Spring 5-28-2022

LIFESTYLE MODIFICATION INTERVENTIONS ON HEMOGLOBIN A1c LEVEL IN PATIENTS WITH TYPE II DIABETES MELLITUS IN AN UNDERSERVED COMMUNITY: A PILOT PROJECT

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UNIVERSITY OF SAN DIEGO
Hahn School of Nursing and Health Science
Beyster Institute of Nursing

DOCTOR OF NURSING PRACTICE PORTFOLIO

by

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A portfolio presented to the

FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE
UNIVERSITY OF SAN DIEGO

In partial fulfillment of the
requirements for the degree

DOCTOR OF NURSING PRACTICE

May 22, 2022

Abstract

Abstract: Type 2 diabetes mellitus (T2DM) is a pandemic of great concern among the nutrition-related non-communicable diseases. Its prevalence is mounting worldwide, particularly in underserved communities and minority groups. In 2019, 463 million people were diagnosed with T2DM, a number expected to increase to 578 million by 2030 globally. The prevalence of T2DM is increasing the mortality rate from cardiovascular complications. The social and health costs of treating this disease is currently 11% of the global health budget. This project aims to utilize an evidence-based approach to assess lifestyle interventions' effectiveness at decreasing the Hemoglobin A1c levels in T2DM individuals after 3 months of lifestyle modifications.

Keywords*:* type 2 diabetes mellitus, physical activity, lifestyle modifications, prevention, HgA1c

Diabetes Mellitus in an Underserved Community: A Pilot Project

Diabetes mellitus (DM) is a chronic non-communicable disease affecting carbohydrate and glucose utilization due to the pancreas' inadequate insulin production. DM develops when the body cannot regulate glucose balance, leading to complications such as heart disease, blindness, kidney failure, nerve damage, and lower-extremity amputations (CDC, 2020). Common causes of mortality among patients with uncontrolled DM include heart disease, chronic renal failure, and cerebral vascular accidents. As a result of the high morbidity rates, individuals with DM require more support in managing the disease. There is no cure for DM; however, DM can be adequately controlled with pharmacological interventions and lifestyle modifications, such as a healthy diet and aerobic exercise.

Background

According to the Center for Disease Control and Prevention (CDC, 2020), DM is the seventh leading cause of death in the United States, affecting about 34.2 million people in 2018. The rate of DM continues to rise both in the United States and globally. The CDC projected an increase of DM cases by 54% (54.9 million) by 2030. Concern is growing about this disease due to the rise of cases and possibly earlier onset of type 2 DM (T2DM). T2DM is the most common type of DM, affecting about 90%-95% of America's total cases (CDC, 2020). T2DM most often develops in people over age 45. However, more young adults, teenagers, and even grade school children are developing this disease (CDC, 2020).

The rate of obesity and cardiovascular disease in urban communities has been rising, increasing the likelihood of T2DM (Animaw & Seyoum, 2017). The clinic used for this project was a Federally Qualified Health Center (FQHC) clinic located in an urban community in southern Los Angeles with a significant number of patients at risk of cardiovascular disease from worsening DM. The high rate of DM seen in this community could be attributed to socioeconomic status, education level, diet, cultural beliefs, treatment compliance, and resources to encourage optimal health. This project aimed to improve patient outcomes by introducing a designated follow-up visit to discuss DM management aligned with the American Diabetes Association's (ADA) recommended lifestyle modifications.

Literature Review

According to a Diabetes Prevention Program (DPP; National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], n.d.) people with prediabetes who take part in a structured lifestyle change program and lose 5% to 7% of their body weight through healthier eating and 150 minutes of physical activity per week decrease their risk of developing T2DM by 58%; 71% for people over 60 years of age. Engaging in lifestyle change programs can also reduce the risk of heart attack and stroke associated with prediabetes and improve overall health (NIDDK, n.d.). In completing this review, a literature search was conducted using PubMed, CINAHL Plus with Full Text, and the Cochrane Database, National Institutes of Health using MESH Type 2 Diabetes Mellitus, Prevention, Lifestyle management, Pharmacotherapy, Cost-effectiveness. Four studies provided evidence in support of physical activities in decreasing HbA1c in T2DM individuals.

Study I: Diabetes Prevention Program (DPP). The DPP examined whether the DPP Lifestyle Change Program or taking metformin would delay or prevent T2DM. The DPP study was a randomized, controlled clinical trial conducted at 27 clinical centers around the United States from 1996 to 2001. The ages of the study participants (N = 3,234) were not specified. The participants were 55% Caucasian, 45% were minority groups, and at high risk for DM, including African American, Alaska Native, American Indian, Asian American, Hispanic/Latino, or

Pacific Islander. Other groups at high risk for T2DM were included, such as people ages 60 years and older, women with a history of gestational DM, and people with a parent, brother, sister, or child who had T2DM.

DPP participants were randomly assigned to three groups; the Lifestyle Change Group provided intensive training. Participants tried to lose 7% of their body weight and maintain that weight loss by eating less fat and fewer calories and exercising 150 minutes per week. In this group, researchers met with participants individually at least 16 times in the first 24 weeks, then every 2 months with at least one phone call between visits. In the metformin group, participants took 850 mg of metformin twice a day and were given standard advice about diet and physical activity. Lastly, the control group took a placebo twice a day instead of metformin and were provided with standard advice about diet and physical activity.

