Project Proposal: Evaluating Diabetes Prevention Interventions Among High Risk

Hispanic/Latino Patients in Primary Care

Cindy Millan, MN, FNP-C

Oregon Health & Science University School of Nursing

Abstract

Pre-diabetes and diabetes are on the rise in the U.S. According to the Centers for Disease Control and Prevention, the disease disproportionately impacts ethnic minority groups. The Hispanic/Latino population is of particular concern given that both the prevalence and incidence of the disease is increasing in this group. Effective evidence based interventions, such as the National Diabetes Prevention Program, exist to modify the risk of diabetes in high-risk patients. This intervention however has yet to be exclusively tested in the Hispanic/Latino population. There is also limited data on what, if any, other interventions have been successful in modifying diabetes risk among the specified population. The proposed program evaluation aims to evaluate existing diabetes prevention interventions at a primary care clinic in Oregon serving a large Hispanic/Latino population. The goals of the program evaluation are to identify the most effective intervention at reducing A1c, as well as to identify specific tailoring to meet the needs of the population.

Evaluating Diabetes Prevention Interventions Among High Risk Hispanic/Latino Patients in

Primary Care

The Clinical Problem

According to the Centers for Disease Control and Prevention [CDC] (2018), 33.9% of

U.S. adults have a diagnosis of pre-diabetes. In Oregon, it is estimated that 8% of adults have a

diagnosis of pre-diabetes (CDC, 2017). Evidence suggests that approximately 25% of these

patients will progress to diabetes within 3-4 years, and carry a lifetime incidence rate of 75%

(Hostalek, 2019). Complications associated with pre-diabetes and subsequent diabetes

development include diabetic retinopathy, peripheral neuropathy, chronic kidney disease, and

cardiovascular disease (Hostalek, 2019). Risk factors for pre-diabetes are the same for diabetes.

These include family history of diabetes, race/ethnicity, age, overweight/obese, sedentary

lifestyle, dyslipidemia, and hypertension among other risk factors (Wilson, 2017).

Disparities are evident among those with type II diabetes. According to epidemiological

data from the CDC (2018), racial and ethnic minority groups such as Alaskan Native/American

Indians, Hispanics, and Black Americans have a higher prevalence of diabetes. Diabetes is also

more common in individuals with low levels of education, low income, and low socioeconomic

status (CDC, 2017). The Hispanic population is of particular concern given that both prevalence

and incidence of the disease appear to be increasing in this group. (Soltero et al., 2019). Given

the fact that Hispanics compromise the largest ethnic minority group in the U.S., researchers

suggest special attention should be directed toward creating evidence based, culturally

appropriate prevention programs for this disadvantaged group (Soltero et al., 2019).

The potential for reversibility of pre-diabetes has significant implications for affected

populations, more importantly those affected at disproportionate rates such as Hispanic/Latino

adults. Programs such as the National Diabetes Prevention Program (NDPP) have the potential to prevent the progression to diabetes. Results from the original randomized control trial found that evidence based life style interventions decreased progression to diabetes by 58% (Wilson, 2017). Subsequent studies found the benefits of these interventions were sustained for up to 20 years post intervention (Wilson, 2017). Although these studies included robust numbers of racial/ethnic minorities, these interventions have yet to be tested exclusively among Hispanic/Latino patients. Studies are also limited with regard to other existing interventions effective in preventing diabetes among high-risk Hispanic adults. The purpose of this program evaluation is therefore to evaluate existing diabetes prevention interventions in Hispanic/Latino patients.

<div align="center">Review of the Literature</div>

A literature review was conducted in June 2019 using PubMed database. Articles pertinent to the literature review at hand were selected by utilizing the key terms "diabetes, prevention program, evidence-based programs, Hispanics, and community based. This search yielded 212 articles, which were narrowed down further by applying criteria such as articles published within the last 5 years. A total of 13 articles were reviewed. Data regarding epidemiology, prevalence, morbidity, and mortality for diabetes were obtained from the Centers for Disease Control and Prevention in addition to research articles providing in-depth background and statistical data.

