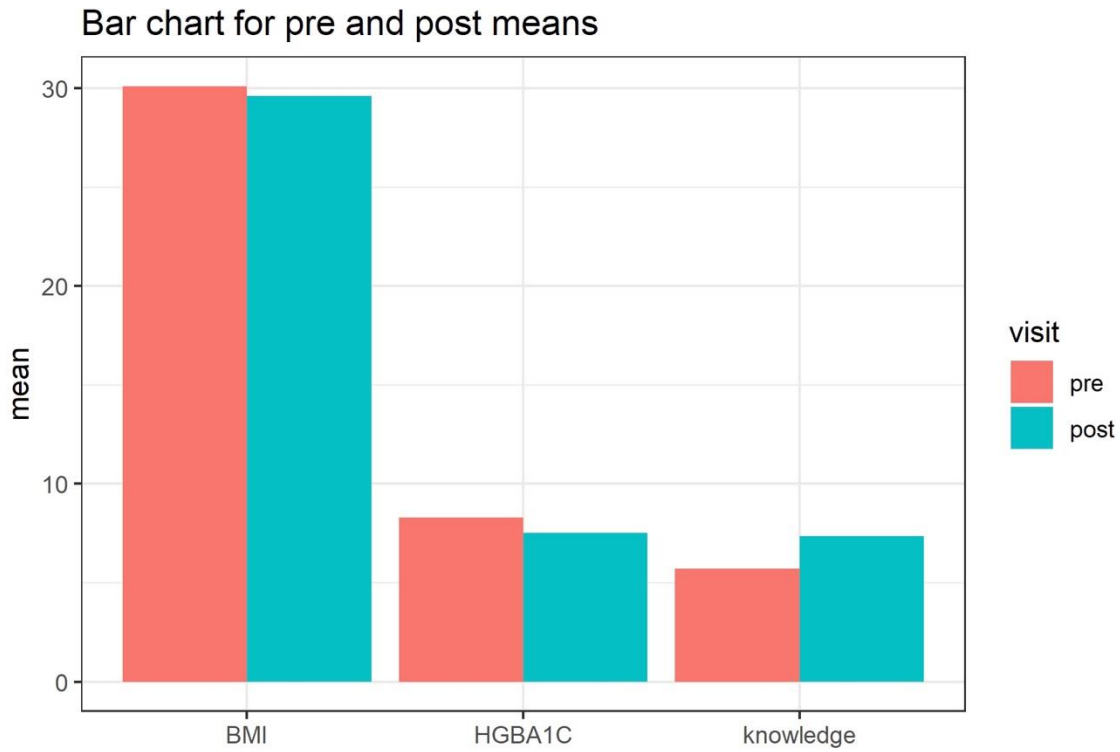
Overweight and obesity are positively associated with T2DM in population data (Morris et al., 2019). For this sample, body mass index (BMI) ranged from 21.5 to 58.4 kg/m2 at the baseline visit. The mean and median BMI were closely approximated: 30.1 (SD: 9.2) kg/m2 and 29.2 kg/m2, respectively (Table 2). At the follow-up visit, the average BMI was slightly narrower, ranging from 22.3 to 58.0 kg/m2, and the mean and median were similarly closely approximated, 29.6 (SD: 9.04) and 27.65 kg/m2, respectively (Table 2). Changes in BMI between the pre- and post-intervention visits ranged from -3.0 to 2.3. Nine participants demonstrated a decrease in BMI, two showed no changes, and three noted an increase in BMI at the post-intervention mark (Table 2). In addition, participants reported an increase in weekly exercise compared to their baseline visit: <60 minutes (0), 61 to 90 minutes (2, 14%), 120 to 180 minutes (5, 35%), or >180 minutes (7, 50%).

Figure 12: Arrow Plot of BMI between Pre-Intervention and Post-Intervention Visit



The mean change in BMI was -0.51 kg/m^2 (95% CI: -1.26, 0.25), p=0.17. Using the Wilcoxon test, p= 0.07 changes in BMI did not show any statistical significance. See the boxplots for a visualization of the distribution of pre- and post-intervention levels (see Appendix D) and the arrow plot for a visualization of the changes for each individual (Figures 12).

Figure 13: Bar Chart of Pre-Intervention and Post Intervention Means of BMI, HgbA1c, and Knowledge Assessment



Patient Satisfaction

Patient satisfaction survey data evaluated eight concepts: the value of time used, the usefulness, engaging nature, informativeness, and organization of the presentation, as well as the usefulness of the MyPlate Method and general characteristics of food apportionment control calorie intake, and nutrition label reading. All participants responded affirmatively to questions about the presentation's organization, helpfulness, informativeness, and engagement. All responded that they would be "Very likely" (7) or "Likely" (7) to use MyPlate Methods or other portion-control strategies at the post-intervention visit, and, remarkably, very little variation in the responses between two visits scheduled eight weeks apart (Supplementary Figure 2 and 3). All responded, "Very Likely" (8) or "Likely" (6) to employ nutrition-label surveillance as a strategy to improve nutritional intake (Supplementary Figures 4). Comments from participants were similarly positive (see Appendix G).

CHAPTER SIX: DISCUSSION

This QI project was initiated to determine if a standardized, evidence-based nutrition education intervention can improve adherence to a low-carbohydrate diet, portion-size control, and nutrition-label literacy to improve HgbA1c, T2DM knowledge, and BMI over a short period of follow-up time. The project results demonstrate a decrease in HgbA1c for 9 of 14 participants and improved knowledge about T2DM. These findings show promise for personalized nutritional education to improve glycemic control in adults with T2DM. One on one nutritional education by an advanced-practice nurse provider offered an opportunity for individually tailored, patient-centered nutritional education consistent with the TTM framework. One-on-one counseling that results in healthier low-carbohydrate meal choices, portion control, and improved selection through nutrition label reading holds promise for improved health. Building confidence and self-efficacy suggests these participants would be able to begin self-care and improved T2DM management with time and repeated counseling. All participants completed the counseling and returned for an eight-week follow-up visit, suggesting interest and investment in the project.

These findings are supported by the work of others, using larger samples and longer follow-up time to reinforce training more frequently. Tseng et al. (2017) showed that knowledge about T2DM risk factors and dietary practices to improve glycemic control was positively affected by one-on-one instruction. Holmen et al. (2016) report that initiating dietary interventions based on one's current stage of change was positively associated with daily diabetes self-management. Although other studies demonstrated larger samples and longer duration of instruction, our data similarly points to a positive effect of one-on-one instruction on knowledge about T2DM. In addition, a meta-analysis of 44 studies found that low calorie, low-carbohydrate diets with education can be deemed the most effective in managing one's BMI among T2DM-

affected adults (Maula et al., 2019). Increases in score of the post-intervention knowledge questionnaire compared to the pre-intervention scores demonstrate an improvement in knowledge retention among the participants. Of the 14 participants, 12 improved their post-intervention knowledge questionnaire by one point or higher. These results reflect a statistical improvement in knowledge; however, there were no statistical changes in BMI. Menezes et al. report a>5% change in BMI after 12 weeks of nutritional education, calorie restriction, and intense follow-up with dieticians and clinical psychologists in a systematic review (2020). Our study suggests that the standardized, evidence-based nutrition education intervention may impact BMI for a larger sample of affected adults observed for a longer duration of time of 12 weeks or greater. Findings show that success measures might be expected with a small sample of T2DM-affected adults conducted over a brief follow-up period with two intervention visits.

