American Journal of Men's Health
July-August 1–12

DOI: 10.1177/1557988320945457
journals.sagepub.com/home/jmh
SAGE

Strong Men, Strong Communities: Design of a Randomized Controlled Trial of a Diabetes Prevention Intervention for American Indian and Alaska Native Men

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Abstract

Type 2 diabetes is a serious global epidemic that disproportionately affects disadvantaged populations. American Indians and Alaska Natives (AIs/ANs) have the highest rates of diabetes in the nation with a prevalence of 14.7% in 2018, more than twice that of non-Hispanic Whites. AI/AN men have the highest prevalence of diagnosed type 2 diabetes (14.5%) compared to non-Hispanic Black (11.4%), non-Hispanic Asian (10.0%), and non-Hispanic White (8.6%) men. Several landmark clinical trials have shown that lifestyle interventions can effectively prevent or delay the onset of diabetes among those at risk, including in AIs/ANs. Despite positive outcomes for AIs/ANs in these studies, very few were men. To date, there have been no concerted efforts to recruit and retain AI/AN men in interventions that promote weight loss and healthy lifestyles to prevent diabetes, and they remain underrepresented in these types of studies. This article describes the design and methods of the first randomized controlled trial of a diabetes prevention program with a study sample comprised entirely of AI/AN men. Research to date has demonstrated suboptimal patterns of recruitment and retention of AI/AN men, resulting in their virtual absence in health and intervention research. Effective methods to recruit and retain AI/AN men, and potential benefit gained from participation in diabetes prevention research, are unknown for this population who experience a high prevalence of type 2 diabetes. The study design presented in this article offers promising insights to help remedy these important shortcomings in the science of recruitment and retention of AI/AN men in research.

Keywords

Culture, general health and wellness, health inequality/disparity, health-care issues, behavioral research, research, American Indian, diabetes prevention

Received March 4, 2020; revised June 29, 2020; accepted June 30, 2020

Type 2 diabetes is a serious global epidemic that disproportionately affects disadvantaged populations. Minority groups constitute 25% of all adults with diabetes in the United States (U.S. Department of Health and Human Services, 2010). In particular, American Indians and Alaska Natives (AIs/ANs) have the highest rates of diabetes in the nation with a prevalence of 14.7% in 2018, more than twice that of non-Hispanic Whites (Centers for Disease Control and Prevention, 2020). The number of men with type 2 diabetes has steadily climbed in recent years, presenting a substantial public health problem producing excess morbidity, mortality (Yu & Suissa, 2016),

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and overall health-care costs of $327 billion (American Diabetes Association, 2018). Men from racial and ethnic groups in the United States experience a disproportionate burden of type 2 diabetes (Centers for Disease Control and Prevention, 2019). AI/AN men have the highest prevalence of diagnosed type 2 diabetes (14.5%) compared to non-Hispanic Black (11.4%), non-Hispanic Asian (10.0%), and non-Hispanic White (8.6%) men (Centers for Disease Control and Prevention, 2020).

Landmark clinical trials, such as the U.S. Diabetes Prevention Program (DPP), have shown that lifestyle interventions can effectively prevent or delay the onset of diabetes among those at risk (Knowler et al., 2002; Tuomilehto et al., 2001). The Special Diabetes Program for Indians – Diabetes Prevention (SDPI-DP) is the largest DPP translation effort for an ethnic minority group (i.e., AIs/ANs) in the United States, and it was largely successful (Jiang et al., 2013). Furthermore, long-term follow-up of these randomized clinical trials has demonstrated that lifestyle interventions can yield sustained risk reduction in diabetes incidence over a long time period, even 15–20 years after the intensive phase of the intervention (Diabetes Prevention Program Research Group, 2015; Jiang et al., 2018; Knowler et al., 2009; Lindstrom et al., 2006).

Despite positive outcomes experienced by AIs/ANs in the SDPI, very few were men. Only 25% of 2,553 AI/AN participants were men and there was significant loss to follow-up, particularly among men (Jiang et al., 2013). To date, there have been no concerted efforts to recruit and retain AI/AN men in interventions that promote weight loss and healthy lifestyles to prevent diabetes. AI/AN men remain underrepresented in these types of interventions (Rounds & Harvey, 2019). The high prevalence of type 2 diabetes in AI/AN men and their underrepresentation in diabetes prevention interventions underscores the importance of developing tailored recruitment and retention strategies to effectively engage AI/AN men in diabetes prevention research.