The original diabetes prevention program study conducted by the Diabetes Prevention Program Research Group (2002) was a randomized control trial consisting of 3,234 study participants from 27 different health centers. Eligible participants were those with high risk for developing type II diabetes and included criteria such as age 25 or older, BMI greater than 24,

and status of pre-diabetes. Approximately half of the study participants were from racial/ethnic

minority groups to ensure representation of those disproportionately affected by diabetes were

included. Participants were assigned to either one of three different interventions by double

blinded randomize methods; placebo, Metformin 850mg twice daily, or intensive lifestyle

interventions. Components of the lifestyle intervention group included the following; weight

reduction of seven percent or more, low calorie/low fat diet, 150 minutes of moderate intensity

physical activity, as well as a 16-lesson curriculum focusing on diet, exercise, and behavior

modification taught by trained case managers that were considered culturally sensitive. These

classes were offered individually or in groups. The measured outcome was diabetes defined by

diagnostic criteria for diabetes; Fasting blood glucose greater than 126, or plasma glucose greater

than 200 two hours post oral glucose tolerance test. The results of this study showed participants

assigned to the lifestyle intervention group had greater changes in weight reduction and

increased physical activity. The incidence of diabetes in the lifestyle intervention group was

decreased by 58% compared to placebo (95% CI), and by 31% in the Metformin group compared

to placebo (95% CI). These differences were statistically significant between the 3 groups as

evidenced by a P-value less than 0.001 for each comparison. These results were consistent in

both men and women across all ethnic groups in the study. A 15-year follow up study found that

participants from the lifestyle intervention group continued to have lower incidence rates of

diabetes; incidence was reduced by 27% (P<0.0001) compared to the placebo group (Diabetes

Prevention Program Research Group, 2015).

The success of the Diabetes Prevention Research Groups original study findings

prompted many follow up studies to assess the efficacy of the comprehensive lifestyle

intervention program. One study examining the comprehensive lifestyle intervention program at

YMCA centers of the U.S. found the program was not only effective for weight reduction, but also resulted in better care, in the form of decreased hospitalizations, and improved spending (Alva, Hoerger, Jeyaraman, Amico, & Rojas-Smith, 2017). Another study evaluating the CDC's National Diabetes Prevention Program noted similar results with regard to weight loss, highlighting that those who remained in the program longer were more successful in their weigh loss efforts (Ely et al., 2017). Another report produced by the Oregon Health & Science University's Center for Evidence Based Policy (2017) evaluated the long term effects of individuals who took part in studies that adapted the diet and physical activity protocol from the original DPP; they found the majority of these participants decreased their risk of diabetes by nearly 50% even in those with minimal weight loss. Studies evaluating cost-effectiveness and utility of such programs were also reviewed. One Study by Herman (2015) evaluated the cost effectiveness of the 2002 Diabetes Prevention Program study. Their cost-effective analysis demonstrated lifestyle intervention cost was $31,500 per quality adjusted life year (QALY) compared to $99,600 for the Metformin group from a healthcare perspective. From the societal perspective, the lifestyle group cost $51,600 per QALY compared to $99,200 per QALY for the Metformin group (Herman, 2015). A 10-year cost-effectiveness analysis was also performed, which noted the lifestyle intervention cost per QALY was $15,000 from the health system perspective, and $8,400 from the societal perspective (Herman, 2015). These are considered optimal, given the typically accepted cost effectiveness threshold of $50,000 to $150,000 per QALY (Frick, 2012).

This robust data led to the development of the National Diabetes Prevention Program (NDPP), a partnership between private and public organizations that offered evidence-based interventions that mimic those of the original Diabetes Prevention Program study. Many health

centers around the country have obtained recognition by the CDC as meeting criteria for the lifestyle change program. Resources are available through the CDC website for centers seeking to become nationally recognized.