Our data suggest that T2DM-affected adults are interested in receiving help that improves their health. Specifically, patient satisfaction scores favored interest, and all participants reported that the educational sessions were helpful and informative. The primary goal of this standardized, evidence-based nutrition education intervention was to improve T2DM biomarkers, however, an indirect measure of success was the feasibility of one-on-one counseling and participants' appreciation for the attention to their challenges and their effort to improve knowledge. This project underscored the potential benefit adults with T2DM may receive through comprehensive, tailored, and focused nutritional education to improve their health.

Strengths and Limitations of Project

Some limitations were identified in this quality improvement project. The COVID-19 pandemic delayed both implementation and negatively impacted participation. The academic calendar left limited flexibility for longer follow-ups. The sample size was small, and participants were predominantly Hispanic English speakers, limiting the generalizability of the findings to the general population of T2DM-affected adults. Potential barriers to participation and implementation included socioeconomic, cultural, personnel, resources, and financial factors that constrain participation in primary care settings. However, improved patient-centered care with tailored education may be reimbursable in some settings. Lengthening the follow-up time and increasing the number of one-on-one counseling and education visits may improve outcomes, especially for low health literacy populations in the short term (Dewalt et al., 2006; Baker et al., 2011). Following participants for a longer period may provide more meaningful improvement for future studies.

There were many strengths of the QI project. The project had 100% of participants attend their follow-up visit. The project improved the HgbA1c biomarker in 64% of participants reducing their HgbA1c from their pre-intervention to post-intervention visit. The self-reporting of increased weekly exercise in nearly half of the participants highlights the potential efficacy of the design. Participant-centered nutritional instruction was well received and consistent with improving value-based care (Catalyst NEJM, 2017). This approach was cost-effective, all printed materials were retrieved from the online CDC and the American Diabetes Association libraries. Thus, the project highlights the potential for success in a primary care setting that requires both efficient and economic approaches to improving self-care among adults with T2DM.

Role of DNP Leadership

To ensure the DNP QI project's success, various leadership practices were implemented to uphold the QI project's goals. The true essence of daring leadership is building partnerships and working collectively to achieve a shared goal (Weberg & Davidson, 2019). Partnership with the patient was vital to achieving the underlying purpose of lowering HgbA1c through nutritional interventions. This DNP QI project aimed to steer away from a hierarchical relationship that often leaves the patient dispirited and unmotivated to change and created a patient-centered dynamic through honest conversations (Weberg & Davidson, 2019).

Taking on a blameless approach was a form of leadership practice utilized when executing the DNP QI project. Substantial shame may often be experienced by patients when discussing weight, diet, and overall health (Browne et al., 2013). Studies have illustrated the social stigma around T2DM care and how patients feel reluctant to go to their health provider due to fear of being blamed for their condition (Weberg & Davidson, 2019). Condemning patients for poor health outcomes neglects a learning opportunity to improve daily practices and misses an opportunity to educate individuals on making healthier choices. The DNP QI project aimed to execute a leadership practice that followed a blameless approach rather than faulting patients for their current practices (Tseng et al., 2017).

Application of DNP Essentials

This project employed the second DNP Essential: Organizational and Systems Leadership for Quality Improvement and Systems Thinking. Applying evidence-based practice guidelines and taking leadership to initiate change within a healthcare system to improve outcomes (Zaccagnini & Pechacek, 2019). Nurse leaders recognize areas needing improvement

and create change by challenging inefficient and dated assumptions, procedures, and methods (Zaccagnini & Pechacek, 2019). According to the diabetes prevention research group (DPP), lifestyle intervention has significantly reduced weight and achieved glycemic control over the placebo effect or metformin alone (DPP, 2002). The DNP QI project can generate system-wide change by providing consistent, standardized nutritional education for T2DM that can be applied for all patients to enhance current standards of diabetes care.

Essential VIII, Advanced Nursing Practice, can improve population health by applying advanced assessment skills and knowledge of biological, physical, physiological, psychosocial, and nursing science principles to healthcare practice. Consistent with the ADA recommendations, this QI project adds a standardized, evidence-based nutrition education intervention that focuses on using a low carbohydrate diet, nutrition-label literacy, and portion-size control to standard-of-care education to achieve glycemic control (Diabetes Care, 2021). Essential VIII allows the DNP leader to facilitate health by applying advanced clinical judgment and adapting evidence-based interventions to improve health. This essential was a crucial component in executing the DNP QI project through comprehensive needs assessment, utilizing the TTM framework to facilitate disease remission, and guiding patients with complex chronic care needs, ultimately alleviating the financial burden associated with long-term illnesses.

Interdisciplinary Practice

A DNP leader possesses the tools and knowledge necessary to work among interprofessional teams to address complex chronic care needs by utilizing evidence-based literature to support clinical change (Zaccagnini & Pechacek, 2019). Diabetes management is a complex, multifactorial medical challenge with many moving parts: abiding by controlled dietary

plans, managing multiple medications, visiting specialists, and regulating daily glucose levels; requiring the expertise of many health specialties. The project team, comprised of a DNP-APRN candidate and a Registered Dietician, selected patient-friendly educational materials published by the ADA and CDC (CDC, 2021; U.S. Department of Agriculture, n.d.). After being selected, each educational brochure was scored separately using the Patient Education Assessment Tool (PEMAT) based on its patient's appropriateness (Shoemaker et al., 2014). The team came to a consensus on each handout and finalized the educational materials packet provided to each patient participant. The team finalized a script detailing the nutritional education program and had it reviewed by two APRN providers for revisions and feedback. Utilizing the expertise of clinical experts enhanced the team's ability to deliver appropriately leveled, patient-centered education. Collectively, these activities alleviate barriers and empower patients to effect better health outcomes.

Ethical Implications

Diabetes is a complex, chronic disease requiring T2DM patients to make daily self-management decisions that can be arduous and taxing. The above literature review and gap analysis highlight a need for improved diabetic management. This gap analysis underlines an ethical implication and demand for improved, comprehensive diabetic care. The DNP QI project aimed to serve those most in need providing quality nutritional education, professional guidance, and objective support to individuals to improve their glycemic control. The DNP QI project design has undergone a thorough IRB review. The DNP project is in the form of quality improvement and has received IRB exemption due to not conducting human research.

Implications for Clinical Practice and Research

The ADA establishes nutritional counseling as the primary element to combating rising cases of T2DM in the U.S. (Diabetes Care, 2021). However, the literature review illuminates a notable lack of standardization of nutritional education within a primary care setting, leading to poor glycemic control and complex diabetes progression (Ahmed et al., 2020; Ma et al., 2020; Muchiri et al., 2021). This DNP QI project aimed to fill this gap in care by utilizing expert nutritional knowledge and personalized guidance as a viable tactic to deter the advancement of T2DM in a primary care setting. If implemented in current practice, a market analysis was conducted to determine the QI project's strengths, weaknesses, threats, and opportunities (SWOT) (see Appendix H). A SWOT analysis highlighted several strengths. The educational materials employed for this quality improvement project have been previously developed and made publicly available by CDC and the ADA (CDC, 2021; USDA, n.d.). These include an apportioned 9-inch MyPlate, images of culturally varied plated foods for portion size reference, and samples of food labels that allow patients to compare and identify important nutritional information (CDC, 2021; USDA, n.d.). These multi-modal tactile tools provide nutrition education to support the feasibility and sustainability of this QI project in primary care.