The results of the DDP study were as follows; during the 10-year follow-up period, participants who took part in the DPP Lifestyle Change Program continued to delay the development of DM by 34% and developed DM 4 years later compared with participants who took a placebo. Also, participants from this group ages 60 years and older had a delay in the development of DM by 49%. In the metformin group, participants who continued with the medication had a delay in developing DM by 18% and developed DM about 2 years later compared with participants who took a placebo. In all studied groups, participants improved their risk factors for cardiovascular diseases, such as high blood pressure and cholesterol. However, the participants from the DPP Lifestyle Change Program achieved these results while taking less blood pressure and cholesterol-lowering medications. This study was worthy to practice as Level II evidence. The study conclusively showed that the DPP Lifestyle Change Program was cost-effective, while metformin was a cost-saving form of controlling or preventing T2DM. The DPP also showed that people at high risk for T2DM could prevent or delay the disease by losing a modest amount of weight through lifestyle changes such as dietary changes and increased physical activity (NIDDK, n.d.).

Study II: Walking prescription of 10 000 steps per day in patients with T2DM mellitus: a randomized trial in Nigerian general practiced conducted by Fayehun et al. (2018). This study used a randomized design of two groups: an intervention group with a walking prescription goal of 10 000 steps per day, and a control group who continued with their typical daily activities. The study participants were 46 adults with T2DM, aged 18–64 years, diagnosed at least 12 months previously in the clinic. Participants were non-insulin-dependent, on dietary control with or without oral hypoglycemic agents, and could walk without limitations or pain. Weight, height, waist and hip circumferences, heart rate, and blood pressure were measured. Glycosylated hemoglobin (HbA1c) was measured with the Clover A1cTM analyzer (EuroMedix, Leuven, Belgium), and steps were measured using the waist-mounted Digi-Walker SW-200 electronic pedometer.

Data included standard deviations, intention-to-treat analysis, and analysis of covariance (ANCOVA) utilizing SPSS. Results showed an average count of 4,505 steps per day for all participants, with the average step count in the intervention group in the last 4 weeks of the study period of 2,913 steps per day ($F[2, 37.7] = 18.90$, $p < 0.001$; 95% CI [1274, 4551]). Also, the mean baseline HbA1c was 6.6% (range 5.3%–9.0%) for all participants. The endline HbA1c was lower by 0.74% ($F = 12.92$, $p = 0.015$; 95% CI [−1.32%, −0.02%] in the intervention compared with the control groups, after adjusting for baseline HbA1c levels with ANCOVA. Fayehun et al., (2018) study was worthy to practice as Level II evidence. The study strength provided evidence regarding the use of a step-count prescription for T2DM. This study's limitations included the lack of generalizability of the findings as this was a single-center study with little ethnic diversity. In addition to a high attrition rate, participants could have been motivated by the pedometer to increase their step count above their habitual level at baseline. The study's conclusion noted that motivational strategies and adherence to a 10,000 steps-per-day prescription, however low, may still have been associated with improved glycemic control in T2DM.

Study III: The study by García-Molina et al. (2019) used a systematic review and meta-analysis to analyze scientific evidence concerning nutritional intervention in the glycemic control of T2DM. The research was conducted through PubMed, Scopus, the Cochrane Library, and Web of Science databases for randomized controlled trials (RCTs) that included lifestyle intervention (i.e., based on diet, nutritional education, physical activity) in the management of patients with T2DM. Twenty-eight studies were systematically reviewed with a sample size ranging from 45 to 1004 adult participants with a mean age ranging between 50 years and 67 years. Participants included non-hospitalized patients or DM patients with complications including diabetic nephropathy, dementia, cognitive alterations, and mental disorders. Data were analyzed using several tools, such as the Cochrane risk of bias tool for randomized trials (RoB 2), which was used to assess the included studies' methodological quality. The PRISMA Flow diagram displayed the selection process of the studies included in the systematic review and meta-analysis. Lastly, statistical analysis was conducted using Stata Release14 software (StataCorp., 2015). The result of this study demonstrated that lifestyle interventions significantly lowered HbA1c levels when compared to the usual care for patients with T2DM. The overall weighted mean difference (WMD = −0.51 (95% CI [−0.67, −0.35] for post-intervention HbA1c levels when comparing lifestyle intervention groups to the usual diabetic care controls. The

WMD of post-intervention HbA1c levels increased with the increase in follow-up duration, from −0.20 (95% CI [−0.34, −0.05], I^2 = 18.5%, p = 0.293) for follow-up of 4–6 months, to − 0.36 (95% CI [−0.56, −0.16], I^2 = 73.0%; p = 0.000) when the follow-up length is 7–12 months, and − 0.79 (95% CI [−0.88, − 0.71), I^2= 28.8%, p = 0.239) for patients followed up for more than 12 months. However, the most effective increase was seen when combining individualized and group-based activities (WMD = −0.95; 95% CI [−1.24, −0.66]).

García-Molina et al. (2019) study was worthy to practice as Level I evidence. This study's strength could be noted in the applicability of the results to improving the management of T2DM and decreasing other risk factors for cardiovascular diseases. This study's limitations ere the variability in the applied interventions' contents and the inability to assess pharmacological treatment compliance due to lack of data. The study's conclusion noted that lifestyle interventions significantly improve glycemic control of T2DM, mainly when there was a weight loss greater than 5% of the starting BMI. The improvement of T2DM concerning lifestyle intervention was significant when the intervention includes diabetes self-management education, combined individual and group sessions, and/or was over a more extended period.