Men of all races are underrepresented in randomized controlled trials of lifestyle interventions. On average, men account for only 27% of participants across 244 studies (Pagoto et al., 2012). Extant literature offers little guidance on effective strategies to increase recruitment or retention of men in lifestyle interventions, although many explanations have been posited for the low participation rates among men of all races (Pagoto et al., 2012; Taylor et al., 2013). For example, men's perceptions of normative health behaviors and social roles may influence their participation in lifestyle interventions, particularly in male–female groups (Mroz et al., 2011; Taylor et al., 2013). These perceptions, combined with attitudes about masculinity and male–female relations, may also affect participation in lifestyle interventions (Mroz et al., 2011). In one study, perceptions of masculinity and the normativity of other men's health behaviors significantly predicted participants' own health behaviors, beyond sociodemographic factors (Mahalik et al., 2007). These findings suggest that traditional masculine roles and social norms encourage men to put their health at risk (Williams, 2008). No studies have explored why AI/AN men do, or do not, choose to participate in lifestyle interventions.

Health behaviors of AI/AN men, including recruitment and retention patterns in health interventions, exist in the context of historical, intergenerational, and contemporary experiences of colonization and colonial trauma responses (Evans-Campbell, 2008; Gonzales et al., 2018; Paradies, 2016). Numerous studies with AIs/ANs show that psychosocial stress responses to colonial trauma may have important impacts on retention, health-care utilization, and achievement of therapeutic outcomes promoted in health interventions (Gonzales et al., 2014, 2018; Jacob et al., 2015; Walls & Whitbeck, 2012). A recent study conducted among AIs/ANs enrolled in a culturally informed diabetes prevention program demonstrated that colonial trauma adversely impacted retention and intervention outcomes (Gonzales, forthcoming) (Gonzales et al., forthcoming).

This article describes the design and methods of the first randomized controlled trial of a diabetes prevention program with a study sample comprised entirely of AI/AN men. Research to date has demonstrated suboptimal patterns of recruitment and retention of AI/AN men, resulting in their virtual absence in health research. Effective methods to recruit and retain AI/AN men, and potential benefit gained from participation in diabetes prevention research, are unknown for this population who experience a high prevalence of type 2 diabetes. The study design presented in this article offers promising and rare insights to help remedy these important shortcomings in the science of recruitment and retention of AI/AN men in research. Such information is highly warranted, particularly because AI/AN men experience health as a socially racialized and oppressed group whose health is deeply rooted in the enduring legacy of colonization—a traumatizing act of foreign invasion and cultural genocide. Ongoing colonial violence that contemporary AI/AN men experience continues to disrupt their relationship with traditional values, cultural practices, and ancestral knowledge that previously guided AI/AN men's journeys to manhood and warrior status. Culturally and contextually tailored approaches, like those described in this article, are required for research with AI/AN men since methods used with other populations would likely yield information that is misguided and ineffective. The exclusive focus on AI/AN men's health in a culturally safe environment (Curtis et al., 2019), where experiences of historical and contemporary

trauma can be acknowledged and validated, may serve as a starting point to mitigate the effects of settler colonial practices (Brave Heart, 1999). Therefore, this article provides information that may elucidate effective ways to recruit and retain AI/AN men in health research and build a new understanding of a pathway to health equity for AI/AN men.

Methods

Study Aims

There are three specific aims that the Strong Men, Strong Communities (SMSC) study addresses. They are to (a) refine the SMSC intervention in response to feedback from focus groups in three recruitment sites, (b) compare change in diabetes risk scores (primary outcome) and modifiable diabetes risk factors (secondary outcomes) between the intervention and waiting list control groups, (c) evaluate the ability of SMSC to retain 80% of 240 AI male participants aged 18–75 years with no previous diagnosis of type 1 or type 2 diabetes.