T2DM specialty services, prescription drug costs, PCP visits, diabetic supplies, and hospital inpatient care may total $16,752 per patient, on average, in annual care-related expense (Riddle & Herman, 2018). Improving T2DM management and implementing preventive efforts may substantially reduce health expenditures. This standardized, evidence-based nutrition education intervention requires minimal expenses by utilizing existing resources, including CDC and ADA's dietary education materials and free mobile applications. With the QI project

focusing on preventive, long-term lifestyle changes, there is a substantial potential return of investment through focused efforts on preventing the progression of T2DM and limited expenditures on specialty care services. This QI project can potentially standardize a low-cost and time-effective approach of including nutritional education in primary care through the utilization of APRN's or Registered Dieticians.

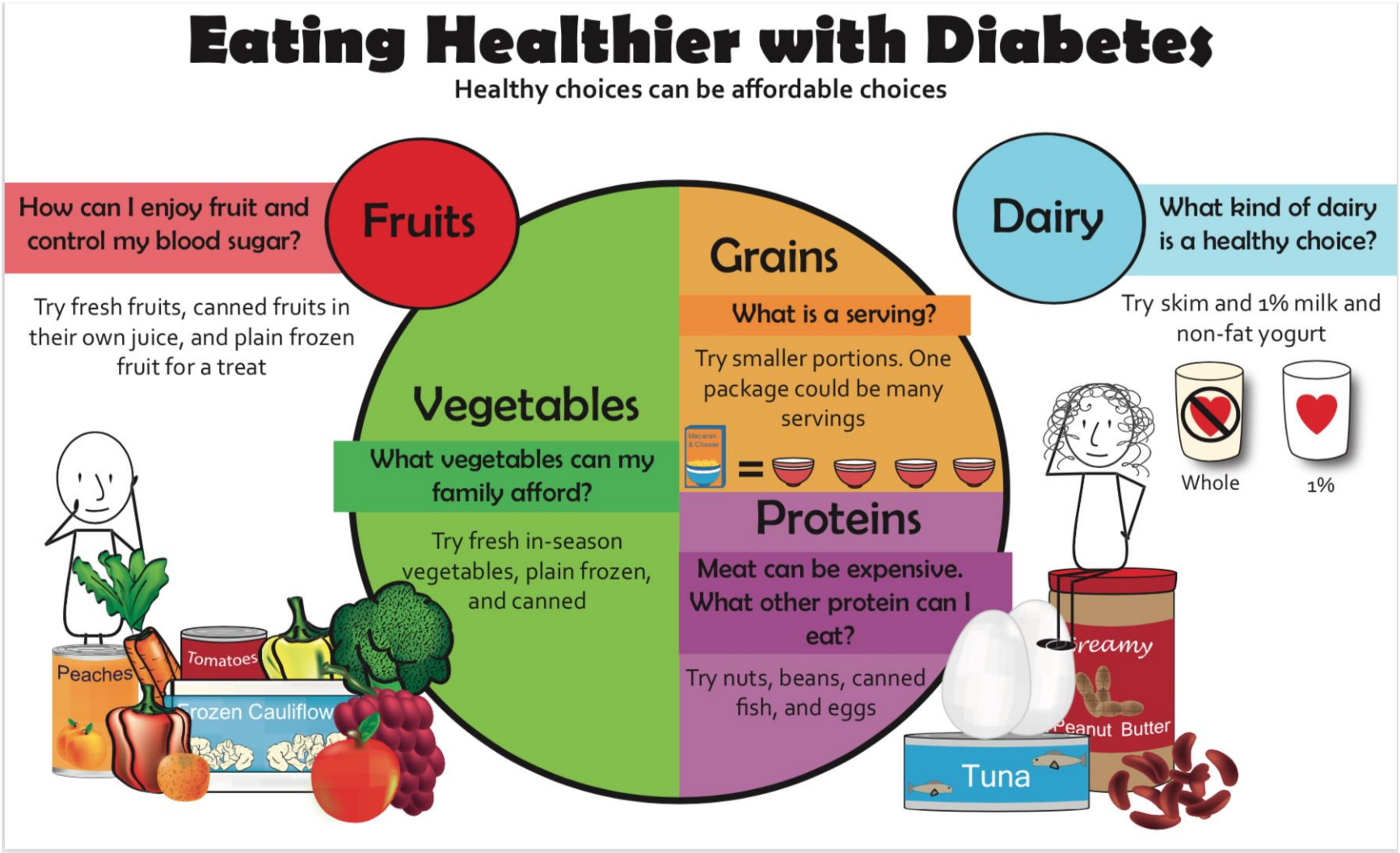
The USPSTF found substantial evidence to support multi factorial behavioral education interventions can lead to clinically meaningful improvements in BMI in T2DM affected adults (US Preventive Services Task Force, 2018). Behavior-based interventions such as portion size control, MyPlate Method, and nutrition label literacy can help achieve glycemic control and contribute to an overall healthier society. A potential system barrier is limited access to Registered Dieticians within community practices. Private practices in low-income neighborhoods face limited resources for non-medical interventions. Nonetheless, community collaborations with the Los Angeles County Department of Public Health's Nutrition and Physical Activity program allow registered dieticians to collaborate with community groups to enhance the food environment (County of Los Angeles Public Health, 2021). The success of this quality-improvement project can continue to catalyze collaboration between small private practices, community members, business owners, and the public health department to improve access to healthy food in the San Fernando Valley. Key stakeholders include PCPs, including physicians, APRNs, physician assistants, affected patients and their family members, and the business community. These parties may form an influential nexus to spur the development of better community food resources to prevent and treat T2DM.

CONCLUSION

The steady rise of T2DM in the U.S. highlights a need for improved disease management. This DNP QI project aimed to investigate a standardized, evidence-based nutrition education intervention to improve HgbA1c, BMI, and increase knowledge within eight weeks. The intervention emphasized low carbohydrate intake, nutrition label literacy, and portion size control demonstrated improved glycemic control and decreased long-term cardiovascular risk factors. The study design was chosen to meet the aims of the clinical question of a standardized nutritional-based education intervention to improve glycemic control within an outpatient setting. Identifying a need for improved care and filling a clinical gap through a cost-effective approach supports the sustainability of this QI project. Utilizing the TTM framework through personalized care may help address diabetes knowledge deficits, ease clinician time constraints, and provide holistic, comprehensive diabetes services. Healthy People 2030 calls for the need to mitigate disease progression and enhance health promotion (McGinnis, 2021). To alleviate the burden of chronic disease, particularly diabetes, on today's health system, a DNP leader is at the forefront of primary care and well-equipped to provide a holistic system thinking approach to patient care (Zaccagnini & Pechacek, 2019). The DNP leader can fill the fragmented gaps in current practice through transformational leadership and advanced standardization of care through the application of evidence-based research, as demonstrated with this DNP project. This DNP QI project can contribute to future diabetic research by providing preliminary data regarding the feasibility of implementing a standardized evidence-based nutrition education intervention in the primary care setting.

APPENDICES

Appendix A: Clinic Brochure



Eating Healthier with Diabetes

Healthy choices can be affordable choices

To stay healthy with diabetes, focus on what's on your plate. Fill half of your plate with non-starchy vegetables. The other half should be filled with grains and protein. Fruits and milk should be on the side. Fruits, milk, and grains will raise your blood sugar so pay attention to serving sizes. If you eat more of one, eat less of another. For example, if you eat 2 servings of grains (2 slices of bread), skip the fruit or milk. Eating this way can actually be really cheap! Let's explore how and why...

Blood Sugar Key:
- won't raise blood sugar
+ will raise blood sugar a little
++ will raise blood sugar a lot

Fruits

Blood Sugar: ++

Good to Know: Will raise blood sugar, especially dried fruit and fruit juice. Serving size is important!

