

A Patient-Centered Strategy For Improving Diabetes Prevention In Urban American Indians

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1. PURPOSE OF THE STUDY

a. Brief Summary

American Indians and Alaska Natives (AIAN) have disproportionate rates of obesity and diabetes and are more likely to suffer from psychosocial stressors than their white counterparts. These stressors increase obesity risks and are barriers to fully participating in lifestyle interventions. While lifestyle interventions such as the Diabetes Prevention Program have been effective among racial/ethnic groups, including American Indians, these interventions have not been studied in primary care or community-based settings and have not addressed barriers pertaining to psychosocial stressors or historical traumas.

b. Objectives

Our specific aims are:

1. To deepen engagement of patient and provider stakeholders to better understand the patient-centered perspective on psychosocial issues that influence progression to diabetes among urban AIANs.
2. To refine, strengthen, and test an enhanced DPP that incorporates psychosocial support for urban AIANs in a RCT (n=204).
3. To rapidly disseminate research findings to key stakeholders at the local state, and national level. These aims address the priority of eliminating health disparities by addressing the context of prevalent diabetes in a marginalized population.

c. Rationale for Research in Humans

Human subjects must be used to inform the development of a culturally appropriate and enhanced diabetes prevention program addressing psychosocial stressors and to evaluate the effectiveness of this program compared to the standard program.

2. STUDY PROCEDURES

a. Procedures

Phase 1, we will use the first six months of the study to refine and strengthen the intervention and study protocol by analyzing existing deidentified data from the Indian Health Center and using Talking Circles(TCs), Modified Photo Voice, and Digital Storytelling:

- 1) We will analyze existing, deidentified pre- and post-intervention data from the existing IHC diabetes prevention program to identify information on the association between mental health, BMI, and other indicators.
- 2) Talking Circles: A total of five Talking Circles (TCs) will be conducted with participants (50 total participants) who are interested in urban AIAN health and wellness to gain relevant insights. Each talking circle will have up to 10 participants in the session and, in keeping with tradition, each session will have unlimited time. Skilled facilitators will lead participants in a process to set ground rules, share a meal, and participate in guided discussions. Participants will decide if the session will be audio recorded or if an alternative method to summarize the key points from the session will be used.
- 3) Modified Photo Voice: Ten AIAN community members who participated in a TC will be invited to participate in a 6-week Modified Photo Voice project. Participants will participate in 6 sessions (one session per week) use a digital camera to take photographs and write photo narratives pertaining to health needs and assets in AIAN communities. During photo sharing sessions, participant discussions will be audio recorded and transcribed for data analysis to uncover relevant themes. Participants will share photos and findings with stakeholders during a Community Action Board (CAB) meeting so that the CAB can use these findings to develop appropriate interventions for the enhanced diabetes prevention program.
- 4) Digital Storytelling: Ten AIAN community members who participated in a TC but did not participate in the Modified Photovoice project, will be invited to participate in a 3-day digital storytelling project. A skilled facilitator will guide participants through a process of storytelling combined with technology and digital media to create a 1-3 minute video. Open-ended interviews will be conducted with participants one week after video completion. These interviews will be audio recorded and transcribed to identify relevant themes. Participants will be invited to present their videos to the Community Action Board and discuss their experience with the process.

In phase 2, we will conduct a randomized controlled trial with up to 210 participants for the 16 week intervention.

Recruited participants will be screened using a set of entry criteria, including a BMI between 30 and 55, and one criterion for metabolic syndrome (e.g. triglycerides, HDL, blood pressure, fasting blood glucose). Patients cannot already have received a diagnosis of Type II diabetes (among other exclusionary criteria). Potentially eligible patients complete a written consent process which includes a thorough presentation of the study's purpose, procedures, and potential risks & benefits.

- 1) Participants will be referred or self-referred to the study.
- 2) Initial Screen (self-report): Conducted either in-person or by phone.
- 3) Clinical Screen*: In-person verification of eligibility measurements (ie. Weight and lab measurements). *The clinical screen can be skipped if clinical values <3 months are available (ie. weight and lab measurements)
- 4) Consent: Written, informed consent will be obtained

Participants will be recruited by Timpany Center staff and community members. If they are otherwise eligible except that some of their information is more than 3 months old, we will conduct a clinical screening to collect recent blood pressure, and blood test for cholesterol and blood sugar. They will consent in- person for the clinical screening. Eligible participants will receive an explanation about the study and sign the full study consent form. After signing the consent form, the participant completes baseline data collection. This includes an interviewer administered questionnaire, a blood test, clinical measurements, and wearing a pedometer for 7 days. After all baseline data is collected, the participant is randomly assigned to ONE of two groups: 1) diabetes prevention program (DPP) or 2) enhanced diabetes prevention program (DPP+).

