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The Implementation of Diabetes Prevention Program at a Community Health Center

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The Implementation of Diabetes Prevention Program at a Community Health Center

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requirements for the degree

Doctor of Nursing Practice

by

Monika Kumari Badyal

2022

ABSTRACT OF THE DISSERTATION

The Implementation of Diabetes Prevention Program at a Community Health Center

by

Monika Kumari Badyal

Doctor of Nursing Practice

University of California, Los Angeles, 2022

Professor Dorothy J. Wiley, Chair

Background: Time-trend Hispanic population data spanning 2007-2012 shows a stronger association between obesity trends and a higher prevalence of Type 2 Diabetes Mellitus (T2DM) in Hispanic than non-Hispanic Whites (NHW): 40.1% and 44.4% for male and female Hispanic adults, respectively, and 32.4% and 32.8 % for male and female NHW adults. Patients with T2DM have 2-3-fold higher mortality than unaffected adults, and the disease is strongly correlated with obesity[1]. Obesity, insulin resistance, and abnormal glucose metabolism are strongly associated with diabetes. Reducing the incidence of T2DM depends upon body weight control. The Center for Disease Control and Prevention (CDC)'s Diabetes Prevention Program (DPP) strategies evidence 58% reduced incidence of T2DM over three years of study[2].

Objectives: The purpose of this quality improvement (QI) project is to implement a modified Diabetes Prevention Program (DPP) curriculum in the underserved, uninsured Hispanic patient population by imposing health-promoting behaviors through weight loss, diet, and exercise. One of the main objectives of this QI is to demonstrate to clinic leadership the efficacy of this modified DPP curriculum in preventing diabetes so it may be adopted as a standard of care across all prediabetic patients within the clinic's healthcare system.

Methods: We modified the DPP curriculum to better reflect the culture and language represented by Spanish-speaking adults with prediabetes and obesity. A fluent Spanish-speaking diabetic educator implemented this QI project at a Federally Qualified Health Center (FQHC) over 13 weekly sessions covering 16 DPP core concepts. Pretests and posttests were administered to 18 participants to measure knowledge before and after the intervention. Bodyweight was measured at the pretest and each weekly session, as well as self-reported minutes of exercise. Waist circumference and point of care HbA1c were evaluated at week 1 and week 13. Each measure was discussed with participants for personal reflection.

Results: Of 18 planned, 61% (=11/18) enrolled and completed the program; all the participants were female. Nutritional and diabetes prevention knowledge increased ($p<0.003$), and waist circumference decreased ($p=0.005$), but no change in HbA1c, weight loss, or BMI change were noted over the period compared to baseline data. The week 13, HbA1c is inversely associated with an absolute change in waist circumference over the period ($p=0.043$); however, a low-sample size limited associations of change in HbA1c with either weight loss or BMI trend.

Conclusion: Over the relatively short period of 13 weeks, those Hispanic women received linguistically and culturally competent education therapy to change their T2DM-associated behaviors, and the absolute changes in waist circumference were inversely accompanied by lower levels of post-DPP HbA1c. Improving the appeal of DPP to male Hispanics is an important next step. Also, developing a culturally competent follow-on approach to promoting further adherence to evidence-based exercise and dietary recommendations is essential to improving the public's health.

(1) Fryar, C. D., Carroll, M. D., & Ogden, C. L. (2014). *Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, 1960–1962 Through 2011–2012* https://www.cdc.gov/nchs/data/hestat/obesity_adult_11_12/obesity_adult_11_12.pdf

(2) La Sala, L., & Pontiroli, A. E. (2020). Prevention of diabetes and cardiovascular disease in obesity. *International Journal of Molecular Sciences*, *21*(21), 1-17. https://doi.org/10.3390/ijms21218178

The dissertation of Monika Kumari Badyal is approved.

Catherine L. Carpenter

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2022

Dedication

This dissertation is dedicated to my family, notably Anushka and Aryan. I want to show my children that anything is possible with hard work and persistence. Thank you for your words of encouragement and forgiveness for not being fully present at your special events in recent years.

TABLE OF CONTENTS

List of Figures and Tables

Acknowledgments

As this long-term goal of acquiring a terminal degree in the profession of nursing comes to an end, I would like to thank everyone who has contributed to my achievement in accomplishing my dream. First and foremost, I want to thank God; none of this would be possible without his help.

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To my family, Gautam (Husband), Anushka (Daughter), Aryan (Son), Santosh (Mom), Vasdev (Dad), Vinod (Brother), Indu (Sister-in-law), Aisha (Niece), Alyia (Niece) thank you for your support, understanding, and motivation in moments of frustration and hardship. I am confident that none of this would be possible without the love and support you have shown me throughout this academic journey.

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Biographical Sketch

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Education

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Work Experience

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Registered Nurse, Clinical Nurse II, Oncology Unit

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Professional Associations

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Chapter One: Introduction

This project implemented a program to teach Hispanic patients in a community clinic how to prevent type 2 diabetes (T2DM) through lifestyle modification with diet, exercise, and close follow-up care. Diabetes is the seventh leading source of death in the United States, with diabetics facing a two- to threefold increase in mortality risk compared to nondiabetic patients (Center for Disease Control [CDC], 2020). T2DM places a significant burden on society, contributing to premature mortality, lower quality of life, increased medical expenditure, and productivity loss (American Diabetes Association [ADA], 2018). Relative to other race and ethnic groups, Hispanics are disproportionately affected by T2DM and its complications compared to other ethnicities due to several risk factors, including genetic susceptibility, lack of health equity, quality of care, and access to evidence-based interventions (Aguayo-Mazzucato et al., 2018; CDC, 2020; Russell et al., 2019). Hispanics are America's largest and fastest-growing ethnic community, comprising 17% of the population in 2013 and projected to reach 31% by 2060 (Russell et al., 2019). T2DM is becoming a significant public health problem in the United States (U.S.) Hispanics have a greater prevalence of diabetes and an earlier age of onset than whites (Russell et al., 2019).

Obesity and insulin resistance are all strongly intertwined, and prediabetes is a strong risk factor for T2DM. However, not all prediabetics develop T2DM. For example, genetics contributes significantly to this process, with only 5% to 10 % of prediabetes-affected adults developing T2DM annually (Miao et al., 2020). Pre-diabetes is generally diagnosed for abnormal values using fasting glucose ($\geq$100 and <126 mg/dL), HgbA1c (5.7% to 6.4%), or glucose tolerance ($\geq$140 and <200 mg/dL) (Khan et al., 2019). When fasting glucose (>126 mg/dL), HgbA1c ($\geq$6.5%), or glucose tolerance ($\geq$200 mg/dL) exceed evidence-based criteria, T2DM is

diagnosed (Khan et al., 2019). Impaired beta-cell function and increasing insulin resistance are two pathogenic processes contributing to prediabetes and, eventually, T2DM (Khan et al., 2019). Often, insulin resistance develops years before the onset of prediabetes and T2DM (Khan et al., 2019).

Patients with T2DM have high blood glucose levels because their bodies do not respond or generate enough insulin, a hormone that helps regulate blood glucose levels by signaling cells to take up glucose and blocking hepatic glucose synthesis (Khan et al., 2019). Diabetes and prediabetes are diagnosed and evaluated using a variety of diagnostic tests, including fasting glucose, HbA1c, and glucose tolerance tests (Appendix A). To analyze the current scholarly project, HbA1c is employed, a test that evaluates protein glycation and may indicate persistent hyperglycemia (Khan et al., 2019).

The risk of T2DM grows exponentially when the body mass index (BMI) exceeds 25kg/m2, the standard definition of overweight (Lau & Toeh, 2015). A systematic review of nine U.S. and European cohort studies reports that men and women showing BMI greater than 30 kg/m^2 evidenced a 7- to 12-fold higher risk for T2DM (Lau & Toeh, 2015). The relative incidence of T2DM increases 9% to 16% with each kilogram increase in body weight (Holt, 2005; Lau and Toeh, 2015). Overweight and obesity, and physical inactivity are high among individuals with T2DM, 89% and 39%, respectively (CDC, 2020).

Obesity is often a chronic condition where environmental factors, such as poor eating habits, physical inactivity, sedentary lifestyle, and heredity are risk factors for weight gain (Carbone et al., 2019). Obesity is one of the most powerful risk factors for T2DM. In addition, obesity is modifiable through lifestyle changes. BMI of 40 kg/m^2 or greater confers a six-fold higher risk for incident T2DM (Leung et al., 2017). Compared to those with normal weight (18.5

to 24.9 kg/m^2 BMI), T2DM-affected adults spend 20% of household income on diabetes-related healthcare (Leung et al., 2017). The total direct and indirect cost related to diabetes care in the United States is $327 billion (CDC, 2020).

Clinical evidence gathered from the Diabetes Prevention Program (DPP) shows that increased physical activity; a healthy, well-balanced diet, and portion control; and cessation of tobacco, alcohol, and stress will reduce the incidence of T2DM by 58% over 3 years of observation (La Sala & Pontiroli, 2020). The DPP protocol is a one-year structured core curriculum featuring 16 core sessions completed over 24 weekly meetings. Meetings are devoted to education and follow-up activities aimed at increasing exercise, self-monitoring and self-care, and healthy behaviors that overcome psychological, social, and motivational obstacles to success (ADA, 2020). The program's primary goals include 5% to 7% weight reduction during the first six months and 150 minutes of weekly physical activity equivalent to brisk walking (ADA, 2020). This program is typically administered by community health workers, is cost-effective, and is reimbursed by third-party payers (ADA, 2020). However, in the absence of health insurance coverage or CDC-certified providers, support for the program is limited in federally qualified healthcare centers (FQHC). For example, reimbursement for DPP programs is currently $536/patient/year (Managed Care Delivery System (MCO), n.d.). At the target clinic, 2530/6229 (41%) Hispanic adults are diagnosed with T2DM, and 635/6229 (10%) Hispanic adults are diagnosed with prediabetes, suggesting as much as $340,360 annually in reimbursement could be realized with an effective program certified by CDC.

Organizationally, DPP implementation is difficult in clinics that serve uninsured and underserved populations because the costs and personnel resources strain FQHC budgets (Horowitz et al., 2011; Jiang et al., 2018). Nonetheless, these evidence-based lifestyle changes

eliminate diabetes-related disparities among Whites, Blacks, and Latinos (Horowitz et al., 2011). Experts suggest communities most affected by prediabetes, such as Hispanics, lack resources that sustain effective interventions (Horowitz et al., 2011). Modestly modifying DPP recommendations to streamline resources required to deliver high-quality care may improve health outcomes for affected adults without losing the integrity of the intervention (Geria & Beitz, 2017).

Thus, this quality improvement (QI) project condenses the 24-week procedure by delivering a 16-module core curriculum to provide all curriculum over a targeted 13-week educational intervention (ADA, 2020; Brey et al., 1999; O'Brien et al., 2017; Konig et al., 2018; McCurley et al., 2017). If successful, we anticipate testing the durability of the shortened intervention over one year of periodic follow-up. To this end, the Spanish version of the core curriculum was modified to combine some sessions to condense the delivery time and reduce implementation costs for the agency (Appendix I). The total cost to implement a 13-week procedure is $5,105 compared to $10,049 for the 24-week procedure (Appendix B). This modified version of the DPP is tailored to deliver an evidence-based intervention that improves knowledge and adherence to diet and exercise.

Problem Statement

This DNP project will implement strategies to combat obesity and prediabetes in the Hispanic community. Prediabetes affects over 88 million individuals in the U.S., yet eight in ten people are unaware of the diagnosis (CDC, 2020). Limited income and healthcare access increase the risk for T2DM among Hispanic adults, compared to Whites, particularly among the undocumented (Russell et al., 2019; Ayon et al., 2020). Healthcare interventions to reduce overweight and obesity will likely reduce T2DM risk or slow disease progression (Carbone et al.,

2019; Holt, 2005; Lau & Teoh, 2015; Leung et al., 2017; La Sala & Pontiroli, 2020). Increases in exercise intensity gradually enhance insulin sensitivity and promote long-term weight loss management (Bray et al., 1999).

PICOT Question

This QI project focuses on implementing lifestyle intervention that includes diet and exercise improvement, as well as close monitoring. The PICOT question is: Does evidence-based 13 weekly lifestyle education for diet, exercise, and weekly follow-up visits (I) with 18 years or older Hispanics with BMI >30 kg/mm2 and prediabetes (P) show 5% to 7% weight loss (weight, BMI, and waist circumference) and improvement in the level of knowledge from baseline (O) in comparison to patients receiving standard care (C) at 3 months follow-up (T)? In addition, significant associations between diet, exercise, and physiological measures of glucose intolerance will be assessed with follow-up measures compared to baseline.

Chapter Two: Theoretical Framework

The Health Promotion Model (HPM) supports the implementation of the DPP intervention. The model proposes that health-promoting behaviors and reduced obstacles will improve health and prevent disease (Heydari & Khorashadizadeh, 2014). Specifically, HPM suggests that each person is a biopsychosocial being partly influenced by the environment. However, HPM attempts to create an environment where inherent and acquired human potential can be fully expressed (Aqtam & Darawwad, 2018). Three categories of variables that affect health behavior using the HPM include human traits, cognition and consequences unique to behavior, and immediate behavioral contingencies (Heydari & Khorashadizadeh, 2014). These concepts, directly and indirectly, work together to promote behaviors that increase physical activity and healthy eating (Butt & Rich, 2018). The HPM is illustrated in Appendix C.

Human traits are unique personality features and experiences that shape individual actions (Butt & Rich, 2018). Education, genetic susceptibility, prior experience with T2DM, and socioeconomic status can impact adopting and maintaining health-promoting behaviors (Butt & Rich, 2018). For example, social media, opinions of family members, and medical provider perceptions affect the adoption of healthy behaviors (Butt & Rich, 2018). Implicit and explicit biases about obesity and T2DM can significantly impact health-promoting behaviors (Puhl et al., 2016). Prior related behavior is vital in determining future behavior, such as success with diet, exercise, and weight loss, influencing future lifestyle modification (Butt & Rich, 2018).

Perceived benefits of action, the barrier to action, self-efficacy, activities linked to emotional impacts, and interpersonal and situational factors, all examples of cognition and consequences unique to behavior (Butt & Rich, 2018), are targeted by nursing interventions. Success is influenced by the patient's perception of the benefit of the lifestyle intervention, the

patient's capacity to overcome barriers, and the patient's ability to achieve dietary and physical activity (Butt & Rich, 2018). Patients' perceptions of prediabetes and obesity as perceived health status and risk factors for the development of T2DM may serve as self-motivator for change. Furthermore, lifestyle intervention is more likely to be implemented if the patient understands it and overcomes challenges such as a lack of time, resources, and knowledge (Butt & Rich, 2018). Several interpersonal influences, such as family, peers, social support, societal norms, and healthcare providers, can promote healthy behaviors (Butts & Rich, 2018). The DPP will increase perceived benefits of action, reduce perceived barriers to action, and increase perceived self-efficacy and activity-related affect by implementing lifestyle modifications with education to promote the benefits of diet and exercise and exploring and assisting with barriers to change (Butt & Rich, 2018).