Check your Plate: 1 small piece of fruit

Benefits: Helps you feel full, full of vitamins and fiber

Some Examples: 1 small apple, apricot, banana, orange, peach; or 1 small bowl of berries, grapes, melon, pineapple

Suggestion: Try a serving of fruit for dessert

Vegetables

Blood Sugar: -

Good to Know: Does not include corn, peas, potatoes, pumpkin, or winter squash

Check your Plate: ½ of your plate

Benefits: Won't raise blood sugar, helps you feel full, full of vitamins and fiber

Some Examples: 1 cup cooked or raw beets, broccoli, carrots, cauliflower, cucumbers, green beans, radishes; 2 cups kale, spinach, leafy greens

Suggestion: **Try adding** spices, herbs, and oils to add great flavor, especially to roasted vegetables

Grains

Blood Sugar: ++

Good to Know: Will raise blood sugar- read labels to find out serving sizes

Check your Plate: ¼ of your plate

Benefits: Provide energy, fiber, and vitamins

Some Examples: 1 slice bread, ½ bun or English muffin, ½ cup of bulgur, corn, pasta, peas, popcorn, potatoes, pumpkin, winter squash, rice

Suggestion: Aim for whole-grain products (first ingredient is whole-grain)

Proteins

Blood Sugar: +

Good to Know: Will raise blood sugar a small amount

Check your Plate: ¼ of your plate

Benefits: Helps you feel full, gives you energy

Some Examples: Beef, beans, canned tuna, eggs, fish,nuts, peanut butter, poultry, tofu, cheese

Suggestion: Try lean cuts of meat-they are healthier and often less expensive

Dairy

Blood Sugar: ++

Good to Know: Will raise blood sugar- avoid high sugar products like chocolate milk and flavored yogurt

Check your Plate: 1 cup milk/yogurt, ½ cup pudding/ice cream

Benefits: Good for your bones, gives you energy

Some Examples: Milk (skim or 1%), low-fat plain yogurt, sugar-free pudding

Suggestion: Try plain yogurt with some fruit for a healthy dessert or snack. Skip starches if you do.

DINING with DIABETES
NATIONAL EXTENSION WORKING GROUP

Acknowledgment: This handout was developed through the collaborative efforts of the National Extension Dining with Diabetes Working Group. Special thanks to:
Kali McCrackin Goodenough, Marketing Coordinator, Cent$ible Nutrition Program, Family and Consumer Sciences Department, University of Wyoming Extension (Illustrator/Designer)
Daniel T. Remley, MSPH, PhD, Assistant Professor, Field Specialist, Food, Nutrition, and Wellness, Ohio State University Extension
Mary Liz Wright, Nutrition and Wellness Educator, University of Illinois Extension
Kimberly Wilson-Sweebe, MS, EFNEP Extension Associate, SDSU Extension

Appendix B: Refrigerator Poster

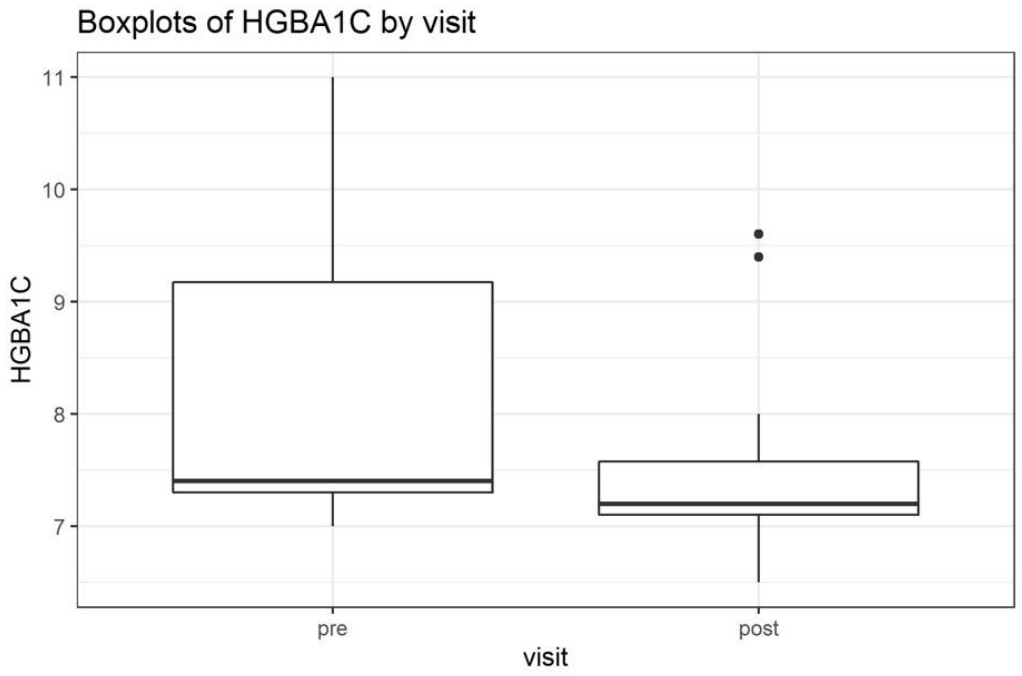
Appendix C: Participant Data

(Supplementary Table 1)**:** Pre-Intervention and Post- Intervention HgbA1c and Knowledge Assessment Score for Each Participant

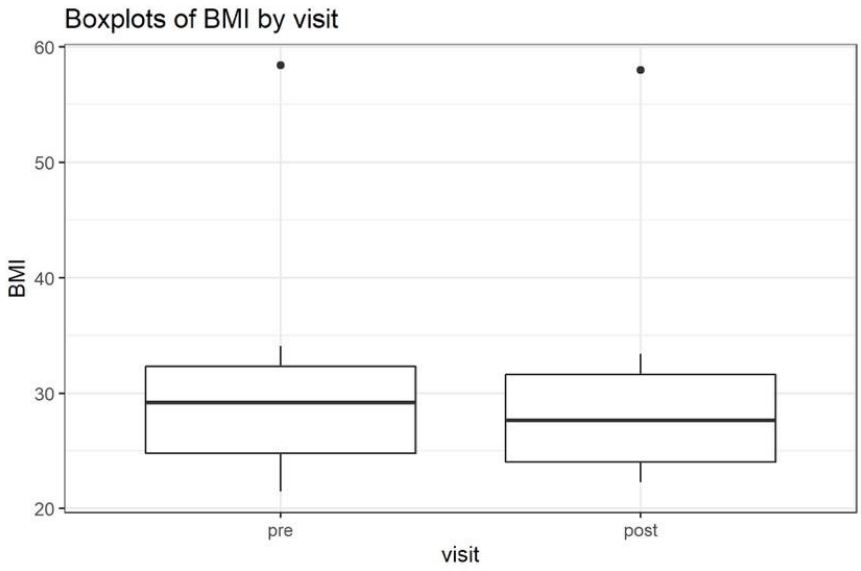
Participant ID	Pre-Intervention HgbA1c	Post-Intervention HgbA1c	Δ	Pre-Intervention Knowledge Assessment	Post-Intervention Knowledge Assessment	Δ
101	11	8	-3	4	7	3
102	7.4	7.5	0.1	6	8	2
103	7.6	6.5	-1.1	5	6	1
104	9.1	9.6	0.5	5	5	0
105	7.4	7.2	-0.2	6	7	1
106	7.4	7.1	-0.3	7	9	2
107	10	7.2	-2.8	8	10	2
108	7.2	7	-0.2	6	7	1
109	7	7.1	0.1	7	8	1
110	7.3	7.1	-0.2	5	6	1
111	9.2	6.9	-2.3	4	10	6
112	11	9.4	-1.6	6	7	1
113	7.3	7.3	0	8	10	2
114	7.2	7.6	0.4	3	3	0