Although the original Diabetes Prevention study had a robust number of racial/ethnic minority participants, there are limited studies examining the effect of the NDPP exclusively among Hispanic/Latinos. There is also limited research on what specific tailoring is needed when implementing such programs among this population. The few studies available evaluating NDPP type interventions among Hispanic/Latinos noted several common themes. Ritchie, Christoe-Frazier, McFann, Havranek & Pereira (2018) examined outcomes of Latinos from 6 different primary care clinics enrolled in a 12-month long NDPP like intervention. Their findings demonstrated that compared to non-Hispanic Whites, Latinos were less likely to attend at least one class session, attended fewer total number of classes, and were less likely to achieve >5% weight loss (Ritchie, et al., 2019). Venditti (2017), found that lifestyle behavior intervention programs led by trained community health workers, referred to as "promotores de salud" (health promoters), were an effective means of achieving weight loss among Mexican American women at high risk for developing diabetes. Translation of the Diabetes Prevention Program to Hispanic/Latino Americans was examined in another study. Although results from this study have yet to be published, promising data are arising. In their review of the preliminary study, Hall, Lattie, McCalla, and Saab (2016) noted that bilingual interventionist, culturally tailored interventions, Spanish language, and consideration of low literacy are all important factors to consider when tailoring the NDPP to Hispanic/Latino populations. In addition to these factors, Rosas et al., (2018) found from their Hispanic/Latino focus groups that participants felt the presence of a bicultural coach and family involvement to be most influential in making

interventions feel relevant. The results of 2014 randomized control trial conducted by Vincent, McEwen, Hepworth, and Stump (2014) demonstrate such effects. In their study, they found that Mexican American adults who took part in their 5-month NDPP like intervention that was culturally tailored saw significant improvement in weight reduction, BMI, and diet self-efficacy (Vincent et al., 2014). Cultural tailoring in this study included the use of Spanish language materials, use of visual aids, culturally acceptable exercise such as walking and dancing, and providing alternative cooking demonstrations of traditional Mexican American foods (Vincent et al., 2014).

Several conclusions can be drawn from these studies. First, comprehensive lifestyle intervention programs that mimic that of the original Diabetes Prevention Programs study are effective at decreasing the incidence of diabetes. Given this data, this approach should be the gold standard intervention for patients newly diagnosed with pre-diabetes. Second, the program is cost effective as evidenced by the studies. Resources should therefore be directed toward funding of such programs. Third, although the original study included racial/ethnic minority groups, programs need to be tailored for their efficacy to translate to Hispanic/Latino populations. Factors to ensure are components of the program include Spanish language materials, bilingual/bi-cultural coaches, engagement of the whole family, providing education on culturally appropriate exercise such as walking and dancing, and providing education on culturally appropriate food choice alternatives that emphasize traditional Mexican food. Collaboration with community health workers should also be considered to fully engage patients and their families.

Study limitations and areas for further research include identifying reasons for poor attendance to sessions and whether results of these studies are applicable to the Hispanic/Latino

population. One study examined in this review found Hispanic participants were not as likely to attend all sessions required. The study researchers however failed to identify potential barriers to attendance, a critical step in finding solutions to increase attendance. The study evaluating the role of community health workers focused on Mexican American women at risk for diabetes, therefore its utility can not be determined in high risk men. Data is also lacking on the long-term efficacy of NDPP like interventions among Hispanic/Latino patients that have been culturally tailored to the population.

In summary, the purpose of the project at hand is to evaluate existing interventions aimed at decreasing A1c and subsequent diabetes development among high-risk Hispanic/Latino patients at a primary care clinic in Oregon. Based on the success of the National Diabetes Prevention Program findings, it can be hypothesized that interventions, which include comprehensive lifestyle changes, will be most effective. Interventions that are culturally tailored to the populations specific needs are expected to be highly efficacious as demonstrated by the studies evaluating NDPP type interventions among Hispanic/Latinos.

<div align="center">Project Methods</div>

Setting

The project setting is a primary care federally qualified health center in Oregon. The clinic at hand serves a large Hispanic/Latino population, migrant farmworkers of Hispanic origin, as well as many uninsured individuals.

Participants

Study participants will be the charts of 200 Hispanic/Latino adults aged 21-64 years old. Additional filter criteria will include having been diagnosed with pre-diabetes between August 2018 and August 2019. There are no anticipated ethical issues or concern for protection of

human subjects given that this project will only consist strictly of chart review, without human interaction, or collection of protected health information.

Proposed Implementation

Three pre-diabetes interventions will be evaluated at the health center. The interventions to be evaluated are individualized meetings with the clinic nurse, individualized meetings with the clinic behavioral health provider, and meeting with the clinics designated diabetes nurse educator.