Study IV: The study by Johansen et al. (2017) aimed to assess whether an intensive lifestyle intervention would result in equivalent glycemic control compared with standard care and, secondarily, led to a reduction in glucose-lowering medication in participants with T2DM. the study's design was a randomized, assessor-blinded, single-center study within Region Zealand and the Capital Region of Denmark between April 2015 and August 2016. The study's participants included 98 adult participants with non–insulin-dependent T2DM who were diagnosed for less than 10 years. Participants were randomly assigned (2:1; stratified by sex) to the lifestyle group (n = 64) or the standard care group (n = 34).

Steps and exercise data were collected with a smartwatch (Polar V800) and measurements (e.g., blood pressure, cholesterol panel, fasting blood work) were performed in one laboratory. At the same time, biochemical analyses were completed at the central laboratory. Statistical analysis utilized STATA/IC Release 13.1 (StataCorp, 2013) for intention-to-treat and repeated-measures mixed linear model (Johansen et al., 2017). All study participants received standard care, including medical counseling, education in T2DM, and lifestyle advice by the study nurse at baseline and every 3 months for 12 months. The study included an endocrinologist who regulated all glucose-lowering, lipid-lowering, and blood pressure-lowering medications during the study. The endocrinologist was blinded to group allocation and received all clinical variables from the study nurse. To minimize the risk of bias, prespecified treatment targets and algorithms for glucose-lowering, lipid-lowering, and blood pressure-lowering medications were followed by the study endocrinologist to reach standardization across groups.

This study was worthy to practice as Level II evidence. The study's strengths included the extensive exercise intervention; the blinded, highly standardized algorithm; and the target-driven approach to regulating glucose-lowering medication in both the lifestyle and standard care groups. Limitations of the study included adverse events observed in the lifestyle group and the fact that only participants with T2DM diagnosed for less than 10 years were followed, limiting the study's generalizability. Lastly, the lifestyle intervention included several lifestyle elements that presented a challenge in interpreting each intervention's effects. This study concluded that a lifestyle intervention compared with standard care resulted in a change in glycemic control.

Table 1

Review of Literature: Evaluation Table

Citation: (i.e., author(s), date of publication, & title)	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Worth to Practice Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses]) Feasibility conclusion RECOMMENDATION
A **Title:** Walking prescription of 10 000 steps per day in patients with type 2 diabetes mellitus: A randomised trial in Nigerian general practiced **Publication date:** January 16, 2018 **Authors:** Ayorinde F Fayehun, Olufemi O Olowookere, Adetola M Ogunbode, Adedotun A Adetunji & Arinola Esan	**IV:** Goals to accumulate 10,000 steps every day for 10 weeks **DV:** HbA1c endline	Waist- mounted Digi-Walker SW-200 electronic pedometer Weight, height, waist and hip circumferences, heart rate, and blood pressure were measured. Glycosylated hemoglobin (HbA1c) was measured with the Clover A1cTM analyzer (EuroMedix, Leuven, Belgium) and a questionnaire administered.	Summary statistics are reported as mean ± standard deviation Sample size was calculated with a 2-sided statistical superiority design An intention-to-treat analysis Analysis of covariance (ANCOVA) A linear regression model Analysis performed using	Average step count was 4505 steps per day for all participants, average step count in intervention group for the last 4 weeks of the study period was 2913 steps per day (95% confidence interval [CI] = 1,274 to 4,551, $F(2, 37.7) = 18.90$, $p<0.001$). Only 6.1% of the intervention group participants achieved the 10 000 steps per day goal. The mean baseline HbA1c was 6.6% (range = 5.3 to 9.0). Endline HbA1c was lower in the intervention group than in the control group (mean difference –0.74%, 95% CI = –1.32 to –0.02, F = 12.92, P = 0.015) after adjusting for baseline HbA1c.	**Appraisal:** Worth to practice **LOE:** 2 **Recommendation:** A 10,000 step per day prescription recommendation was associated with significant decrease in HbA1c levels and improved glycemic control in T2DM individuals.
B **Title:** Improving type 2 diabetes mellitus glycaemic control through lifestyle modification implementing diet intervention: a systematic review and meta-analysis	**IV:** Lifestyle interventions Diabetes self-management education **DV:** HbA1c reduction Decreased in BMI	Assessment of glycemic control, HbA1c	Cochrane risk of bias tool for randomized trials (RoB 2) PRISMA Flow diagram Means and standard deviations reported by the authors for HbA1c levels for the intervention and control groups at the	Lifestyle interventions significantly lowered glycosylated hemoglobin (HbA1c) levels compared to the usual care for patients with type 2 diabetes mellitus, overall weighted mean difference, WMD = − 0.51 (−0.67, −0.35). Strategies combining individualized and group-based activities were the most effective, WMD = − 0.95 (− 1.24, − 0.66).	**Appraisal:** Worth to practice **LOE:** I **Recommendation:** lifestyle interventions significantly improve the glycemic control of type 2 diabetes mellitus and should be implemented to improving the management of T2DM, and other risk factors for cardiovascular diseases.