Overview and Study Design

The SMSC study is a blocked partially clustered randomized controlled trial to compare the effects of the SMSC between two groups: intervention and waiting list control group. The study title reflects a strengths-based, rather than a deficits-based, perspective or disease focus. Washington State University has partnered with AI-/AN-serving organizations located in three cities with large AI/AN populations to conduct the study: Minneapolis, Minnesota; Portland, Oregon; and Phoenix, Arizona. Cohorts of 8–12 AI/AN men are recruited concurrently in each recruitment site. Following written informed consent and the baseline data collection, men are randomized to either the intervention or the waiting list group. Data is collected at four timepoints (baseline, 3, 6, and 12 months after intervention). Men in the waiting list group receive the SMSC intervention following the 6-month data collection to reduce loss to follow-up, which may be more likely if they have to wait 12 months to receive the intervention. Therefore, between-group comparisons will not be made at 12 months. Research staff in all three study sites and the principal investigator (first author) are American Indian. The Washington State University Institutional Review Board approved this study (Approval # 15348).

The SMSC intervention is a modified version of the 22-session Group Lifestyle Balance (GLB) program (Kramer et al., 2009), which is modeled closely on the original 28-session DPP (Diabetes Prevention Program Research Group, 2002; Knowler et al., 2002). The GLB consists of 12 weekly core sessions and 10 biweekly maintenance sessions delivered in a group format rather than the individual format of the DPP. For SMSC, the GLB has been adapted to appeal to AI/AN men and includes peer-led physical activity in each session. The SMSC intervention is delivered in 18 group-administered sessions, called "men's gatherings" rather than classes or sessions. The SMSC intervention goals are to increase moderate-intensity physical activity to at least 150 min per week and achieve a 7% weight loss from baseline weight. Incentives include gift cards of local stores, items that are relevant to session topics, and sponsoring local events that men are interested in, such as sporting events, hiking, and cultural activities.

Sampling Design

AI/AN men between the ages of 18 and 75 years who live in one of the 3 study sites are recruited for the SMSC. Additional eligibility criteria are those with a baseline body mass index of $\geq$25 kg/m^2 and who do not self-report a physician diagnosis of type 1 or type 2 diabetes.

Power Analysis and Sample Size

For Aim 1, previous research that engaged AI/AN in an intervention with similar design and aims (Jiang et al., 2013) suggests that a sample size of 240 men will provide ~80% power to detect a difference of 0.40 in the Diabetes Risk Score for the intervention and control arms for the primary outcome of change in Diabetes Risk Score. For Aim 2, power was estimated using the *clsampsi* command in STATA (StataCorp LLC, College Station, TX) and was based on the following assumptions: 12 clusters of size 10 in the intervention group, 120 clusters of size 1 in the control group, alpha = 0.05, and an intraclass correlation coefficient = 0.03 in the intervention group. Loss to follow-up of approximately 20% increases the minimum detectable difference to 0.44. Power for secondary outcomes varies, but, as an example, the study will have excellent power (~94%) to detect a 0.5 *SD* difference in fasting glucose between the intervention and control groups. For Aim 3, the precision (width) of the confidence interval for the proportion of retained participants has a range of $\pm$4%–8%, depending on the reduction in effective sample size and the actual proportion retained.

Recruitment Procedures

AI/AN staff in each site use active and passive recruitment strategies. Active approaches include meeting directly with potential participants at local health fairs, powwows, and sporting events and with individuals who

may know potential participants (i.e., presenting information about the study to community organizations). Passive recruitment efforts include local media releases (print, radio), word of mouth, and social media (e.g., Facebook). All study advertisements include a brief description of the SMSC study for AI/AN men, eligibility criteria, and staff contact information. Snowball sampling (Fowler, 2014), whereby participants earn a $50 store gift card for referrals of other men who are eligible to participate and enroll in the study, is also used to recruit AI/AN men.

Retention Strategies

Incentives—A store gift card is offered to participants for each data collection visit: $25 for baseline, $50 for 3-month follow-up; $75 for 6-month follow-up, and $100 for 12-month follow-up. A light meal is served at each intervention session, and when available, wild game, salmon, trout, wild rice, or other traditional AI/AN foods are offered. Public transportation vouchers for travel to and from the study sites are offered to participants who request them. Incentives related to the topic of each session (i.e., water bottles and logbooks with the study logo, digital weigh scales, measuring cups, stretch bands, etc.) are offered at intervention sessions. Participants are actively engaged with other men in their cohort in identifying the types of cultural and physical activities they are interested in doing, either during or after intervention sessions, budget permitting.

