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Development and evaluation of an enhanced diabetes prevention program with psychosocial support for urban American Indians and Alaska natives: A randomized controlled trial

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ABSTRACT

Diabetes is highly prevalent, affecting over 25 million adults in the US, yet it can be effectively prevented through lifestyle interventions, including the well-tested Diabetes Prevention Program (DPP). American Indian/Alaska Native (AIAN) adults, the majority of whom live in urban settings, are more than twice as likely to develop diabetes as non-Hispanic whites. Additionally, prevalent mental health issues and psychosocial stressors may facilitate progression to diabetes and hinder successful implementation of lifestyle interventions for AIAN adults. This 2-phased study first engaged community stakeholders to develop culturally-tailored strategies to address mental health concerns and psychosocial stressors. Pilot testing (completed) refined those strategies that increase engagement in an enhanced DPP for urban AIAN adults. Second, the enhanced DPP will be compared to a standard DPP in a randomized controlled trial (ongoing) with a primary outcome of body mass index (BMI) and a secondary outcome of quality of life (QoL) over 12 months. Obese self-identified AIAN adults residing in an urban setting with one or more components of the metabolic syndrome (excluding waist circumference) will be randomized to the enhanced or standard DPP (n = 204). We hypothesize that addressing psychosocial barriers within a culturally-tailored DPP will result in clinical (BMI) and superior patient-centered (QoL) outcomes as compared to a standard DPP. Exploratory outcomes will include cardiometabolic risk factors (e.g., waist circumference, blood pressure, fasting glucose) and health behaviors (e.g., diet, physical activity). Results of this trial may be applicable to other urban AIAN or minority communities or even diabetes prevention in general.

1. Introduction

One-third (36%) of American adults are considered obese [1]. Obesity is associated with leading causes of preventable death such as Type 2 diabetes [2]. Type 2 diabetes affects an estimated 25.8 million US adults and an additional 79 million adults have prediabetes [3]. The 5.2 million adults living in the US who identify as American Indian/Alaska Native (AIAN) alone or in combination with some other race are at higher risk of obesity and of developing diabetes compared to non-Hispanic whites [4–7]. Self-reported national data indicate obesity rates to be 46% higher in AIANs (42%) compared to non-Hispanic whites adults (29%) [8]. The prevalence of diabetes in AIANs (18%) is more than double that in non-Hispanic white Americans (8%) [8].

The landmark Diabetes Prevention Program (DPP) trial demonstrated that an intensive lifestyle intervention targeting modest weight loss (7% of baseline weight) and increased physical activity (150 min per week) was effective for preventing diabetes among high-risk adults, although American Indians represented only 5% of the study population [9]. To promote dissemination in American Indian/Alaska Native communities in the US, the Indian Health Service implemented the Special

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Diabetes Program for Indians Diabetes Prevention (SDPI-DP) [10]. SDPI-DP supported AIAN health care programs to implement and evaluate the 16-session Lifestyle Balance curriculum, a group-based adaptation of the original DPP. The annual incidence of diabetes among participants (n = 2553) was 4.0%, which is similar to the incidence for AIAN participants in the original DPP trial (4.7%) [10]. After one year of follow-up, 22.5% of participants in the SDPI-DP had achieved the weight loss goal of 7% of baseline weight.

As a result of implementing the SDPI-DP, one urban AIAN community was motivated to further examine how to optimize diabetes prevention for urban AIAN adults given stakeholder concern regarding barriers related to mental health issues and psychosocial stressors. Compared to non-Hispanic whites, AIAN adults have higher rates of depression symptoms (e.g., sadness some of the time 14% vs. 8%), any illicit drug use (18% vs. 9%) [6], more than once binge drinking in the last month (32% vs. 17%), reported "not satisfied with life" (10% vs. 5%), 14+ days/month with poor mental health (18% vs. 11%) [11], and serious psychological distress (5.2% vs. 3.1%). The community established a community-university partnership with the goal of conducting research to elucidate effective strategies that address mental health issues and psychosocial stressors for preventing diabetes among urban AIAN adults.

Support for this approach derives from a recent analysis of the SDPI-DP evaluation showing that several psychosocial factors including depressive symptoms, family support, and psychological distress were related to the degree of weight change [12]. These findings underscore the importance of incorporating strategies to address mental health issues and psychosocial stressors in diabetes prevention for AIAN communities as identified by the community-university partnership. The goal of this study is to develop and test a diabetes prevention program for AIAN adults that incorporate culturally sensitive strategies to address mental health concerns and psychosocial stressors in a comparative effectiveness trial.