Citation: (i.e., author(s), date of publication, & title)	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Worth to Practice Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses]) Feasibility conclusion RECOMMENDATION
Publication date: November 28, 2019 **Authors:** García-Molina, L., Lewis-Mikhael, A.-M., Riquelme-Gallego, B., Cano-Ibáñez, N., Oliveras-López, M.-J., & Bueno-Cavanillas, A.			end of the intervention/standard care Stratified articles based on different characteristics of the interventions Stratification based on characteristics of the participants including BMI and the average duration in years since the diagnosis of diabetes. Sensitivity analyses excludes low-quality studies as well as studies providing outliers. Statistical analysis was conducted using Stata v.14 software (Stata Corp., 2015, College Station, TX, USA).		
C **Title:** Effect of an Intensive Lifestyle Intervention on Glycemic Control in Patients with Type 2 Diabetes A Randomized Clinical Trial	**IV: M**edical counseling education in type 2 diabetes Lifestyle advice at baseline and every 3 months for 12 months Intensive lifestyle intervention- 5 to	Steps and exercise sessions were objectively monitored with a smartwatch (Polar V800). Measurements were performed in 1 laboratory and biochemical	Intention-to-treat principle repeated-measures mixed linear model 1-sided tests Statistical analyses were performed using STATA/IC (StataCorp), version 13.1,	Mean HbA1c level changed from 6.65% to 6.34% in the lifestyle group and from 6.74% to 6.66% in the standard care group (mean between-group difference in change of −0.26% [95% CI, −0.52% to −0.01%]), not meeting the criteria for equivalence (P = .15). Reduction in glucose-lowering medications occurred in 47 participants (73.5%) in the lifestyle group and 9	**Appraisal:** Worth to practice **LOE:** 2 **Recommendation:** a lifestyle intervention compared with standard care resulted in a change in glycemic control however further research is needed to assess superiority, generalizability and durability of findings.

Citation: (i.e., author(s), date of publication, & title)	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Worth to Practice Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses]) Feasibility conclusion RECOMMENDATION
Publication date: July 10, 2017. **Authors:** Mette Yun Johansen, Christopher Scott MacDonald, Katrine Bagge Hansen, MD, PhD et al.	6 weekly aerobic sessions (duration 30-60 minutes) with 2 to 3 sessions were combined with resistance training Individualized dietary plan Physically active (≥10 000 steps per day) **DV:** change in HbA1c level from baseline to 12-month follow-up reduction in glucose-lowering medication from baseline to 12-month follow-up	analyses were completed at the central laboratory		participants (26.4%) in the standard care group (difference, 47.1 percentage points [95% CI, 28.6-65.3]).	
D **Title:** Walking away from type 2 diabetes: A cluster randomized controlled trial. **Publication date:** September 02 2016 **Authors:** T. Yates C. L. Edwardson J. Henson L. J. Gray N. B. Ashra J. Troughton K.	**IV:** 3-h Walking Away from Type 2 Diabetes Mellitus group-based structured educational programmed Increase physical activity by promoting self-regulatory skills through pedometer use.	Standardized booklet detailing information on Type 2 diabetes mellitus risk 3-h Walking Away from Type 2 Diabetes Mellitus group-based structured educational programmed accelerometer (GT3X, Actigraph,	Generalized estimating equation models with an exchangeable correlation structure Intent to treat Data processed through a bespoke computer programme (KineSoft version 3.3.76, KineSoft, New Brunswick, Canada)	Increases in ambulatory activity of 411 steps/day [95% confidence interval (CI): 117, 704] and self-reported vigorous-intensity physical activity of 218 metabolic equivalent min/week (95% CI: 6, 425) at 12 months.	**Appraisal:** Worth to practice **LOE:** 2 **Recommendation:** Diabetes prevention guidelines recommend the use of group-based interventions

Citation: (i.e., author(s), date of publication, & title)	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Worth to Practice Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses]) Feasibility conclusion RECOMMENDATION
Khunti M. J. Davies	**DV:** Physical activity Biochemical variables Arterial blood pressure measured in the sitting position. Body weight, Waist circumference, Height	Pensacola, FL, USA).	International Physical Activity Questionnaire (IPAQ) Metabolic equivalents (METS) Oral glucose tolerance test (OGTT)		
E **Title:** Effectiveness of non-pharmacological strategies in the management of type 2 diabetes in primary care: a protocol for a systematic review and network meta-analysis **Publication date:** Janurary 12, 2020 **Authors:** Renata Giacomini Oliveira Ferreira Leite, Luísa Rocco Banzato, Julia Simões Corrêa Galendi, Adriana Lucia Mendes,	**IV: A**ll non-pharmacological and patient-mediated strategies. Nutritional therapy (dietary quality or energy restriction Physical activity programmed Psychological interventions Social network Multidisciplinary lifestyle Diabetes self-management education	N/A	Bayesian hierarchical model Surface under the cumulative ranking curve (SUCRA). Grading of Recommendations Assessment Development and Evaluation (GRADE) approach. Calculate numerical outcome data from available statistics ex *p* values SDs will be imputed for outcome value without measure of variance Boxplots	Inadequate glycemic control in diabetes is most often related to poor adherence to lifestyle changes and to the proposed treatment	**Appraisal:** Worth to practice **LOE:** I **Recommendation:** to have individuals have a more active participation in the control of the disease, thus achieving higher rates of glycemic control and fewer complications associated with dysglycaemia.