Appendix D: Boxplot Diagram

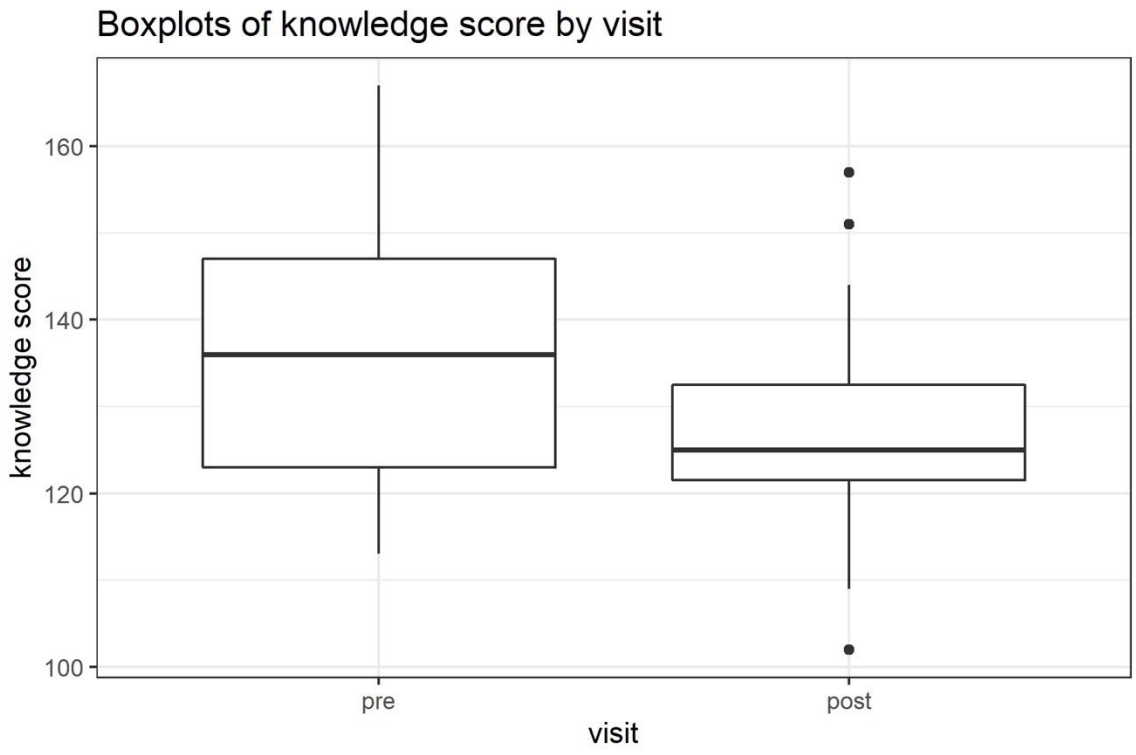
Boxplot of Pre-Intervention and Post-Intervention HgbA1c by Visit



Boxplot of Pre-Intervention and Post-Intervention BMI by Visit



Boxplot of Pre-Intervention and Post-Intervention BMI by Visit



Appendix E: Diabetes Pre and Post Test-Knowledge Assessment Survey

Answers are in **BOLD** (1=c, 2=c, 3=a, 4=d, 5=a, 6=a, 7=b, 8=d, 9=b, 10=b)

1. Diabetes is a condition that is a result of:

a. being overweight

b. too much insulin

c. not enough insulin or insulin isn't working effectively

d. eating too much sugar and drinking sweetened beverages

e. I don't know

2. Diabetes occurs due to problems in which organ?

a. intestines

b. stomach

c. pancreas

d. gallbladder

e. I don't know

3. High blood sugar levels can cause:

a. increased thirst and urination

b. increased energy levels

c. weight gain

d. improved vision

e. I don't know

4. Losing weight may have which benefits for people with diabetes?

a. help the body use insulin more effectively

b. lower blood sugar levels

c. decrease the risk of heart disease

d. All of the above

e. I don't know

5. Healthy eating for people with diabetes means:

a. spacing meals and snacks evenly throughout the day

b. never eating snacks

c. eating only lean meat and vegetables

d. following a set meal plan

e. I don't know

6. People with diabetes should NEVER eat or drink:

a. sweetened beverages like soda pop, sweetened iced tea, or juice drinks

b. any white-colored food

c. any type of fruit

d. pasta and rice

e. I don't know

7. The nutrient that has the greatest effect on blood sugar levels is:

a. protein

b. carbohydrate

c. sugar

d. fat

e. I don't know

8. When grocery shopping, a person with diabetes should:

a. buy only special diabetic foods

b. buy only foods labeled 'sugar-free'

c. avoid all foods that contain carbohydrate

d. read food labels to evaluate calorie, carbohydrate, and fat content of foods

e. I don't know

9. Fiber is the part of food that:

a. causes blood sugar levels to rise higher

b. is incompletely digested and provides roughage

c. should be avoided by people with diabetes

d. can only be consumed in adequate amounts with supplements

e. I don’t know

10. Physical activity and exercise:

a. is never a good idea for people with diabetes

b. helps lower blood sugar levels

c. only counts when you exercise for at least 30 minutes at one time

d. has to hurt in order to be beneficial

e. I don’t know

Appendix F: Participant Satisfaction Survey

Did the presentation provide the following?	Yes	No	Comments
1. Presentation was clear and organized.			
2. Presentation was useful and helpful.			
3. Time for presentation used effectively.			
4. Brochures and education materials were informative.			
5. Presentation was done in a way that engaged audience.			

1. **How likely are you to practice portion control after this presentation?** ***(circle one)***

   Not at all likely Somewhat likely Neutral Likely Very likely

2. **How likely are you to practice the MyPlate Method after this presentation?** ***(circle one)***

   Not at all likely Somewhat likely Neutral Likely Very likely

3. **How likely are you to read nutrition labels after this presentation?** ***(circle one)***

