

A PILOT STUDY TO EVALUATE THE EFFECTIVENESS OF THE
NATIONAL DIABETES PREVENTION PROGRAM IN AN
URBAN MEDICALLY UNDERSERVED COMMUNITY

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By

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ABSTRACT

This study evaluated the effectiveness of participation in the National Diabetes Prevention Program (NDPP) for weight reduction in a sample of prediabetic individuals in an urban medically underserved community. The NDPP was developed from research demonstrating a reduced risk for diabetes in prediabetic individuals who participated in an intensive lifestyle intervention program aimed at reducing weight and improving lifestyle habits. The NDPP was integrated into existing services within a medically underserved urban community health center to provide this evidence-based program targeted to high-risk prediabetic patients. The participants received weekly group sessions aligning with the 2012 NDPP curriculum. Study data was obtained through the 16-session core program of the NDPP. Pre-test, post-test paired group *t*-tests were completed to evaluate the change in mean weight and body mass index (BMI) at the beginning and end of the core program. Correlational analyses were completed to evaluate the association between weight change, age, gender, number of sessions attended, and total minutes of physical activity. Twelve participants initiated the program, and eight completed at least four of the 16 sessions. The mean weight loss for all participants was 5.3 pounds, and 7.4 pounds for those who completed at least four sessions. There was a significant difference in pre-weight, post-weight and BMI ($p < 0.05$) for all participants and those who completed a minimum of four sessions. Weight loss was independent

of age and gender. A significant positive correlation was found between weight loss and both number of sessions attended ($p < 0.05$) and total minutes of physical activity ($p < 0.05$). Participation in the core portion of the NDPP significantly reduced weight and BMI in a group of prediabetic individuals in an urban medically underserved community, with weight loss unrelated to age and gender. A greater level of weight loss was associated with higher levels of program participation through session attendance and physical activity. There was an observable discrepancy between the final program weight and the lowest weight attained, suggesting the importance of considering weight fluctuations in evaluating program effectiveness in communities where medical and psychosocial impacts on weight loss are likely to occur.

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Chapter 1 - Introduction

The American Diabetes Association (ADA) defines diabetes as a “group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both” (ADA, 2004, p. s5). Type II diabetes accounts for the majority of diabetes cases, is a condition of insulin resistance, and is often related to obesity and a sedentary lifestyle. The ADA defines prediabetes as a state of increased risk for diabetes (ADA, 2016a). Prediabetes is diagnosed by a fasting blood glucose level between 100 and 125 mg/dl, a two-hour plasma glucose level of 140 to 199 mg/dl following a glucose load, or a hemoglobin-A1c (HgbA1c) level between 5.7 and 6.4 percent (ADA 2016a; Abraham & Fox, 2013).

Type II diabetes is a worsening problem in the United States (U.S.), with increases in both prevalence and incidence since the 1990’s, particularly in minority racial and ethnic groups [Centers for Disease Control and Prevention (CDC), 2015]. According to the CDC (2015a), approximately 1.4 million adults in the U.S. were diagnosed with diabetes in 2014, compared with only 493,000 in 1980. The CDC reported in 2014 that 29.1 million people in the U.S., or 9.3 percent of the population, have diabetes. Additionally, between 2009 and 2012, approximately 37 percent of adults in the U.S. had prediabetes (CDC, 2014).

There is significant long-term evidence that diabetes is related to increased rates of cardiovascular disease, renal failure, blindness and amputations. Cardiovascular disease and stroke account for approximately two-thirds of deaths in individuals with diabetes, and diabetics are between two and four times more likely to die from heart disease than non-diabetics (Deshpande, Harris-Hayes & Schootman, 2008). Kidney disease additionally contributes significantly to morbidity and mortality in diabetics. Diabetes is the primary causative factor in

kidney disease in the U.S. (de Boer et al., 2011). Tuttle and co-authors (2014, p. 2864) report that diabetic kidney disease “is the leading cause of end-stage renal disease (ESRD), accounting for approximately 50% of cases in the developed world. Although incidence rates for ESRD attributable to [diabetic kidney disease] have recently stabilized, these rates continue to rise in high-risk groups such as middle-aged African Americans, Native Americans, and Hispanics.” African Americans have a higher mortality rate from renal and heart failure secondary to diabetes than other racial and ethnic groups (Conway, May, Fischl, Frisbee, Han & Blot, 2015). Individuals with diabetes have a 90 percent higher risk of early mortality than individuals who are not diabetic (Conway, May & Blot, 2012). Individuals with prediabetes not only have an increased risk for developing diabetes, but also have an increased risk of cardiovascular disease and mortality similar to that of diabetics (Abraham & Fox, 2013). Diabetes and its complications accounted for approximately 245 billion U.S. dollars per year of indirect and direct medical costs in the U.S. alone in 2012 (CDC, 2014). Clearly, there is a nationwide need to address diabetes and its risk factors early in order to reduce the risk of future complications.

Background

Ward 8 is an area of Washington, D.C. (D.C.) that is a predominantly African American community, characterized by poverty, low education levels, and high unemployment rates (D.C. Department of Health, 2013). This section of the city is estimated to have a prevalence rate of diabetes that is 15.2 percent, nearly twice the prevalence rate (8.3 percent) for D.C. as a whole (D.C. Department of Health, 2011).

The National Diabetes Prevention Program (NDPP) was developed to address the increasing prevalence of diabetes and prediabetes in the U.S. Legislation was approved in 2010, as part of the Affordable Care Act, for a nationwide initiative to “build an infrastructure of

[intensive lifestyle intervention] programs across the country” (ADA, 2016b). The Community Preventive Services Task Force (USPSTF) currently recommends the use of diet and physical activity intervention programs to aid in the prevention of type II diabetes (Pronk & Remington, 2015), and currently the ADA (2016a), American Association of Clinical Endocrinologists (2016), U.S. Preventive Services Task Force (USPSTF; Siu, 2015), and other health care organizations recommend programs such as the NDPP for prediabetic patients who are at increased risk of becoming diabetic. The ADA currently recommends early intervention to prevent the development of diabetes through intensive diet and exercise counseling programs specifically designed for prediabetics (ADA, 2016a). Individuals with prediabetes may significantly decrease their risk for developing diabetes and cardiovascular disease through intensive weight loss, reduction of total and fat calorie intake, and an increase in physical activity (Liburd, 2010).