Behavioral outcomes are the final category that determines adherence to an action plan and results in activities to promote wellbeing (Butt & Rich, 2018). The first step in making such adjustments is to commit to planned activities that will aid in the effective adoption of a diet and exercise regimen, and the DPP will provide the necessary tools to assist patients in making those changes and achieving beneficial behavioral outcomes (Butt & Rich, 2018). Implementing the DPP has demonstrated a reduction in weight and waist circumference, improving prediabetes and preventing diabetes in previous investigations (O'Brien et al., 2018; Van Name et al., 2016; Jiang et al., 2018; Konig et al., 2018; Shubrook et al., 2018).

Chapter Three: Synthesis of Evidence

A comprehensive literature search is conducted using PubMed, CINHAL Complete, Medline, and EMBASE. Several medical subject headings (MeSH) are used to extract research supporting diabetes prevention through diet, exercise, and weight loss. The search terms used to describe the population as Hispanic, Latino, or Latina. Additionally, published evidence was identified using obesity, obese, overweight, pre-diabetic, prediabetic, or diabetes prevention as terms. Diet, nutritional management, lifestyle intervention, exercise, and physical activity are other terms for the intervention. Search terms used for outcome include A1c, BMI, hemoglobin A1c, body mass index, and fasting glucose. Using the above MeSH and Boolean terms, over 1890 articles were obtained, reducing to 792 with less than a 5-year publication period, further reducing to 577 after filtering for full-text articles. These articles were further reduced to 152 after a brief title review for their relevance to Hispanics, Latinos, lifestyle intervention implementation, and community-based program implementation, which is further reduced to nine articles after a detailed evaluation and review of each abstract for its relevance to the clinical project with a similar patient population, lifestyle intervention with diet and exercise, prediabetes prevention and utilization of diabetes prevention program. The PRISMA diagram is described in Appendix D, which illustrates the article selection process. Furthermore, the DPP landmark trail, which is the foundation for developing the DPP, is being evaluated (ADA, 2020).

Evidence Search

The DPP established the groundwork for this evidence-based approach by conducting the first multi-center landmark clinical trial in the U.S of an education-based intervention to improve lifestyle change for prediabetics. This intensive lifestyle intervention (ILI) is widely regarded as a seminal study in lifestyle modification for diabetes prevention, which included 5% to 7%

weight loss and 150 minutes or more of moderate-intensity physical activity per week, resulting in a 58% reduction in diabetes incidence after an average of 2.8 years (Brey et al., 1999; Cefalu et al., 2016; Knowler et al., 2002). The program included 16 sessions led by case managers trained in behavior modification in the first 24 weeks, followed by monthly sessions for up to two years, and followed for five years after the intervention (Brey et al., 1999; Knowler et al., 2002). The study was a randomized control trial (RCT) with over 3,234 participants assigned to one of the three intervention groups: an intensive lifestyle intervention, metformin, or placebo combined with standard diet and exercise recommendations (Bray et al., 1999; Knowler et al., 2002). The total effect sample size necessary to achieve 90% statistical power was 2,279 participants. It concludes that participants assigned to the ILI or metformin group reduced the hazard rate of diabetes development by more than 33%, or 4.33 per 100 person-years (Bray et al., 1999; Knowler et al., 2002). Additionally, for those with standard care plus placebo, time to the development of diabetes is exponentially distributed with a hazard rate for diabetes development of 6.5 per 100 person-years, a two-fold higher hazard rate compared to ILI.

The secondary variables measured included blood pressure, glycemia, cholesterol, body composition through BMI, waist, and hip circumference (Bray et al., 1999). Additionally, approximately half of the sample size comprises high-risk ethnic minorities: African American, Hispanic, American Indian, and Asian American. Ten years following the initial DPP, researchers found that diabetes prevalence was lowered by 34% in the lifestyle cohort and 18% in the metformin group compared with placebo (Diabetes Prevention Program Outcomes Study [DPPOS], 2012).

Shubrook et al. (2018) reviewed and evaluated the evidence of diabetes prevention and summarized seminal research from several nations. The authors examined and analyzed data

from the National Diabetes Prevention Program in the U.S., the Diabetes Prevention Research in Finland, and the Da Qing research in China. The sample size ranged from 577 to 3234 and investigated ILI, medication, and metabolic surgery to prevent diabetes development. The researchers concluded that ILI (39%-71%), medication (28%-79%), and metabolic surgery (75%) prevented or delayed the development of diabetes.

Other meta-analyses also found risk reduction from lifestyle modification. Haw et al. (2017) conducted a systematic review and meta-analysis of over 43 RCTs evaluating the long-term sustainability of diabetes preventive programs. It was concluded that lifestyle modification had a relative risk reduction (RRR) of 39% in diabetes prevention, and after 5-7 years, follow-up RRR was sustained up to 29%. Medications such as insulin-sensitizing and weight loss drugs reduced the relative risk of diabetes by 36%; however, the RRR was not sustained after medication discontinuation at 2- to 52-week follow-up. While lifestyle modifications were maintained for several years, their effects waned over time, implying the necessity for interventions to prolong the effects.

Qualitative research may provide information about cultural relevance in relationship to diabetes interventions. Rosas et al. (2018) conducted qualitative research to explore the best way to implement culturally adapted evidence-based DPP intervention among Latinos in the primary care setting. For the adaptation process, the researchers used the Patient-Centered Outcomes Research Institute's (PCORI) Patient Engagement Rubric to guide engagement with Latino patients, their family members, physicians and health care system officials (Rosas et al., 2018). The program's main objective was to tailor the group lifestyle balance (GLB) intervention to the cultural preferences and needs of the Latinos. The researchers concluded that over 62% of participants preferred Spanish for written and oral communication (Rosas et al., 2018). Some of

the common themes that emerged during group participation included the involvement of family members, community participation through a smartphone application, incorporating a healthy meal at group sessions, including more Latino food examples in intervention materials, designing all meals to be budget-friendly, providing times for physical activity in groups during the sessions, emphasizing the use of pedometers to account for all type of activity, and included culturally congruent physical activity such as dancing and soccer (Rosas et al., 2018).

The research conducted by the following authors is further analyzed in-depth in the table of evidence (TOE) and demonstrates the effectiveness of intensive lifestyle intervention in preventing prediabetes and delaying the development of T2DM: Brey et al., 1999; Jiang et al., 2018; Konig et al., 2018; O'Brien et al., 2017; Rosas et al., 2020 and Van Name et al., 2016 (see Appendix I). These studies were chosen because they were carried out in similar clinical settings, with similar patient demographics, and some used culturally tailored DPP curriculum. These studies support the implementation of behavioral modification with the promotion of 5% to 7% weight loss, 150 minutes of moderate-intensity exercise per week, and a healthy, well-balanced diet in preventing or delaying the onset of T2DM and prediabetes (Brey et al., 1999; Jiang et al., 2018; Konig et al., 2018; O'Brien et al., 2017; Rosas et al., 2020 and Van Name et al., 2016). Foods with a low glycemic index, reduced dietary fat, and energy-dense meals are also recommended (Konig et al., 2018).

Some researchers compared the efficacy of ILI to that of medications along with the standard of care. In an urban community clinic, 92 Latinas aged 20 and older with impaired fasting glucose (110-125m/dl), elevated HbA1c (5.7% to 6.4%), and average BMI of 33 kg/m^2 were randomly assigned to ILI, metformin, or standard care using 1:1:1 ratio (O'Brien et al., 2017). The researchers concluded that on average ILI group lost 5% weight, compared to 1.1%

with the metformin group and 0.9% weight gain with the conventional care group ($p<0.001$) (O'Brien et al., 2017). Contrasting to metformin and usual care, ILI resulted in a significant reduction in waist circumference and a modest improvement in HbA1c (O'Brien et al., 2017). Under the guidance of the Promotora, the researchers carried out the DPP curriculum with the ILI group in Spanish for a year. The current QI project is similar to patient demographic and clinical settings, except it does not utilize any insulin-sensitizing drugs as part of the intervention with a modified version of the DPP curriculum.

Some studies employed a modified version (14 weeks) of the DPP curriculum comparable to that of the QI project, with a one-year follow-up period. Van Name et al. (2016) conducted another RCT, which utilized ILI in Latinas aged 18 to 65 with prediabetes, BMI greater than 30kg/m^2, and at least one T2DM risk factor. For one year, 75 Latinas participated in the ILI and control group at a 1:1 ratio using the DPP curriculum (Van Name et al., 2016). This community-based program was held at a federally qualified health center (FQHC) in a comparable setting with a similar demographic to the QI project, which is a 14-week modified version of the DPP curriculum that is monitored for a year. The usual care group receives a provider visit and one-time diabetes prevention counseling with encouragement to lose 7% weight along with 150 minutes of exercise per week. The research concluded that the ILI group lost 4.4% (3.8kg) weight at 12 months, while the control group gained 1.6% (1.8kg) weight ($p<0.0001$) (Van Name et al., 2016). Additionally, the ILI group lost 3.87% (3.19kg) weight after the 14-week intervention. According to the study's findings, the percentage of weight loss was positively correlated with the amount of exercise and attendance of lifestyle classes. Compared to the control, the ILI demonstrated a lower 2-hour glucose tolerance excursion (18.9mg/dL) (Van Name et al., 2016). The ILI group dramatically lowered their BMI, percent

body fat, waist circumference, triglycerides, and fasting insulin levels after one year, while their high-density lipoprotein (HDL) levels increased (Van Name et al., 2016).

Similar to the QI project, other researchers employed a culturally modified ILI with comparable participant demographics. Rosas et al. (2020) conducted an RCT of culturally tailored ILI among Latino adults 18 years and older (mean BMI 32.4kg/m^2) with prediabetes and high-risk factors for T2DM. For two years, the 92 participants are randomly allocated a 1:1 ratio to the ILI arm and usual care. The researchers utilized the DPP curriculum with 22 in-person group sessions over 12 months, then switched to web-based self-monitoring for the second year (Rosas et al., 2020). The researchers concluded that the ILI group lost significantly more weight than the control group after 12 months (-2.6 [6.0] kg vs. -0.3[4.2]kg with p=0.005) (Rosas et al., 2020). Nonetheless, after 24 months, there was no significant difference between the intervention and control groups (-1.1 [7.1] kg vs. -1.1 [5.7] kg with p=0.93) (Rosas et al., 2020). In addition, the researchers determined that more frequent session attendance was associated with considerable weight loss at the one-year point (Rosas et al., 2020). This QI project is comparable to this research intervention with similar demographics and clinical settings except for a modified short version of the DPP curriculum with participants having employer-based insurance. Conversely, the majority of patients at the current clinic are uninsured and have a lower socioeconomic standing. Other differences include a shorter implementation period and the absence of web-based monitoring, which would be difficult to establish considering the current patient population's technological literacy and access to electronic devices.

Long term effects of the ILI program were also explored by some researchers. Jiang et al. (2018) studied the long-term effects of the ILI program on Native Americans over ten years in a multicenter quasi-experiment. The researchers used the DPP curriculum with 16 core sessions

administered over 16 to 24 weeks after the baseline evaluation on a large sample size of 8,652 prediabetic adults 18 years and older (Jiang et al., 2018). Participants who lost over 5% of their body weight had a 64% reduced likelihood of developing T2DM over the first six years of follow-up (95% CI 54-72; $p<0.0001$), whereas those who lost 3% to 5% of their body weight showed a 40% reduced incidence of T2DM diagnosis (95% CI 24-53; $p<0.0001$) (Jian et al., 2018). In addition, the intervention resulted in reduced triglycerides, HDL, and low-density lipoprotein (LDL) (Jiang et al., 2018). One of the study's limitations was the attrition of samples over time, ranging from 64% to 84% after the first year, which significantly threatens validity (Jiang et al., 2018).

Konig et al. (2018) conducted a quasi-experiment in Germany with 2,227 obese (BMI 30-40 kg/m^2), prediabetic adults 18 years and older. The researchers ran a community-based program identical to this QI project but did not utilize the DPP curriculum. However, 61 sessions of the interdisciplinary group focused on physical activity, changes in diet, and lifestyle behavior for 12 months (Konig et al., 2018). The dietary intervention was based on the glycemic index, reduced energy-dense foods, and dietary fat intake (Konig et al., 2018). The researchers concluded that 37.7% of participants did not demonstrate criteria for prediabetes, and 46.7% had improvement in metabolic syndrome (Konig et al., 2018). The study also concluded a 6% weight loss ($p<0.001$), including waist circumference (-6.8cm, $p<0.001$), a reduction in cholesterol (TG, -13.7, $p<0.001$), fasting glucose (-3.3, $p<0.001$), blood pressure (systolic BP [-4.3, $p<0.001$], diastolic BP [-2.7, $p<0.001$]), a 15% physical health improvement ($p<0.001$), and lower HbA1c (-0.15, $p<0.001$) at one year study mark.

Synthesis

ILI may effectively reduce weight and waist circumference (Jiang et al., 2018; Konig et al., 2018; O'Brien et al., 2018; Shubrook et al., 2018; Van Name et al., 2016). Some researchers examined the long-term effects of ILI on the risk of diabetes and concluded overall risk reduction and prevention of diabetes development (Haw et al., 2017; Jiang et al., 2018; Shubrook et al., 2018). Furthermore, adoption of lifestyle interventions reduced metabolic syndrome in obese, prediabetic patients (Konig et al., 2018). Three studies on the Hispanic underserved population have been published; however, two of the studies only included female participants, while the third included both genders (O'Brien et al., 2017; Rosas et al., 2017; Van name et al., 2016). Rosas et al. (2020) assessed Hispanic patients, although these individuals were eligible for employer-based health insurance.

Studies that included diet and exercise appeared to induce weight loss and diabetes risk reduction. A comprehensive lifestyle intervention included diet, 5% to 7% weight loss, and weekly activity of 150 minutes was evaluated in multiple studies (Jiang et al., 2018; O'Brien et al., 2017; Shubrook et al., 2018; Van name et al., 2016). The DPP, which includes both diet and exercise has been shown to have long-term sustainability with interventions to assist with lifestyle modification (Haw et al., 2017). There is significant evidence to support the effectiveness of the DPP in preventing and delaying the onset of T2DM. With lifestyle intervention, the relative risk reduction ranged from 39% to 58% with T2DM prevention with landmark studies in the U.S, Finland, and China (Shubrook et al., 2018). Participants who lost more than 5% body weight had a 64% lower risk of developing T2DM during the first six years of follow-up from the study (Jiang et al., 2018). However, 37.3% of participants reversed from prediabetes to normal glucose metabolism within one year of implementation (Konig et al.,

2018). Average weight loss ranged from 3.8 kg to 6 kg at the end of the one-year implementation (Konig et al., 2018; O'Brien et al., 2018; Van Name et al., 2016).

Although the evidence supports utilizing the DPP curriculum to assist in T2DM prevention and delaying T2DM onset, there is a substantial gap in implementing these effective and evidence-based guidelines (Shubrook et al., 2018). The knowledge gap in the literature contains an insufficient understanding of applying these evidence-based principles among underserved, underprivileged Hispanic individuals who live below the poverty line. There is inadequate knowledge about the feasibility and practicality of these interventions and the DPP in this high-risk patient population. There is also a gender disparity in the current research, with most studies focusing on Hispanic females rather than males (O'Brien et al., 2017; Van name et al., 2018).