Citation: (i.e., author(s), date of publication, & title)	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Worth to Practice Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses]) Feasibility conclusion RECOMMENDATION
Fernanda Bolfi, Areti Angeliki Veroniki, Lehana Thabane, Vania dos Santos Nunes-Nogueira	DV: glycemic control (HbA1c %). Anthropometric measurements (measured by weight or waist circumference (WC), or body mass index (BMI)), Quality of life, patient satisfaction, Frequency of cardiovascular events and deaths Number of patients in each group with HbA1c <7 Adverse events related to non-pharmacological strategies Medication adherence		Stata Statistical Software V.16 (StataCorp LLC) Random effects (RE) model Design-by-treatment model based on χ 2 test		
F **Title:** Effects of a 12-week moderate-intensity exercise training on blood glucose response in	**IV:** 12-week moderate exercise program Times of exercise **DV:** Reduce blood glucose level	Graded exercise test Motorized treadmill (Track- master 400, JAS Fitness System, USA) One-touch glucometer	Modified Balke protocol. Training protocol followed the ACSM's guidelines "FITT" Frequency, Intensity, Time, and Type	The BEBG declined progressively (b=!1.69, P<.001); while the PEBG (b=!0.18, P=.08) remained stable over time during the 12-week exercise training. Higher BEBG predicted higher (b=0.53, P<.001) PEBG. Higher baseline maximum oxygen uptake (VO2max)	**Appraisal:** **LOE:** 4 **Recommendation:** preforming moderate- intensity exercise 1-2 hours post- meal for individuals taking only oral antidiabetic medication is safe and beneficial.

Citation: (i.e., author(s), date of publication, & title)	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Worth to Practice Strength of the Evidence (i.e., level of evidence + quality [study strengths and weaknesses]) Feasibility conclusion RECOMMENDATION
patients with type 2 diabetes A prospective longitudinal study **Publication date:** July 24, 2019 **Authors:** Shang-Lin Chiang, PhD, RN, Margaret McLean Heitkemper, PhD, RN, FAAN, Yi-Jen Hung, BS, MD, Wen-Chii Tzeng, PhD, RN, Meei-Shyuan Lee, PhD, Chia-Huei Lin, PhD, RN		(FreeStyle Blood Glucose Monitoring System, TheraSense, USA) Glucose analyzer (YSI model 1500 glucose analyzer, Yellow Springs Instrument Company Inc., USA)	PSS version 16.0 (SPSS Inc., Chicago, IL) Descriptive data as mean/ standard deviation (SD) and numbers/percentage (%) Univariate analysis Multivariate analysis G*Power analysis (version 3.1) SPSS version 16.0 (General linear model	contributed to a larger magnitude of EIGR; higher HgbA1c and BEBG predicted higher EIGR (b = 0.27, P = .02; b = 0.45, P < .001); afternoon or evening exercise predicted lower (b = -13.2, P = .04; b = -5.96, P = .005) EIGR than did morning exercise.	Overall moderate high intensity exercise produce improvement in metabolic control.

Methods

Design

This EBP project was a nurse practitioner (NP) driven educational intervention utilizing the ADA (2019) guideline, "Prevention or Delay of Type 2 Diabetes Standards of Medical Care in Diabetes- 2021." This 24-week evidence-based practice (EBP) project utilized pre-post intervention data. The goal was to improve HgA1c levels among pre-diabetic and T2DM patients. The population for this project included patients diagnosed with T2DM with HbA1c 6.5% or greater. The intervention included education on an exercise plan for a minimum of 150 minutes a week and the ADA diet. There was also an emphasis on low carbohydrate and low sugar intake to further decrease the HA1c level by 15% or greater in a period of 3 months. The project was approved and received exempt status from the University of San Diego's Institutional Review Board (IRB)

The Stetler (2001) Model of Evidence-Based Practice was utilized for the implementation of this EBP project to evaluate the effectiveness of the interventions. The Stetler model facilitates the implementation of research findings into clinical practice. This model is known as the practitioner-oriented model geared to advanced practitioners, such as clinical nurse specialists (CNS), NPs, and Doctor of Nursing Practice (DNP)-prepared nurses (Melnyk & Fineout-Overholt, 2019). The Stetler model enables practitioners to assess how research findings and other pertinent evidence are implemented in clinical practice by a series of steps (Stetler, 2001). This model examines the evidence to create change that fosters patient-centered care, including individualized, patient-focused care. The Stetler model was selected for this project to encourage critical thinking and research finding integration, promote EBP practice, and help lessen errors in medical decision-making (Stetler, 2001). The Stetler model includes five phases:

preparation, validation, comparative evaluation/decision making, translation/application, and evaluation.

Setting and Sample

Study participants were recruited from a FQHC community health clinic located in Southern California. This organization offers comprehensive medical services, from routine preventive care to the management of chronic diseases such as DM and high blood pressure. This organization primarily serves all patients regardless of immigration status and socioeconomic status, with a high Hispanic population. The sample for this project was composed of 20 Hispanic patients, aged 18 to 73 years diagnosed with T2DM. Inclusion criteria: 18 years old and older diagnosed with prediabetes or noninsulin DM in the FQHC community health clinic. Exclusion criteria: patients less than 18 years of age and patients diagnosed with insulin-dependent DM.