Among low-income populations for whom rates of prediabetes and diabetes are high, accessibility to effective and comprehensive interventions are often limited by low income, limited transportation, and other socioeconomic factors. The U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA) defines medically underserved areas as having few primary care physicians, higher infant mortality, higher rates of poverty, and more individuals over age 65 (HRSA, 1995). By definition, individuals in medically underserved communities have reduced access to health care, including health intervention programs such as the NDPP. This lack of access to these programs further exacerbates problems in these communities. With regards to diabetes and prediabetes, a lack of access to nationally recommended and evidence-based intervention programs reduces the likelihood of reversing the worsening problem of diabetes in these communities. Federally

qualified health centers (FQHC) provide much-needed health and social services to individuals in medically underserved areas, including communities in D.C.'s Ward 8. The integration of evidence-based programs such as the NDPP into existing health services of FQHC's in high-risk communities provides access to much-needed clinical services, but has thus far not been well documented in the literature.

The purpose of this project was to improve clinical practice outcomes by implementing the NDPP in a FQHC within D.C.'s Ward 8 that provides care to a medically underserved population to reduce diabetes in this high-prevalence community. Findings from this study improved the understanding of the efficacy of the NDPP within this community, and increased access to an evidence-based clinical service that enhanced the community's quality of and access to care specific for prediabetics.

Organizational Needs Assessment

Utilizing the framework of Schein's Level of Culture to evaluate whether the organization was ready for change, artifacts, espoused beliefs and values, and basic underlying assumptions of the FQHC and its parent organization were considered (Schein, 2010). Schein (2010, p. 23) defines artifacts as "all the phenomena that you would see, hear, and feel ... such as the architecture of its physical environment ... its published lists of values." In terms of artifacts, the FQHC had a pre-existing large multipurpose room, with adequate physical space to sponsor a group-based intensive lifestyle intervention program such as the NDPP. The organization's list of values was consistent with a focus on providing compassionate and comprehensive care to the medically underserved population. This pilot study was designed to evaluate the effectiveness of the NDPP within this community to provide a trial of the NDPP in order to identify the requirements and challenges in implementing this program into the health center.

Espoused beliefs and values include the “ideals, goals, values, aspirations” of the organization (Schein, 2010, p. 24). The implementation of the NDPP at the FQHC aligned with the vision of the organization by improving both access to and quality of the comprehensive care services provided by the organization within the community, aligning patient care with the most current evidence-based practice recommendations for the treatment of prediabetes. The implementation of the program additionally provided an opportunity for community and government partnerships, which would allow for potential expansion and improvements to the program and care for the community.

According to Schein, basic underlying assumptions are the “unconscious, taken-for-granted beliefs and values” that influence behavior within the organization (Schein, 2010, p. 24). The NDPP enhances the quality of care for the prediabetic patients at this FQHC, in a manner that is focused on an improved understanding of the condition and self-care strategies. All group visits were billed in the same manner as other visits within the FQHC, through Medicaid or insurance, or utilizing the sliding fee scale of the organization, thereby limiting any financial burden on the participants.

The implementation of the NDPP within the FQHC improved both access to and quality of the comprehensive care services provided by the organization within the community, aligned patient care with the most current evidence-based practice recommendations for the treatment of prediabetes, and provided a potential for future community and government partnerships. The CDC additionally provides recognition for organizations that host the NDPP and meet specific standards. These standards ensure that the programs follow the NDPP curriculum as set by the CDC to ensure quality. CDC-recognized programs receive guidance and support from the CDC

and are listed on the CDC searchable website for locations offering the program, thus potentially increasing referrals (CDC, 2016b).

Research Question

This study was designed to evaluate the effectiveness of an intensive diet and exercise education and counseling program, the NDPP, in reducing prediabetic participants' risk for developing type II diabetes through weight loss and improved dietary habits. The community serviced by the FQHC has a high prevalence of type II diabetes, and was found through an informal random chart review to have a similarly high rate of prediabetes. The investigators sought to determine if the NDPP, an evidence-based lifestyle intervention program directly targeted towards prediabetic patients, is effective in a medically underserved community where poverty and other psychosocial issues are prominent. Additionally, the investigator aimed to identify challenges and barriers of integrating the NDPP into existing services at the FQHC.

Evidence-Based Practice Model of Implementation

The Model for Evidence-Based Practice Change (Melnik & Fineout-Overholt, 2015) was utilized for implementation and dissemination of this project. This model incorporates the identification of the problem, review and analysis of the evidence, practice change design and implementation, monitoring, and integration for long-term change (Melnik & Fineout-Overholt, 2015, p. 286-287). The first step of this model to “assess the need for change in practice” (Melnik & Finout-Overholt, 2015, p. 288) included an evaluation of existing practices within the FQHC, and identification of the problem. Patients in the community serviced by the FQHC lacked access to intensive lifestyle intervention programs for prediabetes, placing them at increased risk for developing diabetes. Through the second and third steps of the Model for Evidence-Based Practice Change to “locate the best evidence” and “critically analyze the

evidence” (Melnyk & Fineout-Overholt, 2015, p. 288) the literature and national clinical guidelines support the use of the NDPP or similar lifestyle intervention programs for the treatment of prediabetes. During the fourth step of this model to “design practice change” (Melnyk & Fineout-Overholt, 2015, p. 288-289), the plan for change within the FQHC was developed and proposed. The NDPP program is clearly delineated and is publically available on the CDC website, as are recommendations for implementing the program within an organization. Within the FQHC, staff and material resources were identified, location and scheduling for the program was planned, and participants were identified and enrolled once approval was obtained through the organization and the Institutional Review Board (IRB) at Georgetown University. The fifth step of the process, to “implement and evaluate change in process,” (Melnyk & Fineout-Overholt, 2015, p. 289) included completion of the initial program, and the quantitative and qualitative evaluation of the data. The final step of the model, to “integrate and maintain change in practice” (Melnyk & Fineout-Overholt, 2015, p. 289) involved the dissemination of the results and outcomes, and determination of any recommended changes for long-term sustainability.