2. Methods

A community-university partnership, established in 2011 collaborates to lead this comparative effectiveness trial. The design and implementation of this study prioritizes the community-driven research agenda while balancing the importance of scientific rigor.

2.1. Patient and stakeholder engagement

This study is guided by principles of Community-Based Participatory Research: (1) Recognize the community as a unit of identity; (2) Build on strengths and resources of the community; (3) Facilitate collaborative partnerships in all phases of the research; (4) Integrate knowledge and action for mutual benefit of all partners; (5) Promote co-learning and empowering process that attends to social inequalities; (6) Involve a cyclical and iterative process; (7) Address health from both positive and ecological perspectives; and (8) Disseminate findings and knowledge gained to all partners [13]. The community-university partnership developed a community advisory board known as the American Indian Community Action Board (AICAB) in 2011 that is made up of local community members and leaders. The AICAB meets at least monthly and serves as the central governing body of the partnership making key decisions and participating in all phases of the research process (see Fig. 1). In addition, the project includes a steering committee with community and university representatives that manage the day-to-day functions of the study, a scientific advisory board made up of national experts in diabetes prevention, AIAN health, and community-based participatory research, the National Council of Urban Indian Health to facilitate rapid dissemination of results, and a Data and Safety Monitoring Board.

2.2. Study design

This study (05/2014–10/2018) has 2 phases. Phase I (completed) involved pilot testing culturally-tailored strategies to address mental health concerns and psychosocial barriers for incorporation into an enhanced DPP intervention to increase engagement for urban AIANs. Phase II (ongoing) is a comparative effectiveness trial (n = 204) to test the enhanced DPP developed in Phase I. The comparison group will receive a standard DPP program based on the SDPI-DP as recommended by community stakeholders given their assessment of the significant burden of diabetes in this community and the proven success of lifestyle interventions for preventing diabetes in high-risk groups. The entire study protocol was approved by the Institutional Review Boards (IRBs) of the Stanford University and San Jose State University. Additionally, the AICAB was trained to serve as an ethical review board representing community interests.

2.3. Phase I: develop enhanced DPP for urban AIAN adults

The goal of Phase I was to refine and strengthen the existing DPP intervention based on the SDPI-DP to create an enhanced DPP. Early on in the development of an enhanced approach to diabetes prevention, the AICAB identified the issue of historical trauma as a key factor in the AIAN experience that has led to persistently high prevalence of diabetes among AIAN adults. Historical trauma refers to the cross-generational harms created by an experience dominated by attempts to systematically destroy AIAN communities and cultures [14–18]. This concept is closely tied to the personal distress and community cultural displacement that are often labeled mental health disorders in a western medical model. As suggested by the AICAB, confronting historical trauma provides a means of addressing mental health issues, but requires a broader range of services. Thus, the partnership undertook a 12-month formative research phase to pilot test 3 culturally-congruent strategies: (1) Talking Circles; (2) Modified Photovoice; and (3) Digital Storytelling. These strategies were identified by the AICAB as being able to engage urban AIANs in addressing underlying social, historical and psychological stressors within a framework congruent with AIAN culture. Additionally, these strategies were identified as reinforcing AIAN cultural identity, thereby enhancing social support in the group sessions. The aim was to pilot test each strategy to assess feasibility and draw a conclusion regarding their incorporation into an enhanced DPP. In addition to pilot testing these strategies in Phase I, the partnership developed a protocol for providing culturally congruent and accessible mental health support to participants in the enhanced DPP.

2.3.1. Foundation: existing DPP intervention

A group-based adaptation of the original one-on-one intensive lifestyle intervention from the DPP trial [9,19,20,21] based on the SDPI-DP serves as the foundational intervention for this study. The theoretical basis is derived from Social Cognitive Theory [22] and the Transtheoretical Model of Behavior Change [23,24]. The primary goals of the intervention are loss of at least 5% of baseline weight and 150 min of moderate physical activity per week by 6 months. Although the original DPP trial targeted 7% weight loss, 5% weight loss has been found to be sufficient for prevention of chronic disease and is commonly accepted as the goal [25]. The intervention is delivered by a trained lifestyle coach over 16 weekly group sessions covering information on moderate calorie restriction, physical activity, and proven behavioral strategies (see Table 1 for a list of topics). In addition, participants are invited to attend ongoing support sessions for maintenance of lifestyle changes after the completion of the first 16 weeks. The support sessions are offered weekly and participants are encouraged to attend at least once per month.