   Not at all likely Somewhat likely Neutral Likely Very likely

4. **What did you like most about the presentation?**

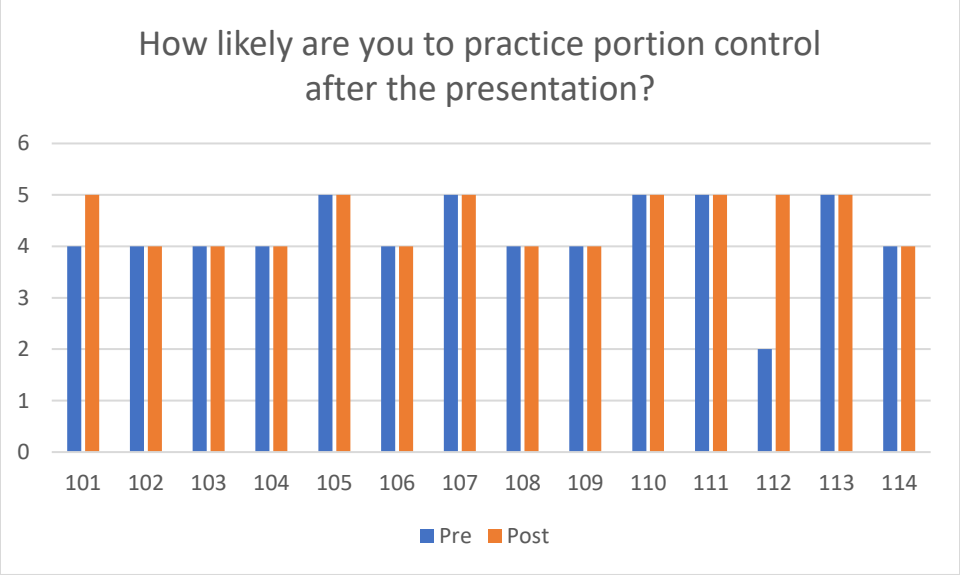
Appendix G: Participant Testimony

Table 3: Participant's Anecdotal Testimony on Lifestyle Habits Post-Intervention

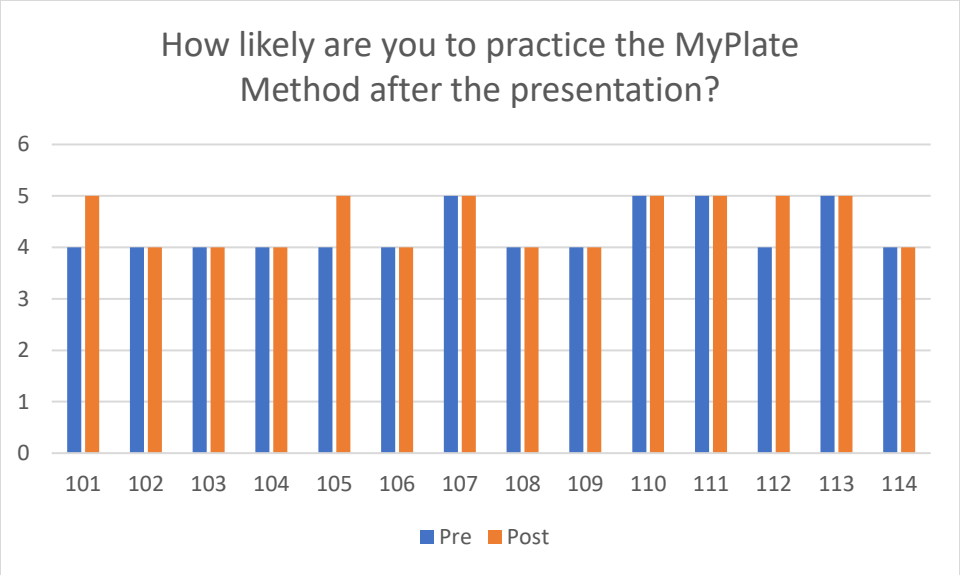
Participant ID	Lifestyle Changes Reported
101	Started food log x1 week then stopped. Stopped eating flour tortillas, soda, juice. Has been reading nutrition labels more
102	Admits to consuming ice cream daily after dinner
104	Was substituting wheat tortilla then went back to flour tortilla, admits to eating 4-6 tortillas with breakfast. Eats out once a week.
105	Has increased weekly exercise from no exercise to walking 40 minutes daily
107	Has increased weekly exercise to 60 minutes biking and 60 minutes walking daily, counting carbs, keeps daily food log on phone, has cut all carbs, sweets and pastries
108	Increased in weekly exercise (walk, swim, bike 30 minutes daily); has decreased juices and pastry intake
109	Increased weekly exercise (walking) from 90 minutes to 120 minutes/week
110	Increase in weekly exercise, mixing flavored oatmeal with plain oatmeal, drinks sugar free iced coffee
111	Significantly increased daily exercise from no exercise to 90 minutes cardio daily; counting carbs, reads nutrition labels, has cut out all sweets & sodas. Desires to be off his medications eventually
112	Partner prepares meals at home in efforts to decrease fast food intake, eating more fruits & vegetables. Has noticed an improvement in his energy.
113	Eating less carbohydrates and sugary snacks, has cut out sweetened oatmeal and adding more protein
114	Has been reading nutrition labels, eats less than a cup of rice; increased cereal intake for breakfast

Appendix H: Participant Satisfaction Survey Results

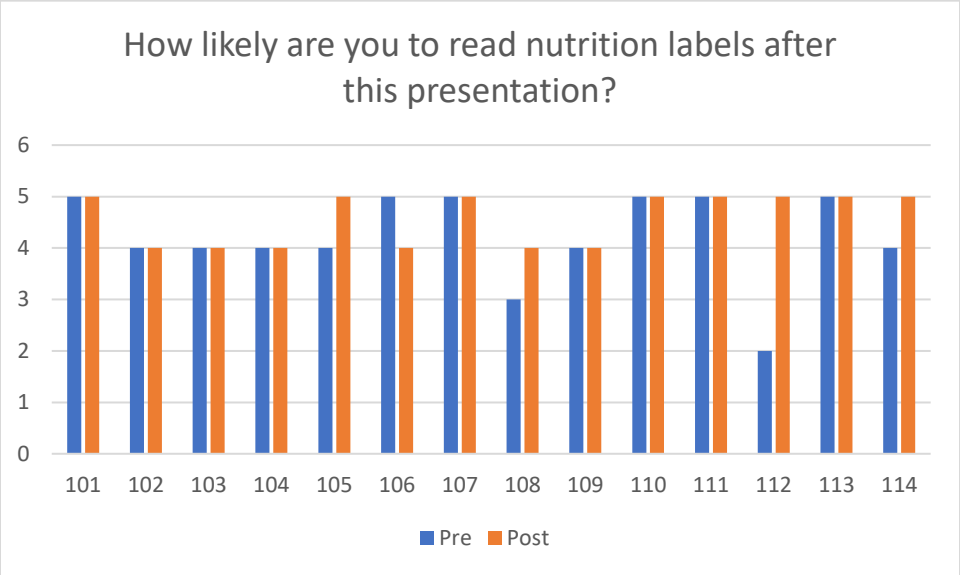
Supplementary Figure 2: Comparison of Pre-Intervention and Post-Intervention responses to Satisfaction with Portion Control Strategies to Control Caloric and Food Quality Intake (Likert Scale, 1-5).



Supplementary Figure 3: Comparison of Pre-Intervention and Post-Intervention responses to Satisfaction with MyPlate Portion Control and Dietary Quality Strategies to Control Food Intake (Likert Scale, 1-5).



Supplementary Figure 4: Comparison of Pre-Intervention and Post-Intervention responses to Satisfaction with Nutrition Label Practice Exercise (Likert Scale, 1-5).



Appendix H: SWOT Analysis

Nutritional Management for Type 2 Diabetes

S
Strengths

- Improve standards of practice to incorporate both medication and nutritional management for diabetes care
- Feasible to implement in primary care practice
- Low-Cost approach to improving diabetes management
- Can be implemented within primary care home
- Utilizing already existing data, information, patient education from MyPlate.gov, American Diabetes Association, MyFitPal
- Using multi modalities to meet educational objectives

W
Weaknesses

- Nutritional management to include cultural and personal nutritional plans/goals
- Time constraints of providers to educate during 20-minute visit
- Will need follow up visits with patient; requires provider and patient availability
- Requires both provide and patient commitment

O
Opportunities

- Ability to personalize care to patients' nutritional habits
- Improve knowledge base of both provider and patient
- Potential to decrease clinic expenditures on tertiary care of poorly controlled T2D patients
- Reverse progression of diabetes and limit comorbid conditions such as kidney failure & adult-onset blindness requiring more specialty care services and cost
- Improve partnership between provider and patient to achieve health goals
- Improve standard of practice for diabetes and its comorbid conditions

T
Threats

- Limited time to discuss with patient nutritional changes in 20-minute visit
- Need follow up visits to reinforce nutritional education materials
- Lack of patient motivation to change nutritional habits
- Lost to follow up patients
- Lack of provider support to initiate nutritional education in practice