Chapter 2 – Review of the Literature

Introduction to the Search Criteria

A review of literature on PubMed was completed in order to identify evidence-based intervention programs for prediabetes. The term “diabetes type 2” was utilized initially with title and abstract terms “prediabetes” and “diabetes prevention,” resulting in 8,206 results. The search was then narrowed using the terms “African Americans,” “socioeconomic factors,” “poverty,” “disparities, health status,” “disparities, health care,” and “minority health,” with a title and abstract term “African American,” which resulted 536 articles. The results were then reduced by text availability, English language, and publication year 1995 to 2015, resulting in 512 articles. All 512 articles were reviewed for appropriateness by title and abstract, incorporating inclusion criteria of adult participants, prediabetes, and study completion in the U.S., thus narrowing the search to a final 96 articles. An additional search was completed using the term “Diabetes Prevention Program Research Group” resulting in 100 articles, which were reduced to 40 via review of the abstracts and titles for similar inclusionary criteria. Out of the final 136 articles, five were manuscripts detailing the initial, bridge and ten year follow up outcome studies of the multicenter Diabetes Prevention Program Research Group. Thirty-two articles were additional publications by the DPPRG detailing secondary data analyses, results and interpretations. Four articles were systematic literature reviews or meta-analyses, and nine were studies that applied principles of the NDPP to specific localities. However, seven of these nine application studies were summaries of methods only, and did not include results as studies had not yet been completed. The remaining manuscripts were excluded due to lack of applicability or poor study design.

Critique and Synthesis of Previous Evidence

The NDPP was developed from substantial evidence demonstrating that an intensive lifestyle intervention program is effective in reducing the risk of developing diabetes in at risk patients. The DPPRG (Knowler et al., 2002) conducted a randomized, experimental clinical trial to determine if an intensive lifestyle intervention (ILI) program, a thiazolidinedione, or metformin prevented or delayed the onset of diabetes when compared to placebo. The study enrolled and randomly assigned 3,234 adults at 27 locations who met the eligibility criteria of 25 years of age or older, a BMI of 24 or higher, and either a fasting blood glucose level of 95 mg/dl to 125 mg/dl or a blood glucose of 140 mg/dl to 199 mg/dl two hours after a 75 gram oral glucose load (a two-hour glucose tolerance test). The participants were recruited specifically to include 50 percent from racial and ethnic minorities. The 27 recruitment sites and their participants were selected to ensure that at least half of the participants were from racial or ethnic minority groups, and that the participants were from a variety of localities with varying socioeconomic backgrounds. The study participants were randomly assigned into one of four groups, although the fourth group (a thiazolidinedione) was discontinued prematurely due to the concern for potential hepatic toxicity with the medication. The three remaining groups included a metformin group, a placebo group and the ILI group. The metformin group participants received a standard lifestyle recommendation plus metformin 850 milligrams twice per day. The placebo group received the standard lifestyle recommendation plus a placebo pill twice a day. The ILI group received 16 sessions of intensive individual education and counseling regarding diet and exercise modifications followed by additional individual and group counseling sessions. The ILI group was given a specific goal to lose at least seven-percent of their initial body weight,

and to engage in at least 150 minutes per week of moderate intensity physical activity. All participants were followed for an average of 2.8 years (Knowler et al., 2002).

Among the ILI group participants in the original study, 50 percent achieved their weight loss goal of at least seven percent reduction by at the end of the 16 initial sessions, and 38 percent had achieved the goal by the last visit. Seventy-four percent of the ILI group attained the physical activity goal of at least 150 minutes per week by the end of the 16 sessions, and 58-percent had achieved this goal by the last visit. The placebo group decreased their daily caloric intake on average 249 calories, the metformin group by 296 calories, and the ILI group by 450 calories, which were significant findings. Average fat intake was reduced by 0.8 percent in the placebo and metformin groups, but 6.6 percent in the ILI group, which was also a significant finding. Overall, the ILI group experienced a statistically significant 58 percent lower incidence of diabetes than the placebo group, and the metformin group experienced a 31 percent lower incidence of diabetes. These effects did not significantly differ with regards to demographic or social variables (Knowler et al., 2002). The results of this study were so significant, particularly for the ILI group, that following the completion of the initial study, all participants were offered the ILI intervention and the study was then continued for 10 additional years. The findings of this continuation, longitudinal study including a cohort of 2,766 demonstrating that participants from the original ILI group continued to maintain their significant weight loss, and their reduction in diabetes incidence remained reduced and stable (DPPRG, 2009). Participants from the original metformin and placebo groups experienced a reduction in their incidence of diabetes following their participation in the ILI. The researchers reported that onset of diabetes was delayed by approximately four years in the original ILI group, and by two years in the metformin group when compared with the placebo group. The ILI intervention had the most significant

impact in the age group of 60 to 85 year olds (DPPRG, 2009). These studies reduced sources of bias by utilizing blind randomization, recruitment from multiple sites and varied populations, detailed selection criteria, and consistency with instruments and measurements. The study results are widely viewed as valid, reliable and applicable to clinical settings.