A roster of patients diagnosed with pre-diabetes between the dates of August 2018 and August 2019 will be generated with assistance from the organization's manager and data analyst. Filter criteria to be applied to the list will include Hispanic/Latino and age 21-64. With assistance from the data analyst, the charts of 200 patients will be randomly selected for review. The researcher will then review each patient chart individually, and record the following information: A1c at initial diagnosis, intervention the patient was assigned to, and A1c six months after the diagnosis of pre-diabetes and attendance to one of the intervention groups. The researcher will also collect information on the components of each intervention by interviewing staff responsible for carrying out the programs.

Measures/Outcomes

Data will be collected solely from patient chart review. Demographic data such as age, gender, and race/ethnicity will be recorded. The primary measure/outcome to be evaluated will be pre and post intervention A1c given that this is the primary marker for diabetes risk. Descriptive statistics will be used to make general observations. Paired t-test will be utilized to analyze pre and post intervention A1c. This statistical method will help to inform of mean A1c before and after the assigned interventions, to identify the most effective at reducing A1c. A bar

graph will be utilized to show differences in mean pre and post intervention A1c for each group.

There are no anticipated projected costs for this program evaluation. This project is strictly a

chart review for informative purposes to help guide future interventions and resource allocation.

Results

A total of 200 patient charts were reviewed. One chart was disqualified because of the

recorded A1c being in diabetic range. The overall mean age of participants at the time of pre-

diabetes diagnosis was 48. The overall mean A1c was 5.9. Out of 199 charts, 72 had a recorded

A1c at the six-month time frame being evaluated. Nine were assigned to the nurse intervention

group, 30 assigned to the diabetes nurse educator, and one to the clinic's behavioral health

specialist. 159 patients were not assigned to an intervention. Of the 9 patients assigned to

meetings with the team nurse, 3 had complete data sets (pre and post intervention A1c's). The

average baseline A1c for patients in this group was 5.9, and the average post intervention A1c

was 5.8. Of the 30 patients assigned to meetings with the diabetes nurse educator, 10 had

completed data sets. The mean baseline A1c for this group was 6.0, and the mean post

intervention A1c was 5.9. The individual patient assigned to the clinics behavioral health

specialist did not have a post intervention A1c, therefore no further statistics or observations

were made for this group. Paired T test were performed only for those patients that had complete

data sets (pre and post intervention A1c) for both groups. Although there was a reduction in the

mean post intervention A1c for the nurse meeting group, the difference noted was not

statistically significant ($P= .90$). The change noted in the mean post intervention A1c for the

diabetes nurse educator group was also not found to be statistically significant ($P= .67$).

Limitations

Several limitations were noted. Although there was a large sample size to begin, six-month A1c follow up measurements were only available for 72 out of 199 patients. Additionally, not all patients with a six month follow up A1c were assigned to an intervention. Of the 40 patients assigned to an intervention group, complete data sets were only available for a total of 13 patients. The computed P values for mean change in post intervention A1c's were also found not to be statistically significant, which indicates that changes noted in post intervention A1c were attributed to sampling or experimental error. Another limitation was the designated follow up time period. Follow up A1c's were recorded at 6 months, which is earlier than the recommended one year follow up that most practice guidelines suggest. Extending the follow up time to one year may have yielded more post intervention A1c's. No patients in either group developed diabetes mellitus in the time frame being evaluated.

Conclusion and Practice Implications

Although both groups demonstrated a decrease in post intervention A1c, the differences were not statistically significant. Differences noted therefore can be attributed to sampling or experimental error, not the intervention that took place. The limitations listed above are believed to have contributed to the statistical outcomes. Having more documented follow up A1c's, larger numbers of patients assigned to intervention groups, and a longer follow up time frame may have contributed to stronger statistics. The practice implications concluded in this study are many, and weigh heavier for clinics that serve large numbers of Hispanic patients. First, clinics should have a way to keep track of patients with pre-diabetes diagnosis to better evaluate their interventions. This could be accomplished through a registry which prompts case management, or other appropriate personal, to make appropriate outreach and follow up. Second, clinics should have

clearly defined interventions and implement standardized workflows to ensure patients who

receive a pre-diabetes diagnosis are assigned to a group and receive equivocal treatment. Many

patients in this study were not assigned and the reasoning as to why was unclear. Last, clinics

should incorporate outcome evaluations of their interventions in their quality improvement

meetings to make appropriate changes and allocation of resources to their programs.

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