The groundbreaking DPP trial using ILI has not yet been widely disseminated, particularly in poor communities lacking access to healthcare (Van name et al., 2016). Obstacles to adopting these interventions in socially disadvantaged settings include insufficient financial resources, limited access to safe exercise areas, a shortage of Spanish-speaking staff, and physicians' belief that they lack the knowledge or time to offer comprehensive lifestyle intervention (Shubrook et al., 2018; Van et al., 2016). The majority of these interventions require considerable time and resources, and many organizations may not be financially capable of implementing them or appreciating their value without a thorough understanding of these programs and their significant benefit to T2DM prevention in these underserved communities at large (Shubrook et al., 2018). The literature's generalizability to the community under consideration is one of its limitations. Some of the most recent studies have been done outside the U.S., further limiting the generalizability of the research (Konig et al., 2018).

The research analysis has shown consistent results indicating a significant reduction in T2DM development over the years with the implementation of ILI through the DPP curriculum. Still, the effects wane over time, leaving a gap in research that can only be closed with long-term strategies for close follow-up care (Rosas et al., 2020). Future research should also focus on translating this evidence into clinical practice by developing local and community programs to assist patients in adapting ILI to prevent and delay the onset of diabetes, especially in communities hardest hit by T2DM.

Multiple researchers employed the DPP curriculum to implement ILI with community-based programs comparable to the clinical endeavor at hand (Jiang et al., 2018; O'Brien et al., 2017; Rosas et al., 2020; Van Name et al., 2016). In other studies, the intervention was delivered by community health professionals such as promotoras and health coaches (O'Brien et al., 2017; Rosas et al., 2020). Few researchers performed an ILI in a community health center, similar to the planned clinical setting, with a comparable patient group of inner-city, low-income Hispanics, but only utilized women (O'Brien et al., 2019; Van Name et al., 2016). The curriculum was conducted and managed by a bilingual Spanish nurse practitioner (van et al., 2016). In contrast to other studies, a dietitian or health educator-led the DPP curriculum (Jiang et al., 2018). Culturally adaptive behavioral ILI is conducted by some investigators comparable to the clinic project under consideration (Rosas et al., 2020).

Rosas et al. (2018) examined strategies for culturally modifying the DPP curriculum in the Latino community. The index clinic is implementing several culturally sensitive strategies to provide care to the Hispanic community, including handouts on diet and exercise that are culturally adapted for Hispanic patients (Appendix E). This 13-week modified DPP curriculum will include group exercise classes and at least two healthy, culturally sensitive recipes to share

with the group each month (Rosas et al., 2018). Currently, this QI project has no plans to incorporate family members into the program, which was also highly suggested. However, future incorporation would be highly regarded for patient-centered care (Rosas et al., 2018).

Chapter Four: Methods

The main objective of this QI project was to implement a modified DPP curriculum at an FQHC clinic for patients with prediabetes and obesity. The ultimate goal was to increase access to evidence-based clinical guidelines (DPP curriculum), standardize care for all prediabetic patients at the FQHC clinic, and enhance access, quality of care, and health equality in this vulnerable and underserved population. The project implementation began in December 2021 and concluded in March 2022. A Gantt chart was used to track project progress (see Appendix F).

Design

This QI project employed a one-group pretest-posttest evaluation of the educational intervention, including improved knowledge, behavior modification, and outcome evaluation. All patient participants who met inclusion criteria were offered the intervention and also served as their own control.

Sample and Setting

Participants were identified by retracting data from the clinic's electronic medical record (EMR) and using the inclusion criteria of patients recently seen within the past twelve months with a documented HbA1c (%) of prediabetes. Before the program began, the HbA1c was rechecked for data collection purposes and not to exclude patient participation with glycemic excursions. A total of 270 participants were identified and contacted via phone by a caseworker or office staff and were invited to participate in the program. Those patients expressing interest were enrolled in the program and were surveyed regarding the day and time best suited for attending the intervention. The majority of participants (n=50) surveyed expressed that Saturdays were most convenient, with some agreeing to morning classes (n=27) and others seeking

afternoon classes (n=23). Based on the participant survey and all considerations, the instructional sessions were arranged every Saturday, with one session in the morning and one in the afternoon, and patients could attend either session.

Even though over 50 participants expressed interest in the program, only 18 patients participated in the program between the two class sessions, with the mean and median number of participants being the same at 9.5 (*SD* = 5.34). According to the index clinic's registered dietician, most nutritional and educational sessions at the clinic had a no-show rate of upwards of 50%. The interprofessional collaborative team provided attentive follow-up, with the case manager initiating appointment reminder calls the day before scheduled classes to prevent attrition.

Participants were limited to those with EMR evidence of HbA1c of 5.7% to 6.4% within the past twelve months, BMI measurement of 30 kg/m^2 or greater, self-reported Hispanic ethnicity, males or females, and 18 years and older. Inclusion criteria were designed to be similar to the DPP study. The index clinic submits demographic data annually to the Uniform Data System of the Health Resources and Services Administration (HRSA) (2020). The 2020 demographic data suggests the clinic provided healthcare for 11,731 individuals (HRSA, 2020). The clinic's 11,731 patients are predominantly adults (78.81%) between 18-64 years old, and 91.36% identify as Hispanic/Latino (HRSA, 2020). Additionally, most speak a language other than English (71.04%) (HRSA, 2020). More than half (54.56%) are uninsured/underinsured, and 41.32% are recipients of Medicaid-funded programs (HRSA, 2020). Local, recent EMR data reflected visits for fewer patients between January 2020 and March 2021. The data retrieved for the project population demonstrated that 12.21% (N=635) of patients visiting the clinic within the previous 14 months were diagnosed with prediabetes, showing an HbA1c of 5.7% to 6.4%.

The implementation of this QI project occurred at an FQHC clinic in central Fullerton, California. The clinic is surrounded by high-density housing, including subsidized apartments and housing. In central Fullerton, many patients seeking healthcare are undocumented, Hispanic, and lack access to preventative care and medical insurance. Researchers have reported that participants with low socioeconomic status also demonstrated insufficient knowledge about the importance of lifestyle intervention in diabetes prevention (Aguayo-Mazzucato et al., 2018). At this FQHC clinic, 94.78% of patients report income at or below 200% of the Federal Poverty Level (HRSA, 2020; Office of the Assistant Secretary for Planning and Evaluation [ASPE], 2021). Most patients seeking services at this clinic have multiple co-morbid conditions such as diabetes (28.67%), dyslipidemia (54.79%), hypertension (23.35%), and are overweight or obese (84.10%) (HRSA, 2020).

Each education class was held at a nearby community center in one of the subsidized apartment complexes. The apartment management had granted permission for the clinic's use of the facility.

Ethical Consideration

Although QI projects generally do not require Institutional Review Board (IRB) approval. The index clinic requested that all patients consent to participate in the QI project, which required IRB approval. The IRB approval (IRB#22-000252) was obtained from the University of California, Los Angeles (South Campus) with some modifications to the informed consent (Appendix H). Clinic administrators who are certified translators and have translated the English-language consent into Spanish; both the dietician and the case manager collaborating on this project are certified as fluent in English and Spanish and have reviewed and agree with the translation. The medical director reviewed the English-language version of the consent and

approved it prior to translation. The DNP-prepared provider and the case manager reviewed consent with participants and obtained written informed consent. Consents were placed into the medical record. The voluntary nature of participation was underscored in the informed consent. Patients may meet with the DNP-prepared provider individually to clarify questions.

Confidentiality was maintained by abstracting EMR data to a data collecting form coded with a Study ID number to de-identify data. A single "ID-Key" file of identifiers and Study ID Numbers were kept at the clinic in a locked filing cabinet for the duration of the project. After the completion of the QI project, the ID-Key file was destroyed. This project adhered to Health Insurance Portability and Accountability Act (HIPAA) regulations (National Institutes of Health [NIH], 2004).

Intervention

To implement and evaluate the effectiveness of a CDC-developed evidence-based T2DM prevention behavior modification program, a modified version of the 16-session core curriculum was condensed into 12 sessions and presented weekly for 13 weeks by a dietician (Appendix I). Session zero marked the program's commencement and was primarily focused on orienting participants to the program and obtaining baseline biometric measurements and HbA1c. The modified DPP curriculum was provided in Spanish because the predominant language of all clients attending the sessions is Spanish. The intervention evaluated whether patients met two major goals over 13 weekly observations: 5-7% weight loss and 150 minutes of moderate-intensity activity each week. Intensive lifestyle intervention with the application of DPP has demonstrated a reduced prevalence of metabolic syndrome, improvement in physical fitness, fasting glucose, insulin sensitivity, and reduction in weight and waist circumference (Jiang et al., 2018; Konig et al., 2018; O'Brien et al., 2017; McCurley et al., 2017; Rosas et al., 2017;

Shubrook et al., 2018; Van name et al., 2016). On average, weight loss ranged from 3.8 kg to 6 kg at the end of the one year of implementation (Konig et al., 2018; O'Brien et al., 2017; Van name et al., 2016). The intervention group was encouraged to exercise 150 minutes per week, monitor portion control, and eat a healthy, well-balanced diet. The intervention group served as its own control.

In collaboration with the dietician, the NP project lead conducted in-person educational sessions and closely followed and monitored patients' weekly weight and minutes of exercise. The intervention group received diet and exercise education in groups of 8 to 10 people by attending weekly sessions; one offered in the morning and the second session in the afternoon, every Saturday for 13 weeks. Participants were allowed to attend live virtual due to the covid 19 surge in the winter months via the Zoom platform as few patients and their close contacts had contracted Covid 19 infection. Strict guidelines were followed to prevent the spread of infection, such as temperature checks, symptoms screening, mask mandate, and social distancing. Weekly follow-up by the NP project lead entailed weight measurement and counseling to investigate barriers to lifestyle change and stress the project goal of health-promoting behaviors, including weight loss and daily exercise. Patients were asked to maintain physical activity to document the minutes of exercise performed for the week.

Data Collection

Weight, height, waist circumference, HbA1c BMI, age, gender, and knowledge about the DPP curriculum, were collected to measure evaluating outcomes of the intervention. Weight, measured in pounds, converted to kilograms (kg), was performed in street clothing without shoes at the weekly visit, and height was measured in millimeters (mm) only at the initial visit. BMI was estimated from height and weight measurements collected by the NP provider at baseline

(week 0) and post-intervention (week 12). The patients' HbA1c (%) was collected and measured with a point of care testing machine at the clinic at baseline and after the 13-week DPP curriculum implementation. The patients' waist circumference was measured in centimeters (inches) was measured at baseline (week 0) and post-intervention (week 12). Demographics such as age and gender were abstracted from the EMR on the initial visit. Each patient served as their own control. The weekly activity (exercise in minutes/week) was self-reported by participants on a weekly basis. The class attendance rate was recorded by the course coordinator (Registered Dietician). Session attendance was also evaluated as some studies demonstrated greater weight loss with increased session attendance (Rosas et al., 2020; Van name et al., 2016). Attendance at each of the 13 sessions was recorded weekly as a discrete variable, ranging from 0 to 13.

A pre-post knowledge evaluation of the DPP curriculum with diet, exercise, and T2DM prevention was administered at week 0 and again at week 13 (Questionnaire #1) as well as prior to and at the end of week 4 (Questionnaire #2) (see Appendix G). The project lead developed both questionnaires, with the first questionnaire having 16 items pertaining to the DPP curriculum, nutritional and diabetes prevention, and complications. The second questionnaire consisted of five questions about the reading of food labels and the application of knowledge. The second survey was administered pre-post-class on the day the reading label was introduced. Both questionnaires were graded by the project lead. Data abstracted from the EMR was stored in an electronic file with the intervention ID number to protect privacy. An "ID-Key" file included patient identifiers (name, date of birth) and the intervention ID number, which was secured in a cabinet at the clinic under lock and key and was destroyed at the completion of the QI project. A post-curriculum survey was developed and administered at week 13 by the clinic

staff (registered dieticians) to obtain participant feedback to improve the program for future use and to validate the program's usefulness.

Measurement and Analysis

The data were analyzed using IBM SPSS Statistics (Version 28) predictive analytics software. The patient population was described using descriptive statistics (gender, age, height, level of insurance coverage, class attendance rate, self-reported minutes of exercise per week). Other baseline characteristics, such as weight, HbA1c, BMI, and waist circumference, were also assessed using descriptive statistics.

The participants' demographic data, pre-and post-intervention differences in HbA1c, BMI, waist circumference, weight, and knowledge test were entered into an excel file for data management and analysis. The null hypothesis was: The median differences between pre-and post-intervention variables (HbA1c, BMI, waist circumference, weight, and level of knowledge test) are equal to 0 at the end of three months. The significance level was set at $p < 0.05$, indicating rejecting the null hypothesis. If the significance value was > 0.05, this indicated not rejecting the null hypothesis and concluding that the average difference is near zero and that baseline measurements and three-month post-intervention variables did not differ.

The paired Wilcoxon signed-rank test (nonparametric test) was used to evaluate the median differences between HbA1c, BMI, waist circumference, weight, and level of knowledge with implementing the DPP curriculum. Nonparametric testing is used when the assumptions of parametric tests cannot be met or when the sample size is small (Dwivedi et al., 2017). Wilcoxon signed-rank test is used due to the small sample size (n=11) and the skewness in the normal distribution due to one outlier in HbA1c, which altered the mean score differences and affected the normal distribution (Dwivedi et al., 2017).

A univariate linear regression model evaluated the associations between absolute change in waist circumference from T1 to T13 and its association with post-intervention HbA1c. Linear regression models study the relationship between a single dependent variable (y) and one or more independent variables (x), which formulates a straight line (Bangdiwala, 2018). If the slope of the straight line is zero, there is no association between the x and y; if the slope is negative, the association is negative; if the slope is positive, then the association is positive (Bangdiwala, 2018). The larger the absolute value of the slope, the stronger the association (Bangdiwala, 2018). A linear regression model was used to evaluate the association of minutes of exercise with the difference in T1 to T13 waist circumference, as well as the association of class attendance rate with minutes of exercise and change in HbA1c with change with weight loss or BMI during the observation period.

Chapter Five: Results

Baseline demographic data for 18 participants were collected from electronic medical records (EMR). Overall, 61% (11/18) of baseline participants completed more than 76.9% (more than 10 sessions) of the 13 weeks tailored DPP curriculum, which consisted of 44% (8/18) of participants. Approximately 28% (5/18) of participants completed less than 3 sessions of the 13-week DPP curriculum (Table 1). Of those 11 that completed the curriculum, 73% (8/11) attended 10 or more sessions out of the 13, compared to 27% (3/11) who completed less than 9 sessions out of the 13. Nearly 81% (9/11) of participants were under-insured, showing Emergency MediCal as their primary coverage.