In addition to the original two publications, thirty-two articles were located that summarized various secondary data studies based on data obtained in the original experimental design. For example, a 2004 study evaluated demographic, psychosocial and behavioral factors that were related to achieving weight loss and physical activity goals in the ILI group, and reported that individuals of older age, men, and those with lower baseline BMI had higher rates of goal attainment (DPPRG, 2004). Herman et al. (2007) reported that baseline HgbA1c levels were higher in minority and ethnic groups compared to Caucasian participants before and after adjustment for other factors. Maruther et al. (2013) evaluated the association between early program weight loss, HgbA1c levels, and glucose levels with future diabetes risk. These authors concluded that higher weight loss at six months into the program was related to a reduction in diabetes risk three years later in the ILI group, but there was no similar significant relationship found in the placebo and metformin groups. In addition, this study substantiated that in all three research groups, reducing fasting glucose under 100 or HgbA1c under 5.7 percent at six months, or post-load glucose under 140 mg/dl at 12 months (thereby demonstrating a change from prediabetes to normal state) was associated with a 62 to 70 percent reduced risk of diabetes. Additionally, Perreault et al. (2012) reported that after the ten-year follow-up, individuals who had reverted to normal glucose regulation during the initial program had a significantly reduced risk of diabetes, and those who had attained normal glucose levels more than once during the study period had an even greater risk reduction. Individuals who had reached normal glucose

regulation during the program attended more sessions than those participants who had not attained normal glucose levels. Review of the 32 articles repeatedly confirmed the relationships between the ILI participants and reductions in diabetes and other risk factors, including weight, blood pressure and lipids, and these results were more significant than in the metformin or placebo groups. This data further substantiates the significant effect of the ILI on reducing diabetic risks and related factors.

Since the CDC received approval for the NDPP initiative in 2010, there have not been many large-scale, clinical applications of the program. This may explain the reason that seven of the nine articles related to application of the NDPP to localities and groups were found to be descriptions of methods and did not contain results of research studies. The nine articles summarized the applicability and importance of utilizing the NDPP with low-income, medically underserved and/or racial and ethnic minority groups and reviewed different approaches depending on the setting. For example, Delgadillo et al. (2010) described the adaptation of the NDPP for a low-income, low-literacy population that required Spanish translation and implementation of the program by a local health department. This group focused the program around an introductory session, program binder developed for a fifth grade literacy level, individual sessions, telephone calls and workshops. Williams et al. (2013) described the implementation of the program into African-American churches, incorporating health professionals within the church with church volunteers and ministry. Kumanyika et al. (2010) described the design and implementation of the NDPP into a primary care environment frequented by Hispanics and African-Americans, where clinical staff could operate the program. These seven reports serve to stress the importance of consideration of the participant population

and community, including cultural factors, literacy levels, and lifestyle factors that may impact participant interest, accessibility and participation.

Two small studies described the implementation of the NDPP within community populations. Ruggiero, Oros and Choi (2011) applied the NDPP using a community-based approach, conducting a nonrandomized prospective study of its effectiveness with 69 Hispanic adults. The authors described that at six months into the program, 20 percent of the participants achieved a seven-percent weight loss goal, and 16 percent achieved the goal at 12 months. Participants completed an average of 62.9 percent of the 16 core program sessions. There were statistically significant changes seen in BMI, waist circumference, body fat, dietary habits and physical activity at six months, although physical activity did not remain significant at 12 months. Boltri, Davis-Smith, Okosun, Seale & Foster (2011) implemented the NDPP in two churches in Georgia, with 37 adult participants. One church received a six week translated program, and the other received the core 16 week NDPP. These authors reported that participants at both churches achieved reductions in fasting blood glucose and BMI in the six-week program. However, results of these two studies have limitations due to the selection bias (single locality, single racial and ethnic profile), and small sample sizes.

Three systematic reviews or meta-analyses related to diabetes and prediabetes were located and reviewed. Thompson, Berry and Nasir (2009) completed a review of 16 primary studies, six of which met their inclusion criteria of diabetes prevention programs for African-Americans via church-based interventions, suggesting that the church is a trusted community environment in many African-American communities that can serve as an opportunity for community engagement and intervention. The majority of the studies located by these authors were considered as invalid with low reliability due to small sample sizes, poor study design, and

wide variation in interventions. Only two studies provided results and neither had a control group, therefore the applicability of the data from this review was limited. Aguiar, Morgan, Collins, Plotnikoff and Callister (2014) completed a systematic review of literature from multiple sources through 2013, evaluating the effectiveness of diet, exercise, and resistance training in the prevention of type II diabetes. Eight studies met eligibility requirements, but only two of these studies had been completed within the U.S. The review demonstrated that interventions targeting diet, exercise and resistance training were effective in inducing weight loss, improving physical fitness and diet, and resulting in at least small changes in glucose. The authors detail that the studies with the most significant weight loss and improvements in glucose regulation had individual and/or group intervention, a mean of eight contacts monthly, and a duration of at least six months, although preferably 12 months in duration. Ali, Echouffo-Tcheugui and Williamson (2012) reviewed articles published between 2003 and 2011 that reported translation of the NDPP to communities, and included 28 studies. Summarizing the findings, the authors suggested that attrition was lowest in programs that offered more core sessions, and that this was related to higher amounts of participant weight loss. There was no statistically significant difference in results from programs led by trained lay people versus health care professionals. Cost of staff time and laboratory testing of glucose were the primary causes of higher costs.

A review of the literature consistently demonstrates, despite varying reliability and validity, that intensive lifestyle intervention programs are effective in reducing weight and improving glucose regulation in patients with prediabetes. The results appear most significant at six months following the initiation of the program, and less so at 12 months, implying the importance of continued support for participants following the initial core program. Reviews of the literature suggested that a longer duration of the core program is related to more significant

results and reduced attrition rates, demonstrating the importance of providing the complete 16 core sessions and additional follow-up. Cultural and population characteristics must also be considered in implementing the NDPP into a targeted community. No studies were found that specifically investigated the implementation of the NDPP into an FQHC in a medically underserved community to determine the effectiveness and challenges of the program in a population where medical and psychosocial issues are prevalent.

Following the completion of the literature review, an additional article was located and identified as an important clinical guideline. Pronk and Remington (2015) published a recommendation by the USPSTF advocating for the use of diet and physical activity intervention programs to aid in the prevention of type II diabetes. The USPSTF reviewed data regarding clinical efficacy and cost effectiveness of intensive lifestyle intervention programs, and determined that programs such as the NDPP are cost-effective. These authors indicate that program participation and cost-effectiveness are improved when there is coverage for this service through private or public health insurance programs. The report utilized a NDPP implementation in Montana as an example, where the program was provided to prediabetics and was covered by the state's Medicaid plan. Forty-five percent of participants in the Montana NDPP program achieved the weight loss goal of seven percent.