There are 102 people in the standard DPP and 102 people in the enhanced diabetes prevention program to address historical trauma (DPP+). Participants will complete 3 evaluations during the research study: baseline, 5 months (1 week following the conclusion of intervention). Participants enrolled in the last cohorts will not have as many follow-up evaluations as those enrolled in initial cohorts. The evaluations include blood draws, other measurements (blood pressure, height, weight, and waist circumference), and a series of questionnaires. Blood samples and other measurements will be collected at all of the evaluation visits (baseline, 5 months, 8 months, 14 months, and 20 months) after a more than 8 hour fast. The volume of most blood samples will be 20 cc's (approximately 1.5 tablespoons). Any samples left over after analysis will be destroyed when the study is completed. Questionnaires include a series of questions about their eating patterns, physical activity habits, smoking status, past medical history, current medications, use of additional health care resources, resilience, and emotional status. Questionnaires will be filled out at the clinic visits at baseline, 5 months, 8 months, 14 months, and 20 months.

b. Procedure Risks

We have designed this study to be least risky through the following means:

- 1) The intervention targets improvement of behaviors (diet, exercise, stress reduction) that can help decrease weight; thereby, decreasing the chance of cardiovascular disease.
- 2) The intervention recommendations are based on accepted clinical guidelines.
- 3) The intervention builds on previous trials conducted by key investigators on this project.

c. Use of Deception in the Study:

Deception will not be used in the research study.

d. Use of Audio and Video Recordings

We may use audio recording or video recording for Talking Circles, Modified Photovoice, Digital Storytelling, CAB meetings, and intervention classes for research purposes to analyze transcribed data and for educational purposes in order to review how the health educators are presenting the protocol to the participants. We may also use audio recording for interviewing participants about how they feel about the health education they receive.

We will also use camera pictures (and accompanying written or audio narrative) and video footage created by participants to share cultural stories, and perceptions of health needs and assets in the AIAN community. Audio recordings from interview debriefings will be destroyed once they have been transcribed. Photos, videos, and accompanying audio from Modified Photo Voice and Digital Storytelling maybe used for educational purposes, such as during community presentations or scientific meetings and

conferences. Photos, videos, and audio will not be linked to individuals unless we have received express written approval to use the media for a given purpose.

e. Alternative Procedures or Courses of Treatment

Standard treatments for weight management and diabetes prevention will be described to all participants. This program utilizes existing standards of care. No standard treatment is being withheld. The alternative is not to participate and to individually pursue an exercise program(s), work with a personal trainer, or consult with a dietitian on diet modifications.

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

If funding allows, we will continue with the enhanced diabetes prevention program. However, the enhanced components of the program may not typically be covered by the Indian Health Center of Santa Clara Valley, so we do not guarantee it.

g. Study Endpoint(s)

Because our primary end point is increased resilience and weight loss for diabetes prevention, we do not expect any adverse events to cause us to terminate the study early. We plan to continue the study for the full 20 months and provide participants with the opportunity to participate in several follow-up focus groups to contextualize study results.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

AIANs are more than twice as likely to be diagnosed with diabetes compared to white Americans (8% vs. 18%). Additionally, compared to non-Hispanic whites, AIANs have high rates of depression symptoms (e.g., sadness some of the time 14% vs. 8%), any illicit drug use (18% vs. 9%), 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%), and serious psychological distress (5.2% vs. 3.1%). AIAN scholars have described the cumulative effects of the hardships AIANs have experienced over the centuries as historical and intergenerational trauma. Although diabetes and historical trauma have been researched separately, very little research exists on the conceptualization or measurement of trauma as it relates to metabolic outcomes.

b. Findings from Past Animal Experiments

NA

4. PARTICIPANT POPULATION

a. Planned Enrollment

For Talking Circles:

- i. 10-15
- ii. 10-15

iii. We will enroll talking circle participants based on the following criteria:

- a. self-identified AIAN

For Modified Photovoice Project

- i. 10-15

ii. 10-15

iii. We will enroll 10 AIAN community members who participated in the talking circles

For the Digital Storytelling Project

i. 10-15

ii. 10-15

iii. We will enroll 10 AIAN community members who participated in the talking circles but not the photovoice project