Reminders—Multiple methods are used to maintain contact with participants including documentation of work, home, and cell phone numbers, home and email addresses, confirming whether text messages will be accepted, and obtaining contact information of friends, relatives, or coworkers who will know how to contact them if their phone service is terminated or mailing address changes. Participants receive reminder telephone calls, text messages, and/or emails 2 days prior to and the day of each intervention session and data collection appointment. Participants who miss a session receive a phone call from the peer educator; the peer educator lets them know they were missed, asks why the session was missed for tracking purposes, and provides a reminder for the next session.

Randomization

After cohorts of 8–12 AI/AN men complete their baseline assessment, they are block randomized into the two conditions using the cohort as a block. Microsoft Excel is used to randomly assign participants to one of the two groups. Men randomized to the intervention group begin the SMSC sessions within 1 week after randomization.

SMSC Intervention Development, Materials, and Methods

The SMSC intervention is a modified version of the GLB curriculum (Kramer et al., 2009; Seidel et al., 2008; http://www.diabetesprevention.pitt.edu/index.php/group-lifestyle-balance-materials/) that was adapted from the original DPP (Diabetes Prevention Program Research Group, 2002). Social Cognitive Theory (Bandura, 1986) informed the DPP and GLB interventions and both programs include behavioral strategies, such as dietary and physical activity self-monitoring, participant self-weighing, goal-setting, and behavioral modification for weight loss and physical activity (Diabetes Prevention Program Research Group, 2002). The SMSC intervention retained the curriculum topics, content, goals for physical activity and weight loss, Social Cognitive Theory as the behavior change theory, and behavioral strategies from the GLB program.

Adaptations for the SMSC intervention were informed by focus groups conducted with 193 AI/AN men in the 3 recruitment sites (paper forthcoming). Review of adapted materials and methods was performed by seven AI/AN men who reside in one of the three recruitment sites. In the focus groups, participants discussed multilevel facilitators and challenges to healthy eating, physical activity, and weight loss. Men favored a group-based format for sessions to facilitate social support and to offer the program in a convenient community location by an AI/AN man. Using the term "men's gatherings" was preferred to "class" or "session" as these terms are associated with settler colonial schools or mental health sessions. In addition to education about healthy eating and facilitated physical activity, men recommended allowing time to discuss the effects of colonization on AI/AN men's health and ways to heal trauma brought about by settler colonialism and provide cultural activities that would reinforce a positive AI/AN identity and support cultural resilience.

Information learned from the focus groups was incorporated into the SMSC materials and methods to ensure cultural and contextual relevance. For example, strategies to address challenges to healthy eating identified in the focus groups are included in the curriculum. These include how to shop for healthy foods on a budget, how to eat healthy when eating out, and healthier choices at fast-food establishments. In addition, peer educators invite AI/AN guests to attend some of the gatherings to discuss their life experiences, trauma, their path to healthy living, and AI/AN values that guided their journey. Sociocultural strategies, which present health in the context of cultural values and characteristics of the participants, were incorporated into the SMSC intervention to increase salience. For example, stories shared by invited AI/AN guests (e.g., healthy role models) about making

healthy eating and physical activity part of their healing, and participants sharing their successes, reinforce the tradition of good health in AI/AN communities. Images of AI/AN men and families engaging in healthy eating and physical activities were included in curriculum materials to convey relevance to participants.

Format: The SMSC intervention is delivered in a total of 18 sessions, with 12 weekly group gatherings of AI/AN men, followed by 6 biweekly maintenance gatherings that reinforce the same content with a focus on continuing healthy lifestyle changes. Men sign in and weigh themselves on a digital scale at the beginning of each gathering. Participants meet at a community location for about 1 hr to review the SMSC curriculum content and engage in peer-led physical activity. A light meal is offered at the end of the session.