Table 1: Demographic Characteristics (all participants vs. those who completed the program)

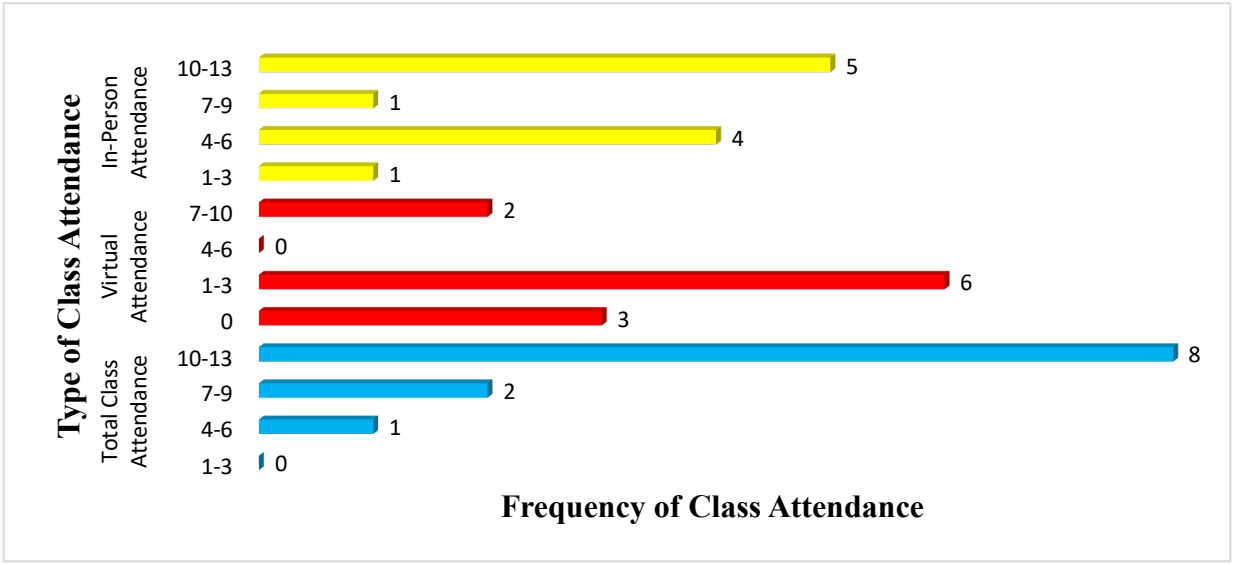
Characteristics		**Total enrolled (N)**	**Total enrolled (%)**	**Total completed (N)**	**Total completed (%)**
Sex	Male	3	16.7	0	0
	Female	15	83.3	11	100
Insurance	MediCal	3	16.7	2	9
	Emergency MediCal	15	83.3	9	81
Class Attendance	1-3	5	27.8	0	0
	4-6	2	11.1	1	9
	7-9	3	16.7	2	18
	10-13	8	44.4	8	73
Age (years)	36 to <47	4	22.2	3	27.3
	47 to <51.5	5	27.8	3	27.3
	51.5 to <59	4	22.2	3	27.3
	59 to 70	5	27.8	2	18.1

Among program initiators, the mean and median ages were closely approximated, 52.4 (*SD* = 8.8) and 51.5 years, respectively. Ages ranged 35 years, from 35 to 70 years of age, and

the interquartile range was 47 to 59 years of age. Among completers, the mean and median ages were again closely approximated (50.3 (*SD* =8.4) and 49 years), although the range (35 to 64 years) and interquartile range (46 to 55 years) were narrower than that of the total sample. Overall, sex was differentially associated with the completion of the program. All participants completing the program were female. Few men enrolled; all three were lost to follow-up within 6 of 13 total visits. Specifically, three males and four females failed to complete the program. One male attended once, and two completed half of the sessions (6 or 7). The four female participants lost to follow-up after 1 to 3 of 13 total visits. Reasons for loss to follow-up remain uncertain and are the subject of future quality improvement projects.

Of the program completers, most attended between 10 to 13 sessions (73%), either in-person or on ZOOM. Most participants completed in-person sessions: 46% (5/11) completed more than 10 classes, while 36% (4/11) completed between 4 to 6 classes (Figure 1).

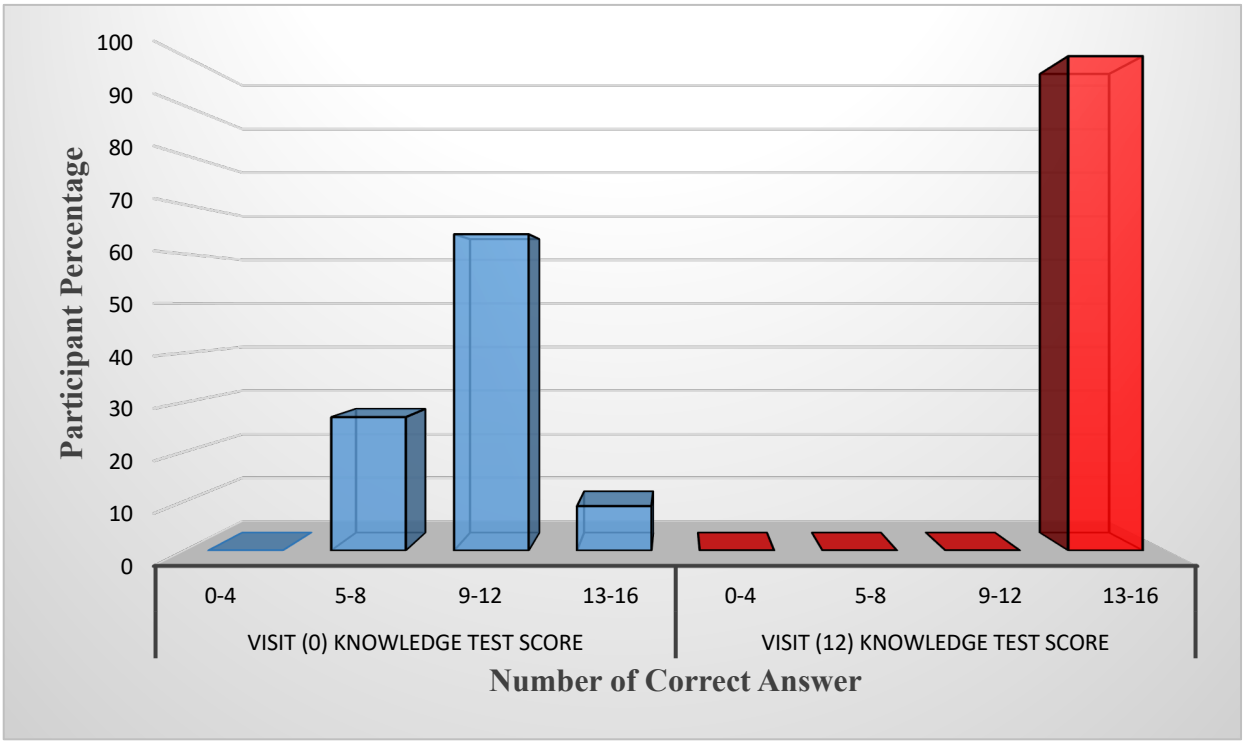
Figure 1: The Frequency of Class Attendance and the Type of Class attendance for the DPP curriculum.



Over 16 questions (Figure 2), pre-test, and post-test evaluations were conducted at baseline (T0) and again end of the DPP curriculum (T12) to evaluate the level of knowledge

regarding diet, exercise, and T2DM prevention. The content of the test was not reviewed before post-test administration. Overall, the participants did well post-test (T12), with 100% (11/11) obtaining scores of more than 13 to 16 out of 16. For most participants, 64% (7/11) had pre-test scores ranging from 9 to 12 out of 16, and 27% (3/11) participants scored 5 to 8 out of 16.

Figure 2: Percent of Correct with Pre-Test and Post Test showing the level of knowledge improvement from visit 0 to visit 12.



The second (5 questions) test was conducted in week 4 at baseline (before T4 class) and at the end of the class (end of T4 class), which focused on reading food labels (Table 2). Overall, week 4 post-test showed 100% (8/8) obtained 4 to 5 out of 5 scores. Of most participants, 62.5% (5/8) obtained pre-test scores of 0 to 3 out of 5. The content was not reviewed before giving either test and reflected the knowledge gained from the DPP curriculum. There was an improvement in knowledge regardless of participants attending remotely or in-person sessions at the end (V13) of the DPP curriculum implementation and the T4 post-test class (Table 4).

Table 2: Pre-Test and Post-Test Score showing the level of knowledge improvement from visit 4

Characteristics		Frequency of Attendance	Total (%)
Visit (4) pre-test Score	0-3	5	62.5
	4-5	3	37.5
Visit (4) post-test Score	0-3	0	0
	4-5	8	100

Those who enrolled and completed the program had an average baseline BMI of 35.03 (SD=5.75), a mean baseline weight (lbs) of 181.56 (SD=27.65), a mean 6 to 12 months prior to program HbA1c of 5.91 (SD=0.22) and mean baseline HbA1c of 6.78 (SD=2.71) (Table 3). There was one outlier within the group with a baseline HbA1c of 14, causing the data to be skewed. Among regular attendees, weekly exercise ranged from 98.3 to 219.1 minutes weekly.

Table 3: Characteristic baseline measurement of participants who enrolled and completed the program

Characteristic	Mean	Std Dev	Median (interquartile range)
Baseline BMI	35.03	5.73	33.6 (3.4)
Baseline weight	181.56	27.65	180 (33.6)
Baseline height	153.52	6.04	154.3 (12.2)
HbA1c 6-12 months prior to DPP	5.91	0.22	5.9 (0.3)
Baseline HbA1c	6.78	2.71	5.9 (0.6)
Baseline WC	41.02	5.46	40 (7)

The following hypothesis is developed when comparing the pre-intervention data to three months post-intervention that there was a median difference between variables (HbA1c, weight loss, waist circumference, BMI, and improvement in knowledge) equal to 0 with $p<0.050$ (Table 4). In order to evaluate if there were changes in HbA1c as a result of the diabetes prevention program curriculum, a Wilcoxon Signed-Rank test was utilized, and it revealed no statistically significant changes in HbA1c following the DPP curriculum (mean rank=5.33), Z= -1.178, p=

0.239. There was also no statistical significance in weight loss or BMI as a result of the DPP curriculum (mean rank=5.13), Z=-1.112, p=0.266. However, there was a statistically significant reduction in waist circumference with implementing the DPP curriculum post-intervention (mean rank=0.00), Z=-2.812, p=0.005. The effect size for change in waist circumference within the group was 0.847, which is very large according to Cohen's classifications of effect size. There was also a statistically significant improvement in diabetes and nutritional knowledge conducted at T13 with implementing the DPP curriculum intervention compared with that measured at T0 (mean = 0.00), Z = -2.946, p = 0.003. The effect size for the level of knowledge improvement was 0.888, which is very large according to Cohen's classification of effect size. There was also statistical significance with improvement in knowledge with reading and understanding of nutritional labels pre-class and post-class T4 (mean = 0.00), Z = -2.060, p = 0.039. The effect size for the level of knowledge improvement with reading nutritional labels within the group was 0.651, which was a large effect according to Cohen's classification.

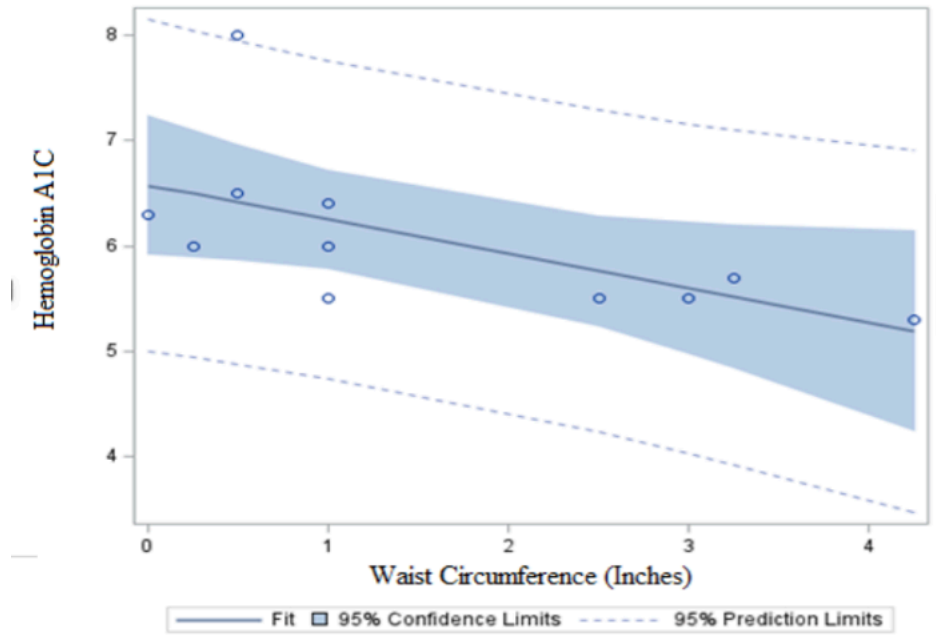
Table 4: DPP evaluation measures using Wilcoxon signed-rank test results (Pre and Post-intervention) N=11

DPP Evaluation measures	Z score	p-Value
Pre-HbA1c and post-HbA1c	-1.178	0.239
prewt and postwt	-1.112	0.266
preWC and postWC	-2.812	0.005
Pre-BMI and Post-BMI	1.217	0.125
pre-test (at T0) and post-test knowledge (atT13),), N=11	-2.946	0.003
Pretest/Posttest knowledge T4 pre/post class, N=10	-2.060	0.039

Simple linear regression was carried out to investigate the relationship between the absolute difference in waist circumference (inches) and post DPP HbA1c (%). The linear regression model (Figure 3) demonstrated an association between the post DPP HbA1c

(outcome) and the absolute change in waist circumference (predictor), suggesting that there is an inverse association between HbA1c, overall, at the T13 visit and the change in waist circumference ($p = 0.043$). The R^2 value was 0.374, so 37.4% of the variation in post HbA1c can be explained by the model containing only an absolute change in waist circumference. The HbA1c level was only measured last time (T13); thus, we do not know that this measure for each participant was decreased or increased compared with the baseline level. There was no association between change in waist circumference with change in HbA1c from baseline to post DPP intervention. There was no association of HbA1c with changes in weight loss or BMI over the period. There was also no association between attendance rate and minutes of exercise or predicted difference in waist circumference. This could suggest that for participants to show greater reduction in A1c will take greater patient perseverance, longer observation, and larger sample size.

Figure 3: Association Between Changes in Waist Circumference Over 13 Weekly Tailored-DPP Instruction Meetings and Changes in HbA1c Measurement Over the Same Period (N=11)



Post Curriculum Evaluation Survey

Ten participants completed a curriculum evaluation after 13 weeks of instruction. All participants expressed high satisfaction with the program's curriculum, agreed on its overall benefit to their health and wellness and diabetes prevention, and recommended that the clinic continue offering these classes. Both in-person and virtual class formats were favored by all. While the majority preferred the continued meetings on Saturdays, at 9 a.m. and 2 p.m., two participants desired weekday evening class meetings. The location of the classes was appreciated by all participants because it was private, clean, new, easily accessible, and, for some (n=3), closer to their homes. The NP provider's presence throughout the curriculum was agreed by all participants to increase motivation, and confidence in achieving their goals, access to additional knowledge and answer any additional questions. Three participants preferred setting their goals individually with the NP provider in a private setting, while six preferred setting their goals in a group setting. One participant desired a mixture of group and individual goal setting.