For the Randomized Controlled Trial (RCT)

i. Up to 210

ii. Up to 210

iii. We will enroll AIAN adults who have a BMI between 30 and 55 and at least 1 risk factor for metabolic syndrome as the ultimate goal of the study is to prevent diabetes in AIAN populations.

b. Age, Gender, and Ethnic Background

i. Older than 21

ii. Men and Women

iii. Self-identified as AIAN

c. Vulnerable Populations

We are working with an AIAN population that may include participants who are economically disadvantaged. The reason for working with these participants is because diabetes is disproportionately prevalent among low-socioeconomic status (SES) and racial/ethnic minority populations in the United States (US), which is why we are trying to improve health care for this population

d. Rationale for Exclusion of Certain Populations

The study is not including children because the focus of our research is diabetes prevention which has a low prevalence among children. Those children with the disease likely necessitate unique intervention strategies not present in our research.

e. Stanford Populations

NA

f. Healthy Volunteers

Up to 210 healthy volunteers may be included in the randomized controlled trial. The study aims to promote healthy lifestyles in people who are at increased risk for diabetes. Other than obesity and risk factors for diabetes, the participants should be generally healthy. The volunteers will not be exposed to any additional risks or harm.

g. Recruitment Details

Timpany Center staff will recruit participants from the center and surrounding community. They will advertise and recruit for the study at cultural events. Staff will: 1) utilize clinical records to identify patients who meet the eligibility criteria; 2) meet with clinical providers and ask them to refer potentially eligible patients; 3) attend numerous AIAN cultural events such as Pow Wows; 4) reach out to public schools in San Jose with the highest concentration of AIAN children.

Talking Circles

We will recruit 10-15 participants for 5 talking circles. We will recruit participants who have expressed an interest in the health of urban AIAN such as IHC staff, founding members and board members, as well as service users and illness survivors .

Modified Photovoice

We will recruit 10 AIAN community members who also participated in the talking circles.

Digital Storytelling

We will recruit 10 AIAN community members who participated in the talking circles but not the modified photovoice.

Randomized Controlled Trial

We will recruit up to 210 AIAN adults who have a BMI between 30 and 55 and at least 1 risk factor for metabolic syndrome. The study will be open to the general public.

h. Eligibility Criteria

i. Inclusion Criteria

Inclusion for Talking Circles

- i. Self-Identified AIAN
- ii. Experience with the historical psychosocial stressors faced by AIANs

Inclusion for Modified Photovoice

- i. 10 participants from the talking circles

Inclusion for Digital Storytelling

- i. 10 participants from the talking circle who did not participate in the modified photovoice

Inclusion for Randomized Controlled Trial

- i. Self-identified urban AIAN men and women
- ii. BMI Between 30-55
- iii. Not diagnosed with Type II Diabetes
- iv. At least one of the following criteria
 - a. Triglycerides: 150mg/dL or higher
 - b. Reduced HDL: <40mg/dL (men); <50mg/dL (women)
 - c. Blood pressure: >130/80 or current treatment with antihypertensives
 - d. Fasting glucose: >100mg/dL

ii. Exclusion Criteria

Exclusion criteria for Randomized Controlled Trial

- i. Significant medical comorbidities, including uncontrolled metabolic disorders (e.g., thyroid, diabetes, renal, liver), unstable heart disease, heart failure, and ongoing substance abuse;
- ii. On greater than 10 prescription medications;
- iii. Psychiatric disorders requiring atypical antipsychotics or multiple medications;
- iv. Inappropriate for moderate exercise according to the Revised Physical Activity Readiness Questionnaire;
- v. Pregnant, planning to become pregnant, or lactating;
- vi. Family household member already enrolled in the study;
- vii. Already enrolled or planning to enroll in a clinical trial that would limit full participation in the

study;

- viii. Resident of a long- term care facility;
- ix. Lack of spoken English by patient or a household member > 18 y who can serve as interpreter;
- x. Plans to move during the study period (9 months post-randomization);
- xi. Investigator discretion for clinical safety or adherence reasons (e.g., unstable housing, chronic pain).

i. Screening Procedures

Exclusion criteria for Randomized Controlled Trial

- i. Significant medical comorbidities, including uncontrolled metabolic disorders (e.g., thyroid, diabetes, renal, liver), unstable heart disease, heart failure, and ongoing substance abuse;
- ii. On greater than 10 prescription medications;
- iii. Psychiatric disorders requiring atypical antipsychotics or multiple medications;
- iv. Inappropriate for moderate exercise according to the Revised Physical Activity Readiness Questionnaire;
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- x. Plans to move during the study period (9 months post-randomization);
- xi. Investigator discretion for clinical safety or adherence reasons (e.g., unstable housing, chronic pain).