Appendix I: Daily Food Log

My Food and Beverage Diary

Date: _____

Monday	
Breakfast	
Snack	
Lunch	
Snack	
Dinner	
Snack	

Tuesday	
Breakfast	
Snack	
Lunch	
Snack	
Dinner	
Snack	

Wednesday	
Breakfast	
Snack	
Lunch	
Snack	
Dinner	
Snack	

Thursday	
Breakfast	
Snack	
Lunch	
Snack	
Dinner	
Snack	

Friday	
Breakfast	
Snack	
Lunch	
Snack	
Dinner	
Snack	

Saturday	
Breakfast	
Snack	
Lunch	
Snack	
Dinner	
Snack	

Sunday	
Breakfast	
Snack	
Lunch	
Snack	
Dinner	
Snack	

Notes:

Learn more at https://www.cdc.gov/healthyweight/losing_weight/eating_habits.html

TABLE OF EVIDENCE

Author, Year, Date, Publication	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions and Measures**	**Results**	**Discussion, Interpretation, Limitation of Findings**
Morris, E., Aveyard, P., Dyson, P., Noreik, M., Bailey, C., Fox, R., Jerome, D., Tan, G. D., & Jebb, S. A. (2019). A food-based, low-energy, low-carbohydrate diet for people with type 2 diabetes mellitus in primary care: A randomized controlled feasibility trial. *Diabetes, Obesity and*	To evaluate the feasibility of a food diet plan consisting of low carbohydrate diet implemented by nursing staff for Type 2 diabetic patients.	Sample: 48 patients screened, 33 enrolled; 21 were assigned to DIAMOND program (Intervention group) Inclusion Criteria: Type 2 diabetes mellitus and BMI of ≥30 kg/m with digital retinopathy in last 12 months	Design: Randomized Controlled Trial Methods: ● Participants recruited through EMR by PCP ● Intervention group assigned to low carb, low energy diet (DIAMOND Program) x12 weeks; daily caloric intake <1,000 kcal/day ● Control group received one-time baseline dietary advice by a nurse and dietary booklet.	Results: Mean weight change -9.5 kg intervention group vs. -2 kg in control group. • Reduce HgbA1c of -16.3 mmol/mol intervention group vs and -0.7 in control group • Improved 62% of HgbA1c for intervention group	Strengths: ● Multi-disciplinary intervention ● First trial to assess energy restriction of 800-1000 kcal/day. ● Significant findings noted (strong p-value). Limitations: ● No blind behavioral interventions. ● Small sample size ● Did not assess for background dietary intake prior to intervention. ● Potential participant bias

Metabolism, *22*(4), 512–520. https://doi.org/10.1111/dom.13915		Exclusion criteria: History of eating disorder, current use of insulin, A1C >10.5 Setting: Three primary care practices	Measures: • Fasting HgbA1c, glucose, insulin, liver function, lipid panel, BMI	• 7 participants discontinued 1 or more diabetic medications. • No change of meds in control group. • Qualitative study found all participants reported sustained behavioral change in intervention group.	Implications to Practice: • Supports dietary program in primary care setting.

Author, Year, Date, Publication	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions and Measures**	**Results**	**Discussion, Interpretation, Limitation of Findings**
Tay, J., Luscombe-Marsh, N. D., Thompson, C. H., Noakes, M., Buckley, J. D., Wittert, G. A., Yancy, W. S., & Brinkworth, G. D. (2015). Comparison of low- and high-carbohydrate diets for type 2 diabetes mellitus	To compare effects of low carbohydrate, low fat diet with a high carbohydrate, low fat diet on glycemic control among type 2 diabetic patients.	Sample: •115 T2DM patients with BMI >34, and HgbA1c average of 7.3. Setting: • Does not specify whether study conducted in outpatient setting. Study conducted over span of 52 weeks.	Design: Randomized Controlled Trial Methods: • Randomly assigned to hypocaloric low carb diet or high carb, low fat diet. • Both groups had 60 min supervised aerobic exercise 3d/wk. Measures: HgbA1c, fasting blood glucose, diabetes medication,	Results: • Both groups achieved similar completion rates. • The low carb group achieved greater reduction of diabetes medication of -0.5 units. • Low carb group achieved 2-fold greater improvement of glucose control. • Overall, 9.1% weight loss was achieved in both groups.	Strengths: • Hypocaloric, low-calorie energy can improve glycemic control, weight loss, and reduce CVD risks. • Low Carb group greater reductions in diabetic medications • Long term study of 52 weeks Limitations: Similar studies shown greater HgbA1c reductions with low carb interventions • Potential participant bias

management: a randomized trial. *The American Journal of Clinical Nutrition*, *102*(4), 780–790. https://doi.org/10.3945/ajcn.115.112581			weight, blood pressure, and lipid profile assessed at baseline, 24, and 52 weeks.		<u>Implications to Practice:</u> Longevity of study supports ability to implement in primary care setting for long term effects of glycemic control.

Author, Year, Date, Publication	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions and Measures**	**Results**	**Discussion, Interpretation, Limitation of Findings**
Ahmed, S. R., Bellamkonda, S., Zilbermint, M., Wang, J., & Kalyani, R. R. (2020). Effects of the low carbohydrate, high fat diet on glycemic control and body weight in patients with T2DM: Experience from a community-based cohort. *BMJ Open Diabetes Res Care*, *8*(1).	To determine if low carbohydrate, high fat (LCHF) diet can improve glycemic control for T2DM	Sample: 49 T2DM patients with BMI≥25kg/m^2 Exclusion Criteria: Pregnant patients or with Stage >4 CKD Setting: Johns Hopkins Endocrinology EMR of patient visits from January 2015-Aptil 2018.	Design: retrospective analysis Methods: EMR visits comparing LCHF diet for ≥3 months, compared with patients who received usual diabetes care Intervention group recommended to restrict net carb (total carbohydrates minus fiber) intake to ≤20 g/day.	Results: LCHF greater reduction in A1C (−1.29% (95% CI −1.75 to −0.82; p<0.001)) and body weight (−12.8 kg (95% CI −14.7 to −10.8; p<0.001) LCHF group had 100% discontinued or reduction in T2DM medication dose, compared with 23.1%	Strengths: Adherence to LCHF <20 g of carb diet Patients successful in keeping detailed food logs Multidisciplinary team approach Limitation: Not RCT; selection and participant bias. LCHF patients had more face-to-face time with healthcare

https://doi.org/10.1136/bmjdrc-2019-000980			Measures: Average HgbA1c and change in total body weight	in the usual care group ($p<0.001$). LCHF group greater reduction in fasting plasma glucose (−43.5 vs −8.5 mg/mL; p=0.03) compared with usual care.	provider vs control group. Implications for Practice: LCHF diet metabolically favorable for T2DM Feasible and safe to implement the LCHF diet in outpatient setting over 3-month span