Content: The interactive SMSC curriculum content (Table 1) promotes goals of increasing moderate-intensity physical activity to at least 150 min per week and achieving a 7% weight loss by the end of the 12-month intervention. The curriculum includes text, discussion, questions, role play, group activities, goal setting, home practice assignments, and handouts. At each gathering, the peer educator devotes time for participants to discuss successes and challenges to achieving their weekly goals, which provides an opportunity for men to share ideas, problem-solve, and support one another. Strategies are offered during each gathering that can help participants limit calories to 1,200–2,000 kcal/day and fat to 33–55 g/day and facilitate the loss of 1–2 pounds per week. However, goals are modified to support progress. Daily self-monitoring of dietary consumption, physical activity, and weight is encouraged, and participants receive feedback and coaching from the peer educators throughout the 12-month program. The interactive nature of the SMSC recognizes participants as having valuable information to share with each other. Peer educators also deliver at least 30 min of physical activity at each gathering. Local events sponsored by SMSC provide opportunities for the men to be active together, build camaraderie, and renew core values of AI/AN men. Family members are invited to participate in the physical and cultural activities.

Session Delivery: The SMSC intervention is designed to be delivered to groups of 8–12 AI/AN men in a community setting. All men's gatherings are facilitated by AI/AN male peer educators from the participating communities. The peer educators were trained to deliver the SMSC curriculum and to provide support and encouragement for healthy lifestyles. Peer educators follow a facilitator's manual to standardize the intervention, but they use "local" language and examples to increase relevance. Intervention sessions are scheduled to meet the needs of as many participants as possible and within the operating hours of partner organizations. Evening sessions after 5 p.m. and weekend sessions are offered as often as possible within each site. One makeup session is offered for each class. If a participant is unable to attend a group gathering or in-person makeup session, the peer educator provides a copy of the curriculum content to the participant and reviews it with him during a scheduled telephone call.

Maintenance Phase: The 6 biweekly maintenance gatherings are intended to help participants retain content beyond the 12 post-intervention sessions and provide opportunities for peer-led physical activity. The maintenance curriculum reviews principles and strategies from prior curriculum content and gives participants a chance to discuss continuing challenges and receive support for their efforts. Brief text messages of one to two sentences are also sent to intervention participants twice each week during the maintenance phase to reinforce and encourage healthy eating and physical activity. Maintenance gatherings are led by the original peer educator at the same community site during the originally scheduled time and day.

Intervention Fidelity Procedures

Several methods are in place to assure the integrity and validity of the SMSC intervention across three sites. The SMSC is a manualized intervention and group facilitation is guided by the detailed peer educator manual. Peer educators, and other site staff who perform recruitment and data collection, attended a series of standardized in-person and virtual training led by the Principal Investigator and university data management team. Training for SMSC included a detailed review of the SMSC manual of procedures including the informed consent process, data collection, study forms and tracking, and the SMSC lifestyle curriculum. Facilitation of several lifestyle sessions were modeled by the PI and followed by practice by peer educators. Data collection procedures were also modeled with site study staff to ensure consistency across sites. Study staff learned how to use Research Electronic Data Capture (REDCap; REDCap, 2020), a freely available secure web application for building and managing online surveys and databases, for data entry. Staff completed a competency exam with the university data manager to ensure data quality. Ongoing assistance is provided to site staff and weekly conference calls are used to ensure recruitment goals are met and troubleshoot intervention and/or staffing challenges. The PI and program manager also conduct site visits two to four times per year to attend sessions in each site and observe and record fidelity to the protocol and curriculum.

Measures

Data collection occurs at baseline, 3 months (post-lifestyle sessions), 6 months (post-maintenance phase), and

Table 1. Strong Men, Strong Communities Classes and Program Content.