j. Participation in Multiple Protocols

Participants will be asked about participation in other studies during the screening process. If they are in another study, they will need to gain approval from both study protocol directors to remain in both studies. Additionally, they will be asked to inform study researchers if they join another study during the duration of their participation in this study.

k. Payments to Participants

Participants in the RCT will receive payment in form of incentives, such as running shoes and farmer's market vouchers. Individuals will receive a gift card for \$20 or equivalent incentive valued at \$20 and a T-shirt valued at \$10 upon completion of the assessment. To promote retention, participants who express that transportation is a barrier will be offered assistance with transportation in the form of bus passes or taxi rides, depending on their circumstances.

l. Costs to Participants

There will be no costs to the subjects for the diabetes prevention intervention.

m. Planned Duration of the Study

The intervention will be conducted over 20 weeks. We anticipate the screening of participants will take 1 hour. Active participation in the study will take a minimum of 2 hours a week for participation in group sessions and 1.5 hours for each evaluation. Participants may decide to

make healthy lifestyle changes, such as increasing their physical activity levels as a result of participating in the study. Finally, we anticipate analysis of participant data will take 3 months.

5. RISKS

a. Potential Risks

i. Investigational devices

NA

ii. Investigational drugs

NA

iii. Commercially available drugs, biologics, reagents or chemicals

NA

iv. Procedures

NA

v. Radioisotopes/radiation-producing machines

NA

vi. Physical well-being:

Randomization to the usual diabetes prevention program (DPP) could improve physical well-being while randomization to the enhanced DDP (DPP+) has greater potential to improve physical well-being.

vii. Psychological well-being

Randomization to the usual diabetes prevention program (DPP) could improve physical well-being while randomization to the enhanced DDP (DPP+) has greater potential to improve psychological well-being.

viii. Economic well-being

Randomization to the usual diabetes prevention program (DPP) could improve economic well-being while randomization to enhanced DDP could improve long-term economic well-being by reducing the chance of costly obesity-related illness.

ix. Social well-being

Randomization to the usual diabetes prevention program (DPP) could improve social well-being while randomization to enhanced DDP could also improve social well-being. However, randomization to both groups could also negatively affect social well-being if someone in the participant's social circle reacts negatively to the participant trying to make healthy changes.

x. Overall evaluation of risk

Low - innocuous procedures such as phlebotomy, urine or stool collection, no therapeutic agent, or safe therapeutic agent such as the use of an FDA approved drug or device.

- b. International Research Risk Procedures
NA
- c. Procedures to Minimize Risk

For Aims 1 and 2, participants will be made aware that they will be audio-taped and that these tapes will be analyzed without identifiable information. Participants will be allowed to discontinue participation at any time if they are uncomfortable. They can also elect to not participate in any portion of the study protocol. For the RCT, participants will be made aware of the study protocol through the informed consent process. The IHC DPP staff members and the Steering Committee will take time to discuss the meaning of participation, including the potential risks, and potential benefits. In addition, the research team will monitor all SAEs and follow appropriate reporting mechanisms. The study will also include a Data and Safety Monitoring Board (DSMB) to monitor and minimize risks to participants. This careful consent process, monitoring of SAEs, and oversight provided by the DSMB are the planned procedures for protecting against and minimizing all potential risks.

- d. Study Conclusion

We will terminate the study if regular comparison analysis shows that the study poses harm to an intervention group. However, because the study is using behavioral change for weight-loss, the chance of termination is remote. In the event of adverse effects, we will have referrals to nurse practitioner as well as primary care physicians.

- e. Data Safety Monitoring Plan (DSMC)
 - i. Data and/or events subject to review:
Data Monitoring Board members:
 - Board members include:
 - Veronica Yank, MD
 - Mike Baiocchi, PhD
 - Virgil Moorehead, PhD
 - Steve Adelsheim, MD
 - ii. Frequency of DSMB meetings
 - DSMB meetings are schedule annually or on an ad hoc basis when needed.
 - iii. Specific triggers or stopping rules
 - There were not triggers or stopping rules.
 - iv. DSMB Reporting
 - Reporting: Hayley Hedlin, PhD
 - v. Will the Protocol Director be the only monitoring entity? (Y/N)
N
 - vi. Will a board, committee, or safety monitor be responsible for study monitoring? (Y/N)
Y

f. Risks to Special Populations

NA

6. BENEFITS

Subjects may experience the benefit of better health behavior and the Timpany Center may have improved ability to address the diabetes epidemic

7. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.