The Implementation of a Culturally Tailored Diabetes Prevention Program among the Adult, Hispanic/Latino, Prediabetes Population, a Pilot Study

Mary Diaz-Garcia

Rutgers, School of Nursing

DNP Chair: Kathy Gunkel, DNP, APN, WHNP-C

DNP Team Member: Tracy Vitale, DNP, RNC-OB, C-EFM, NE-BC

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Abstract

Purpose: The purpose of this pilot study was to determine if the implementation of a weekly, culturally tailored diabetes prevention program for the Hispanic/Latino community, conducted by a bilingual multidisciplinary staff demonstrated a decrease in diabetes risk factors, such as hemoglobin A1c (HgbA1c) and/or body mass index (BMI), in 4 months.

Methods: Participants (N=30) were Hispanic/Latino adult, male and female with prediabetes. The pilot study used a pre-/post intervention design and offered 12 weeks of a one hour culturally tailored education session conducted in Spanish. The intervention was adapted from the Center for Disease Control (CDC) diabetes prevention program Prevent2 curriculum. The intervention focus was on lifestyle modifications to facilitate a reduction in HgbA1c and/or BMI. Clinical assessments were conducted at baseline and at the last education session.

Results: Mean participant age was 63.37 years. All participants were Spanish-speaking from Latin America. Most were female (73%). At 12 weeks, participants achieved a post intervention HgbA1c median difference of -0.1500 and a post intervention BMI median difference of -0.5100.

Implications for practice: This culturally tailored diabetes prevention program for the high-risk Hispanic/Latino population, demonstrated preliminary effectiveness in reduction of HgbA1c and/or BMI. Further research is necessary to identify ways to increase prediabetes awareness via routine screening and delivery of cost effective diabetes prevention programs in this high-risk population.

Keywords: culturally tailored, diabetes prevention, Hispanic, Latino, prediabetes

The Implementation of a Culturally Tailored Diabetes Prevention Program among the Adult, Hispanic/Latino Prediabetes Population: A Pilot Study

In 2015, an estimated 30.3 million Americans were diagnosed with type 2 diabetes (American Diabetes Association [ADA], 2017b). The American Association of Clinical Endocrinologists (AACE; 2017) and the American Diabetes Association (ADA; 2017a), identify persons as high risk for type 2 diabetes as those that are overweight or obese, with symptoms of insulin resistance, elevated cholesterol levels, a personal history of gestational diabetes, and/or those with a family history of diabetes. Uncontrolled diabetes results in costly complications such as amputations, vision loss, kidney disease, and heart disease. The Centers for Disease Control and Prevention (CDC; 2015) approximates 57 million individuals in the United States (U.S.) are of Hispanic/Latino background. It is reported more than 50% of Hispanic/Latino men and women are expected to develop type 2 diabetes over their lifetime (CDC, 2015).

The 2002 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK; n.d.) Diabetes Prevention Program (DPP) study demonstrated for those at high risk for type 2 diabetes, lifestyle modification had a positive effect in diabetes prevention. The focus of this pilot study was to implement an adaptation of the 2002 DPP. This adaptation focused on the outcomes of a culturally tailored lifestyle modifications diabetes prevention program in the Hispanic/Latino community in Hudson County, New Jersey.

Background and Significance

Insulin resistance occurs when there is an imbalance of glucose and insulin levels in the blood (ADA, 2017a). Those individuals with insulin resistance have an increased risk for type 2 diabetes when there are cardio metabolic factors present such as: hypertension, dyslipidemia, and

obesity (ADA, 2017a). In time, the collection of these risk factors play a role in pancreatic beta cell dysfunction (ADA, 2017a). The pancreatic beta cell is responsible for maintaining insulin production based on the amount of glucose present in the body. At the point of pancreatic beta cell dysfunction, the individual is at high-risk for developing type 2 diabetes and is identified as having prediabetes. Prediabetes is the transitional stage between normal glucose levels and type 2 diabetes. A diagnosis of prediabetes is based on fasting plasma glucose (FPG), oral glucose tolerance test (OGTT), and hemoglobin A1c (HgbA1c) (see Appendix A). A HgbA1c is a blood test that provides a 3-month glucose average and is considered the gold standard for evaluation of blood glucose control (AACE, 2017; ADA, 2017a).

In 2015, New Jersey reached an approximate 862,000 adults diagnosed with type 2 diabetes and an estimated 2.5 million adults with prediabetes (ADA, 2017b). Of the estimated 8.9 million New Jersey residents, 20% are of Hispanic/Latino origin (U.S. Census, 2017b). Diabetes and its complications account for approximately 2,000 annual deaths in the state of New Jersey (State of New Jersey Department of Health [NJDOH]; 2017). Among the Hispanic/Latino population, diabetes ranks as the fifth leading cause of death (NJDOH, 2017.)

The classic 2002 DPP study provides a logical response to this epidemic. Outcomes of the DPP highlight significant improvement of type 2 diabetes risk factors among individuals with prediabetes after receiving education on lifestyle modification (NIDDK, n.d). These findings position the DPP as an organizational model for diabetes prevention programs. Diabetes prevention programs that comply with this model and meet outcome benchmarks qualify for recognition by the CDC (NIDDK, n.d). A diabetes prevention program with CDC recognition is eligible for reimbursement by insurance, as discussed later. The literature emphasizes completion of a diabetes prevention program reduces risk factors for type 2 diabetes. Not only is it important

to have access to a diabetes prevention program, but also to a program facilitated in a language easy to understand by the individual. In Hudson County, this proves to be a significant limitation. The CDC registry of Diabetes Prevention Programs does not identify any organizations with CDC recognition or preliminary recognition within Hudson County, New Jersey (CDC, n.d). The nearest program that offers individualized sessions in Spanish is in Bergen County, New Jersey.

In the U.S., diabetes is more common among the non-English speaking population (ADA, 2017a). On average, the HgbA1c among the Hispanic/Latino population is 0.5% higher than that of a non-Hispanic/Latino (Ferguson, Swan, & Smaldone, 2015). This implies the Hispanic/Latino population is at greater risk for developing type 2 diabetes (Ferguson et al., 2015). Long term uncontrolled diabetes is associated with microvascular complications. Therefore, racial and ethnic minority with long term undiagnosed diabetes or undiagnosed prediabetes demonstrate a higher risk for microvascular complications (ADA, 2017c).

From an economic standpoint, in 2017, the burden of diabetes on the U.S. economy was documented to be $327 billion in total costs, $237 billion in direct medical costs, and $90 billion for reduced productivity (ADA, 2017b). These totals equate to approximately 2-3 times higher than the expected expenditure in the absence of diabetes (ADA, 2017b). The 2012 New Jersey economic burden of diabetes was a documented $7.5 billion in direct medical costs and $2.8 billion in lost productivity (ADA, 2017c). The New Jersey Diabetes Action Plan, as explained by the Diabetes Action Plan Committee (DAP; 2016), has projected the total cost will increase to approximately $14.5 billion by 2025. In response to these projections, the DAP committee has proposed the implementation of an evidence-based diabetes prevention programs for the community, family members, and providers (DAP, 2016). Similarly, other organizations have invested in diabetes prevention programs. In 2015, the NIDDK invested approximately $3.2

million in diabetes related projects for New Jersey (ADA, 2017c). More recently, the Division of Diabetes Translation at the CDC invested approximately $1.4 million on diabetes prevention and educational programs in New Jersey (ADA, 2017c).

As noted, there are many organizations advocating for diabetes prevention programs. Like the efforts made by the DAP, CDC, and NIDDK, Centers for Medicare and Medicaid (CMS) has established an agenda for diabetes prevention (CMS, 2018). CMS has developed the Medicare Diabetes Prevention Program (MDPP) modeled after the CDC DPP model. This program serves as a response to the $42 billion surplus among the 2016 beneficiaries with diabetes. On average, Medicare pays $1,500 more on Part D prescription drugs, $3,100 more for hospital and facility services, and $2,700 more in physician and other clinical services for those with diabetes versus those without diabetes (CMS, 2018). The MDPP expanded model allows Medicare beneficiaries to access evidence-based diabetes prevention services. The evidence-based diabetes prevention program is reimbursed for their services via the performance-based payment structure based on participant outcomes, such as attendance and /or weight loss (CMS, 2018). The new CMS MDPP model creates an opportunity for those Medicare beneficiaries to receive more preventative care. Ideally, statistically significant outcomes of this pilot study would provide the community primary care providers and organizational systems data supporting the need to further invest into a CDC recognized diabetes prevention program for the community.

Needs Assessment

Current clinical guidelines by the American Association of Clinical Endocrinologists (AACE) (Gonzlez-Campoy et al., 2013) and the ADA (2017a) recommend implementing

lifestyle interventions for those patients at high risk for diabetes, such as a behavioral counseling program, with a minimum goal of 7% weight loss, weight maintenance, and a minimum of 150 minutes per week of physical activity. The ADA recommends those diagnosed with prediabetes be referred to an intensive behavioral lifestyle intervention program modeled after the 2002 DPP (ADA, 2017a).

In the state of New Jersey, Hudson County has a 43.2% Hispanic/Latino population (U.S. Census, 2017a). As previously stated, Hudson County does not have a recognized diabetes prevention program (CDC, n.d.). Given the astonishing Hispanic/Latino population and death rates secondary to diabetes and its complications, the community begs for access to a culturally tailored diabetes prevention program. Interventions, such as a culturally tailored diabetes prevention program, demonstrate strength in outcomes such as HgbA1c reduction and other risk factors (McCurley et al., 2017).

The primary care practice in Hudson County, chosen as the recruitment site, has a patient population of 9851 with an estimated 80% being of Hispanic/Latino origin. To date, 50% of patients in this practice have a diagnosis of type 2 diabetes. Based on International Classification of Disease (ICD) coding, this site does not have record of patients with an ICD diagnosis code of prediabetes. The site does not have access to a diabetes prevention program nor do they have a diabetes screening protocol.

Purpose Statement

The purpose of this pilot study was to determine if the implementation of a weekly, culturally tailored diabetes prevention program for the Hispanic/Latino community, conducted

by bilingual multidisciplinary staff, demonstrated a decrease in diabetes risk factors, such as HgbA1c and/or BMI, in 4 months.

Clinical Question

The clinical question guiding this project was, "In the adult, Hispanic/Latino prediabetes population, does the implementation of a multidisciplinary diabetes prevention program decrease HgbA1c and/or BMI in 4 months as compared to usual care given by primary care providers?"

Aims and Objectives

The aim was to improve the Hispanic/Latino populations' awareness of their prediabetes status to prevent progression to type 2 diabetes. The objectives of this pilot study were:

- Develop to a culturally tailored pilot diabetes prevention program, based on the 2002 DPP, targeted to the Hispanic/Latino community.
- Implement 12 one-hour weekly group classes for the qualified participants.
- To decrease HgbA1c and/or BMI.
- Compare baseline HgbA1c and/or BMI with post-intervention HgbA1c and/or BMI.

Review of Literature

This section includes definitions of variables and concepts, a description of the theoretical framework, and a review of the literature on diabetes prevention programs for the Spanish speaking Hispanic/Latino person with prediabetes. This review is divided into the following sections: screening and referral to a diabetes prevention program, adaptations of a diabetes prevention program, and outcomes.

A literature search for all English-language studies on diabetes prevention program, translation of diabetes prevention program, adaptations of diabetes prevention program, and culturally tailored diabetes prevention program was performed. First, a search on current guidelines for diabetes prevention programs was performed. This was conducted by a review of the most up to date CDC guidelines, NIH guidelines, NIDDK guidelines, AACE guidelines and ADA guidelines. Second, a search on current adaptations, translations, and/or culturally tailored diabetes prevention programs was performed. The following databases were searched for articles published between 2012 and 2018: PubMed, CINHAL, and Google Scholar. The following key terms were utilized for the search: *adaptation, culturally tailored, diabetes prevention, elevated BMI, Hispanic, hyperglycemia, Latino, metabolic syndrome, obesity, prediabetes, translating, and translation*.

The search yielded 789 studies. After accounting for duplicate studies, 613 studies remained for review based on its title. After application of inclusion criteria, as outlined below, 52 studies remained. Inclusion criteria were original studies, systematic reviews in peer-reviewed journals that studied diabetes prevention programs in adults with prediabetes, written in the English language. After applying exclusion criteria, 16 remained (see Appendix B). Exclusion criteria were studies that included children, participants with known diabetes status, pregnant participants, and gestational diabetes. Studies done prior to 2012 were excluded except for one classic study from 2002. Of these, eight were randomized controlled trials, one a systematic review, one literature review, three quasi experimental, two qualitative, and one non-experimental study and each was critically appraised and included in the Table of Evidence (see Appendix C).