Intervention

The intervention included the introduction of a designated follow-up visit to address DM management with the recommended lifestyle modifications. This NP-driven education utilized the ADA (2021) guideline "Prevention or Delay of Type 2 Diabetes Standards of Medical Care in Diabetes – 2021." Patients diagnosed with prediabetes or T2DM received designated follow-up appointments for non-pharmacological lifestyle modification interventions to improve hemoglobin A1C. This educational intervention was done in correlation with the standards of care listed by the ADA. The ADA Standards of Medical Care in Diabetes-2021 patient education include: (a) engaging in a minimum of 150 minutes of exercise per week; (b) weight loss goal of 7% or 1-2 lbs. per week; and (c) diet education on low carb intake and calorie counting. When clinically appropriate, patients were instructed to subtract 500-1000 calories/day depending on initial body weight and their current eating habits. All participating patients were provided with a log to document their weekly activity. These activity logs were assessed during their routine follow-up visits.

Data

Demographic data included: (a) age; (b) gender; and (c) race/ethnicity. Data were collected from the electronic medical records (EMR). Additionally, the patient's exercise and diet surveys were collected to assess their activity level and dietary habits. Pre- and post-intervention surveys were obtained. The 6-question survey that was used to assess the lifestyle modification practices among the 20 patients can be seen in Table 2.

Table 2

Six Question Survey

Survey Question
1. Do you exercise weekly? if so, how many minutes per week do you exercise?
2. What type of exercise do you do? (e.g., jogging, walking, cycling, etc.)
3. Do you know how many calories per day you should eat?
4. Do you know how to count calories?
5. Do you know which type of diet you should follow?
6. Which foods should you avoid or be limited in your daily diet?

Procedures

The surveys were given to the patients to be completed before the intervention, at 3 months, and 6 months post-intervention during their routine follow-up. In addition, to the survey, additional data were collected to assess the patients' outcomes: (a) BMI; (c) HgA1c, (c) activity levels; and (d) adherence to the ADA diet.

Data Collection

The data for this EBP project were deidentified for the retrospective-prospective chart review. The information was collected from January 2021 to June 2021 to have enough time to see a change in the HgA1c. Data collected included: demographics, weight, medications, and HgA1c level. These data served as the baseline for comparison. All collected data were encrypted and stored in a password-protected laptop using a protected server in the facility. Survey data were collected and recorded using Microsoft Excel.

Data Analysis

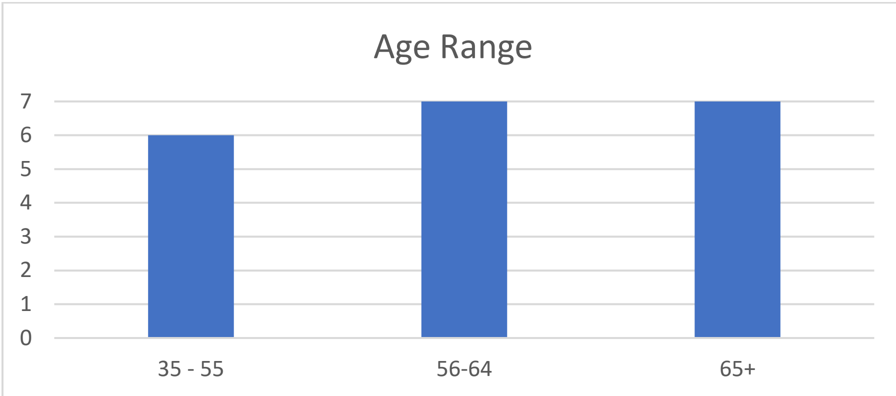
All data analyses were performed using the Intellectus Statistics software ($\alpha \leq .05$ for statistical significance). Descriptive statistics were used to analyze participant demographics using frequencies and percentages, and continuous data were analyzed using means and standard deviations. The primary outcome of improving HgA1c levels among pre-diabetic and T2DM patients was analyzed by a repeated-measures analysis of variance (ANOVA) and descriptive statistics. The secondary outcome measuring the difference in pre and post intervention BMI was analyzed using a two-tailed paired sample *t*-test.

Results

In total, 20 Hispanic patients diagnosed with T2DM participated in the project. The group also include one nurse practitioner. Most participants (n = 16, 80%) were females aged 56 years and older.

Figure 1

Age of Participants



The results of the ANOVA assessing the primary outcome of improving HgA1c levels among pre-diabetic and T2DM patients after education on lifestyle modifications was not significant ($F[2, 38] = 0.49$, $p = .618$), indicating the values of HgA1c at Pre, 3-, and 6-months post-intervention were all similar.

Figure 2

Q-Q Scatterplot for Normality of the Residuals for the Regression Model.

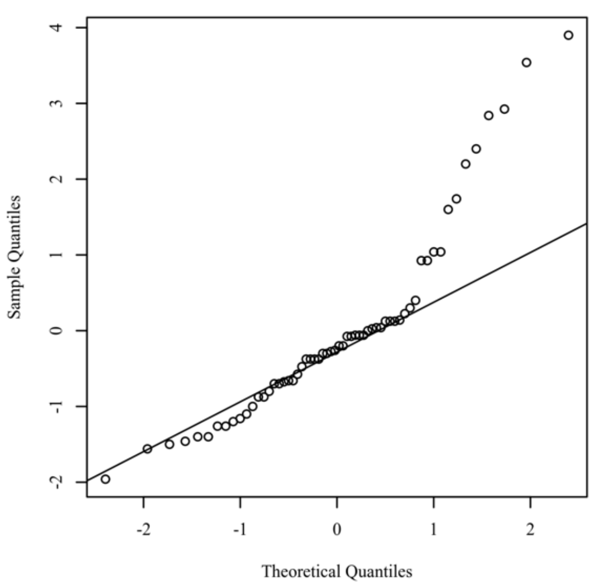


Table 3 presents the ANOVA results. Additional information about the means of the within-subjects factor are presented in Table 3 and Figure 3.