The integration of the NDPP into primary care services, particularly those within FQHC's, was not prevalent within the literature reviews. Tsai and Wadden (2009) published a systematic review of the literature pertaining to obesity treatment within primary care settings and reported that although it is effective, the "time, effort, and expense required for PCPs to provide such care would appear to be prohibitive for most practitioners in the absence of

adequate reimbursement and with the already pressing demands of office practice” (Tsai & Wadden, 2009, p. 1077).

Rationale for the Project

The potential risks of implementing the NDPP into a primary care, medically underserved area were minimal, particularly when compared to the risks of not providing this intervention. No prior research was located to indicate the feasibility of utilizing medical providers as program leaders, which would enable medical organizations to bill Medicaid, Medicare or private insurance for the group visits and reduce the potential cost to the organization and the participants. Resources required to implement this intervention in the community health setting include a trained staff person to initiate and coordinate the program, a location for conducting the sessions, a referral process for identifying and notifying potential participants, and material costs for office supplies, educational materials, and photocopying.

Published literature supports the evidence that an intensive diet and exercise education and counseling program can aid participants in weight loss, improve diet, and provide an overall reduction in the risk of developing type II diabetes. Although the original research included 50 percent of its participants from racial and ethnic minorities (19.9 percent of whom were reportedly African American; Knowler et al., 2002), a distinction was not made to determine the impact of the program on individuals of low socioeconomic status. Understanding a community’s population dynamics and priorities, and a consideration of group characteristics is vital in implementing the program and ensuring success. This pilot study was designed to implement the evidence-based NDPP into a medically underserved community that has high obesity rates and nearly double the national rate of type II diabetes, as well as high rates of other medical conditions such as cardiovascular disease and asthma, and psychosocial issues such as

poverty and substance abuse. The principal investigator (PI) was a medical provider who is experienced in providing primary care services to this community, therefore had an existing understanding of some of the hardships endured by this population that could impact their ability to participate in the group and successfully meet the goals of the program. Having a group leader who is a credentialed medical provider to facilitate the group allowed the organization to submit for reimbursement from participants' Medicaid or insurance plans, which in turn improved the financial sustainability of the program and accessibility of the program to participants. However, it was not expected that the implementation of the program would be without difficulties. An initial impetus of a lack of identified prediabetic patients was addressed via a small quality improvement project within the health center that followed the initiative by the American Medical Association (AMA) and CDC to "Prevent Diabetes Stat" (AMA, 2015) by increasing screening and identification of prediabetic and diabetic individuals. Lack of participant interest and attrition were identified as additional large potential barriers to program success. The program would not be beneficial to the community nor would it be financially sustainable if the participants were not interested in consistently attending group sessions. The socioeconomic challenges of this population required consideration in planning the group sessions. For example, individual make-up sessions were considered weekly at alternate times in order to accommodate fluctuating schedules of participants. Additionally, program enrollment projections had to account for an estimated and anticipated no-show rate, which was expected to be approximately 30 percent based on existing rates within the FQHC.

In summary, the NDPP is based on valid and reliable experimental evidence and is an effective method to aid prediabetic participants in improving their diet and physical activity habits, resulting in an overall reduction in their risk of developing diabetes. The FQHC serves a

community that is in need of such a program, with a local prevalence of type II diabetes nearly twice the national rate, and a high rate of overweight and obesity. Implementation of the NDPP in this community, provided by experienced clinical staff at a well established and respected medical facility provided an essential opportunity to improve the quality and access to specific care for prediabetes that was lacking in this community. The program presented little to no risk to the local population, and its benefits had potential to greatly improve the health of the participants. Although community and cultural factors had to be considered when tailoring this program locally, the resources were already in place for this to occur. Leadership of the program by a primary care provider also served to aid long-term financial sustainability of the program as the group sessions could be billed for medical reimbursement.

Chapter 3 - Methods

Study Framework and Plan

This study aimed to address three critical needs in an evidence-based and innovative manner. The study aimed to evaluate the clinical effectiveness of the evidence-based NDPP in reducing the risk of diabetes (as measured by weight, BMI, blood glucose, and HgbA1c) in a medically underserved community. Secondly, the study aimed to determine the impact of weekly NDPP sessions on participant physical exercise, as well as participant nutritional and caloric intake. Lastly, the study aspired to evaluate the financial and logistical processes for sustainability of the NDPP within the FQHC setting.

Project Sponsors

This pilot study was implemented at a FQHC with support from upper level management who permitted the delegation of one four-hour weekly session for a primary care provider and a medical assistant. External grant funding was received from the D.C. Department of Health starting at the ninth session of the core program, a portion of which allowed financial support for personnel time through the completion of the core program and thereafter.

Cost Benefit Analysis

A thorough cost-benefit analysis of the fiscal sustainability of the NDPP within this FQHC was not completed during this pilot study. The primary cost to the organization included personnel time of one four-hour period per week for one provider and one medical assistant, thereby removing these staff from regular clinic duties. Grant funding was utilized to cover the personnel costs for the latter half of the core program. All participants had active medical coverage through either D.C. Medicaid or one of its managed care organizations, or Medicare.

The group sessions were led by a credentialed provider, therefore were eligible for reimbursement as a group medical visit to offset costs to the organization of conducting this pilot study. Office supplies and educational materials for each participant were purchased by the PI or were available from existing stock within the FQHC, and totaled under \$700. Educational materials aligned with the curriculum of the NDPP (University of Pittsburgh, 2012) and included portion plates, kitchen scales, measuring cups and spoons, pedometers, reusable water bottles, and a drawstring bag to hold the items.

Human Subjects Review

This pilot study was approved through the research committee within the FQHC's parent organization. The investigator applied to the Georgetown University IRB as the IRB of record, and received approval for this study on January 27, 2016. This study was determined to pose minimal risk to participants. All participants were counseled regarding potential risks and participant rights during the informed consent process prior to the initiation of the study, and participation in this pilot study was voluntary. All study data was secured to ensure patient privacy and confidentiality, and safety of study data. The PI successfully completed human subjects research training prior to initiating the study.