Screening and Referral to a Diabetes Prevention Program

The rising prevalence of type 2 diabetes and prediabetes are a major public health concern (ADA, 2017a). There are significant differences in diabetes prevalence in relation to those of Hispanic/Latino background, age, and BMI (Scheiderman et al, 2014). In terms of diabetes risk, individuals between the ages of 18-29 had a 2.6% risk, those between the ages of 70-74 had a 48.4%, and those with a BMI of ≥ 30 had a 22.3% risk (Scheiderman et al, 2014). These individuals should have the highest priority for screening. However, a screening tool only offers one part of the process. A positive screen necessitates a systematic referral to a diabetes prevention program (Dhippayom, Chaiyakunarik, & Krass, 2014). Even though risk assessment tools are intended for diabetes, there is a benefit in the identification of prediabetes. A single positive prediabetes laboratory finding has demonstrated to predict diabetes (Perreault, Pan, Mather, Watson, Hamman, & Kahn, 2012). This reinforced the importance of having a protocol in place for frequent screening and early identification of prediabetes allows for early referral to diabetes prevention education (Dhippayom et al., 2014). A methodological protocol for screening necessitates proper communication with the patient to procure early intervention for behavioral changes (Perreault et al., 2012; Van Name et al., 2016).

Interestingly, the literature demonstrated patients respond best when risk assessment tools were given by the health care providers (Dhippayom et al., 2014). Does this have anything to do with the patients' perception of developing diabetes (Dhippayom et al., 2014)? Patient perception of diabetes risk serves to be important when considering screening and referrals for diabetes prevention education (Joiner et al., 2016). Acculturation, as a sociocultural influence, proved to have an impact on diabetes risk among the Hispanic/Latino population (Joiner et al., 2016; O'Brien, Shuman, Barrios, Alos & Whitaker, 2014). Research suggested access to new foods and

new methods of food preparation impacted the risk of diabetes among the Hispanic/Latino population (O'Brien et al., 2014). Understanding the influence of acculturation on this population allows for proper discussion of potential diabetes prevention interventions by health care providers (O'Brien et al., 2014). Particularly, the primary care setting was shown to be the setting of choice to discuss perception of diabetes and risks of developing diabetes (Dhippayom et al., 2014; Joiner et al., 2016; Ma et al., 2013).

Adaptations of the 2002 Diabetes Prevention Program

In the classic 2002 DPP study, treatment effects did not differ based on sex, race, or ethnic groups (Diabetes Prevention Program Research Group [DPPRG], 2002). Meaning, the study is applicable to ethnically and culturally diverse populations. The data highlighted the benefits of an adaption of the 2002 DPP for the Hispanic/Latino population as it offers the similar outcomes to that of the classic 2002 DPP (Ma et al., 2013; McCurley, 2017; O'Brien et al., 2017; Van Name et al., 2016). Culturally tailored lifestyle intervention programs for the Hispanic/Latino community incorporate bilingual coaches, also known as *promotoras*, and staff to deliver the information (McCurley et al., 2017; O'Brien et al., 2017; Van Name et al., 2016; Vincent et al., 2013; Vincent et al. 2014). Understanding cultural health behaviors and diabetes risks assists in the development of adequate adaptations of the 2002 DPP (O'Brien et al., 2014). In addition to cultural matters, adaptations of the 2002 DPP allow for acknowledgement of changes that occur during acculturation.

Culturally tailored diabetes prevention programs demonstrated great feasibility and acceptability (McCurley et al., 2017; Van Name et al., 2016). Bicultural team members serve as culture brokers in which they provide insight and advice when working with members of the Hispanic/Latino community (Vincent et al., 2013). Their insights and advice on culturally

tailoring the interventions help decrease cultural and contextual barriers (O'Brien et al., 2014; Vincent et al., 2013; Vincent et al., 2014). Designing intervention strategies that are culturally sensitive, inclusive of acculturation changes, may improve the overall effectiveness of a diabetes prevention program (O'Brien, 2014)

Outcomes

In the development of this pilot culturally tailored diabetes prevention program, it was important to keep focus on the desired outcomes. It is integral to maintain similar, if not better, outcomes of the 2002 DPP. To summarize, outcomes of the 2002 DPP demonstrated the incidence of diabetes was lower among the lifestyle intervention group versus the metformin group (58%) (DPPRG, 2002). The metformin group demonstrated a lower incidence than the placebo group (31%) (DPPRG, 2002). Again, there was no significant differences in gender, race, or ethnicity (DPPRG, 2002). In the follow up study to the 2002 DPP, the Diabetes Prevention Program Outcomes Study (DPPOS), diabetes risk was 56% lower for those participants with glucose levels that returned to non-diabetic ranges (Perreault et al., 2012). Perreault et al. (2012) argued even if the return to normal glucose ranges was short lived, it was associated with a 47% reduced risk of the future development of diabetes. This overall outcome was a result of insulin resistance lowering interventions which often improve beta cell function the of the pancreas (Perreault et al., 2012).

Weight loss. Lifestyle interventions in the 2002 DPP incorporated healthy eating and physical activity (DPPRG, 2002). Together, these interventions resulted in a long-term reduced diabetes risk which were seen in the follow up DDPOS study. Outcomes of culturally tailored programs among the Hispanic/Latino community have also demonstrated post intervention

weight loss (McCurley et al., 2017; O'Brien et al., 2017; Ockene et al., 2012; Piatt et al., 2012; Van Name et al., 2016).

As post intervention weight loss was associated with long-term diabetes risk reduction, for this pilot program it was important to consider weight loss barriers seen among the Hispanic/Latino community (O'Brien et al., 2017). Ockene et al. (2012) identified barriers for dietary changes to include 34% stress, 55% lack of will power, 30% home healthy food environment, and 18% knowledge. In addition to these barriers, participant attendance proved to have an impact on weight loss. Participants with high attendance rates were found to have significant weight loss (Ockene et al., 2012).

Glucose tolerance, insulin resistance, and HgbA1c. Microvascular complications such as retinopathy, nephropathy, and neuropathy are complications traditionally seen, or associated with, long-term uncontrolled diabetes (Ghody, Shikha, Karam, & Bahtiyar, 2015). However, individuals that maintain mild hyperglycemia exhibit these same microvascular complications (Ghody et al., 2015). Post intervention data demonstrates improved glucose tolerance and reduction in fasting glucose (Van Name et al., 2016; Weinhold et al., 2015). Lifestyle modifications reveal a slow progression of glucose tolerance, a reduction in HgbA1c, and improved insulin resistance in the intervention group (Ghody et al., 2015; Ockene et al., 2012).

Theoretical Framework

The Ottawa Model of Research Use (OMRU), founded in 1998, is a six-step approach which guides the implementation of continuity of care innovations (Graham & Logan, 2004) (see Appendix D). Commonly categorized as a planned action model, the OMRU provides direction regarding key issues and the activities necessary during the implementation process. The six key

elements are as follows (a) evidence-based innovation, (b) potential adopters, (c) the practice environment, (d) implementation of interventions, (e) adoptions of the innovation, and (f) outcomes resulting from the implementation of the innovation. The foundation of this model is based on a process of continual assessment, monitoring and evaluation at every point during the implementation process (Graham & Logan, 2004). This process incorporates change agents as coordinators of change. Change agents strategically planned and promoted changes throughout this pilot diabetes prevention program (Graham & Logan, 2004).

Methodology

The pilot project used a pre-/post intervention design with review of HgbA1c and BMI values from the participants before and after the implementation of a 12 week, culturally tailored diabetes prevention program.

Setting

The setting for this project intervention was a primary care practice in Hudson County in northern New Jersey. The patients were recruited from the same primary care office located in Hudson County, New Jersey. The practice has three providers and four medical assistants. The patient population is approximately 80% Hispanic/Latino. The study intervention was provided by the Spanish-speaking principal investigator (PI) at the office for one-hour weekly group classes for 12 weeks.

Study Population

The screening and recruitment process of this pilot study took place over the course of six work days. Inclusion criteria consisted of Hispanic/Latino, Spanish speaking women and men between the ages of 18 and 89, a diagnosis of prediabetes, and were seen by a provider of the

practice within the last 12 months. Exclusion criteria consisted of women and men with diagnosis of type 1 or type 2 diabetes, diagnosis of gestational diabetes, those without prediabetes, as well as pregnant or planning pregnancy within the next 4 months, planning on moving, or documented or self-reported cognitive impairments. In accordance to the recruitment algorithm (see Appendix E), the PI identified a total of 130 eligible participants based on initial screening criteria of 268 individuals (see Appendix F). Based on the preliminary screening, 79 individuals chose not to participate because of either work schedule conflicts (N =44), scheduled to be out of the country (N=4), or lack of interest in the study (N=31). Ultimately 51 individuals consented and were either recruited for the pilot study based on HgbA1c (N = 23) or administered the ADA screening tool (N=28), as per the recruitment phase of the algorithm. Of the 28 individuals that were administered the screening tool, 7 individuals opted not to proceed with recruitment and 14 did not qualify based on inclusion / exclusion criteria. A final sample of 30 individuals was obtained for this pilot study.

Subject Recruitment

Information about the pilot culturally tailored diabetes prevention program was shared via recruitment fliers. Recruitment fliers were displayed in the office waiting room and in each examining room (see Appendix G). Access to potential participants was achieved through a daily, practice-generated, list of scheduled patients for the day. The list provided the patient name, date of birth, medical diagnosis, most recent HgbA1c, and ethnicity. The purpose of the daily list was to assist the Spanish-speaking PI in identifying patients with a known diagnosis of prediabetes and to streamline the recruitment process. The subjects were identified upon arrival and were approached for recruitment after their scheduled office visit with the provider. Categories of prediabetes are noted in Appendix A. For purposes of this pilot program**,** an

adaptation of the Point of Care Prediabetes Identification Algorithm, part of the Prevent Diabetes STAT – Screen, Test, Act Today ™ initiative used as a systematic approach to screening and testing potential participants for prediabetes (see Appendix E).

All individuals that meet inclusion criteria were approached by the Spanish-speaking PI and informed about the purpose of the pilot study after their scheduled appointment with the provider. A copy of the ADA Diabetes Risk Test (see Appendix H) and a handout summarizing the project (see Appendix I), as well as contact information, was provided. Those individuals with known prediabetes or a HgbA1c of greater than or equal to 5.7% but less than or equal to 6.4% within the last 3 months, were notified of the pilot study and recruited by the Spanish-speaking PI. The consent process was explained and consent was obtained. Those potential participants without a HgbA1c within the last 12 months or result obtained more than 3 months ago but less than 12 months, were also notified of the pilot study and the screening process. If they agreed, the consent process was explained and consent was obtained. Then, an ADA Diabetes Risk Test (see Appendix H) was administered. In accordance with the algorithm, if the ADA Diabetes Risk Test reveals a score of 5 or higher, the potential participant was asked if they would agree to a repeat of their HgbA1c via their primary care provider to confirm that they were within prediabetes range. A score of 5 or higher placed the individual at high risk for undiagnosed diabetes (Bang et al., 2009). The potential participant was informed that a repeat HgbA1c is compliant with standards of care. The potential participant was made aware of their HgbA1c result via telephone or office visit by the Spanish-speaking PI, as per potential participant request. If the HgbA1c demonstrated to be in prediabetes range, efforts to enroll the potential participant in the 12-weekly group classes was implemented by the Spanish-speaking

PI. The onsite recruitment was scheduled for 8 weeks or until 30 qualified participants were enrolled.

After initial recruitment information was provided, the potential participants were provided a handout summarizing the project as well as contact information for any questions or concerns (see Appendix I). Potential participants were informed that participation in the pilot program was voluntary and constituted a supplemental service and their decision to participate in the program would not impact the usual care provided by their primary care provider. Post intervention HgbA1c done by the primary care provider would be a part of usual care and compliant with standard of care. Potential participants referred by other potential participants, were accepted if they met inclusion criteria.

Consent Procedure

Potential participants were allotted time after their routine office visit to review the consent with the Spanish-speaking PI. The consent was signed at the primary care practice. The potential participants could take the consent home prior to signing. If the potential participant chose to take the consent home for further review they were instructed to return to the Hudson County based practice to sign the consent with the Spanish-speaking PI. All associated risks were discussed with the patient prior to signing the consent as well as the answering of any questions the potential participant may have had (see Appendix J).

Risk/Harms

Participation in this pilot study possessed minimal risk. There was a small possibility that personal health information collected may be inadvertently be shared by participating in this project. The participant name and the personal health information necessary for this project was collected and assigned a number. This allowed for the data to be reviewed without direct link to

the participant's name. Only the PI had access to the list linking the name to the number associated with the data. The participant may have experienced mild discomfort and/or muscular aches from exercise and/or stretching exercises taught during the program. The participants were informed of any new findings that may affect their decision to remain in the study. Participants were reminded they can end their participation in the project at any point without penalty or risk to standard medical care.

Subject Costs and Compensation

There was no cost to the patient to participate in this project. Subjects did not receive monetary compensation for their participation in the project. However, light refreshments and snacks were provided during the educational sessions. Educational and exercise materials were provided at no cost to the participant.

Study Interventions

The pilot program was adapted from the first 16 weeks of the CDC diabetes prevention program PreventT2 curriculum. The pilot program was modified to a shorter time frame of 12 weeks and conducted in Spanish. The education modules and logs were presented to each participant in a binder (see Appendix K). Prior to the start of the first session, participant height, weight, BMI, and attendance were obtained. Prior to the start of subsequent sessions, fifteen minutes were allotted for attendance gathering and discussion of any questions. A grid with the participant specific number were used to track data (see Appendix L). Pre and post intervention HgbA1c were obtained via chart review by the PI. (see Appendix M). Forty-five minutes were allowed for education. Each session was specific to one topic with time allotted for questions and discussion of previous weeks' topic.