Table 3

Repeated Measures ANOVA Results

Source	*df*	*SS*	*MS*	*F*	*p*	η_p^2
Within Subjects						
Within Factor	2	0.82	0.41	0.49	.618	0.03
Residuals	38	31.82	0.84			

Table 4

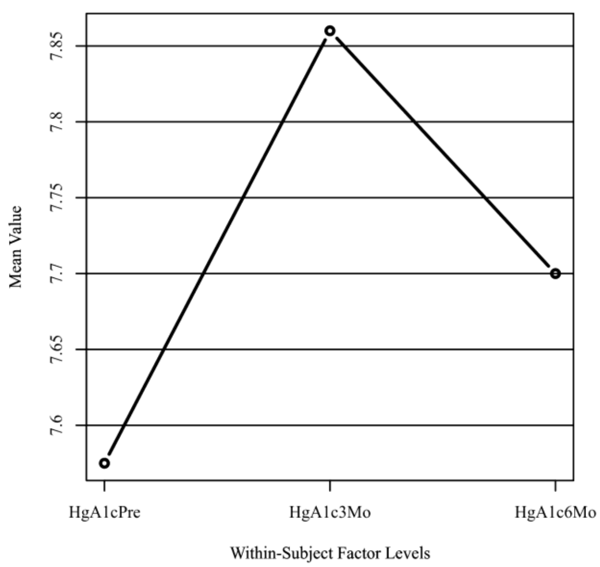
Means Table for Within-Subject Variables

Variable	*M*	*SD*
HgA1cPre	7.58	0.84
HgA1c3Mo	7.86	1.45
HgA1c6Mo	7.70	1.46

Note. n = 20.

Figure 3

Within-Subject Variable Means



The descriptive statistics showed (*n* = 13, 65%) that participants decreased their A1c levels during the project period. In addition, the two-tailed independent samples *t*-test was significant (*t*[18]) = -2.28, *p* = .035). This outcome indicates the mean between the pre and post HgA1c groups was significantly different between participants who gained weight and those who lost weight.

Table 5

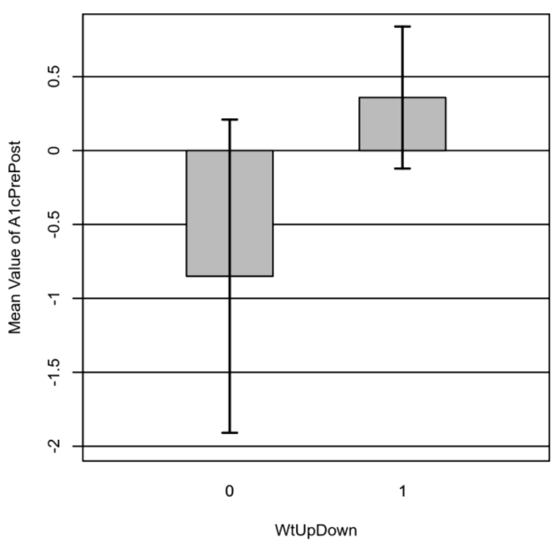
Two-Tailed Independent Samples t-Test for A1cPrePost by WtUpDown

	Pre		Post				
Variable	*M*	*SD*	*M*	*SD*	*t*	*p*	*d*
A1cPrePost	-0.85	1.53	0.36	0.85	-2.28	.035	0.98

Note. N = 20. *d* represents Cohen's *d.*

Figure 4

The Mean of A1cPrePost by Levels of WtUpDown with 95.00% CI Error Bars



The secondary outcome measure of the difference in pre and post-intervention BMI was significant (*t*[19] = 2.32, *p* = .032), which showed a difference in the mean of pre-BMI the mean of post-BMI was significantly different from zero. The two-tailed paired samples *t*-test suggested that pre-BMI mean was significantly higher than the post mean. Before the intervention, 19 or 20 participants did not engage in 150 minutes of exercise a week; however, at 6 months post-intervention, the number of participants rose from 1 to 5 of 20 participants and made a change in their lifestyle. This change could also be noted in the number of reported weight loss (*n* = 12, 60%) between pre and post-intervention by participants. Pre-intervention, none of the participants followed the ADA diet of low carb intake and calorie counting. At the end of the project, 14 of 20 participants were adhering to the ADA diet (Table 6, bar plot of means in Figure 5). Frequencies and percentages are presented in Table 7.

Table 6

Two-Tailed Paired Samples t-Test for the Difference Between BMIPre and BMIPost

BMIPre		BMIPost				
M	*SD*	*M*	*SD*	*t*	*p*	*d*
30.70	4.77	29.83	5.37	2.32	.032	0.52

Note. N = 20. Degrees of Freedom for the *t*-statistic = 19. *d* represents Cohen's *d*.