Although nine participants agreed that while they did not achieve their long-term weight loss goal, they expressed their desire to continue improving their health, increasing physical activity, and working toward their long-term weight loss goal of 5% to 7%. All participants agreed that having exercise classes integrated into the DPP program curriculum each week would increase motivation to continue with increased physical activity. Six participants preferred in-person classes, while four preferred virtual instruction. Multiple forms of exercise, including Zumba, Tai chi, Pilates, and other aerobic exercises, were suggested by participants. Six participants suggested a half-hour of exercise before starting each DPP curriculum session.

Last, participants suggested cooking demonstrations and samples would improve their learning experience. Similarly, members proposed extending the follow-up beyond 13 weeks.

Individual meal planning and field trips to the supermarket were proposed. Participants generally enjoyed the curriculum but desired additional information on impulse control, stress management, weekly lists of healthy foods, and chronic conditions such as arthritis and other diseases associated with poor eating habits. The participants particularly enjoyed sessions that reviewed food-label reading, food intake tracking techniques, shopping and cooking to prevent diabetes, and Impulse control.

Chapter Six: Discussion

The results of this QI project demonstrated a reduction in waist circumference over 13 weeks of measurement and an average reduction of 1.6 inches in waist circumference. Published results suggest a statistically significant reduction in waist circumference may take as many as 12 months of follow-up to achieve (Konig et al., 2018; O'Brien et al., 2017; Van Name et al., 2016). For example, O'Brien and colleagues (2017) reported an average of 4 cm, while Konig et al. (2018) reported a 6.8 cm change, on average, over the study period. Van Name and colleagues (2016) reported an average reduction of 3.3 cm for waist circumference measured at the end of 12 months from baseline. Thus, future quality improvement efforts will employ longer follow-up periods to assess waist circumference, weight loss, and HgA1c.

Over 13 weeks, participants who received the DPP education to improve their T2DM-related behaviors experienced changes in their waist circumference and post-intervention HbA1c, but no association between weight loss, BMI change, and HbA1c. Similarly, Van Name and colleagues (2016) applied a modified version of the DPP over 14 weeks, but the results were gathered and analyzed after 12 months, and it exhibited a statistically significant reduction in weight by 3.8 kg and waist circumference by 3.3cm, but no change in BMI or HbA1c. They also noted a positive correlation between percentage weight loss with amount of exercise ($p=0.031$) and increased class attendance ($p=0.027$) (Van Name et al. 2016). Published results by Rosas et al. (2020), session attendance, was positively correlated with weight loss at 12 months ($p=0.002$), and more weight loss was associated with greater monitoring of weight, diet, and physical activity.

There was no statistical significance with HbA1c, weight, or BMI after the 13-week modified DPP curriculum ($p>0.05$). Multiple published studies have shown that the DPP

curriculum significantly affects lifestyle change over 12 months rather than 13 weeks (O'Brien et al., 2017; Van Name et a., 2016; Konig et al., 2018; Rosas et al., 2020). The DPP education has been shown to be successful and sustainable in the long term with some publications spanning 10 years indicating a 64% relative risk reduction in developing diabetes with 5% weight loss at six-year of intervention (Jiang et al., 2018). Multiple studies have demonstrated a considerable weight loss in 12 months (Konig et al., 2018, O'Brien et al., 2018; Shubrook et al., 2018; Van Name et al., 2016), as well as a reduction in HbA1c (Konig et al. 2018; O'Brien et al., 2017).

A limited sample size of 11 participants, short duration of data collection, and over 39 % attrition rate led to minimal effect size and uncertain results in several variables, such as no association of weight loss, BMI change, HgA1c, or attendance rate to the reduction in HgA1c, weight, BMI or increased exercise. Most studies had a sample size ranging from 92 participants to over 8600 (Jiang et al., 2018; Konig et al., 2018, O'Brien et al., 2018; Rosas et al., 2020; Van Name et al., 2016). A longitudinal study done by Jiang et al. (2018) had approximately 8600 participants and found 34% attrition during the first year and 84% attrition after 10 years. Larger sample size and a longer observation may allow for more accurate adherence measurement and, in the future, may reveal a relationship between other significant biomarkers of reduced risk for T2DM.

The end-of-program curriculum survey provided valuable information on the needs of participants attending the clinic with prediabetes and obesity. Overall, the DPP curriculum received positive feedback. Program participants advised adding an exercise regimen to the curriculum, food demonstrations, culturally specific weekly healthy recipes, and individual meal planning. Multiple published studies have utilized exercise as part of the DPP curriculum (Koning et al., 2018; Van Name et al., 2016). Koning and colleagues (2018) demonstrated a

15% physical health improvement post-12-month implementation ($p<0.001$). Van Name et al. (2016) expanded the DPP curriculum to include weekly hands-on culinary demos utilizing fresh products and group learning at the local grocery store. One publication provided a healthy meal at each in-person session to model healthy eating and boost engagement and retention among Hispanic patients (Rosas et al., 2020). Providing meals and exercise in a controlled setting is likely to produce more compelling results yet is impractical given funding constraints. Overall, there was universal agreement about the program's value and the necessity to continue the curriculum for individuals who are obese and prediabetic and at risk for developing T2DM.

Limitations

This QI project has several limitations, including small sample size, only Hispanic female participants, participant attrition, short duration of project implementation, and a single clinic setting limiting the generalizability of findings and thus influencing external validity. Some of these confounding variables can be minimized by increasing the sample size, longer duration of outcome measurement, and implementing strategies to reduce participant attrition, such as weekly phone calls and text message reminders. Threats to external validity were minimized through consistent conditions throughout the course of the project to help limit variation that may affect the results, such as standardizing training and education of all staff implementing the project. Using measuring tools consistently in methodology decreased the internal threat to validity, such as the same calibrated scale. Covid-19 pandemic also significantly influenced in-person group classes, but modifying the curriculum to include live virtual Zoom classes increased access to the learning material, enhancing DPP knowledge.

Implications for practice and research

Implementing this modified DPP curriculum reverses prediabetes and prevents T2DM in the underserved uninsured Hispanic patient population by imposing health-promoting behaviors through weight loss, diet, and exercise. Implementing this DPP curriculum within this clinical setting shows promising results, but more time and follow-up are needed to show clinical significance. The patient population at this index clinic is heavily burdened by overweight and obesity, and T2DM, with over 29% of the patient population having T2DM and over 84% of the population being overweight or obese (HRSA, 2020). The QI project increased access to evidence-based guidelines to this underserved uninsured Hispanic community, previously unavailable to this population inside this index clinic. Following evidence-based clinical recommendations and offering culturally responsive care enhanced clinical outcomes (Rosas et al., 2018). This modified version of the DPP curriculum is not only efficient but also cost-effective, especially in communities with a language barrier and patients with limited time. Streamlining resources required for the DPP education is essential for an FQHC clinic with limited budgetary resources. Over 82% of participants who attended this program would generally not have access to evidence-based clinical guidelines such as the DPP curriculum due to their limited medical coverage. Having equal access to learning that prevents T2DM is essential to health equity and care quality and breaking barriers to access to care.

One of the goals of this QI was to demonstrate the efficacy of this modified DPP curriculum to leadership within the index clinic so it can be recognized and adopted as a standard of care across all prediabetic patients within the index clinic's healthcare system.

Future research implications include interviewing and probing the needs of Hispanic, Spanish-speaking men with prediabetes are important to providing a standard of care treatment

in this setting. It is also imperative to develop an appealing environment or curriculum for Hispanic, Spanish-speaking males to improve cultural competence in this setting. A follow-up to promote high adherence to evidence-based exercise and dietary recommendations is essential to ongoing success. It is critical to formulate and execute strategies to maintain weight loss as it declines over time (Rosas et al., 2020). Additionally, focusing on strategies to increase patient engagement, thus enhancing participation and reducing sample attrition is essential in the future. Higher insurance compensation is needed to sustain similar initiatives financially. Post-DPP curriculum survey suggested exercise classes in addition to education classes would enhance their satisfaction. Obtaining certification through the CDC's lifestyle coach program recognizing the index clinic as CDC DPP provider would increase financial sustainability for the program (Managed Care Delivery System (MCO), n.d.). For Medi-Cal enrolled patients engaging in the program, CDC authorized providers can receive $536 per patient per year in federal funding (MCO, n.d.).

Chapter Seven: Conclusion

The DPP education and consequent behavior change were associated with a greater difference in waist circumference at week 13 and lower HbA1c. The DPP curriculum provided health equity and care equality to the underserved Hispanic population at this FQHC clinic. Implementing the DPP is vital for eradicating health inequality and improving access to care for those highly burdened by T2DM. Numerous culturally adaptive practices are incorporated into this modified DPP curriculum, including providing handouts on cultural food and physical activity (Rosas et al., 2018). This program is necessary for this community since Hispanics at the index clinic have a greater prevalence of T2DM and obesity (HRSA, 2020). By 2050, the number of Hispanics with T2DM is predicted to more than double (from 5.47 to 12.38%) (Russell et al., 2018). There is a significant level of evidence supporting the effectiveness of the DPP in preventing T2DM (Jiang et al., 2018; Konig et al., 2018; Rosas et al., 2020; Shubrook et al., 2018; Van name et al., 2016). Currently, there is a significant care gap at this FQHC clinic with a lack of evidence-based strategies for prediabetes and T2DM prevention. This QI project developed evidence-based standards for treating prediabetes and T2DM prevention, expanded access to care, and enhanced health equity and equality for the underserved Hispanic population. As DNP leaders, our ethical obligation is to close care gaps, remove barriers to care, and deliver interventions that promote health equity and care equality for all individuals, regardless of financial means and social standing. Our responsibility as DNP leaders is to implement strategies for system-wide change, particularly for diseases that can be delayed or prevented, such as T2DM.

Appendices

Appendix A: Diagnostic criteria for normal blood glucose, Prediabetes, and Type 2 Diabetes

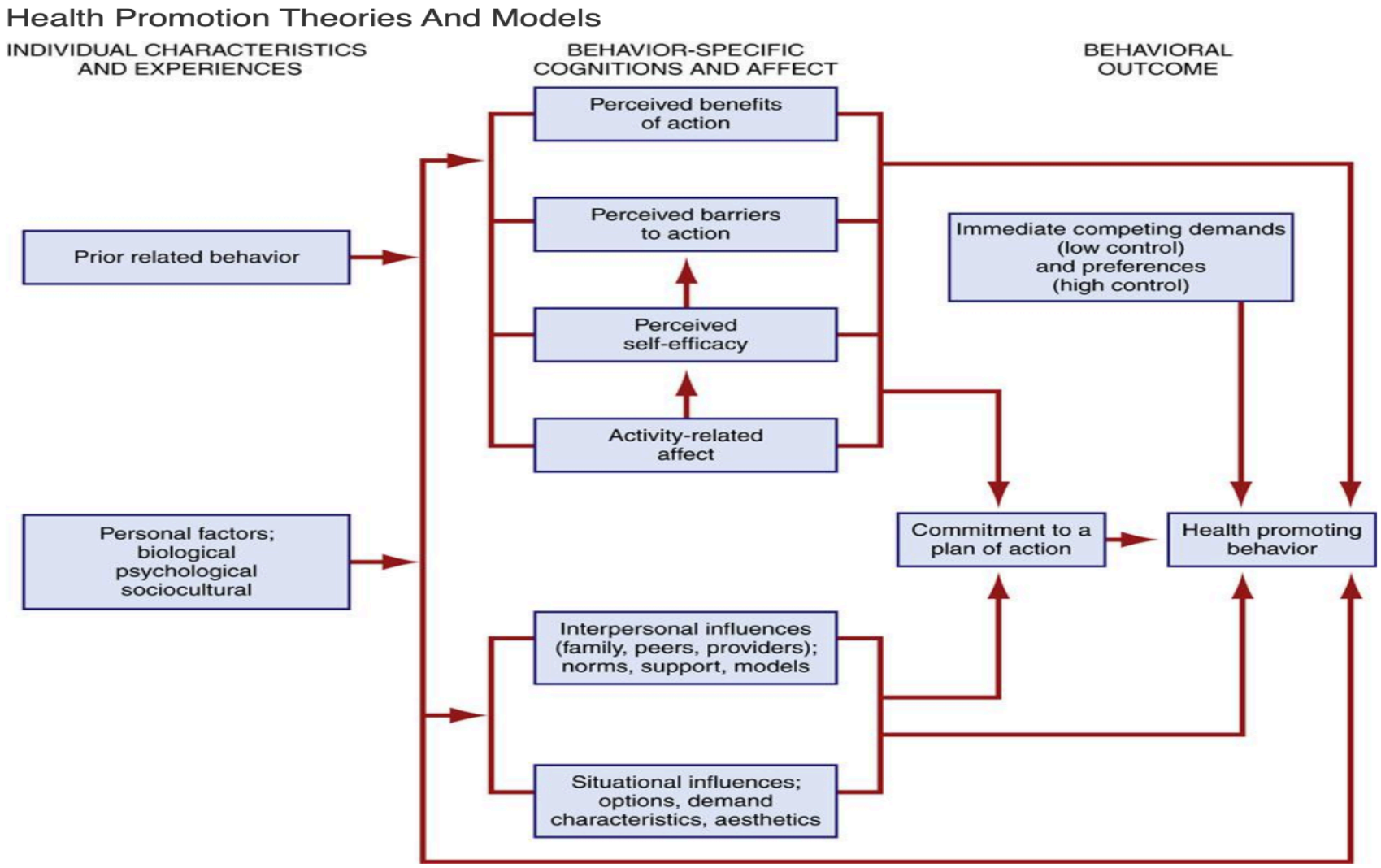
	Fasting Plasma Glucose (at least 8 hrs fast)	Oral Glucose Tolerance Test (OGTT), 2 hrs with 75 g glucose solution	Hemoglobin A1c
Normal	<100 mg/dL	<140 mg/dL	<5.7%
Prediabetes	≥100 mg/dL	≥140 mg/dL	≥5.7 %
Type 2 Diabetes (T2DM)	≥126 mg/dL	≥200mg/dL	≥6.5 %

(Khan et al., 2019)

Appendix B: Cost of 13 weeks of DPP implementation Vs. 24 weeks of implementation