Session one served as the introduction to the program. The participants received a binder with the information regarding the material for the present session and the next 11 sessions. Information included PI contact information and program overview. Included in the program overview was pilot study inclusion criteria, terms, such as, prediabetes, metabolic syndrome, hypertension, hyperlipidemia, dyslipidemia, impaired glucose tolerance, and impaired fasting glucose were discussed. Participant and program expectations, as well as expected outcomes and goals, were addressed. Participants were informed of study completion follow up after statistical analysis. At the end of the first session, time was allotted for questions, comments, and / or concerns.

Session two provided the core principles of healthy eating and tracking foods. Binder handouts for session two were reviewed and discussed. Handouts included daily food logs, portion control via the Healthy Plate, and lists of foods. The lists of foods were categorized based on carbohydrates, proteins, non-starchy vegetables, fruits, and healthy fats. The discussion further detailed culturally relevant foods and styles of preparation to adhere to the core principles of healthy eating and portion control.

Session three introduced the core principles of exercise. The focus was on the benefits of getting active and identification of ways to get active. Binder handouts for session three and food logs from the previous session were reviewed. Handouts included types of exercises and their benefits, goals, and techniques for goal attainment. Discussion for this session was focused around perceived successes and barriers to exercise, such as weather conditions, lack of resources, and lack of time. Individual food logs were reviewed and discussed amongst the participants. Additionally, there was a brief demonstration and explanation of exercise and stretching movements. Steps for prevention of injury were also discussed. Key themes noted

during discussion included portion control, identification of carbohydrates and proteins, and timing of meals and snacks.

Session four focused on continued efforts in increasing exercise. As a continuation of session three, session four centered around increasing activity and accountability via tracking of activity. Handouts for this session identified tracking methods, goals, and hindrances with possible solutions. The participants shared possible solutions to hindrances in scheduling time for exercise, as well as alternative solutions for exercise equipment. There was a brief demonstration and explanation of low weight bearing exercises and cardiovascular exercises. Individual food logs were reviewed and discussed amongst the participants. Key themes noted during the discussion included continued efforts of balancing protein and carbohydrates with all meals, identification of non-starchy vegetables, and hindrances of juices and green smoothies.

Session five provided further understanding of carbohydrates. The focus of this session concerned the link between carbohydrates and type 2 diabetes, types of carbohydrates, and healthy approach to carbohydrates. The discussion also focused on how to identify the number of carbohydrates in foods through reading nutritional facts on each item. The handouts for this session were focused on reading nutritional fact labels, understanding portions, and keeping a food diary of carbohydrates versus protein and non-starchy vegetables. A mock shopping experience was set up with commonly purchased foods as identified by previous food logs. Participants demonstrated how to read nutritional fact labels and identified recommended portions. During the discussion, participants voiced their concerns over recommended portions versus actual portions. Exercise and food logs from the previous weeks were reviewed in detail. Food logs demonstrate continued concerns regarding incorporation of culturally specific foods and staying within portion.

Session six was scheduled to provide teaching on how to buy and cook healthy food. Due to severe weather conditions, the class was cancelled.

Session seven was scheduled to provide teaching on stress management. In view of the cancellation of session six due to severe weather conditions, session seven also provided teaching on session six's how to buy and cook healthy food in addition to the scheduled teaching on stress management. First, session six binder handouts were reviewed. Session six handouts focused on most commonly purchased foods, commonly used spices, and cultural food preparation methods. These handouts were compared with weekly food logs from previous weeks to ensure culturally relevant foods were included. A common theme among the participants was uncertainty of foods that were deemed healthy based on packaging and marketing strategy and spices high in sodium and / or monosodium glutamate. Exercise logs were reviewed and discussed amongst the participants. Participants disclosed hindrances to meeting goals and offered suggestions to one another on how to overcome hindrances.

The second part of session seven focused on how to reduce and deal with stress and how to cope with triggers of unhealthy behaviors. Binder handouts for session seven focused on causes of stress, emotions associated with stress, actions by the participants during time of stress, and methods for prevention and/or overcoming stress. During the discussion, family and personal stressors were addressed. Participants imparted their individual approaches in dealing with family stressors. For those individuals that are experiencing distress, they were referred to their provider for further screening and evaluation of depression. Referrals to proper mental health specialists were made by their primary care provider.

Session eight revisited benefits on being active. This session focused on the benefits of being active, as well as challenges in finding time to be active and challenges of staying active

away from home. Binder handouts were reviewed. Session eight handouts focused on exercise strategies at home, at work, and away from home. Participants were asked to provide individual hindrances to goal attainment as well as one solution. Participants engaged in a dialog surrounding previous exercise/stretches taught in the study and how to apply them at work and during vacation. Exercise and food logs were reviewed. A common theme noted in the food logs was participants were preparing two different meals as family members were not fully engaged as a support system for the participant. After the session, a review of previously taught exercise routines and stretching was done.

Session nine provided teaching on and how to get support for a healthy lifestyle. This session demonstrated to be a positive sequel to session eight in which participants voiced concerns over lack of family support. Binder handouts focused on how to get support from family, friends, coworkers, support groups, classes, and clubs. Binder handouts provided scenarios in which constructive and non-constructive criticism were given. Participants discussed methods to include the family unit and coworkers in their efforts to improve their adoption of healthy living. Examples included food shopping as a family, pot-luck lunches at work, and 10-minute exercise breaks at work. Exercise and food logs from previous weeks were reviewed and discussed amongst participants. Common themes noted were improved efforts on carbohydrate identification and portion control. Exercise goals continued to be dilemma. Hindrances were discussed and solutions were shared amongst the participants. One solution worth mention was fast-paced walking around the supermarket for 10 minutes prior to shopping.

Session ten reinforced session one teaching on benefits of type 2 diabetes prevention. This session focused on the heart healthy eating and maintaining healthy eating goals at restaurants and social events. Binder handouts were reviewed. Heart healthy binder handouts

focused on smoking cessation, cardiovascular exercise weekly goal of 150 minutes and low-fat food options. The participants disclosed they are non-smokers. The discussion provided knowledge regarding correlations between reduction of cholesterol levels and exercise. The participants shared their favorite restaurants. Menus from each restaurant were accessed from the internet. Participants chose their usual choice of meal. The participants dissected each meal, identifying the protein, non-starchy vegetable, and carbohydrate. If the meal did not parallel with the healthy portions discussed, the participants successfully exchanged food options to match the healthy portions. Exercise and food logs were reviewed. Food logs demonstrated great improvement in food portions and shared meals options with family members. Exercise logs demonstrated improved efforts in exercising weekly.

Session eleven aimed at overcoming cessations on weight loss and motivation. Discussions focused on reestablishing eating and fitness goals. Binder handouts were reviewed. The handouts identified snacks under 100 calories and exercises that expend 100 calories. The participants also reviewed food logs in detail to ascertain accountability with portion control. The participants provided emotional support and encouragement for one another. Exercise logs demonstrates an increase in aerobic exercises. Participants were instructed on how to interchange previously learned exercise routines and stretches to prevent monotony.

Session twelve served as the final session. During this session, participant expectations and goals were revisited. Participants were weighed privately. Some of the participants had routine office visits with their primary care provider. As part of their routine visit, participants obtained HgbA1c levels. These results were reviewed and discussed by their primary care provider. Participants reflected on their progress and making positive changes on a long-term basis. The discussion focused on the importance of staying motivated, maintaining healthy

lifestyles and goal setting. Binder handouts focused on methods to overcome hindrances for the long-term. All resources discussed during the pilot program were provided. Participants were informed that after completion of the program, they are to follow with their primary care provider for usual care follow up for their prediabetes.

Outcomes Measured

Outcomes were measured utilizing HgbA1c and BMI. The HgbA1c was measured by the designated laboratory according the participant health insurance provider and as part of their usual care and compliant with standard care by their primary care provider. To determine BMI, body weight and height was measured using standardized procedures with participants wearing only light clothing and shoes. Weight checks were done at first and last session, as per study intervention design. As the HgbA1c was drawn per the provider blood work order, a chart review was done to retrieve this data. Only the PI performed the chart review. A separate list with name and identification number was kept. Only the PI accessed to the list linking the names (see Appendix N). The data was documented on the same tracking grid as the pre intervention HgbA1c (see Appendix M).

The chart review was done only on those participants that have signed a consent for participation in the pilot study. Each chart was identified based on the list linking the name to the identification number (see Appendix N). From each chart, the participant HgbA1c was obtained and documented on a tracking grid (see Appendix M). The charts were reviewed prior to the start of the 12-week pilot program and 2 weeks after the completion of the 12-week pilot program. A chart review was not conducted on those participants that withdrew or did not participate in any sessions from the 12-week program.

Project Timeline

A GANTT chart was created with a description of the projection time line and major steps involved in the project (see Appendix O).

Resources Needed

The costs associated for this project was the sole responsibility of the PI. Costs included recruitment materials, educational handouts, materials for the educational program, exercise resources, etc. There were also research expenses that were included in the budget for this project. The budget can be found in Appendix P.

Evaluation Plan

Data Maintenance and Security

Patients were provided with a randomized ID number by the PI to use on PHI data collection. The master list linking the patient to the random ID code was kept separately from the actual hard copies of blood work results (see Appendix N). Existing lab results were collected by the PI via chart review. Hard copies of lab results were stored within the project site, in a locked cabinet. Data from the chart audit was logged, based on the assigned random ID number, and was also kept in a locked cabinet. The data was de-identified upon completion of data collection and only de-identified data was used for analysis. In accordance with Rutgers University Office of Information Technology guidelines, all data will be maintained by the project chair for 7 years. Hard copies of consents and aggregate data are housed in Dr. Kathy Gunkel's office, project chair, at Rutgers University at the School of Nursing, Ackerson Hall, 180 University Avenue, Newark, New Jersey 07102. In accordance with Rutgers University guidelines, all data and identifiers have been destroyed.

Data Analysis

Analytical statistics were conducted via IBM SPSS Statistics. The data was collected pre-intervention and post intervention. Nominal data included the following categories: gender, age, determination of prediabetes. Interventional data included: height and weight. Ratio data included pre- and post-intervention weight and HgbA1c, as well as number of sessions attended. Descriptive statistics was used to describe the sample of participants. As a result of the small sample size, a Wilcoxon signed-rank test was used. However, normal distribution was not noted; therefore, a sign test was used to determine the efficacy of the project intervention (see Appendix Q).

Findings

Descriptive Statistics

Baseline characteristics for the overall consented sample (N=30) are presented in Appendix R. Participants ranged in age from 40-89 years old (mean = 63.37). All participants were Spanish-speaking and from Latin America. Most participants were female (73%). Participants 70-79 years old represented the majority, followed by participants 50-59 years old. The mean ADA risk assessment score was 6.41 and ranged from 5 (minimum eligibility score) to 9. The mean HgbA1c was 5.98% and ranged from 5.7%-6.3%. The mean BMI was 30.74.

An exact sign test was conducted to determine the association between the pilot culturally tailored diabetes prevention program on HgbA1c and/or BMI. The participants attended 12 one-hour weekly diabetes prevention sessions. Seven of the 30 participants, completed the pilot study. Five participants obtained post intervention HgbA1c, which demonstrated a median

difference of -0.1500. Three participants demonstrated an improvement in HgbA1c, 1 participant saw no change in HgbA1c, and 1 participant demonstrated an increase in HgbA1c.

Seven obtained post intervention BMI, which demonstrated a median difference of -0.5100. Five participants demonstrated an improvement in BMI and 2 participants demonstrated an increase in BMI.

Develop a Culturally Tailored Pilot Diabetes Prevention Program

Development and implementation of a pilot culturally tailored diabetes prevention program in Spanish was met based on the execution of this pilot study. Implement 12 one-hour Weekly Group Class. Completion of 75% of the one hour weekly group class, a de-identified record of participant attendance was used to keep track of the attendance of each participant (see Appendix L and Appendix M). Four out of the 7 participants that completed the pilot study, attended 75% or more of the one hour weekly group classes.

Association Between Pilot Study and HgbA1c

Pre-intervention and post intervention HgbA1c were requested by the primary care provider as per usual care and compliant with standards of care. A post intervention chart review was done within 14 days of completion of the 12-week pilot study. Three participants demonstrated a decrease in HgbA1c. However, there was no statistically significant median decrease in HgbA1c (Mdn = -.1500) when participants attended the pilot program (Mdn = 5.80%) compared to before the pilot program (Mdn = 6.05%), p = .625.

Association Between Pilot Study and BMI

Pre-intervention and post intervention BMI were obtained via a chart review prior to the first session and at the last session of the pilot study. Five participants demonstrated a decreased in BMI. However, there was no statistically significant median decrease in BMI (-.5100) when

participants attended the pilot program (Mdn = 30.4200) compared to before the pilot program (Mdn = 30.7050), p = .453. A post intervention ADA Diabetes Risk test was not done.