Figure 5

The Means of BMIPre and BMIPost with 95.00% CI Error Bars

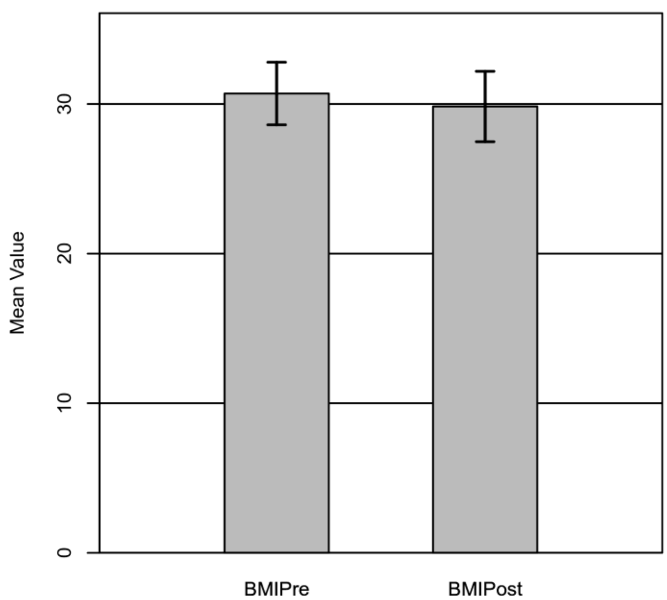


Table 7

Frequency Table for Nominal Variables

Variable	*n*	%
Gender		
Female	16	80
Male	4	20
Race		
Hispanic	20	100
ActivityLevelPre		
Yes	1	5
No	19	95
ActivityLevelPost		
Yes	5	25
No	15	75
ADADietPre		
No	20	100
ADADietPost		
Yes	6	30
No	14	70
WtUpDown		
Up	8	40
Down	12	60
A1cUpDown		
Up	7	35
Down	13	65

Note. Due to rounding errors, percentages may not equal 100%.

Discussion

The DPP states that people with prediabetes who take part in a structured lifestyle change program, lose 5% to 7% of their body weight through healthier eating, and include 150 minutes of physical activity per week will minimize their risk of developing T2DM by 58% in those 59 years of age and younger; that number rises to 71% for people over 60 years of age. This EBP project was designed to increase awareness of the importance of prescribing lifestyle interventions in the management of prediabetes and T2DM. Despite the small participant sample size of (n = 20), this NP-driven educational intervention on lifestyle modifications in DM management demonstrated an overall decrease in group HgA1c levels between participants that lost weight and those that gained weight.

The average pre-intervention A1c level for those who gained weight was 7.75, and for those who lost weight 7.46, there was a 0.29 difference between both groups. After 3 months, the post-intervention A1c level in weight gainers increased from 7.75 to 8.46. In comparison, A1c levels in those that lost weight decreased from 7.46 to 7.44. at 6 months, weight gainers' A1c levels again increased from 8.46 to 8.6, while weight losers' A1c decreased from 7.44 to 7.10. Although only a small decrease in A1c level was observed, it is important to note that individuals who lost weight went from a BMI level classified as *obesity* to *overweight* with a reported increase in adherence to an ADA diet. Although the education on lifestyle modification interventions was not statically significant (p = .618), the findings indicated clinical importance and suggested that small improvements can be made in health promotion, disease progression, and prevention.

Limitations of this project that should be considered include sample size providing inadequate power to demonstrate statically significant results. In addition, data were collected during the holiday seasons of Thanksgiving and Christmas. In December 2021, an online survey conducted by the ADA and the American Heart Association revealed that 73% of people with DM had complete control of dietary choices during a normal week; however, 52% reported less control during holiday weeks due to the many temptations and stress around the festive times. In addition to the holiday season, the participants in this project were affected by the global COVID-19 pandemic guidelines; lockdown and social distancing may have limited patients' access to exercise environments and healthier food choices.

The St John's Community Health organization serves an ethnically- and socioeconomically disadvantaged population across urban and suburban settings with an insurance mix of 80% uninsured and 20% private or public (Medicaid) insurance. Literature has shown that increased prevalence of DM is seen more in urban areas whose residents are noted to be obese, overweight, or have other underlying conditions such as hypertension. As this organization primarily serves a population commonly affected with DM, consideration must be made regarding patients' ability to access healthier foods and engage in physical activities.

Implications for Practice

The literature review supported the use of lifestyle modifications, physical activity, low carb diet, and patient education to manage T2DM to prevent or delay the progression of this chronic disease. Lifestyle modifications can avert disease complications; therefore, providers should employ these interventions in practice. More research is needed to increase patient adherence to these lifestyle modifications.

Conclusion

Lifestyle modifications are considered a cornerstone in managing T2DM. It improves blood glucose control, decreases cardiovascular disease, and improves general well-being. Lifestyle modifications play an enormous role in preventing chronic complications of DM and cardiovascular disease. The results of this EBP project demonstrated a positive correlation to favor lifestyle modifications with an emphasis on increased physical activity and dieting. There were positive results identifying a decrease in hemoglobin A1c levels, weight, and improvement in overall patient well-being. The Level I and II evidence of the reviewed studies provided support for prescribing physical activities in the treatment regimen of T2DM.

Author Note

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In compliance with standard ethical guidelines, the authors report no relationships with business or industry that would pose a conflict of interest.

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