Author, Year, Date, Publication	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions and Measures**	**Results**	**Discussion, Interpretation, Limitation of Findings**
Tseng, H.-M., Liao, S.-F., Wen, Y.-P., & Chuang, Y.-J. (2017). SOC concept of the transtheoretical model for healthy eating links health literacy and diabetes knowledge to glycemic control in people with type 2 diabetes mellitus. *Primary Care Diabetes*, *11*(1), 29–36.	To explore mechanisms of health literacy (HL) associated with TTM SOC and behavior changes associated with health outcomes of diabetic care.	Sample: 273 participants with T2DM Demo: 128 men (55.2%) and 104 women (44.8%) with a mean age of 58.06 ± 9.49. -(51.7%) with secondary education, 89 (38.4%) with primary education or below, and 23 (9.9%)	Design: ● Descriptive, cross-sectional survey. Methods: ● Newest Vital Sign (NVS) assessing HL ● Diabetic Dietary knowledge Assessment Variables studied: TTM Stage of change, nutrition knowledge using 10-item Diabetic Nutrition Knowledge Scale	Results: HL was significantly and negatively associated with HgbA1c (c1 = −0.2995, $p < 0.05$) - Direct effect of HL on glycemic control was not significant ($CI' = -0.2338$, $p = 0.1081$) HL and SOC was significant (Indirect 2: a1a3b2 = −0.0229;	Strengths: Few studies on HL and TTM SOC - Low HL significantly associated with worse glycemic control. -SOC associated with HL; higher dietary knowledge at higher TTM SOC

https://doi.org/10.1016/j.pcd.2016.08.005		with graduate-level degrees. - (78.9%) were over-weight (BMI > 24), with an average BMI of 27.38 ± 4.73. Setting: Regional Hospital in Northern Taiwan, Endocrinology clinic	Data analyzed using SPSS version 18.0	CI = −0.0648 to −0.0019)	Limitation: Findings may not be generalizable; non-probability sampling, from single hospital - Based on cross-sectional data Implications for Practice: HL associated with HgbA1c, SOC, & dietary knowledge

Author, Year, Date, Publication	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions and Measures**	**Results**	**Discussion, Interpretation, Limitation of Findings**
Holmen, H., Wahl, A., Torbjørnsen, A., Jenum, A., Småstuen, M., & Ribu, L. (2016). SOC for physical activity and dietary habits in persons with type 2 diabetes mellitus included in a mobile health intervention: The norwegian study in renewing health. *BMJ Open Diabetes Research & Care*, *4*(1), e000193.	To understand SOC for physical activity and dietary habits of T2DM using a mobile health intervention	Sample: 151 participants with T2DM Inclusion criteria: HgbA1c level ≥7.1% (54 mmol/mol), were ≥18 years of age, and must complete questionnaire in Norwegian. Must have a smartphone Demo: Middle-aged with median age of 58 years (range 20–	Design: RCT with three study sections Methods: SOC and self-management measured using a five-point Likert scale Variables studied: Health Education Impact Questionnaire (HEIQ)	Results: Median HgbA1c level of 7.9% ((7.1–12.4%) 63 mmol/ mol (54–112)), and 116 (90%) with BMI as obese (BMI >25 kg/m^2). -Average years with T2DM 9 years (1–36) and 30 (20%) had three or more comorbidities. - Higher scores on HEIQ associated with	Strengths: Highlighted TTM SOC associated with being in action stage for dietary and physical activity change. Limitation: Volunteer bias Findings not generalizable due to self-reported measures

https://doi.org/10.1136/bmjdrc-2016-000193		80), 89 (59%) were male, 51 (34%) with higher education (>12 years), and more than half were currently working (n=79; 53%) Setting: southern and northern parts of Norway recruited by PCP	All analyses were performed using SPSS V.21	being in action stage for physical activity. -Most participants placed themselves in the precontemplation stage for dietary behavior change	Implications for Practice: SOC positively associated with daily diabetes self-management

Author, Year, Date, Publication	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions and Measures**	**Results**	**Discussion, Interpretation, Limitation of Findings**
Muchiri, J. W., Gericke, G. J., & Rheeder, P. (2021). Effectiveness of an adapted diabetes nutrition education program on clinical status, dietary behaviors and behavior mediators in adults with type 2 diabetes mellitus: A randomized controlled trial. *Journal of Diabetes & Metabolic Disorders*, *20*(1), 293–306.	To evaluate effectiveness of diabetes nutrition education program on HgbA1c, BMI, blood lipids, blood pressure.	Sample: 41 T2DM patients Demo: 30% of adults aged >20 years and education above grade 12; 5% with grade level <12th grade. -Between 40-70 years with T2DM diagnosis ->80% of were unemployed	Design: 1-year RCT with two parallel groups Methods: Intervention group received 8-monthly group education sessions, bi-monthly follow-up sessions, 15-minute individual session, workbook + educatio n materials) or	Results: 7.3% of intervention group decreased oral diabetic medications; control group 2.5% reduction in oral diabetic meds -At 12 months 7.9% increased oral diabetic medications in intervention group vs 18.4% in control group	Strengths: 1% decrease in HgbA1c results leading to 37% decrease in microvascular complications; present study reduce risk by 25% and death by 14% Limitation: Nutritional sessions conducted by

https://doi.org/10.1007/s40200-021-00744-z		Setting: Two community health centers in North West Province, South Africa	control group (*n = 38*: education materials only) Measures: HgbA1c, lipid panel, BMI, blood pressure, energy intake Stata statistical software utilized	0.53 % reduction in, HgbA1c for intervention group, no statistical change at 12 months -intervention group significantly lower blood pressure at 6 and 12 months; higher diabetes knowledge scores	nutrition students, not RD; facilitators not conversant in native language, education materials not culturally appropriate. Implications for Practice: Future studies explore employing health professionals to deliver nutritional education in resource limited clinic. -Cost saving approach

Author, Year, Date, Publication	**Purpose**	**Sample & Setting**	**Methods, Design, Interventions and Measures**	**Results**	**Discussion, Interpretation, Limitation of Findings**
Johansen, M., MacDonald, C., Hansen, K., Karstoft, K., Christensen, R., Pedersen, M., Hansen, L., Zacho, M., Wedell-Neergaard, A.-S., Nielsen, S., Iepsen, U., Langberg, H., Vaag, A., Pedersen, B., & Ried-Larsen, M. (2017). Effect of an intensive lifestyle intervention on glycemic control in patients with	To test whether intensive lifestyle intervention results in glycemic control compared with standard care and lead to reduction in glucose-lowering medication for T2DM patients	Sample: 98 non-insulin dependent T2DM adults diagnosed <10 years Recruited via Danish Diabetes Association Inclusion criteria: T2DM diagnosed less than 10 years, BMI of 25- 40, with 2 or fewer glucose-	Design: Single-center, assessor-blinded, randomized clinical trial Methods: Participants received standard care included medical counseling, education in T2DM and lifestyle advice by nurse at baseline and every 3 months for 12 months	Results: HgbA1c level changed from 6.65% to 6.34% in intervention group vs. 6.74% to 6.66% in control group, not meeting criteria for equivalence ($P = .15$) Reduction in glucose-lowering medications in 47 participants (73.5%) of	Summarize: : -blinded, highly standardized, algorithm approach -mean change in HgbA1c level of −0.31% vs −0.04%. Limitation: Multiple interventions at one setting Not generalizable findings

type 2 diabetes mellitus. *JAMA*, *318*(7), 637. https://doi.org/10.1001/jama.2017.10169		lowering medications. Exclusion criteria: HgbA1c greater than 9%, insulin-dependence, or presence of diabetic retinopathy or nephropathy Setting: Single center, Region Zealand and the Capital Region of Denmark from April 2015 to August 2016	Intervention group had individual dietary plan with macronutrient distribution of 45% to 60% carbohydrate, 15% to 20% protein, and 20% to 35% fat, & weekly aerobic sessions Measures: HgbA1c, reduction of diabetic medications	intervention group vs. 9 participants (26.4%) in the control group	Volunteer bias Implications for Practice: lifestyle intervention resulted in glycemic control although not significant supported need for future research.

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