Recommendations and Discussion

Diabetes prevention is certainly a public health issue. The overarching aim of this pilot study was to improve the Hispanic/Latino populations' awareness of their prediabetes status to prevent progression to type 2 diabetes. Although the pilot program did not yield statistical significance, it offered an opportunity for a busy primary care practice to implement a screening and referral process for the prediabetes Hispanic/Latino population and implementation of Spanish-led diabetes prevention program.

Economic/Cost Benefit of the Project

There is vast research which demonstrates the need for a cost-effective diabetes prevention program for the Spanish-speaking, Hispanic/Latino prediabetes population. In accordance with the clinical guidelines set forth by AACE (Gonzalez-Campoy et al., 2013) and ADA (2017a), it is recommended all those at high risk for diabetes be referred to a lifestyle intervention program. The data clearly outlines the economic burden of diabetes not only in New Jersey, but also across the U.S. (ADA, 2017b; ADA, 2017c). Zhuo et al. (2014), stress that despite having reduced life expectancy, persons with diabetes are associated with higher lifetime medical expenditures. High risk populations that enroll in diabetes prevention programs can have a significant effect on diabetes incidence and the economic burden of diabetes. The American Medical Association (2017) offers an online tool that providers can access to calculate net savings and return on investment (ROI) for their sample population that attend diabetes prevention programs. This pilot study did not provide a cost analysis as it was out of the scope of

this pilot study. Further research is warranted to further augment the data surrounding cost effectiveness of diabetes prevention programs.

Impact Health Care Quality/Safety

The National Diabetes Prevention Program (NDPP) was created in 2010 as a national effort to address the increasing burden of prediabetes and type 2 diabetes. This evidence based intervention was created because of the growing research surrounding lifestyle modifications programs and their effect on the prevention or delay of onset of type 2 diabetes (CDC, 2019). Recalling the DPPOS, the follow up study to the 2002 DPP, demonstrated a 56% decrease of diabetes risk among those participants that returned to non-diabetic range (Perreault et al., 2012). Although this 12-week pilot study did not demonstrate statistical significance in HgbA1c reduction, it is important to note those individuals that did achieve a decrease in their HgbA1c. Limitations noted to this aspect of the pilot study included work schedule conflicts, lack of childcare, lack of transportation, and severe weather conditions. An additional limitation to this 12-week pilot study was that it was adapted from the NDPP one-year PreventT2 curriculum. The one-year PreventT2 curriculum allows for continued support and guidance towards the desired outcome. This pilot program was not designed to continued follow up post 12-week intervention.

Implications for Policy

The NDPP offers an evidence based curriculum for the prevention of type 2 diabetes. Additionally, the NDPP offers CDC recognition for organizations that deliver the program effectively (CDC, 2018). Recalling the MDPP, modeled after the CDC DPP, offers reimbursement for diabetes prevention services via a performance-based payment structure based on participant outcomes (CMS, 2018). Although this is only one insurance payer, there room for more action on the behalf of other insurance payers for a similar coverage. Further research is

necessary surrounding expansion on policy and payment reforms on this chronic disease. Nurses, of varying degrees, must continue to research cost-effective approaches to quality healthcare for the prevention of type 2 diabetes.

Translation

While there was certainly room for improvement, the pilot program demonstrated promise as the primary care practice in which the pilot study was performed did not have a policy or procedure for prediabetes screening in place. Successful outcomes of a diabetes prevention program among the Spanish-speaking Hispanic/Latino population is multifactorial (Konchak, Moran, O'Brien, Kandula, & Ackermann, 2016). First, the person must be aware of their prediabetes status. Second, the individual must be in possession of insurance that offers coverage for a DPP-based intervention program. However, for those that do not have access to this coverage, if diabetes prevention programs costs can be kept low, diabetes prevention may lead to a reduction in long-term medical costs (Zhuo et al., 2014). Third, access to DPP-based intervention programs. This pilot program addressed the three factors. Individuals were made aware of their prediabetes status via a screening process and were referred to a primary care office based DPP-based intervention program conducted by a Spanish-speaking health coach, at no cost of their own. Similarly, this two-step pilot program can be translated to other primary care practices that do not have a prediabetes screening/referral policy or procedure in place. To better accommodate a broader target audience, the culturally-tailored diabetes prevention program would implement the PreventT2 curriculum in Spanish at an unbiased location to decrease conflict of interest among primary care providers.

Dissemination

After completion of data analysis, participants are scheduled to be notified of their HgbA1c and BMI change by the PI. After completion of this pilot study, the Hudson County primary care office in northern New Jersey has agreed to a poster presentation during their 2019 first quarter meeting. All site stakeholders of the primary care office are scheduled to attend.

Professional Reporting

In addition to the primary care office's first quarter meeting in 2019, a poster was presented at Rutgers University DNP Poster Day. Applications for poster presentations at the annual AADE and ADA sessions are scheduled. The poster discussion is also scheduled at local community health fairs/screenings.

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Appendix A

American Diabetes Association Standards of Medical Care in Diabetes 2017

Categories of increased risk for diabetes (prediabetes)

American Diabetes Association (ADA). (2017a). Standards of medical care in diabetes - 2017. *Diabetes Care, 40*, S1-S135.

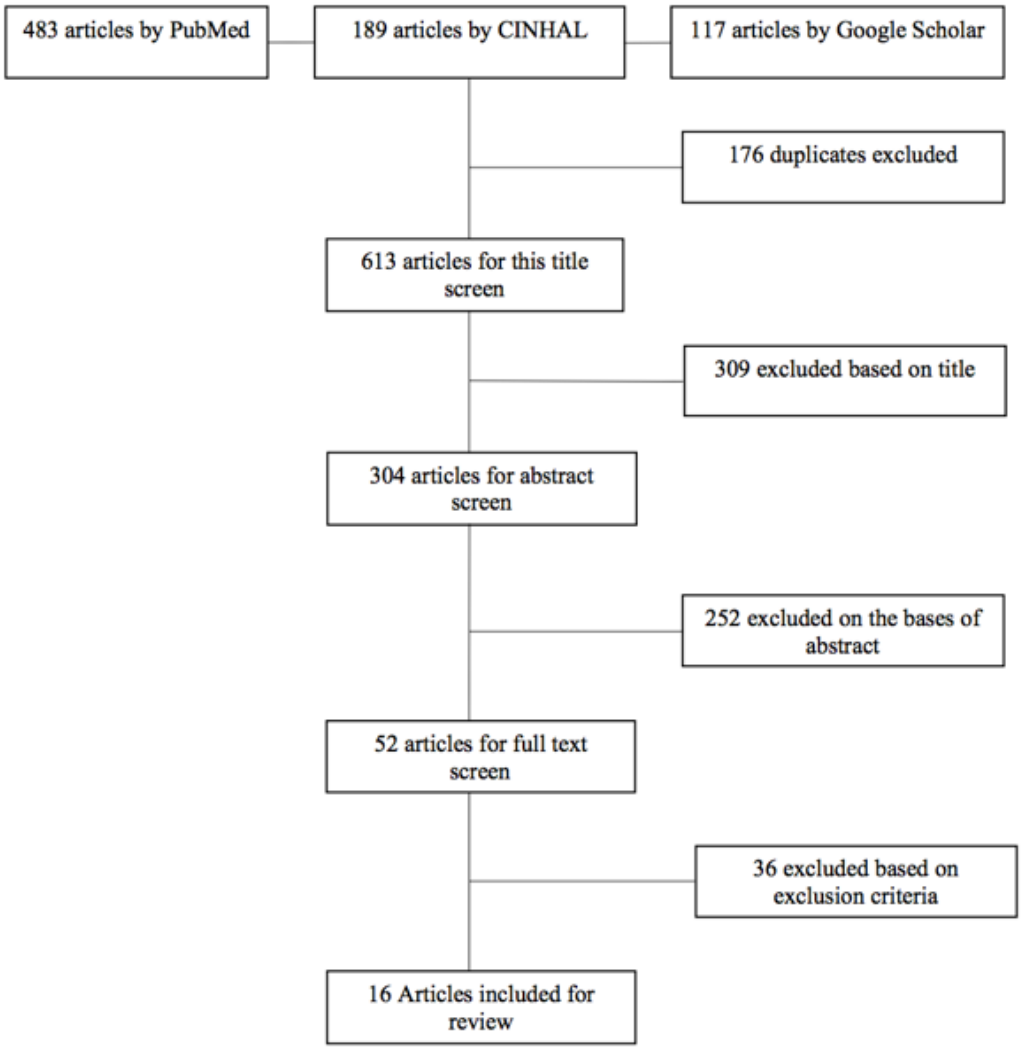
Table 2.4—Categories of increased risk for diabetes (prediabetes)*

FPG 100 mg/dL (5.6 mmol/L) to 125 mg/dL (6.9 mmol/L) (IFG)
OR
2-h PG in the 75-g OGTT 140 mg/dL (7.8 mmol/L) to 199 mg/dL (11.0 mmol/L) (IGT)
OR
A1C 5.7−6.4% (39−47 mmol/mol)

*For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at the higher end of the range.

Appendix B

PRISMA diagram of article selection



Adapted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *Preferred Reporting Items for Systematic Reviews and Meta-Analyses:* The PRISMA Statement. J Clin Epidemiol 2009; doi:10.1016/j.jclinepi.2009.06.005

Appendix C

Table of Evidence

Article #	Author & Date	Evidence Type	Sample Sample Size Setting	Study finding that help answer EBP question	Limitations	Evidence Level & Quality
1	Dhippayom, T., Chaiyakunapruk, N., & Krass, I 2014	Systematic Review	• 24 articles 3 Denmark, 2 Germany, 1 Ireland, 1 Netherlands, 1 Sweden, 1 UK, 6 USA, 2 India, 1 Thailand, 1 Africa, and 1 Australia. General practices (6), health centers (4), community pharmacies (3) internet (3), emergency departments (3), public housing developments and 1 research center	• diabetes risk assessment tools and outcomes • The administration of risk assessment tools by health care professional/researchers appeared to yield higher rates of uptake than self-administration. • highest rate of uptake was observed when the risk assessment took place in a health care setting. • barriers inhibiting healthcare practitioners to use tool are perception towards the tools, interference with physician-patient interaction, lack of knowledge/training, and lack of time. • essential to establish a practical referral system for high risk individuals identified by assessment to receive appropriate health care.	• The direct comparison of the uptake rate and outcomes among the included studies could not be performed due to the variety of study designs and the tools used. • may not have captured all the grey literature • not possible to determine the application and accessibility of diabetes risk assessment tools available to the public via internet or smart phone apps.	Level II, Quality A

2	The Diabetes Prevention Program (DPP) Research Group 2002	Randomized Control Trial	3234 study participants, White, African American, Hispanic, American Indian, Asian 27 centers	• three arm study: lifestyle group, metformin group, and placebo group • assigned to the lifestyle intervention had much greater weight loss and a greater increase in leisure physical activity than did participants assigned to receive metformin or placebo. • 58% lower incidence of diabetes in the lifestyle group • 31% lower in the metformin group than in the placebo group • The incidence of diabetes was 39% lower in the lifestyle-intervention group than in the metformin group. • The estimated cumulative incidence of diabetes at three years was 28.9% (placebo), 21.7% (metformin), and 14.4 % in lifestyle-intervention • effects were similar in men and women and in all racial and ethnic groups.	• not designed to test the relative contributions of dietary changes, increased physical activity, and weight loss to the reduction in the risk of diabetes	Level I, Quality A