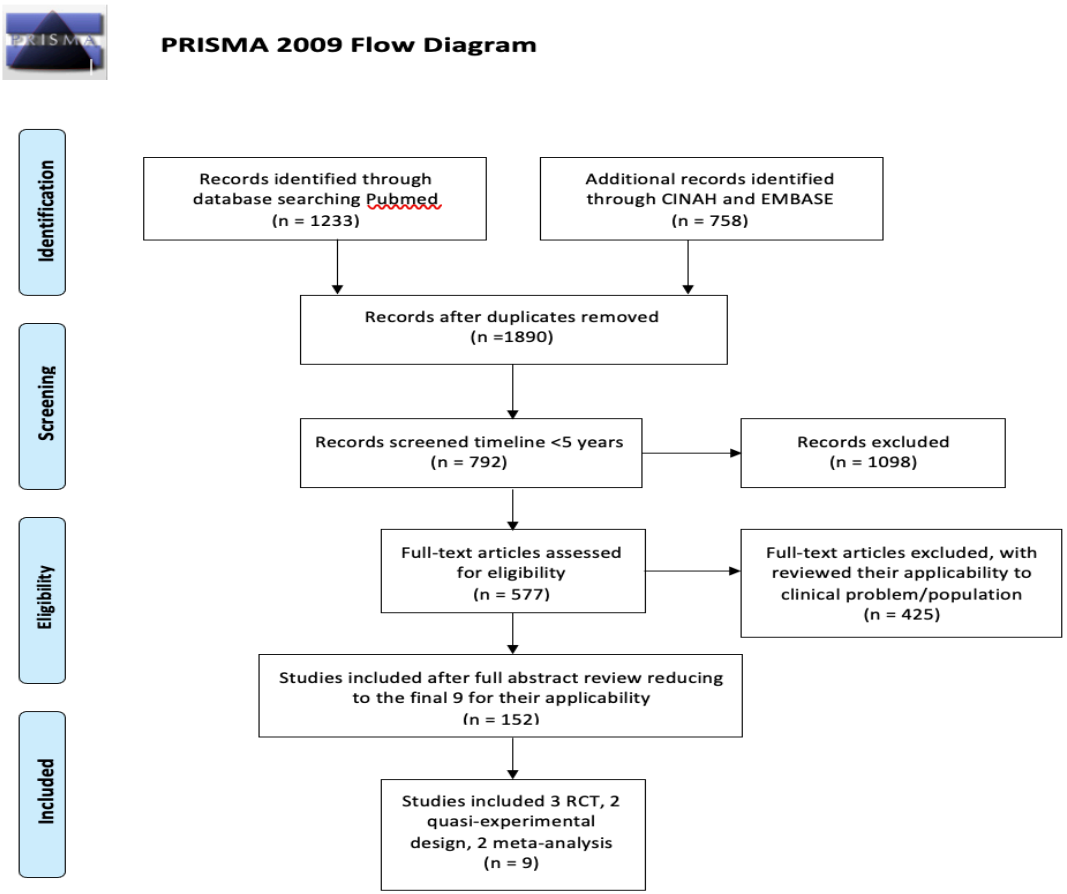
Resources	**Cost for** 12 weeks	Cost for 24 weeks
Dietician 2hrs/wk @ $35	$840	$1,680
Promotora 4 hrs/wk @ $18	$840	$1680
Case manager 1hr/wk @ $27	$324	$648
NP 4 hrs/wk @$55	$2640	$5280
Healthy recipes 2x month	$200	$400
Bottle water for participant	$100	$200
Pedometer 100@ $1.61	$161	$161
Total	$5105	$10,049

Appendix C: Pender's Health Promotion Model (HPM)



Appendix D: PRISMA Diagram for article selection for DPP

PRISMA Diagram for article selection for DPP



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Reduce Riesgo de Diabetes

1 **Hacer ejercicio 30 min/dia , 5x/semana o 10,000 pasos/dia**



2 **Bajar de peso - 7%** (Si 200lbs bajar 14 lbs; 150lbs bajar 10.5 lbs)

3 **Tomar más agua -** No refrescos, Jugos, bebidas energeticas


4 **Limitar las porciones**

Thumb
1 oz of cheese

Fist
1 cup of (cooked rice, pasta, cereal)

Thumb Tip
1 Tbsp. – Peanut Butter

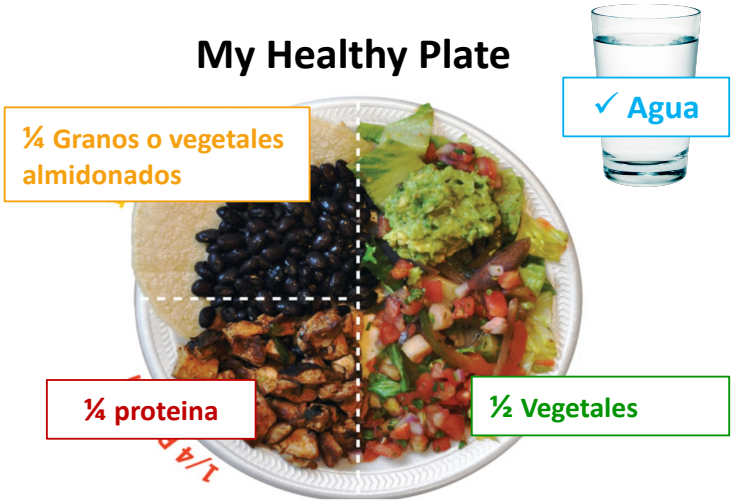
Palm of Hand
3 oz lean meat, poultry

5 **Comer más saludable**



6 **Eliminar comida chatarra** (Leer etiquetas)


My Healthy Plate



My health plate and options from Institute of family health: https://institute.org/health-care/services/diabetes-care/healthyplates/

Frutas: 2 tazas/dia

Manzana Platano Guayaba Mango

Lacteos: 3 tazas/dia

1% leche plain/light yogurt

*Queso
(2 oz = porcion)

Vegetales: 2 ½ tazas/dia

Chayote Gherkin Jicama Calabaza

1 taza es equivalente a:

- 2 tazas de espinaca
- 1 pimiento morron
- 1 taza de zanahorias
- 1 taza de chicharos
- 1 taza de champinones

Nepal Cebolla Pimiento Salsa Fresca

Salsa Verde chiles tomatillo jitomates

Granos: 6 oz/dia, integrales

Cereal Elote Tortilla (1-2) Todtada (1-2)

Avena Pasole Arroz Saltine (5)

Camote (mediano) Tamal (1/2)

1 oz es equivalente a

- 1 rebanada de pan
- ½ taza de avena
- 1 tortilla
- ½ tazas de arroz integral

Proteina: 5.5 oz /dia

1 oz es equivalente a

- ¼ taza de frilojes
- 1 huevo
- 1 cucharita de mantequilla de mani

Frijoles Carne Huevo Ceviche (1 taza)

Pollo Puerco Camaron(1 taza)

My health plate and options from Institute of family health: https://institute.org/health-care/services/diabetes-care/healthyplates/
National Institute of Diabetes and Digestive and Kidney disease:https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-type-2-diabetes/game-plan

Reduce Your Risk of Diabetes

1 **Exercise 30 min/day, 5x/wk or 10,000 steps/day**



2 **Lose weight - 7% weight loss** (If 200lbs lose 14 lbs; 150lbs lose 10.5 lbs)

3 **Drink More Water -** No Soda, Juice, Energy or Sports drinks


4 **Limit Portion Sizes**

Thumb
1 oz of cheese

Fist
1 cup of (cooked rice, pasta, cereal)

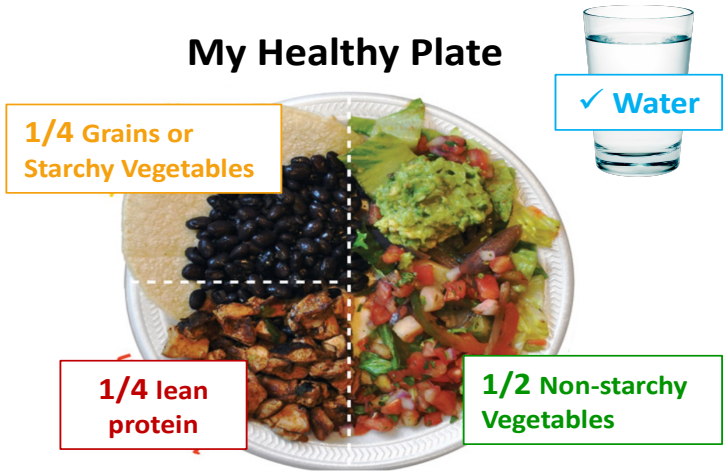
Thumb Tip
1 Tbsp. – Peanut Butter

Palm of Hand
3 oz lean meat, poultry

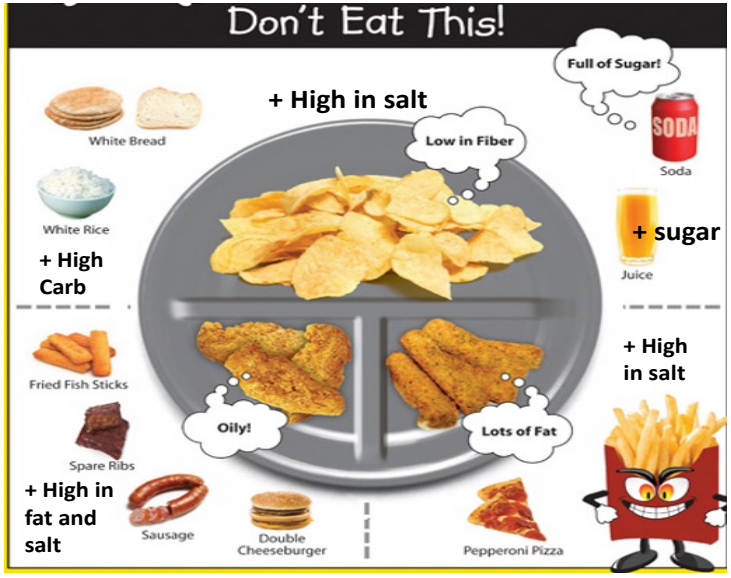
5 **Eat Healthier**



6 **Eliminate Junk Food** (read labels)

My health plate and options from Institute of family health: https://institute.org/health-care/services/diabetes-care/healthyplates/



Fruit: 2 cups/day

Apple Banana Guava Mango

Non-Starchy Vegetables: 2 ½ cups/day

1 cup counts as
- 2 cups of spinach
- 1 large bell pepper
- 1 cup carrots
- 1 cup of green peas
- 1 cup mushrooms

Dairy: 3 cups/day

1% milk plain/light yogurt

*Cheese (2 oz = a serving)

Chayote Gherkin Jicama Mexican squash

Nepal Onion Bell pepper Salsa Fresca

Salsa Verde hot pepper tomatillo tomatoes

Grains: 6 oz/day, whole grain

Cereal Corn Tortilla (1-2) Hard Shell Tortilla (1-2)

Oatmeal Pasole Rice Saltine (5)

Yam (medium) Tamale (1/2)

1 oz counts as
- 1 slice of bread
- ½ cup cooked oatmeal
- 1 small tortilla
- ½ cup cooked brown rice

Protein: 5.5 oz /day

1 oz counts as
- ¼ cup cooked beans
- 1 egg
- 1 tbsp peanut butter

Beans beef egg ceviche (1 cup)

Chicken Pork Shrimp (1 cup)

My health plate and options from Institute of family health: https://institute.org/health-care/services/diabetes-care/healthyplates/
National Institute of Diabetes and Digestive and Kidney disease:https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-type-2-diabetes/game-plan

Appendix F: GANTT Chart for Diabetes Prevention Program Implementation

GANTT Chart for Diabetes Prevention Program Implementation

Diabetes Prevention Program Implementation Plan/Timeline

PROJECT TITLE	Diabetes Prevention Program
PROJECT LEAD	Monika Badyal
COMPANY NAME	St. Jude Neighborhood Health Centers
DATE	

TASK ID	TASK TITLE		Month	PHASE ONE (2021)												PHASE TWO (2021)												PHASE THREE (2022)												PHASE FOUR											
				JUNE				JULY				AUGUST				SEPTEMBER				OCTOBER				NOVEMBER				DECEMBER				JANUARY				FEBURARY				MARCH				APRIL				MAY			
			Week	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
1	Analysis/Design Phase																																																	
1.1	Finalize Design																																																	
1.1.1	Obtain and finalize instrument																																																
1.2	Finalize Educational content/materials																																															
1.3	Form and meet with Doctoral Committee																																															
1.4	Prepare Materials/Consent																																															
1.5	Scholarly Proposal preparation																																															
1.6	Written Qualifying Exam																																															
2	Planning Phase	PLAN																																															
2.1	Proposal to Committee/Review																																																
2.2	Oral Qualifying Exam																																																
2.3	Committee Aproval																																																
	IRB submission/clinical setting																																																
	IRB approval																																																
	Staff Meetings																																																
	Staff Education																																																
2.4	Material Placement																																															
3	Implementation Phase	DO																																															
3.1	Advance to Candidacy																																																
3.2	Conduct DNP project/Intervention																																																
3.2.1	Data Collection																																																
3.2.2	Staff Huddles/Updates																																																
4	Data Analysis	CHECK																																															
4.1	Review Data																																																
4.2	Statistical Analysis																																																
4.3	Translate Findings																																																
4	Concluding Phase	ACT																																															
4.3	Evaluate Project																																																
4.3	Report to Leadership																																																
	Develop Spread Strategy																																																
4.3																																																	
4.3	Write/Complete DNP Project																																																
4.3	Scholarly Paper & Oral Defence																																																

Appendix G: Pretest/Posttest questionnaire #1 and questionnaire #2

Pre-Test/Post-Test Questionnaire #1
(Circle one)

Name: _____

Date: _____

1. Type 2 diabetes is a disease:
    a. People get only when they get older
    b. That happens when the body has too much sugar and it can't be processed correctly
    c. That can be passed from one person to another person
    d. That you usually cannot prevent
2. According to the Diabetes Prevention Program (DPP), how many minutes of exercise is recommended **per week**
    a. 60
    b. 150
    c. 30
    d. 300
3. According to the Diabetes Prevention Program (DPP), what is the goal weight loss percentage for the program?
    a. 5-7%
    b. 5-10%
    c. 2-3%
    d. 10-15%
4. What is the most important drink we can put in our bodies?
    a. Milk
    b. Gatorade
    c. Water
    d. Fruit juice
5. What are some ways a person can prevent type 2 diabetes?
    a. Eating healthy food
    b. Being active and exercising
    c. Staying a healthy weight
    d. All of the above
6. A person should eat at least _____ fruits and vegetables each day
    a. 3
    b. 5
    c. 1
    d. 0
7. Stress causes the blood sugar to
    a. Go up
    b. Go down
    c. Nothing happens
8. Processed foods are found packed in boxes, cans or bags and are not found in nature

a. True
b. False

9. If you have diabetes in your family, you are at a high risk of developing diabetes, but type 2 diabetes can be prevented or delayed.
    a. True
    b. False
10. Nothing can be done to prevent diabetes
    a. True
    b. False
11. What are some of the complications of diabetes?
    a. Kidney failure
    b. Blindness
    c. Numbness, tingling and burning sensation to the feet
    d. High blood pressure or heart problem
    e. All of the above
12. Eating carbohydrates makes your blood sugar go up
    a. True
    b. False
13. The only way to know if you are overweight is to
    a. Measure waist size
    b. When medical problems start to arise
    c. Using Body Mass Index (BMI)
    d. Not sure
14. Type 2 diabetes
    a. Can occur at any age
    b. Is more common in older adults
    c. Can cause problem with the eyes, feet and kidneys
    d. All of the above
    e. Not sure
15. What does the diabetes prevention program recommend for people to measure portion size?
    a. Use a cupped hand to estimate the number of servings in a portion
    b. Always use a food scale to be precise
    c. Use everyday objects to estimate (for example, a deck of cards equals to 1 serving of meat)
    d. Not sure
16. Risk factors for developing diabetes include
    a. Having had gestation diabetes (diabetes when pregnant)
    b. Being overweight
    c. Sedentary lifestyle (lack of physical activity)
    d. Being over the age of 45
    e. All of the above
    f. Not sure

Pre-Test/Post-Test questionnaire #2
(Circle one)

Name: _____

Date: _____

1. What 3 things are important to look at when reading a nutrition label when counting carbohydrates?
    a. Serving size, total fat and protein
    b. Serving size, calories, and carbohydrates
    c. Serving size, serving per container and carbohydrates
2. Refer to the Nutritional label below. If Rose ate 15 crackers, how many servings did she eat?
    a. 15
    b. 3
    c. 2
    d. 5

3. Refer to the Nutritional label above. How many crackers can Rose eat with one serving?
    a. 15
    b. 5
    c. 25
    d. 12
4. Refer to the Nutritional label above. How many calories are in 1 serving of crackers?
    a. 60
    b. 15
    c. 12
    d. 40
5. The nutrition facts label includes information on
    a. Total number of calories in a serving of that food
    b. The number of servings in the container
    c. Number of calories from fat in that food
    d. All of the above
    e. Don't know

Appendix H: Consent in English/Spanish

University of California, Los Angeles
CONSENT TO PARTICIPATE IN RESEARCH

The Implementation of Diabetes Prevention Program at a Community Health Center

INTRODUCTION

Dr. Dorothy J. Wiley and Ms. Monika Badyal from the School of Nursing at the University of California, Los Angeles, and under the guidance of Dr. Milie Tolentino from St. Jude Neighborhood Health Centers are conducting a quality improvement project. You were selected as a possible participant in this study because your doctor reviewed the education classes presented and recommended to you that you participate. All of the educational information is the care recommended nationally for people with prediabetes. Your participation in this research study is voluntary.