Population

Participants were recruited for this pilot study from a convenience sample of existing and active patients receiving care within the FQHC. Potential participants with a diagnosis of prediabetes as defined by HgbA1c 5.7 to 6.4 percent were identified by the primary care providers within the FQHC, and were referred to the PI via secure messaging within the patient's electronic health record. No participants were excluded from the study due to racial or ethnic identification, national origin, minority status, economic status, or gender.

Procedures

The study served as a pilot study, using a single group, pre-test, post-test design. Research was completed at a FQHC within a low-income, medically underserved urban residential area, where there is a high prevalence of prediabetes and diabetes. Clinical indicators of weight, BMI, random blood glucose levels, HgbA1c, caloric intake, and physical activity (in minutes per week) were documented throughout the 16-session NDPP core program.

Inclusion criteria:

- Adults age 18 years and older
- Identified prediabetes as defined by HgbA1c level within the past year between 5.7 and 6.4 percent
- Established patient receiving primary care services within the FQHC
- BMI of 24 and higher.

Exclusion criteria:

- Previous or current diagnosis of type I or type II diabetes
- Previous or current HgbA1c level 6.5 percent and higher
- Use of medication to improve glycemic control (e.g., metformin, glipizide, etc.).

A maximum potential enrollment was set at 15 participants in order to provide beneficial group and interpersonal dynamics, and to allow for attrition and the expected no-show rate.

As mentioned above, potential participants were identified by their primary care providers at the FQHC, and were referred to the PI via secure messaging within the electronic health record. The PI then verified that each potential participant met criteria, and potential participants were then contacted via telephone to introduce the program and determine initial interest. The potential participants who expressed interest in participating in the program and

study were scheduled to meet with the PI individually, at which time the program and study protocol were discussed in more detail. Informed consent was obtained at this visit, as well as any missing demographic or preliminary laboratory data. Each participant was provided with a list of scheduled session dates, times and location information, as well as contact information for the PI.

The core program of the NDPP was completed within a time frame of 19 weeks, allowing missed session dates for two holidays and one scheduling conflict. Participants' weights and vital signs were collected at each session by the medical assistant, and data was securely maintained by the PI. Clinical interventions and laboratory studies did not defer from standard recommended clinical practice for prediabetic patients, and posed minimal risk of harm to the patient. The post-core program of the NDPP continued for all participants following completion of the core program and this pilot study, however data collection ceased at the completion of the core 16 sessions.

The program followed the NDPP curriculum per the CDC website (University of Pittsburgh, 2012; CDC, 2016b). Program details and permission for use was verified verbally from a representative within the CDC's Diabetes Prevention Recognition Program (DPRP) office prior to start of the program. The principal investigator had previously completed required training and certification as the lifestyle coach to lead the sessions.

Data Analysis

Demographic data, including age, race and gender were obtained at the beginning of the study, and all participants were verified to have an inclusionary HgbA1c level consistent with prediabetes within the previous year. All participants had vital signs obtained at each group session, including weight, blood pressure, random blood glucose (finger stick), and heart rate.

BMI was automatically calculated by the electronic medical record system when vital signs were entered into the participant's health record. Participants self-reported their minutes of physical activity for the week at the beginning of each session consistent with the program, starting in the fifth week of the core program. Participants were encouraged to document their dietary intake and calculate their total calories and fat gram intake per week, and were instructed to bring the documentation to each session. At the final session of the core program, a post-program HgbA1c level was obtained for all participants.

The primary study variables included pre- and post-program weight and BMI, which was defined as the weight (in pounds) at the first and last attended session of the core program. Other variables included participation rates, pre- and post-program HgbA1c and random blood glucose, total minutes of physical activity throughout the core program, and total calories and fat grams throughout the core program. Study variables were evaluated using SPSS Statistics Version 24, utilizing frequency, descriptive, paired group *t*-tests, nonparametric Wilcoxon Signed Ranks tests, and correlational analyses.

Chapter 4 – Evaluation and Results

Analysis of Data

Thirteen potential participants were recruited for this pilot study, although one was excluded from study data due to lack of attendance at any group sessions. Data from the remaining 12 participants were therefore included in the evaluation of demographic data, Table 1. Eight participants completed the study, as defined by the CDC as an attendance at a minimum of four of the 16 group sessions. Study data was analyzed using SPSS Statistics Version 24. The mean patient age was 56 years (SD 11), with a range between 37 and 70 years. Seventy-seven percent of the participants were female, and 23 percent were male. All participants were African American, and all were identified as prediabetic by HgbA1c level prior to enrollment in the study, with no history of diabetes or use of hypoglycemic medications per the inclusionary criteria. All participants were established patients at the FQHC. Although the study design included an evaluation of total caloric and fat gram intake, this variable was ultimately excluded from analysis due to lack of data from the participants.

Table 1.	
<i>Demographic Data. n = 12.</i>	
<u>Variable</u>	<u>Mean (SD) or %</u>
Age (years)	56.0 (11)
Gender	
Female	77%
Male	23%
Ethnicity	
African American	100%
Caucasian	0

The participants had a mean pre-program weight of 227.1 pounds, a mean pre-program BMI of 36.7, and a mean pre-program HgbA1c of 6.0 percent. The participants had a mean post-program weight of 221.8 pounds, although the mean lowest average weight attained during the program was 218.5 pounds. The mean weight change from the beginning to the end of the core program was 5.3 pounds, although the mean weight change when comparing the pre-program weight to the lowest weight attained was 8.0 pounds. The mean post-program BMI was 35.9, and mean post-program HgbA1c level was 6.1. Participants attended an average of 7.7 group sessions, and the mean of total physical activity was 601.5 minutes throughout the duration of the core program (compared to no reported physical activity at the beginning of the program). The pre- versus post-program data for all participants is in Table 2.