				• intensive lifestyle intervention was at least as effective in older participants • applicability to the ethnically and culturally diverse population		
3	Perreault, L., Pan, Q., Mather, K.J., Watson, K.E., Hamman, R.F., & Kahn, S.E. 2012	Non-Experimental	2761 participants who were at high risk for developing diabetes	• Diabetes risk 56% lower for participants who had returned to normal glucose regulation versus consistently in prediabetes • Those who attained normal glucose regulation during DPP attended more classes • Beta cell function and insulin sensitivity were higher with normal glucose vs prediabetes • achievement of normal glucose regulation during DPP reduced risk of diabetes at DPPOS. 1x by 47%, 2x by 61%, 3x by 67% • patients who remain with prediabetes despite intensive lifestyle intervention are a high-risk state and needs	• Cannot exclude that attendance during the bridge affected normal glucose regulation status or diabetes development during DPP • metformin group could have benefited from continued treatment in DPPOS • lifestyle intervention adherence diminished, weight regain and reduced attendance • Could have increase potency of combination therapy in a multicultural cohort • misclassification of people as having normal glucose regulation versus prediabetes	Level III, Quality A

				further prevention strategies. • Preservation of beta cell function more closely related to long-term prevention than insulin sensitivity		
4	Van Name, M.A., Camp, A.W., Magenheimer, E.A., Li, F., Dziura, J.D., Montossa, A., Patel, A., & Tamborlane, W.V 2016	Randomized Controlled Trial	122 (at the end), women between 18 and 65 years of age with at least one risk factor for diabetes Fair Haven, CT Fair Haven Community Health Center	• weight, percent weight, body fat, and waist circumference, which were all strikingly improved in the ILI group but worsened or varied little from baseline in the usual care group. • fasting glucose remained stable in both groups • ILI, lower fasting insulin levels and lower mean glucose excursions • ILI: -3.58% in body weight at 14 wks, -4.4% at 12 month. Usual care +1.6% • demonstrates the feasibility and effectiveness of an ILI program in a CHC setting caring for predominantly low-	• did not carry out more comprehensive metabolic assessments, due to high cost • Despite the randomization, there were significant differences in baseline fasting plasma lipid and insulin concentrations • Since 90% of the study participants were Hispanic women • the findings of the study may not be generalizable	Level I, Quality A

				income Hispanic patients • highlight the benefits of implementing DPP-style interventions to high-risk minority populations in community settings.		
5	Ghody, P., Shikha, D., Karam, J., & Bahtiyar, G. 2015	Non-Research Literature Review	n/a	• mild hyperglycemia exhibit microvascular complications like retinopathy, nephropathy and neuropathy that are traditionally associated with DM. • cost effectiveness analysis from DPP and DPPOS demonstrate lifestyle interventions to be highly cost effective. • few trials have demonstrated cost effectiveness of DM screening in the general population. • Lifestyle and almost all pharmacological interventions appear to slow to progression • lifestyle interventions appears to be the most effective approach,	n/a	Level V, Quality A

				social policy changes should be implemented to endorse them as the most important strategy for management of prediabetes.		
6	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	Randomized Controlled Trial	92 Latinas >/= 20 yrs of age mean age: 45 Spanish-speaking Mostly foreign born	• participants with prediabetes who received a promotora-led ILI lost significantly more weight than either metformin or standard care participants • no significant difference in weight loss between the metformin and standard care arms • ILI -5%, met -1.1%, standard care +0.9% • small magnitude and not statistically significant, reduction in HbA1c among ILI participants, compared with slight increases in the metformin and standard care groups • ILI 23.3% normoglycemia, met 11.1%, standard care 7.1% • first DPP translational study to test the	• the study was underpowered to detect a modest but clinically meaningful weight difference between the metformin and standard care arms • potentially limiting the external validity of the findings among all Latinas with prediabetes • Generalizability is also limited in men and other racial/ethnic groups • the inability to blind participants or promotoras to treatment assignment was inherent to the study design, and could have introduced bias	Level I, Quality A

				comparative effectiveness of ILI and metformin in a community-based setting • study suggests that ILI delivered by promotoras is superior to metformin and standard care at inducing clinically and statistically significant weight loss. • Data allows for conversation on prediabetes management between patients and healthcare providers		
7	Ockene, I., Tellez, T.L., Rosal, M.C., Reed, G.W., Mordes, J., Merriam, P.A., Olendzki, B.C., Handelman, G., Nicolosi, R., & Ma, Y. 2012	Randomized Controlled Trial	312 self-reported Latino participants prediabetes 25 yrs + mean age: 52 74% women BMI: greater than 25; 30% greater	• focus groups identify knowledge gaps, attitudes toward diabetes prevention, and challenges to lifestyle change for weight loss • LLDPP used a simple screening methodology and a less intensive intervention tailored to the needs of our low-literacy, low-socioeconomic status Latino participants	• did not achieve any meaningful improvement on physical activity • may have been related to the characteristics of a less educated, low-socioeconomic status population living in neighborhoods not conducive to physical activity • Second, the intervention did not produce	Level I, Quality A

			likelihood of being diagnosed with diabetes over the next 7.5 years Lawrence Senior Center Lawrence, Massachusetts	• significant degree of weight loss associated with significant improvement in insulin resistance and HbA1c. • Implementation of this intervention at similar community settings and populations has the potential to bring about important public health benefits.	significant changes in fasting blood glucose • Third, the relatively short-term follow-up (1 year) precluded clinical endpoint assessment of diabetes incidence as a primary outcome • could not evaluate long-term maintenance • the lack of validated measures appropriate for this low-literate Spanish-speaking population • unable to measure knowledge, attitudes, and expectations • Fifth, attendance at the group sessions was low • sample size of 312 was not sufficient to look for age effects.	
8	Weinhold, K.R., Miller, C.K., Marrero, D.G., Nagaraja, H.N., Focht, B,C., & Gascon, G.M. 2015	Randomized Controlled Trial	69 participants with prediabetes Major university in the Midwest US	• intervention group achieved greater reductions in waist circumference, fasting glucose, and systolic and diastolic blood pressure than did the control group	• Follow-up was limited to 3-months post-intervention; thus, long-term outcomes are unknown • 80% of the participants were women, whereas 62% of the benefits-eligible university employees were women	Level I, Quality A

			Employee 18-65 yrs of age BMI 25+ ADA 7 item risk test score: 5+	• Total cholesterol declined significantly in the intervention group • Mean post-intervention weight loss was 5.5%, considered clinically significant and is frequently associated with reduced morbidity and mortality • IG: 32.4% met goal of achieving 7% or more weight loss. CG: 2.9% • Fasting glucose values returned to near-normal levels in the intervention group post-intervention, and the improvement was maintained at 3-month follow-up.	• Disparity in enrollment by sex is common in weight-loss studies, and recruitment of men deserves further evaluation	
9	McCurley, J.L., Fortmann, A.L., Gutierrez, A.P., Gonzalez, P., Euyoque, J., Clark, T., Preciado, J., Ahmad, A., Philis-Tsimikas, A., & Gallo, L.C 2017	Quasi Experimental	61 Latina women BMI >/= 25 San Diego County	• At 6 month follow up, -7lb or 4.1% mean reduction in body weight • Strong feasibility and acceptability, low attrition • Statistically significant improvements in dietary behaviors, perceived stress, and depression symptoms	• Did not result in significant changes in glucose regulation, waist circumference and blood pressure over 6 months • Small sample size and stat. power limitations • No control group • Low attendance rates • Self report • Brief follow up	Level II, Quality A

				• Pilot consolidated core elements of the DPP into 12 sessions for a 25% time reduction		
10	Vincent, D., McEwen, M.M., Hepworth, J.T., & Stump, C.S. 2014	Randomized Controlled Trial	58 participants 77.6% female mean age: 50.9 married: 60.3% Tucson, Arizona Community rooms of churches in the Tucson Metropolitan Area	• Intervention participants mean weight loss of 6.2 lbs, approximately 3% of mean baseline body weight at 5 month • Waist circumference decreased by mean 1.56 inches at 5 month • Weight loss has statistically and clinical significance, risk for diabetes decreases with modest weight loss of 5% to 7% total body weight.	• Small sample • Low participation rate among men • High attrition rate in the attention control group	Level I, Quality A
11	Scheiderman, N., Llabre, M., Cowie, C.C, Barnhart, J., Carnethon, M., Gallo, L., Giachello, A.L., Heiss, G., Kaplan, R.C., LaVange, L.M., Teng, Y., Villa-Caballero, L., &	Quasi Experimental	16,415 women and men ages: 18-74 59% 45-74 41% 18-44 Bronx, NY Chicago, IL Miami-Dade County, FL	• Diabetes prevalence increased with age from 2.6% (18-29) to 48.4% (70-74). • Increased by 22.3% with BMI >30 • Negative association of diabetes prevalence with education • Negative association of diabetes prevalence with household income	• Participants could not be compensated • Did not differentiate type 1 from type 2 diabetes • Does not provide a representative sample of all Hispanic/Latino heritage groups in terms of their demography	Level II, Quality A

	Aviles-Santa, M.L. 2014		San Diego, CA	• Individuals that were aware of their diabetes showed greater diabetes control than those who were unaware • Those with health insurance more likely to be aware than those that did not		
12	Ma, J., Yank, V., Xia, L., Lavori, P.W., Wilson, S.R., Rosas, L.G., & Stafford, R.S. 2013	Randomized Controlled Trial	241 participants mean age: 52.9 47% women baseline BMI 32 78% non-Hispanic white 17% Pacific Islander 4.1% Hispanic / Latino 54% prediabetes	• Primary care-based translational interval trial • IT supported DPP-based lifestyle intervention led to clinically significant reduction in body weight • Improvement in waist circumference • Improvement in fasting plasma glucose levels • All compared to usual care over 15 months	• Participants were primarily of high socioeconomic status • Single primary care clinic • May not be directly generalizable • Use of EHR for missing data • Not designed to evaluate event-based outcomes or cost effectiveness	Level I, Quality A

			87% metabolic syndrome 41% both conditions Silicon Valley, Los Altos, CA			
13	Vincent, D., McEwen, M.M., Hepworth, J.T., & Stump, C.S. 2013	Randomized Controlled Trial	58 Spanish-speaking adults Arizona	• Despite efforts in gaining patients, poor retention rate (57%) • Most effective of the multiple recruitment methods used was healthy living and diabetes prevention presentations conducted at the churches • Ineffectiveness of flyers • Provider referrals were disappointing • High refusal rates (69%), reflect the importance of personal relationships in the Mexican culture • Study design was revised to provide for control participants to cross over at 5 months	• Small sample size • Low participation rate of men	Level I, Quality A

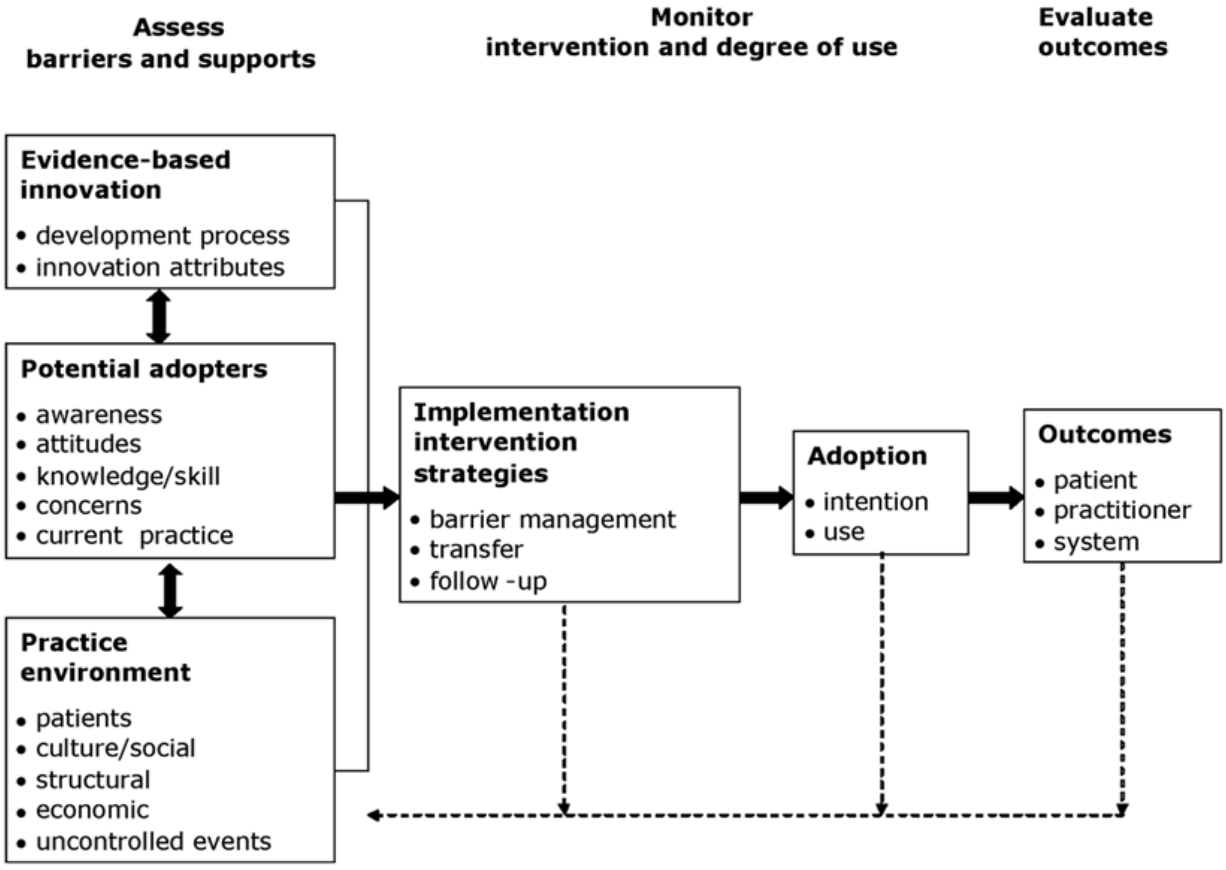
14	O'Brien, M.J., Shuman, S.J., Barrios, D.M., Alos, V.A., & Whitaker, R.C. 2014	Qualitative	26 urban immigrant Latinas Philadelphia, PA	• Acculturation: adoption of less healthy diet and physical activity behaviors was their newfound ability to afford them • Large amount sugar-sweetened beverage consumption; developed cravings • Abandoning traditional methods of food preparation practices • Not enough time due to changed family roles • Working outside the home and earning independent income for the first time • Husbands have taken on more home-based responsibilities • Admitted they needed more education about healthy habits • Tension between participants and their roles • Discussion illustrated acculturation and socioeconomic status are strongly intertwined among Latinas	• Findings reflect the experiences and opinions of a small convenience sample of urban immigrant Latinas who were at high clinical risk for developing diabetes • Results cannot be generalizable • Not videotaped, unable to identify the voices of specific participants.	Level III, Quality A