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
-

WHY IS THIS RESEARCH BEING DONE?

This project aims to improve your ability to follow diet and exercise recommendations that have been shown to prevent diabetes in people diagnosed with pre-diabetes. We aim to improve healthcare procedures for people with prediabetes who are cared for at St. Jude Neighborhood Health Centers.

HOW LONG WILL THE RESEARCH LAST AND WHAT WILL I NEED TO DO?

Participation will take a total of 24 hours. Each class is 2 hours and you are asked to attend 12 weekly classes.

If you volunteer to participate in this study, the researcher will ask you to do the following:

- Take a pencil and paper 21 question pre-test and post-test to assess knowledge about diabetes and prediabetes.
- You will receive a packet of written information about information presented in class each week.
- You will be asked to attend the weekly class at Ross Compass Community Center, 411 west ave, Fullerton, CA 92832.

ARE THERE ANY RISKS IF I PARTICIPATE?

You may be uncomfortable with the types of changes to our diet and exercise recommendations.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

You may benefit from the study because changing your diet and exercise habits may prevent you from developing diabetes.
From this study, we may learn how to better help people with pre-diabetes develop diet and exercise habits that prevent diabetes from developing.

What other choices do I have if I choose not to participate?

There are education classes for people with prediabetes in the community. Your provider may recommend other classes for you.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:

The researchers will collect your name, date of birth, and sex at the first education class to be sure that the information from your participation is correctly linked to you using an ID number. A test measuring your understanding of pre-diabetes and diabetes is given before your first class and at the last class to measure how much you learned. During the weekly classes, your weight and the last week's minutes of exercise. All records will be labeled with the ID number and once checked after the classes are over, the researcher will destroy the identifying information about you before they evaluate your weight and exercise and attendance of the classes.

How information about you will be stored:

All information about you, personally, is stored in your medical record. When the class is completed, the study ID number will be removed from that record. Removing the study ID number will break the link between your personal information and the information from the classes.

People and agencies that will have access to your information:

Ms. Monika Badyal will have access to your medical record data during this education project. Dr. Dorothy Wiley is her university advisor and she will see the data, but not have access to any personal information about you. Dianet Pineda-Valadez, Rosa Robledo-

Naranjo, Lucero Estrada Rebollar and Lizette Gonzalez will have access to your information.

The research team, authorized UCLA personnel may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

USE OF DATA FOR FUTURE RESEARCH

Your de-identified data may be kept for use in future research.

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for your participation in this research study.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The research team:
If you have any questions, comments or concerns about the research, you can talk to one of the researchers. Please contact: Monika Badyal (monikabadyal@g.ucla.edu by email or telephone 562-713-0759). Alternatively, you may contact her advisor, Dr. Dorothy Wiley (dwiley@sonnet.ucla.edu by email or telephone 310-292-8466). Last, you may contact your clinic provider, medical director (Dr. Milie Tolentino) or the administration by telephone (714) 446-5100).

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

You will be given a copy of this information to keep for your records.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you want to participate in this study you should sign and date below.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

Universidad de California, Los Ángeles

CONSENTIMIENTO PARA PARTICIPAR EN LA INVESTIGACIÓN

La implementación del programa de prevención de la diabetes en un centro de salud comunitario

INTRODUCCIÓN

Dr. Dorothy J. Wiley Y Ms. Monika Badyal de la escuela de enfermería de la Universidad de California, Los Ángeles, y bajo la guía de la Dra. Milie Tolentino de St. Jude Neighborhood Health Centers están llevando a cabo un proyecto de mejora de calidad. Usted fue seleccionado como un posible participante en este estudio porque su médico reviso las clases de educación presentadas y le recomendó que participara. Toda la información educativa es la atención recomendada a nivel nacional para las personas con prediabetes. Su participación en este estudio de investigación es voluntaria.

¿QUÉ DEBO SABER SOBRE ESTE ESTUDIO DE INVESTIGACIÓN?

* Alguien le explicara este estudio de investigación.
* Si participa o no depende de usted.
* Puede optar por no participar.
* Puede aceptar participar y luego cambiar de opinión.
* Su decisión no será tomada en su contra.
* Puede hacer todas las preguntas que quiera antes de decidir.

¿POR QUÉ SE ESTÁ REALIZANDO ESTA INVESTIGACIÓN?

Este proyecto tiene como objetivo mejorar su capacidad para seguir las recomendaciones de dieta y ejercicio que se ha demostrado que previenen la diabetes en personas

diagnosticadas con prediabetes. Nuestro objetivo es mejorar los procedimientos de atención médica para las personas con prediabetes que son atendidas en St. Jude Neighborhood Health Centers.

¿CUÁNTO TIEMPO DURARÁ LA INVESTIGACIÓN Y QUÉ TENDRÉ QUE HACER?

La participación durara un total de 24 horas. Cada clase es de 2 horas y se le pide que asista a 12 clases semanales.

Si se ofrece como voluntario para participar en este estudio, el investigador le pedirá que haga lo siguiente:

- Tomar examen escrito de 21 preguntas antes y después para evaluar el conocimiento sobre la diabetes y la prediabetes.
- Recibirá un paquete de información escrita sobre la información presentada en clase cada semana.
- Se le pedirá que asista a la clase semanal en el centro comunitario Compass Rose, localizado en 411 West Ave., Fullerton, CA 92832.

¿HAY ALGÚN RIESGO SI PARTICIPO?

Es posible que se sienta incomodo con los tipos de cambios en nuestra dieta y recomendaciones de ejercicio.

¿HAY ALGÚN BENEFICIO SI PARTICIPO?

Usted puede beneficiarse del estudio porque cambiar su dieta y hábitos de ejercicio puede evitar que desarrolle diabetes.

Por este estudio, podemos aprender cómo ayudar mejor a las personas con prediabetes a desarrollar hábitos de dieta y ejercicio que eviten que se desarrolle la diabetes.

¿QUÉ OTRAS OPCIONES TENGO SI DECIDO NO PARTICIPAR?

Hay clases de educación para personas con prediabetes en la comunidad. Su proveedor puede recomendarle otras clases.

¿CÓMO SE MANTENDRÁ CONFIDENCIAL LA INFORMACIÓN SOBRE MÍ Y MI PARTICIPACIÓN?

Los investigadores harán todo lo posible para asegurarse de que su información privada se mantenga confidencial. Su información se manejará de la manera más confidencial posible, pero participar en la investigación puede implicar una pérdida de privacidad y la posibilidad de una violación de la confidencialidad. Los datos del estudio estarán protegidos física y electrónicamente. Al igual que con cualquier uso de medios electrónicos para almacenar datos, existe el riesgo de violación de la seguridad de los datos.

Uso de información personal que pueda identificarle:

Los investigadores recopilaran su nombre, fecha de nacimiento, y sexo en la primera clase de educación para asegurarse de que la información de su participación este correctamente vinculada a usted utilizando un número de identificación. Se administra una prueba que mide su comprensión de la prediabetes y la diabetes antes de su primera clase y en la última clase para medir cuanto aprendió. Durante las clases semanales, su peso y los minutos de ejercicio de la última semana serán colectados. Todos los registros se etiquetarán con el número de identificación y, una vez verificados después de que terminen las clases, el investigador destruirá la información de identificación sobre usted antes de evaluar su peso y ejercicio y asistencia a las clases.

Como se almacenará su información:

Toda la información sobre usted, personalmente, se almacena en su registro médico. Cuando se complete la clase, el número de identificación del estudio se eliminará de ese registro. Eliminar el número de identificación del estudio romperá el vínculo entre su información personal y la información de las clases.

Personas y agencias que tendrán acceso a su información:

Ms. Monika Badyal tendrá acceso a los datos de su registro medico durante este proyecto educativo. Dra. Dorothy Wiley es su asesora universitaria y vera los datos, pero no tendrá acceso a ninguna información personal sobre usted. Dianet Pineda-Valadez, Rosa Robledo-Naranjo, Lucero Estrada Rebollar y Lizette Gonzalez tendrán acceso a su información.

El equipo de investigación, el personal autorizado de UCLA pueden tener acceso a los datos y registros del estudio para monitorear el estudio. Los registros de investigación proporcionados al personal autorizado que no pertenece a UCLA no contendrán información identificable sobre usted. Las publicaciones y/o presentaciones que resulten de este estudio no lo indicaran por su nombre.

USO DE DATOS PARA FUTURAS INVESTIGACIONES

Sus datos no identificados pueden conservarse para su uso en futuras investigaciones.

¿ME PAGARÁN POR MI PARTICIPACIÓN?

No se le pagará por su participación en este estudio de investigación.

¿A QUIÉN PUEDO CONTACTAR SI TENGO PREGUNTAS SOBRE ESTE ESTUDIO?

El equipo de investigación:

Si tiene alguno pregunta, comentario o inquietud sobre la investigación, puede hablar con uno de los investigadores. Favor de contactar: Monika Badyal (monikabadyal@g.ucla.edu

por correo electrónico o teléfono 562-713-0759). Alternativamente, puede ponerse en contacto con su asesor, Dra. Dorothy Wiley (dwiley@sonnet.ucla.edu por correo electrónico o teléfono 310-292-8466). Por último, puede comunicarse con el proveedor de su clínica, la directora médica (Dra. Milie Tolentino) o la administración por teléfono (714) 446-5100.

Oficina del Programa Protección de la Investigación Humana (OHRPP) de UCLA:

Si tiene preguntas sobre sus derechos como sujeto de investigación, o tiene inquietudes o sugerencias y desea hablar con alguien que no sean los investigadores, puede comunicarse con UCLA OHRPP por teléfono: (310) 206-2040; por correo electrónico: participants@research.ucla.edu o por correo: Box 951406, Los Ángeles, CA 90095-1406.

¿CUÁLES SON MIS DERECHOS SI PARTICIPO EN ESTE ESTUDIO?

- Puede elegir si desea o no participar en este estudio, y puede retirar su consentimiento y dejar de participar en cualquier momento.
- Cualquier que sea la decisión que tome, no habrá ninguna penalización para usted, ni perdida de beneficios a los que de otro modo tenía derecho.
- Puede negarse a responder cualquier pregunta que no desee responder y aun así permanecer en el estudio.

Se le dará una copia de esta información para guardarla para sus registros.

¿CÓMO INDICO MI CONSENTIMIENTO PARA PARTICIPAR?

Si desea participar en este estudio, debe firmar y poner fecha a continuación.

FIRMA DEL PARTICIPANTE

_____
Nombre del Participante

_____ _____
Firma del Participante Fecha

FIRMA DE PERSONA OBTENIENTO CONSENTIMINTO

_____ _____
Nombre de Persona Obteniendo Consentimiento Numero de Contacto

_____ _____
Firma de Persona Obteniendo Consentimiento Fecha

Appendix I: Outline of DPP Class schedule and Topic covered

Session	Date	Topic	Assessment
0	December 4, 2021	**Orientation** Staff Introductions/ Rules Expectations Goal Setting (will be done at each session)	**Consent Forms** ****Pre-Test**
1	December 11, 2021	**Get active to prevent DM & Track your activity**	
2	December 18, 2021	**Eat well to prevent DM & Track your food**	
3	January 8, 2022	**Get more active**	
4	January 15, 2022	**Burn more calories than you take in**	
5	January 22, 2022	**Shop and cook to prevent DM**	
6	January 29. 2022	**Manage Stress**	
7	February 5, 2022	**Find time for fitness/Cope with Triggers**	
8	February 12, 2022	**Keep your heart healthy**	
9	February 19, 2022	**Take charge of your thoughts & Get support**	
10	February 26, 2022	**Eat well away from home**	
11	March 5, 2022	**Stay motivated to prevent DM**	
12	March 12, 2022	**Review** Graduation	**Optional: End of program survey** *****Post-Test**