Table 2.			
<i>Pre- vs. Post-Program Data. n = 12.</i>			
<u>Variable</u>	<u>Pre-Program Mean (SD)</u>	<u>Post-Program Mean (SD)</u>	<u>p-Value</u>
Weight (pounds)	227.1 (61.4)	221.8 (59.2)	<i>p</i> = 0.022 *
Body Mass Index	36.7 (7.0)	35.9 (6.9)	<i>p</i> = 0.021 *
Hemoglobin-A1c (%)	6.0 (0.2)	6.1 (0.2)	<i>p</i> = 0.395
Random Blood Glucose	106.3 (12.7)	113.8 (26.6)	<i>p</i> = 0.521

* = $p < 0.05$

A two-group, paired sample *t*-test was conducted to evaluate the difference between pre- and post-program weight, HgbA1c, random blood glucose level, and BMI. Paired sample *t*-tests were also performed between pre-program weight and lowest weight attained. A significant result was found between pre- and post-program weight ($p = 0.022$, $n = 12$), pre-program weight and lowest weight attained ($p = 0.005$, $n = 12$), and pre- and post-program BMI ($p = 0.021$, $n =$

12). Pre- and post-program comparisons between HgbA1c and random blood glucose were not significant ($p = 0.395$ and $p = 0.521$, respectively). Because of the small sample size, non-parametric Wilcoxon Signed Ranks tests were also completed. The nonparametric test results were consistent with the paired sample t -tests.

Pearson correlational analyses were conducted between total number of sessions attended, pre- to post-program weight change, weight change pre-program to lowest weight attained, total minutes of physical activity, gender, and age. Significant correlations were found between number of visits attended and both weight change to lowest weight attained ($p = 0.018$) and total minutes of physical activity ($p = 0.005$). Pre- to post-program weight change was correlated with total minutes of physical activity ($p = 0.006$). Gender and age were not significantly correlated with weight change or total minutes of physical activity. Analyses were repeated using non-parametric Spearman correlations due to the low sample size, and the significance of results was consistent. Results from the Pearson correlations are in Table 3.

Table 3.						
<i>Correlational Analysis, Sig. (2-tailed). n = 12.</i>						
Measure	1	2	3	4	5	6
1. Number of sessions attended	---					
2. Weight Change Pre- to Post-Program	0.151	---				
3. Weight Change Pre-Program to Lowest Weight Attained	0.018*	0.021*	---			
4. Total Minutes of Physical Activity	0.005*	0.006*	0.088	---		
5. Gender	0.508	0.788	0.939	0.616	---	
6. Age	0.068	0.761	0.394	0.396	0.533	---

* = $p < 0.05$

Data were re-analyzed including only the study data for the eight participants who attended a minimum of four program sessions to determine if the results were skewed by attrition. The minimum of four sessions attended was utilized due to the CDC's inclusion of these data only in their calculations for program recognition. These eight participants attended a mean of 11.8 of the 16 provided group sessions. A revised pre-program mean weight for these eight participants was 234.5 pounds, with a post-program mean weight of 227.1 pounds, and a mean weight loss of 7.38 pounds. The mean lowest weight attained at any point in the program for these eight participants was 222.3 pounds, with a mean weight loss to lowest weight attained was 12.3 pounds. Pre- and post-program weight and BMI were compared using the paired

samples t-test, and were found to be significant ($p = 0.030$, $n = 8$). Analysis was repeated using a Wilcoxon Signed Ranks test, and significant results persisted ($p = 0.050$, $n = 8$). The significance level diminished slightly with the exclusion of data from the four participants who did not complete at least four sessions, although the p -value remained significant at less than 0.05, Table 4.

Table 4.			
<i>Pre- vs. Post-Program Data, Participants who completed 4 or more sessions. n = 8.</i>			
<u>Variable</u>	<u>Pre-Program Mean (SD)</u>	<u>Post-Program Mean (SD)</u>	<u>p-Value</u>
Weight (pounds)	234.5 (65.0)	227.1 (62.0)	$p = 0.03$*
Body Mass Index	37.5 (6.7)	36.3 (6.5)	$p = 0.03$*

* = $p < 0.05$

Of clinical significance, the eight participants who completed at least four program sessions had a mean weight loss of 3.05 percent of their initial body weight, which increased to 5.21 percent if the initial weight was compared with lowest weight attained during the program rather than final weight. Table 5 demonstrates the difference in results when comparing all participants versus only those who completed at least four sessions of the NDPP core program. These participants reported a mean of 137.2 minutes of weekly physical activity, and reported a minimum of 150 minutes of weekly physical activity 44 percent of the time.

Table 5.		
<i>Comparison Between All Participants and Participants Who Completed 4+ Sessions.</i>		
<u>Variable</u>	<u>All Participants, <i>n</i> = 12</u>	<u>Participants Who Completed 4+ Sessions, <i>n</i> = 8</u>
Mean Pre-Program Weight (pounds)	227.1	234.5
Mean Post-Program Weight (pounds)	221.8	227.1
Mean Lowest Weight Attained (pounds)	218.5	222.3
Mean Weight Loss Pre-Program to Post-Program (pounds)	5.3	7.4
Mean Weight Change Pre-Program to Lowest Weight Attained (pounds)	8.6	12.3
Mean Percent Weight Loss Pre-Program to Post-Program	2.3	3.1
Mean Percent Weight Loss Pre-Program to Lowest Weight Attained	3.7	5.2

The results of the statistical analyses demonstrate an improvement in weight loss and BMI in participants who attended the core program of the NDPP. Greater weight loss was related to both more sessions attended and higher amounts of physical activity. Results were not influenced by the gender or the age of the participants. No significant change in random blood glucose or HgbA1c occurred within the short time frame of the core program.

Chapter 5 - Discussion and Conclusions

Discussion of Findings

The results of this pilot study indicate that there are statistically significant improvements in weight and BMI in prediabetic individuals in a medically underserved area who participate in the core program of the NDPP, irrespective of gender or age. All of the participants lived in a medically underserved area. Weight loss was positively correlated with higher levels of participation (reflected in number of visits attended) and physical activity. These findings are consistent with the results of the large multicenter study conducted by the DPPRG (Knowler et al., 2002) that documented the benefits of an intensive lifestyle intervention program on weight and therefore diabetic risk of prediabetic patients. The results of this study also support the CDC's guidelines for inclusion of data only for participants who complete a minimum of four group sessions, with noticeable differences in percent weight loss and number of sessions attended between all participants and those who completed four or more sessions.