15	Joiner, K.L., Sternberg, R.M., Kennedy, C.M., Fukuoka, Y., Chen, J., & Janson, S.L. 2016	Qualitative	146 participants foreign-born Spanish-speaking US Latinos San Francisco Bay area of California	• 81% BMI >25, 23% ADA risk score of 5+, 12% with A1C prediabetes range, 2% undiagnosed diabetes • Sixteen percent of participants reported a perception of high risk for developing diabetes • 31.5% had a perception of moderate or high risk • factors that influenced predicted perception: history of gestational diabetes, high school graduate, realistic view of personal risk, greater degree of worry or concern, and having a perception of greater risk of chronic diseases and health condition	• unable to generalize findings • adequate, yet small sample size	Level III, Quality A

16	Ritchie, N.D., Christoe-Frazier, L., McFann, K.K., Havranek, E.P., & Pereira, R.I. 2018	Quasi Experimental	567 Latino (45.2%) 175 non-Hispanic white Healthcare System; Denver Metro Area	• Latinos at risk for diabetes were less likely than non-Hispanic white to attend program sessions and achieve the recommended >5% weight loss • Resolving low attendance among Latinos may be a key to obtain risk reduction results • Implemented: culturally competent lifestyle coaches, sessions in Spanish, sessions at familiar sites to increase access • Need better practices for retaining Latino participants in program to obtain risk reduction	• Poor retention	Level II, Quality A

Appendix D

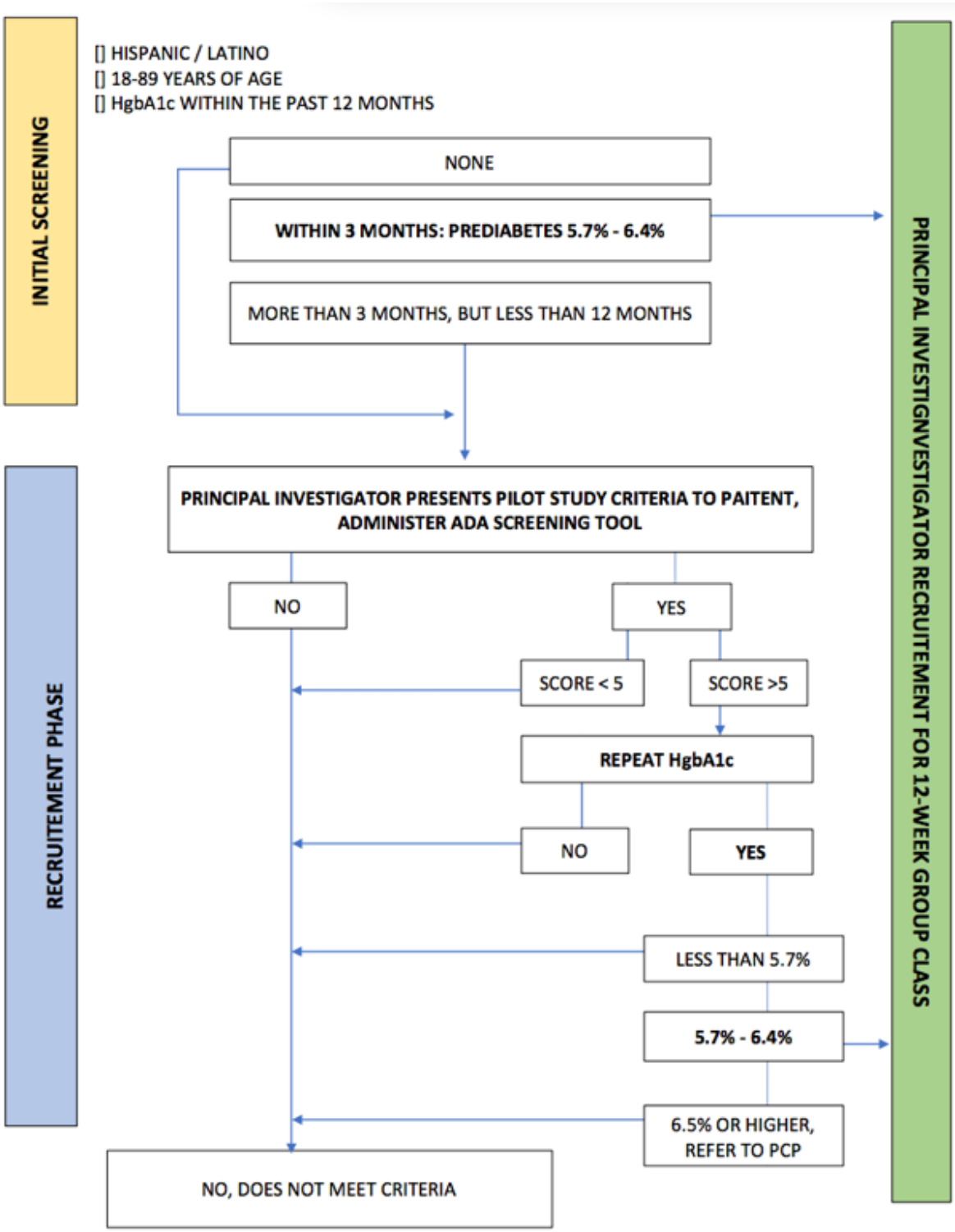
Theoretical Framework



Graham, I.D., & Logan. J. (2004). Innovations in knowledge transfer and continuity of care. Canadian Journal of Nursing Research, 36(2), 89-103.

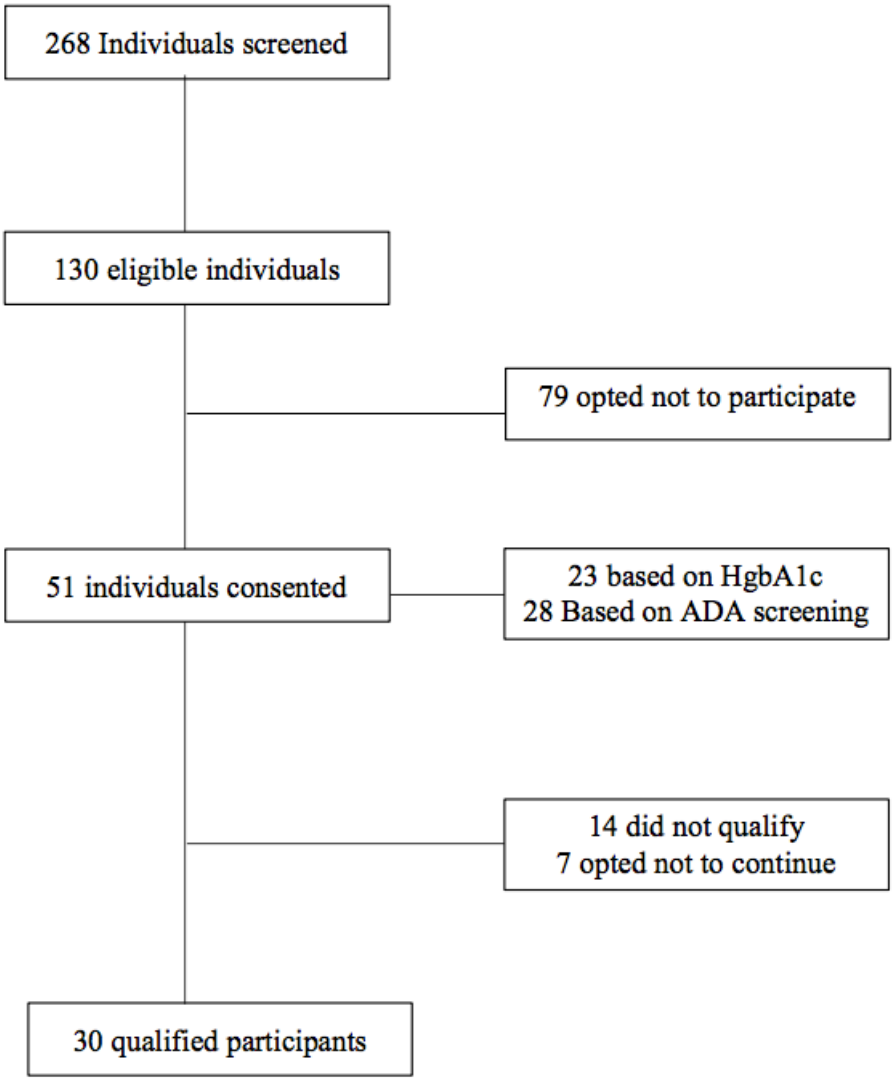
Appendix E

Recruitment Algorithm



Appendix F

PRISMA diagram of participant recruitment



Adapted from: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *Preferred Reporting Items for Systematic Reviews and Meta-Analyses:* The PRISMA Statement. J Clin Epidemiol 2009; doi:10.1016/j.jclinepi.2009.06.005

Appendix G

Recruitment Flier

RUTGERS
School of Nursing

Prediabetes Research Study

The Implementation of a Culturally Tailored Diabetes Prevention Program among the Adult, Hispanic/Latino, Prediabetes Population, a Pilot Study

Purpose of this research:

- ✓ Implementation of a Spanish diabetes prevention education program to reduce factors of prediabetes such as weight and Hemoglobin A1c

You may be eligible if you are:

- ✓ 18-89 years of age
- ✓ Have a diagnosis of prediabetes
- ✓ Spanish speaking
- ✓ Hispanic/Latino

Activities & time frame:

- ✓ One hour group education program
- ✓ Every Saturday for 12 weeks
- ✓ Conducted in Spanish

Location:

[redacted]

For more details and eligibility criteria please contact:

Mary Diaz-Garcia, APN, NP-C (Principal Investigator)

[redacted]

Version 1.1, 10/14/2018

Rutgers, The State University of New Jersey

Appendix H

American Diabetes Association Risk Test: English version

Are you at risk for type 2 diabetes?

ALERT!DAY
TYPE 2 DIABETES AWARENESS

WRITE YOUR SCORE IN THE BOX.

1. How old are you?
Less than 40 years (0 points)
40–49 years (1 point)
50–59 years (2 points)
60 years or older (3 points)

2. Are you a man or a woman?
Man (1 point) Woman (0 points)

3. If you are a woman, have you ever been diagnosed with gestational diabetes?
Yes (1 point) No (0 points)

4. Do you have a mother, father, sister or brother with diabetes?
Yes (1 point) No (0 points)

5. Have you ever been diagnosed with high blood pressure?
Yes (1 point) No (0 points)

6. Are you physically active?
Yes (0 points) No (1 point)

7. What is your weight category?
See chart at right.

Height	Weight (lbs.)		
4′ 10″	119–142	143–190	191+
4′ 11″	124–147	148–197	198+
5′ 0″	128–152	153–203	204+
5′ 1″	132–157	158–210	211+
5′ 2″	136–163	164–217	218+
5′ 3″	141–168	169–224	225+
5′ 4″	145–173	174–231	232+
5′ 5″	150–179	180–239	240+
5′ 6″	155–185	186–246	247+
5′ 7″	159–190	191–254	255+
5′ 8″	164–196	197–261	262+
5′ 9″	169–202	203–269	270+
5′ 10″	174–208	209–277	278+
5′ 11″	179–214	215–285	286+
6′ 0″	184–220	221–293	294+
6′ 1″	189–226	227–301	302+
6′ 2″	194–232	233–310	311+
6′ 3″	200–239	240–318	319+
6′ 4″	205–245	246–327	328+
	1 point	2 points	3 points

If you weigh less than the amount in the left column: **0 points**

Adapted from Bang et al., Ann Intern Med 151:775–783, 2009.
Original algorithm was validated without gestational diabetes as part of the model.

ADD UP YOUR SCORE.

If you scored 5 or higher:

You are at increased risk for having type 2 diabetes. However, only your doctor can tell for sure if you do have type 2 diabetes or prediabetes, a condition in which blood glucose levels are higher than normal but not yet high enough to be diagnosed as diabetes. Talk to your doctor to see if additional testing is needed.

Type 2 diabetes is more common in African Americans, Hispanics/Latinos, Native Americans, Asian Americans, and Native Hawaiians and Pacific Islanders.