Appendix J: Table of Evidence

Lifestyle Intervention to Prevent Diabetes in Prediabetic and Obese Patients

Author, Year	Purpose	Sample & Setting	Methods/Design/Interventions/Measures	Results	Discussion, Interpretation, Limitation of Findings
Knowler, W. C., Barrett-Connor, E., Fowler, S. E., Hamman, R. F., Lachin, J. M., Walker, E. A., Nathan, D. M., & Diabetes Prevention Program Research Group (2002). Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *The New England journal of medicine*, *346*(6), 393–403. https://doi.org/10.1056/NEJMoa012512	To assess the efficacy of DPP in preventing or delaying the onset of T2DM in high-risk people with higher fasting plasma concentrations and impaired glucose tolerance.	Sample: · 3,234 participants, both genders, 50% minority, 20% >65 years older · Ethnic minority included : African American, Hispanic, American Indian, Asian American, and Pacific Islander · Impaired GTT, BMI> 24 kg/m^2 · Exclusion: ischemic heart disease, aortic stenosis, uncontrolled HTN, renal insufficiency, pregnancy, or nursing, Setting: 27 clinical centers in U.S	· Study design: RCT · Random assignment to ILI (n=1079), Metformin (n=1073), or placebo (n=1082) · Standard therapy- written information and 20 to 30 min individual sessions with case manager, guidance on following food pyramid, 5-10% weight loss through diet and exercise (30 min/5x wk), avoid excessive etoh use, stop tobacco use. · Metformin arm-850mg daily for 1 month then bid, adherence by pill counting · ILI arm- same care as standard therapy but more intensive, 7% weight loss, 150min/wk exercise, moderate intensity exercise. 16 core sessions in the first 24 weeks · Primary outcome, time to develop T2DM · Study timeline 3 1/3 yrs and 6 yrs	· Terminated 1yr earlier based on the +data results · 50% participants weight loss goal of 7% at 24 wks, 38 % weight loss at least 7% at time of recent visit. · Average weight loss 0.1, 2.1, 5.6kg in the placebo, metformin and lifestyle intervention group ($p<0.001$) · Crude incidence was 11.0, 7.8 and 4.8 cases per 100 person years for the placebo, metformin, and lifestyle of DM. · 58% T2DM lower (95% CI, 48% to 66%) with ILI and 31% (95% CI, 17% to 43%) in metformin group than placebo group. · Cumulative T2DM incidence at 3 yrs was 28.9%, 21.&% and 14.4% in placebo, metformin and ILI · 6.9 person needs to be treated for 3 yrs to prevent one case of T2DM (95% CI, 5.4 to 9.5) for ILI and 13.9 (95% CI, 8.7 to 33.9) for metformin. · Secondary outcomes—reduction of risk factors for CV disease	Strengths: · The study was done with large sample size with 50% minority population including the Hispanic patients. · Large sample size · Replicability of the current study to other landmark trails done in Finland and China Limitations: · Generalizability to specific to Latinos both genders and minority · Conclusion: · Supports that T2DM can be prevented or delayed in person at high risk for the disease. · T2DM incidence is reduced by 58% in ILIL and 31% with metformin as compared to placebo. · The effects were similar in men and women and in all racial and ethnic groups. · The study indicated that treatment with metformin and ILI were two highly effective means of delaying or preventing T2DM. · 1 case T2DM preventing per 7 people treated for 3 yrs. ·

Author, Year	Purpose	Sample & Setting	Methods/Design/Interventions/Measures	Results	Discussion, Interpretation, Limitation of Findings
O'Brien, M. J., Perez, A., Scanlan, A. B., Alos, V. A., Whitaker, R. C., Foster, G. D., Ackermann, R. T., Ciolino, J. D., & Homko, C. (2017). Prevent-DM comparative effectiveness trial of lifestyle intervention and metformin. *American Journal of Preventive Medicine*. *52*(6), 788-797. https://doi.org/10.1016/j.amepre.2017.01.008	To evaluate the effects of an intensive lifestyle intervention (ILI), metformin, and conventional treatment on prediabetic Hispanic women	Sample: · 92 Female · Latinas > 20 yrs with impaired glucose fasting bs 100-125 · A1c 5.7-6.4% · exclusion of elevated BP >160/100, other chronic medical conditions, contraindication to metformin. Setting: Puentes De Salud, a Latino serving community health center in Philadelphia	· Study design: RCT · Random assignment to ILI, Metformin, or standard care for 12 months long given by Promotora. · ILI arm- Promotora lead 4 groups of 5-9 participants in a 90-minute session, a total of 24 session · Metformin arm-850mg daily for 1 month then bid · Standard care- regular medical care with education material on DM prevention · Data collected baseline, 6months, and 12 months. · Measures: weight loss, waist circumference, blood pressure, fasting bs, and a1c · Descriptive statistics and ANOVA model, post hoc comparison between groups conducted using Tukey's test at 5% significance	· ILI indicated significantly greater weight loss (-4.0 kg, 5.0%) then metformin (-0.9 kg, 1.1%) and standard care (+0.8 Kg, 0.9%), P<0.001. · ILI greater reduction in waist circumference than standard care p=0.001 and marginal improvement in A1c compared to metformin and standard care p=0.063	Strengths: · The study was done on Latinas females with prediabetes in the urban community, · Significant power difference large weight loss with ILI, Limitations: · Generalizability to men and other ethnic and racial groups · The modest clinical weight difference with metformin and standard care. · Inability to blind participate or promotoras to treatment assignment, which could introduce bias. · Prevented long term weight loss assessment since the study was only for 12 months Conclusion: · Participants who were in the ILI arm lost significantly more weight than either metformin or standard care. · Greater reduction in waist circumference · small not statistically significant with the reduction in A1c with ILI intervention compared with an increase in metformin and standard care group

Key: ANOVA=analysis of variance, A1c=glycolated hemoglobin A1c, BP=blood pressure, bs=blood sugar, DM=diabetes mellitus type 2, ILI=intensive lifestyle intervention, kg=kilogram, p=probability, RCT=randomized control trial,

Author, Year	Purpose	Sample & Setting	Methods/Design/Interventions/Measures	Results	Discussion, Interpretation, Limitation of Findings
Van Name, M. A., Comp, A. W., Magenheim, E. A., Li, F., Dziura, J. D., Montoso, A., Patel, A., & Tamborlane, W. V. (2016). Effective translation of an Intensive lifestyle Intervention for Hispanic women with prediabetes in a community health center setting. *Diabetes Care, 39*(1), 525-531 https://doi.org/10.2337/dc15-1899	Implementing a diabetes prevention program in a community health center would help Hispanic women with prediabetes lose weight and improve their metabolic measurements.	Sample: · 75 participants in an intensive lifestyle intervention and 75 participants in standard care · 18-65-year-old females with at least 1 risk factor for DM such as BMI>30, family Hx of DM, gestation DM, HTN, dyslipidemia, CV disease Setting: Fair Haven Community Health Center	· Study design: RCT · Randomly assigned to ILI and standard care. · ILI- 14 wk intervention measurements and labs were done before the intervention and 12 months again. · Participants attended 1hr lifestyle class 1 evening per wk, and 1 hr training led group exercise class occurs 2-3 nights per wk, · Standard care- one-time diabetes prevention counseling and advised to lose 7% of the weight and increase activity to 150 minutes/wk · Data collected baseline and 12months · An Independent and paired T-test was used to analyze the data.	· ILI group lost 3.8kg while the usual care group gained 1.4kg (1.6%), P< 0.0001) · 2 Hr GTT excursion decreased by 15mg/dl in the ILI group and 1 mg/dl in the usual care group · BMI, % body fat, waist conference, and fasting insulin with a significant decrease favoring the ILI group.	Strengths: · Studied in low-income Hispanic females with prediabetes · ILI programs have been shown to be successful in preventing prediabetes in a culturally diverse, obese central city population. it is reproducible Limitations: · Generalizability to men and other ethnic/ racial groups · Due to cost, could not do comprehensive metabolic assessments · Goal sample 65 and actual sample size 61 at end. · Despite randomization, significant differences in fasting plasma, Lipid, and insulin concentration, hard to explain. Conclusion: · Statistical significance with weight and BMI 12 months · There was a 5.2kg (6%) difference in weight between the two groups at 12 months. If sustained, it is projected to postpone the risk of developing diabetes. · Sustained improvement in glucose tolerance in the ILI group, which was the secondary outcome · When compared to the control group, there was a significant improvement in waist circumference, triglycerides, and HDL in the ILI group.

Key: 2 Hr GTT=2 hours glucose tolerance test, A1c=glycolated hemoglobin A1c, BMI=body mass index, bs=blood sugar, CV=cerebral vascular disease, DM=diabetes mellitus type 2, HDL=high density lipoprotein, hr=hour, HTN= high blood pressure, Hx=history, ILI=intensive lifestyle intervention, kg=kilogram, mg/dl=milligram per deciliter, p=probability, RCT=randomized control trial, wk=week

Author, Year	Purpose	Sample & Setting	Methods/Design/Interventions/Measures	Results	Discussion, Interpretation, Limitation of Findings
König, D., Hörmann, J., Predel, H. G., & Berg, A. (2018). A 12-month lifestyle intervention program improves body composition and reduces the prevalence of prediabetes in obese patients. *Obesity Facts*, *11*(5), 393–399. https://doi.org/10.1159/000492604	Implement a 12-month interdisciplinary standardized lifestyle program for obese prediabetic patients that focuses on physical activity, dietary improvements, and lifestyle intervention.	Sample: 2227, both male and females >18 years of age Exclusion: hepatic/renal disease, type 1 DM, psychiatric disorders, cancer, bariatric surgery Setting: 100 German communities	· Study Design: Quasi-experiment · No control group · Lifestyle intervention, including low glycemic index food, reduction is energy-dense food and reduces dietary fat intake and physical activity. · Addressing physical activity with 41 sessions · Psychological/self-management intervention with 12 sessions · eight sessions of nutritional counseling are done to measure obesity pre and post-intervention by assessing BMI, waist circumference, cardiopulmonary fitness, and metabolic parameters.	· Program of behavioral modification Decreased body weight (-6%) p0.001, significantly reduced waist circumference (-6.8) p0.001, and BMI (2.1) p0.00. (+15 %) improvement in physical fitness · All metabolic parameters, along with blood pressure, HbA1c, cholesterol, and fasting blood glucose, improved. 839/2227. After the intervention, 37.7% of respondents no longer met the prediabetes eligibility requirements and had normal HbA1c.	Strengths: · International study using lifestyle intervention program · Largest lifestyle intervention program in obese and prediabetic patients · Included both male and female samples · Lifestyle intervention programs are effective in reversing prediabetes in the German population Limitations: · Generalizability to other ethnic and racial groups · Lack of randomization design Conclusion: · Statistical significance with reduction of weight, BMI, and improvement in physical fitness. · Reversal of prediabetes (37.7%%) with normalization of HbA1c. · Improvement in metabolic syndrome 766/1641 (46.7%) participants.

Key: HbA1c=glycated hemoglobin A1c, bs=blood sugar, DM=diabetes mellitus, p=probability,

Author, Year	Purpose	Sample & Setting	Methods/Design/Interventions/Measures	Results	Discussion, Interpretation, Limitation of Findings
Jiang L., Johnson, A., Pratte, K., Beals, J., Bullock, A., Manson, S. M., & Special Diabetes Program for Indians Diabetes Prevention Program. (2018). Long-term outcomes of lifestyle intervention to prevent diabetes in American Indian and Alaska Native communities: The special diabetes program for Indians diabetes prevention program. *Diabetes Care*, *41*(7), 1462–1470. https://doi.org/10.2337/dc17-2685	Long term effective translation of lifestyle intervention in minority population up to 10 years to prevent diabetes in American Indian and Alaska Native communities	Sample: · 8652 enrolled, 65% finished the post curriculum assessment, sample attrition occurred over the 10 years, and only 13% completed post curriculum assessment at the 10 yrs. · >18 yrs, prediabetic, exclusion: ESRD on dialysis, pregnancy, DM Setting: >80 tribes across 18 states, 11/12 Indian Health Service area	· Study design: Quasi Experiment · No control group or randomization · The intervention took place from 2006 to 2016 with baseline, post curriculum, and annual assessment · 16 lifestyle balance curriculum drawn from the diabetes prevention program (DPP) · DPP involves 7% initial weight loss through a healthy diet, exercise, and behavior modification · Measures: weight loss, blood pressure, lipid profile, diet, A1c, 1hr OGTT, fasting blood glucose · X2 test and ANOVA used to analyze data	· 2028 (36%) lost >5% of initial weight and 978 (17%) lost 3-5% weight and 2604 (47%) did not achieve a weight loss >3%. · Compared to <3% to >5% of initial weight loss had 64% (95% CI 54-72; p<0.0001) lower risk of developing diabetes during the first 6 years · Those with 3-5% weight loss had 40% (95% CI 24-53; p <0.0001) lower risk on average · After 6 yrs, >5% weight loss had 38% (95% CI 14-56; p=0.005) lower risk of DM than <3% weight loss group Small and consistent improvement in TG, HDL-C, LDL-C but not BP	Strengths: · Studied in minority Indian and Alaska Native with prediabetes · Long term implementation indicated a beneficial effect of ILI Limitations: · Generalizability to minority native American and other ethnic/racial groups · Large attrition rate over the year with the sample size · Lack of control and randomization in the group. Conclusion: · Diabetes incidence of 3.5 cases/100 person · Strong diabetes risk reduction effect with DPP lifestyle intervention · Long-term benefits of modest weight loss reduce DM the in long-term · Results are consistent with other studies, replicability

Key: ANOVA=analysis of variance, A1c=glycolated hemoglobin A1c, 1hr OGTT=1 hour glucose tolerance test, BP=blood pressure, CI=confidence interval, DM=diabetes mellitus type 2, DPP=diabetes prevention program, ESRD=end stage renal disease, HDL=high density lipoprotein, ILI=intensive lifestyle intervention, LDL=low density lipoprotein, p=probability, TG=triglyceride, X2=chi square

Author, Year	Purpose	Sample & Setting	Methods/Design/Interventions/Measures	Results	Discussion, Interpretation, Limitation of Findings
Rosas, L. G., Lv, N., Xiao, L., Lewis, M. A., Venditti, E., Zavella, P., Azar, K., & Ma, J. (2020). Effect of a culturally adapted behavioral intervention for Latino adults on weight loss over 2 years: A randomized clinical trial. *JAMA Network Open*, *3*(12), 1-16e2027744. https://doi.org/10.1001/jamanetworkopen.2020.27744	To determine if a culturally tailored behavioral modification was more efficient than traditional care in Latino individuals over a 24-month period at losing weight.	Sample: · 191 Latino adults, >18 years of age in primary care settings. 92 in intervention and 99 in the control group · Web-based self-monitoring. · >24 BMI, high risk of DM (metabolic syndrome, prediabetes, gestational DM) · San Francisco, CA. 3- different primary care setting	· Study design: RCT · Randomized standard treatment to standard care + culturally adapted behavioral modification (Vida Sana). · All participants given wearable activity tracker · Group lifestyle balance curriculum derived from the original DPP lifestyle intervention was conducted in Spanish by a bilingual life coach · Family members were also included in the sessions · For one year, intervention sessions were conducted in person, second year with monthly email review of 1st year material · Goal 7% weight loss, 150 minutes/wk moderate intensity physical activity	· At 24 months, mean weight loss was not significantly different between intervention and control groups (-1.1 [7.1]kg vs -1.1 [5.7]kg; adjusted mean difference, 0.1 [95% CI, -1.8 to 1.9]kg; p=0.93). · Mean weight loss at 12 months was significantly greater with intervention group compared to control group -2.6 [6.0]kg vs -0.3 [4.2]kg; adjusted mean difference, -2.1 [95% CI, -3.6 to -0.7] kg; p=.005) At 12 months, greater class attendance was positively associated with obtaining clinical significance with weight loss.	Strengths: · Only 2 studies RCT of culturally adapted DPP with 24 month of follow up · Session attendance associated positively with weight loss · Technology medicated Limitations: · Insufficient power · Finding may not apply to other Latino population · Pt's had an advantage of being recruited from employer-based health insurance · Lack of generalizability to other Latino with different socioeconomic conclusion: The RCT found that a technologically mediated culturally designed behavioral modification was efficient at reducing weight at 12 months but not at 24 months.

Key: BMI=body mass index, CI=confidence interval, DM=diabetes mellitus type 2, DPP=diabetes prevention program, kg=kilogram, p=probability, RCT=randomized control trial

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