This pilot study demonstrates some of the challenges of implementing the NDPP into a primary care setting within a medically underserved community where participants may have weight fluctuations due to medical and psychosocial issues. Although there was a significant result between the pre- and post-program weight as well as the pre-program weight and lowest weight attained, the correlational analysis between the number of sessions attended and weight change to post-program weight was not significant. However, the correlation between number of sessions attended and weight change to lowest weight attained was significant. The mean percent weight loss of the eight participants who completed a minimum of four sessions was 3.05 percent when comparing pre-program and post-program weight. However, the mean percent weight loss

increased to 5.21 percent for this same group when comparing pre-program weight and lowest weight attained. Anecdotally, the PI noted medical and psychosocial impacts on their weight loss efforts through the program, particularly in the final sessions. In order for an organization to receive full CDC recognition for the NDPP, the participants must obtain a minimum average of five percent weight loss in the first six months (i.e., in the core program). The results of this pilot study suggest that the post-program weight may differ from the lowest weight attained; therefore it may not be an accurate portrayal of the program's effectiveness to evaluate only the final weight in the core program, not the lowest attained. For FQHC's seeking recognition for offering the NDPP to underserved communities where medical and psychosocial comorbidity rates are higher than average, it may be important to consider lowest weight attained versus final weight in evaluating the benefits and efficacy of a program. The FQHC otherwise was able to meet all performance standards for the core portion of the program set by the CDC for recognition (CDC, 2015b), including utilization of the curriculum, 16 weekly sessions delivered within six months, an average participant attendance of nine sessions, documentation of body weight at a minimum of 80 percent of sessions, and documentation of physical activity at a minimum of 60 percent or more sessions.

Although all participants reported no physical activity at the beginning of the program, and reportedly were physically active at the end of the program, they reported a minimum of 150 minutes weekly at only 44 percent of the visits where physical activity was recorded. This may be reflective of the challenges that individuals face in this community accessing safe methods of exercise, and may contribute to difficulties in achieving weight loss goals.

There were not significant changes noted in random blood glucose and HgbA1c level between the beginning and the end of the core program. This was not a surprising result, as the

study period occurred over only 19 weeks, and a HgbA1c level may require a longer period of time to significantly change after the initiation of diet and exercise changes.

Limitations

There were several limitations of this study. First, the sample size was small and there was no control group utilized for comparison because the study was conducted as a quality improvement initiative in one health center location. Sample size was small due to time constraints of the study, and an unofficial referral process. A control group was not utilized due to ethical concerns of not providing an evidence-based treatment program to a high-risk population. Future research considerations would include improvements in both of these factors. It would be beneficial to compare outcomes of group participants versus those who receive individual weekly educational visits for a similar time period to determine if a group-based initiative is the most effective method of delivery for this community.

Second, this pilot study evaluated the effectiveness of only the core program of the NDPP due to time constraints. In order to better evaluate the effectiveness of the NDPP, it would be beneficial to extend the study period beyond the 16-session core program and evaluate the changes in the variables at completion of the full one year program. A longer study time period would also provide more adequate time to observe a potential change in HgbA1c and blood glucose levels.

Third, although it was expected, attrition was noted in the study, with two-thirds of the original participants completing a minimum of four of the 16 group sessions. Attrition occurred regardless of the PI calling each participant who missed sessions and offering alternative make-up group sessions. It would be beneficial to further investigate the reasons for no-shows and program attrition to better identify and address challenges faced by the participants. However,

the percent attrition rate for this pilot study was comparable to the overall individual visit no-show rate for the FQHC, and should be a factor that needs to be considered in planning future initial group size. If staffing permits, a community health worker or support staff may be useful in following up with participants who miss sessions.

Additionally, the planned variables of total calorie and fat gram intake were removed from the study due to participant difficulties with dietary intake and required calculations of calories and fat grams. Anecdotally, the PI noted challenges in literacy and mathematical calculations among the participants, and alternative methods of tracking diet were not located during the short time period of the study. This should be considered in planning future interventions with this community as it may have reduced the benefit that participants may have obtained from dietary calorie and fat tracking. Future considerations should also include patient surveys or focus groups to identify barriers to healthy eating. Receipt of knowledge regarding healthy eating habits does not necessarily equate to healthier habits if individuals face limited food resources in their communities, or cannot fully comprehend nutritional information due to reduced literacy. Considerations may include additions or modifications to the curriculum in order to better address identified barriers and issues. Participants also noted difficulties in finding accessible modes of safe physical activity within their communities, which opens the consideration for community partnerships with organizations offering free or reduced fee exercise classes or groups.

Finally, a thorough cost-benefit analysis needs to be completed to determine the financial sustainability of the NDPP within the FQHC setting. Although the utilization of a provider as group facilitator allowed for reimbursable group medical visits, the number of group encounters did not equate to the individual encounters that the provider would have seen during the same

time frame. The expansion of coverage of the NDPP by Medicare and Medicaid will enable the program to be led by non-provider staff, thus reducing the financial and clinical burden on organizations, particularly FQHC's where resources may be already limited.

Conclusions

This pilot study demonstrates that the implementation of the NDPP in an urban medically underserved community is effective in reducing weight and BMI, and thus assists in reducing diabetes for this high risk group. Despite a high attrition and no-show rate, the participants experienced improvements in their lifestyle habits during participation in this program. This pilot study is an example of the importance of extending access to the NDPP to high-risk communities such as the one serviced by this FQHC. Additional benefit to the community may also be achieved by extending the program enrollment to other FQHC's, and to the local community who do not receive health care services at this FQHC. Alliances and partnerships could be created to provide the NDPP at other community facilities, such as churches or recreation centers in order to increase ease of access to the program, and to provide safe modes of physical activity. Overall, this pilot study suggests that the NDPP can be implemented into a medically underserved area in a manner that is financially sustainable, and provides a clear clinical benefit to a community where the risk for developing diabetes is high.

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