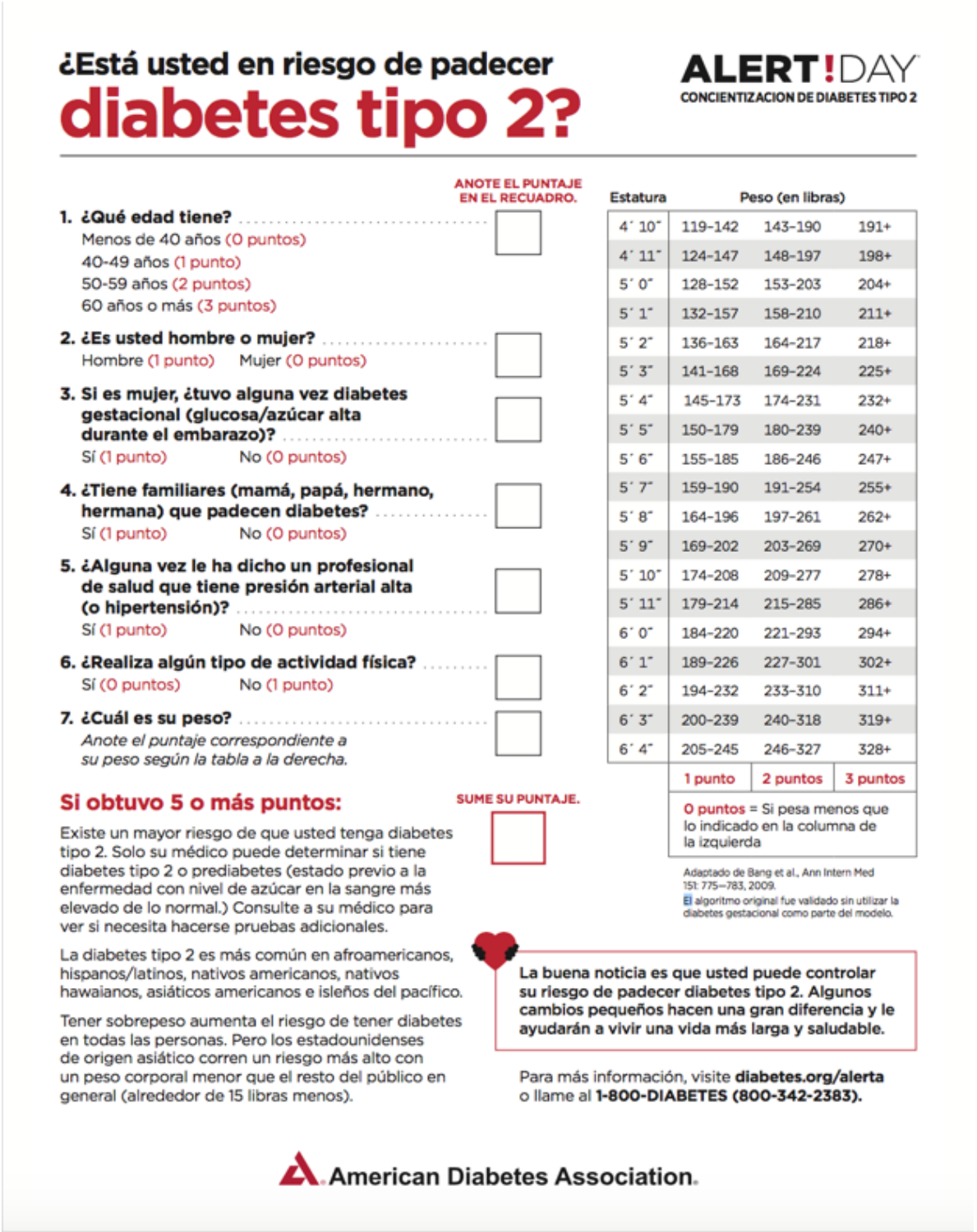
Higher body weight increases diabetes risk for everyone. Asian Americans are at increased diabetes risk at lower body weight than the rest of the general public (about 15 pounds lower).

The good news is you can manage your risk for type 2 diabetes. Small steps make a big difference in helping you live a longer, healthier life.

For more information, visit us at **diabetes.org/alertday** or call **1-800-DIABETES (800-342-2383).**

American Diabetes Association.

American Diabetes Association Risk Test: Spanish version



¿Está usted en riesgo de padecer diabetes tipo 2?

ALERT!DAY
CONCIENTIZACION DE DIABETES TIPO 2

ANOTE EL PUNTAJE EN EL RECUADRO.

1. **¿Qué edad tiene?**
   Menos de 40 años (0 puntos)
   40-49 años (1 punto)
   50-59 años (2 puntos)
   60 años o más (3 puntos)

2. **¿Es usted hombre o mujer?**
   Hombre (1 punto) Mujer (0 puntos)

3. **Si es mujer, ¿tuvo alguna vez diabetes gestacional (glucosa/azúcar alta durante el embarazo)?**
   Sí (1 punto) No (0 puntos)

4. **¿Tiene familiares (mamá, papá, hermano, hermana) que padecen diabetes?**
   Sí (1 punto) No (0 puntos)

5. **¿Alguna vez le ha dicho un profesional de salud que tiene presión arterial alta (o hipertensión)?**
   Sí (1 punto) No (0 puntos)

6. **¿Realiza algún tipo de actividad física?**
   Sí (0 puntos) No (1 punto)

7. **¿Cuál es su peso?**
   Anote el puntaje correspondiente a su peso según la tabla a la derecha.

Estatura	Peso (en libras)		
4' 10"	119–142	143–190	191+
4' 11"	124–147	148–197	198+
5' 0"	128–152	153–203	204+
5' 1"	132–157	158–210	211+
5' 2"	136–163	164–217	218+
5' 3"	141–168	169–224	225+
5' 4"	145–173	174–231	232+
5' 5"	150–179	180–239	240+
5' 6"	155–185	186–246	247+
5' 7"	159–190	191–254	255+
5' 8"	164–196	197–261	262+
5' 9"	169–202	203–269	270+
5' 10"	174–208	209–277	278+
5' 11"	179–214	215–285	286+
6' 0"	184–220	221–293	294+
6' 1"	189–226	227–301	302+
6' 2"	194–232	233–310	311+
6' 3"	200–239	240–318	319+
6' 4"	205–245	246–327	328+
	1 punto	2 puntos	3 puntos

0 puntos = Si pesa menos que lo indicado en la columna de la izquierda

Adaptado de Bang et al., Ann Intern Med 151: 775–783, 2009.
El algoritmo original fue validado sin utilizar la diabetes gestacional como parte del modelo.

Si obtuvo 5 o más puntos:

SUME SU PUNTAJE.

Existe un mayor riesgo de que usted tenga diabetes tipo 2. Solo su médico puede determinar si tiene diabetes tipo 2 o prediabetes (estado previo a la enfermedad con nivel de azúcar en la sangre más elevado de lo normal.) Consulte a su médico para ver si necesita hacerse pruebas adicionales.

La diabetes tipo 2 es más común en afroamericanos, hispanos/latinos, nativos americanos, nativos hawaianos, asiáticos americanos e isleños del pacífico.

Tener sobrepeso aumenta el riesgo de tener diabetes en todas las personas. Pero los estadounidenses de origen asiático corren un riesgo más alto con un peso corporal menor que el resto del público en general (alrededor de 15 libras menos).

La buena noticia es que usted puede controlar su riesgo de padecer diabetes tipo 2. Algunos cambios pequeños hacen una gran diferencia y le ayudarán a vivir una vida más larga y saludable.

Para más información, visite **diabetes.org/alerta** o llame al **1-800-DIABETES (800-342-2383).**

American Diabetes Association.

Appendix I

Handout Summary of Pilot Diabetes Prevention Program with Contact Information

RUTGERS
School of Nursing

Handout Summary of Pilot Diabetes Prevention Program with Contact Information

Principal Investigator: Mary Diaz-Garcia, APN, NP-C, CDE
Telephor[redacted]
Email: m[redacted]

- **Research Site(s)**[redacted]
- **Study Purpose:** The purpose of this pilot study is to determine if the implementation of a weekly, culturally tailored diabetes prevention program for the Hispanic / Latino community, conducted by bilingual multidisciplinary staff, will decrease risk factors, such as hemoglobin A1c (HgbA1c) and/or Body Mass Index (BMI), in four months.
- **Study Activities:** The pilot program will be adapted from the first 16 weeks of the DPP PreventT2 Curriculum and modified to a shorter time frame of 12 weeks. Prior to the start of the pilot program, participant height, weight, and BMI will be obtained. Attendance will be obtained prior to the start of each session. Each session will allow forty-five minutes for education of the predetermined topic and review of data tools from the previous week. Each session will be specific to one topic with time allotted for questions and answers of previous weeks' topic. Overall, the weekly topics will focus on healthy eating, exercise, or resources for behavior modification.

Week	*Topic*	*Estimated time*
1	Introduction to the program	1 hour
2	Principles of healthy eating	1 hour
3	Increasing activity level	1 hour
4	Getting active	1 hour
5	Balancing calories	1 hour
6	How buy and cook healthy foods	1 hour
7	How to reduce and deal with stress	1 hour
8	Finding time to be active	1 hour
9	Support for healthy lifestyles	1 hour
10	Stay on track: heart healthy eating at restaurants	1 hour
11	Stay on track: activity and healthy eating	1 hour
12	A day of reflection	1 hour

- **Anticipated Start Date:** On or about 10/1/2018
- **Anticipated End Date:** On or about 02/31/2019

Version 1.1, 10/14/2018

Appendix J

Participant Consent

The implementation of a culturally tailored Diabetes Prevention Program Among the Adult, Hispanic / Latino, prediabetes population, a pilot study
Mary Diaz-Garcia, APN, NP-C, CDE

RUTGERS

Rutgers School of Nursing
Stanley S. Bergen Building
Rutgers, The State University of New Jersey
65 Bergen Street
Newark, NJ 07101-1709

I. SUBJECT CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: The Implementation of a Culturally Tailored Diabetes Prevention Program Among the Adult, Hispanic / Latino, Prediabetes Population, a Pilot Study
Principal Investigator: Mary Diaz-Garcia, APN, NP-C, CDE

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the Study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?

Mary Diaz-Garcia, APN, NP-C, CDE, is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals who are part of the research team.

Mary Diaz-Garcia, APN, NP-C, CDE, may be reached at [redacted]
The study Principal Investigator, Mary Diaz-Garcia, ARPN, NP-C, CDE will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

SPONSOR OF THE STUDY: Not Applicable

Why is this study being done?

The purpose of this study is to find out if a diabetes prevention program, customized for the Hispanic / Latino community, will lower their risks for type 2 diabetes.

Why have you been asked to take part in this study?

The implementation of a culturally tailored Diabetes Prevention Program Among the Adult, Hispanic / Latino, prediabetes population, a pilot study
Mary Diaz-Garcia, APN, NP-C, CDE

You have been invited to take part in this study because you are a Spanish-speaking adult of Hispanic / Latino ethnicity, with elevated glucose levels, and are at high risk for developing type 2 diabetes.

Who may take part in this study? And who may not?

Hispanic/Latino, Spanish-speaking men or women over the age of 18 years old, but not older than 89, with a diagnosis of prediabetes, and has been seen by a provider of the practice within the last twelve months are included to take part in this study. Any man or woman with a diagnosis of type 1 or type 2 diabetes, diagnosis of gestational diabetes, does not have prediabetes, pregnant or planning pregnancy within the next 90 days, planning on moving, or cognitive impairments are not invited to take part in this study.

How long will the study take and how many subjects will participate?

Thirty (30) participants will be recruited to participate in this study. Everyone will participate for 12 (twelve) weeks.

What will you be asked to do if you take part in this research study?

If you decide to take part in this study, you will be asked to attend a one-hour, weekly class about lifestyle changes for the prevention of type 2 diabetes. At the first and last session, your weight will be taken by the Principal Investigator. Every week a new topic will be discussed. Routine exercise and stretches will be taught. You will be asked to record your food intake and exercise.

Week	***Topic***	***Estimated time***
1	Introduction to the program	1 hour
2	Principles of healthy eating	1 hour
3	Increasing activity level	1 hour
4	Getting active	1 hour
5	Balancing calories	1 hour
6	How buy and cook healthy foods	1 hour
7	How to reduce and deal with stress	1 hour
8	Finding time to be active	1 hour
9	Support for healthy lifestyles	1 hour
10	Stay on track: heart healthy eating at restaurants	1 hour
11	Stay on track: activity and healthy eating	1 hour
12	A day of reflection	1 hour

What are the risks and/or discomforts you might experience if you take part in this study?

Participation in this study possesses minimal risk.

You may experience mild discomfort and/or muscular aches from exercise and/or stretching exercises taught during the program.

If you become pregnant during the course of this study, you should notify the study Principal Investigator of this fact as soon as possible, since the risks to your unborn child are unknown.

You should also tell the study Principal Investigator about all medicines that other doctors may have prescribed for you to take.

There is a small possibility that personal health information collected may be inadvertently be shared by participating in this project. Your name and the personal health information necessary for this project will be collected and assigned a number. This will allow for the data to be reviewed without direct link to your name. Only the research staff will have access to the list linking your name to the number associated with your data.

Are there any benefits for you if you choose to take part in this research study?

The benefits of taking part in this study may be: Reduction of weight, reduction of overall glucose levels, increase in physical activity, and /or improved food choices.

However, it is possible that you might receive no direct personal benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?

There are no alternative treatments available, other than usual care provided by your primary care provider. Your alternative is not to take part in this study.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted by the Principal Investigator via a telephone call.

Will there be any cost to you to take part in this study?

There will be no cost to participate in this study. The only cost you will have is the cost to and from the study site.

Will you be paid to take part in this study?

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

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Each participant will be given a number that will identify them during the study. All information collected is de-identified. Data will be stored on an encrypted USB drive. Upon completion of data analysis of the pilot project and final writing of the manuscript, all data and identifiers will be destroyed in accordance with Rutgers University guidelines.

The records will be retained for seven (7) years after completion of the research.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with Diligent Medical Care will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to the Principal Investigator Mary Diaz-Garcia, APN, NP-C, CDE, [redacted]

Any data that has already been sent to the Data Coordinating Center cannot be withdrawn because there may not be any identifiers with the data.

At any time, the study Principal Investigator can take you out of this study because it would not be in your best interest to stay in it. Your study Principal Investigator can stop treatment even if you are willing to stay in the study.

Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study Principal Investigator:

Mary Diaz-Garcia, APN, NP-C, CDE
[redacted]

If you have any questions about your rights as a research subject, you can call:

Rutgers Health Sciences IRB-Newark, Director
(973)-972-3608 Newark
And
Human Subject Protection Program

The implementation of a culturally tailored Diabetes Prevention Program Among the Adult, Hispanic / Latino, prediabetes population, a pilot study
Mary Diaz-Garcia, APN, NP-C, CDE

973-972-1149 - Newark

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?

- Medical history or treatment
- Medications
- Weight
- Laboratory/diagnostic tests or imaging

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

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Mary Diaz-Garcia, APN, NP-C, CDE

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell her of your decision:
Mary Diaz-Garcia, APN, NP-C, CDE [redacted]

How long will my permission last?

Your permission for the use and sharing of your health information will last until the end of the research study.

_____

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AGREEMENT TO PARTICIPATE

1. Subject consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

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II. SURROGATE CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Not Applicable

Under certain circumstances, an individual can give consent for another person to take part as a Subject in this Research Study (hereinafter "Study") because the Subject is unable to consent to this Study and the Subject has not expressed opposition either to this Study or to the determination of incapacity. This individual is called the Legally Authorized Representative, or Surrogate, and is providing Surrogate consent.

You are being asked to serve as the Surrogate for _____, who is called the Subject in this document. You are being asked to give permission for the Subject to participate in this Study. Your decision should be based on the Subject's individual health care instructions and other wishes, if known, or on your best estimation of what you believe are the Subject's personal values and what the Subject would choose for himself/herself.

Would the person for whom you are signing consent want to take part in this Study?

This form tells you about this Study. After reading this entire form and having this Study explained to you by someone conducting this Study, you can decide if you think the person for whom you are authorizing consent would want to take part in this Study. It is important to note that the person for whom you are signing consent does not have to take part in this Study in order to receive medical care outside this Study.

What will happen if you, as the Surrogate, do not enroll the Subject in this Study, or if the Subject, or you as the Surrogate, later does not want the Subject to participate in this Study?

The Surrogate can decide not to enroll the Subject. The Subject or the Surrogate can decide to discontinue at any time the Subject's participation in this Study. Any decision by the Surrogate not to enroll the Subject or by the Subject or the Surrogate to discontinue the Subject's participation shall not affect the Subject including the Subject's receipt of medical care outside the Study. The Subject may withdraw without penalty and without loss of any benefits to which s/he are entitled.

Regardless of the Surrogate's consent, the Investigator can take the Subject out of this Study at any time because it would not be in the Subject's best interest to stay in it.

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SIGNATURE PAGE WHEN SUBJECT REQUIRES A SURROGATE (OR LAR)

AGREEMENT TO PARTICIPATE

1. Surrogate Consent:
The purpose and procedures for this Study have been described to me verbally and in writing. My questions about this Study have been answered and I have been provided with information about who to contact with additional questions.

As Surrogate, I freely give my consent to have _____take part in this Study and authorize that his/her health information as described above, be collected/disclosed in this Study. I understand that by signing this form I am agreeing for the individual named above to take part in research. I understand that I will receive a copy of this form to take with me.

_____ _____ _____
Signature of Surrogate Printed name of Surrogate Date

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____

3. Signature of Consent Process Witness:

I have observed the consent process which included a description of the purposes and procedures of this Study and an opportunity for questions and answers about this Study. I attest that I am not the subject, his/her guardian or authorized representative, or a researcher on this study and can attest that the requirements for informed consent to the medical research have been satisfied.

_____ _____
Signature of Witness Printed Name of Witness Date

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III. CONSENT TO TAKE PART IN A RESEARCH STUDY FOR INDIVIDUALS ENROLLED UNDER PRIOR SURROGATE CONSENT
TITLE OF RESEARCH STUDY: Not Applicable

Under certain circumstances, someone can give consent for another person to take part in a research study. This person is providing "surrogate consent." The surrogate can make choices for the subject, if the subject is not able to make choices for him or herself. In fact, since *(add date),* you have been enrolled in this research study by your surrogate, *(add name)*.

Now that you can make your own decision about whether or not to participate in this research study, please carefully review this entire form, **including both Section I and Section II**, which tells you about the research study. After reading through this form and having the research explained to you by someone conducting this research, you can decide if you wish to remain in the study or to withdraw.

AGREEMENT TO PARTICIPATE

1. Subject Consent:

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

_____ **I agree** **OR** _____ **I do not agree** to continue to participate.
(Initial) (Initial)

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____

Appendix K

Education Modules and Logs

Appendix L

Weekly Participant Tracking Grid

Session	1	2	3	4	5	6	7	8	9	10	11	12
ID#	*1/12/19*	*1/19/19*	*1/26/19*	*2/2/19*	*2/9/19*	*2/16/19*	*2/23/19*	*3/2/19*	*3/9/19*	*3/16/19*	*3/23/19*	*3/30/19*
26311												
28091	x		x	x	x		x	x		x	x	x
12916	x											
23843												
35985												
29765												
34312												
13600												
15724		x	x		x		x	x	x	x	x	x
12222	x		x	x	x							
27713	x	x	x	x	x		x	x	x	x	x	x
35921												
14794	x											
10631												
13288												
34010	x	x	x	x				x		x	x	x
36485												
11438												
23422		x	x				x	x		x	x	x
13572												
29882												
29803												
30253												
12104												
10944												
34541		x	x									
10647	x	x	x	x	x		x	x	x	x	x	x
11105	x	x										
14996	x	x										
33766	x	x	x		x		x	x	x	x	x	x

Appendix M

Individual Participant Data Tracking Grid

ID# **28091**

	Pre	1	2	3	4	5	6	7	8	9	10	11	12	post
Date	10/15/18	1/12/19	1/19/19	1/26/19	2/2/19	2/9/19	2/16/19	2/23/19	3/2/19	3/9/19	3/16/19	3/23/19	3/30/19	
Attendance				X	X	X		X	X		X	X	X	
Height	62												62	
Weight	229												225	
BMI	41.88												41.15	
HgbA1c	6.2%													

Statistical data
Expected number of classes = 11
Actual number of classes attended = 8
Percentage of class attendance = **72.73%**

ID# **15724**

	Pre	1	2	3	4	5	6	7	8	9	10	11	12	post
Date	12/19/18	1/12/19	1/19/19	1/26/19	2/2/19	2/9/19	2/16/19	2/23/19	3/2/19	3/9/19	3/16/19	3/23/19	3/30/19	
Attendance			X	X		X		X	X	X	X	X	X	
Height	61												61	
Weight	165												161	
BMI	31.17												30.4	
HgbA1c	5.7%													5.8%

Statistical data

Expected number of classes = 11
Actual number of classes attended = 9
Percentage of class attendance = **81.82%**

ID# **27713**

	Pre	1	2	3	4	5	6	7	8	9	10	11	12	post
Date	12/17/18	1/12/19	1/19/19	1/26/19	2/2/19	2/9/19	2/16/19	2/23/19	3/2/19	3/9/19	3/16/19	3/23/19	3/30/19	
Attendance		X	X	X	X	x		X	X	X	X	X	X	
Height	64												64	
Weight	161												158	
BMI	27.63												27.12	
HgbA1c	5.8%													5.8%

Statistical data
Expected number of classes = 11
Actual number of classes attended = 11
Percentage of class attendance = **100%**

ID# **34010**

	Pre	1	2	3	4	5	6	7	8	9	10	11	12	post
Date	12/1/18	1/12/19	1/19/19	1/26/19	2/2/19	2/9/19	2/16/19	2/23/19	3/2/19	3/9/19	3/16/19	3/23/19	3/30/19	
Attendance		X	X	X	X				X		X	X	X	
Height	63												63	
Weight	145												141	
BMI	25.68												24.97	
HgbA1c	5.8%													5.7%

Statistical data
Expected number of classes = 11
Actual number of classes attended = 8
Percentage of class attendance = **72.73%**

ID# **23422**

	Pre	1	2	3	4	5	6	7	8	9	10	11	12	post
Date	10/5/18	1/12/19	1/19/19	1/26/19	2/2/19	2/9/19	2/16/19	2/23/19	3/2/19	3/9/19	3/16/19	3/23/19	3/30/19	
Attendance			X	X				X	X		X	X	X	
Height	56												56	
Weight	128												130	
BMI	30.86												31.34	
HgbA1c	6.1%													5.9%

Statistical data
Expected number of classes = 11
Actual number of classes attended = 7
Percentage of class attendance = **63.64%**

ID# **10647**

	Pre	1	2	3	4	5	6	7	8	9	10	11	12	post
Date	1/5/19	1/12/19	1/19/19	1/26/19	2/2/19	2/9/19	2/16/19	2/23/19	3/2/19	3/9/19	3/16/19	3/23/19	3/30/19	
Attendance		X	X	X	X	X		X	X	X	X	X	X	
Height	65												65	
Weight	175												172	
BMI	29.12												28.62	
HgbA1c	6.3%													5.9%

Statistical data

Expected number of classes = 11
Actual number of classes attended = 11
Percentage of class attendance = **100%**

ID# **33766**

	Pre	1	2	3	4	5	6	7	8	9	10	11	12	post
Date	1/7/19	1/12/19	1/19/19	1/26/19	2/2/19	2/9/19	2/16/19	2/23/19	3/2/19	3/9/19	3/16/19	3/23/19	3/30/19	
Attendance		X	X	X		X		X	X	X	X	X	X	
Height	57												57	
Weight	158												160	
BMI	36.72												37.18	
HgbA1c	6.1%													

Statistical data
Expected number of classes = 11
Actual number of classes attended = 10
Percentage of class attendance = **90.91%**

Appendix N

Name and Participant Key

PARTICIPANT NAME	UNIQUE IDENTIFICATION NUMBER

Appendix O

GANTT Time Line Chart

Project Time Line																							
Activity	**Plan Start**	**Plan Duration**	**Periods**																				
			May 2018	June 2018	July 2018	Aug 2018	Sept 2018	Oct 2018	Nov 2018	Dec 2018	Jan 2019	Feb 2019	March 2019	April 2019	May 2019								
Presentation of proposal to team	Aug 2018	1																					
IRB submission	Sept 2018	2																					
Participant recruitment	Nov 2018	2																					
Project Implementation	Dec 2018	3																					
Data collection	March 2019	1																					
Data analysis	April 2019	1																					
Evaluation / writing	April 2019	1																					
Presentation of final project	April 2019	1																					
Graduation	May 2019	1																					

Appendix P

Budget and Resources

Expenses	*Cost*	*Total Cost*
Recruitment Fliers	20 @ $0.15	$3.00
Educational Materials	12 sheets x 30 copies @ $0.15	$54.00
Statistics resource: Laerd	$9.99	$10.29
Binding of Final Project	5 copies x $50	$250.00
Dissemination Poster	$75.00	$75.00
Light refreshment and snacks	12 sessions x $20.00	$240.00
TOTAL BUDGET		***$632.29***

Appendix Q

Sign test

Frequencies

		N
HgbA1c after intervention – HgbA1c before intervention	Negative Differences[a]	3
	Positive Differences[b]	1
	Ties[c]	1
	Total	5

a. HgbA1c after intervention < HgbA1c before intervention

b. HgbA1c after intervention > HgbA1c before intervention

c. HgbA1c after intervention = HgbA1c before intervention

Test Statistics[a]

	HgbA1c after intervention – HgbA1c before intervention
Exact Sig. (2-tailed)	.625[b]

a. Sign Test

b. Binomial distribution used.

Frequencies

		N
BMI after intervention – BMI before intervention	Negative Differences[a]	5
	Positive Differences[b]	2
	Ties[c]	0
	Total	7

a. BMI after intervention < BMI before intervention

b. BMI after intervention > BMI before intervention

c. BMI after intervention = BMI before intervention

Test Statistics[a]

	BMI after intervention – BMI before intervention
Exact Sig. (2-tailed)	.453[b]

a. Sign Test

b. Binomial distribution used.

Case Processing Summary

	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
HgbA1c before intervention	30	100.0%	0	0.0%	30	100.0%
HgbA1c after intervention	5	16.7%	25	83.3%	30	100.0%
difference_Hgba1c	6	20.0%	24	80.0%	30	100.0%

Report

Median

HgbA1c before intervention	HgbA1c after intervention	difference_Hgba1c
6.0500	5.8000	-.1500

Case Processing Summary

	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
BMI before intervention	30	100.0%	0	0.0%	30	100.0%
BMI after intervention	7	23.3%	23	76.7%	30	100.0%
difference_BMI	7	23.3%	23	76.7%	30	100.0%

Report

Median

BMI before intervention	BMI after intervention	difference_BMI
30.7050	30.4200	-.5100

Appendix R

Baseline Characteristics

Baseline characteristics of study participants (N = 30)

Baseline characteristics	**Value**
Age, mean	63.37
Female	73%
Hemoglobin A1c (HgbA1c), mean	5.98%
Body Mass Index (BMI), mean	30.74
American Diabetes Association Type 2 Diabetes Risk Test, mean	6.41