SMSC Intervention classes	Class Topics
Week 1. Be Physically Active	• Overview of program and rationale • The benefits of physical activity • How to be active • Physical activity and weight loss goals • How to exercise safely • How to make time to be active • Ways to reach goals
Week 2. Develop Flexibility	• How to develop flexibility • Guidelines to increase your flexibility • What is functional range of motion • How to stretch muscles safely - facilitated examples
Week 3. Build Strength	• Resistance training to build muscular strength and endurance • Benefits of resistance training • Strength exercises without weights - facilitated examples • Mental strength can help keep you motivated
Week 4. Increase Endurance	• Being a role model • Muscular and cardiorespiratory endurance • Aerobic activities • How much activity to do to lose weight • Powwow dancing – facilitated examples
Week 5. Eat Less Fat	• Thinking about calorie and fat intake in our diets • How much fat should we eat? • The importance of reading food labels • Know your portion sizes • Strategizing healthy eating • Three ways to eat less fat
Week 6. Take Charge of What's Around You	• Negative food cues • Adding positive cues and changing habits • Activity cues • Make a plan to shop
Week 7. Manage Stress and Problem Solve	• More ways to lose weight • How many calories are burned with exercise • Healthy ways to manage stress • How to problem solve when challenges to healthy eating and physical activity come up
Week 8. Eat Healthy when Eating Out	• Reframing when eating out • Plan ahead before you eat out • How to make healthy choices when eating out • Create healthy social cues
Week 9. Stay Motivated	• Break the negative thought cycle • Focus on the positive • Think about what to do after a slip-up • Fight boredom to stay motivated • Practice positive thinking
Week 10. Healthy Families, Healthy Communities	• Benefits of family support for healthy eating and physical activity • How to ask for support • Family values can help you reach your goals • Set family lifestyle goals • Community resources
Week 11	Review of main points of class 1–5 and Facilitated physical activity
Week 12	Review of main points of class 6–9 and Facilitated physical activity
Maintenance Phase (bi-weekly classes for 3 months)	
Week 13	Facilitated physical activity and/or cultural activity
Week 14	Facilitated physical activity and/or cultural activity
Week 15	Facilitated physical activity and/or cultural activity

(continued)

Table 1. (continued)

Maintenance Phase (bi-weekly classes for 3 months)	
Week 16	Facilitated physical activity and/or cultural activity
Week 17	Facilitated physical activity and/or cultural activity
Week 18	Facilitated physical activity and/or cultural activity
Maintenance Phase Text Messages (Sample of 6 of 24 text messages)	1. Congrats on completing the 3-month intervention phase! We are now entering the maintenance phase where you will receive text messages from us twice a week. 2. Exercise was a daily part of life for our ancestors. Try taking the stairs, parking further away and stretching at home to add movement to your daily routine. 3. You are the answer to your ancestor's prayers. You can honor them today by taking care of your body and getting your heart rate up with a good workout! 4. Chips, soda, and fried foods were not a part of our ancestors' diets. You can replace with modern day adaptations, such as beef jerky, mixed nuts and berries. 5. Native foods are naturally low in fat and can help us connect with our ancestors. 6. Know and recognize your food cues (i.e.: eating chips while watching TV) and try to build healthier habits.

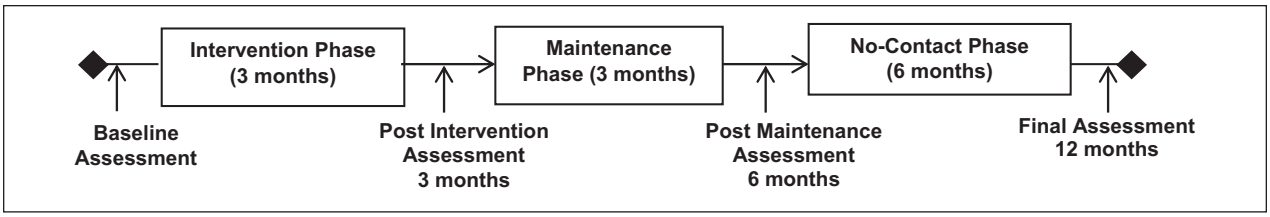

Figure 1. Strong Men, Strong Communities intervention and assessment timeline.

12 months (Figure 1). The SMSC survey is completed by participants in REDCap on a laptop at the data collection site and reviewed for completeness by study staff. This method is most effective for ensuring that all items are completed accurately and questions men may have about question meaning can be immediately answered.

Primary outcome measures are *weight* and *Diabetes Risk Score* (Strong Heart Study, 2011), which is a prediction equation for incident diabetes; specifically, it predicts the risk of type 2 diabetes in the next 4 years for someone who does not currently have diabetes. It was designed for AIs/ANs aged ≥35 years and is based on the following variables: sex, age, waist circumference, hypertension medication (yes/no), systolic and diastolic blood pressure, sisters or brothers with diabetes (yes/no), fasting glucose, A1C, triglycerides, and ratio of urinary albumin and creatinine. A fingerstick sample of blood is collected to assess A1C, glucose, and lipids. A urine sample is collected from each participant for the microalbumin/creatinine test. Blood glucose and plasma levels of high-density lipoprotein (HDL), low-density lipoprotein (LDL), triglycerides, and total cholesterol are measured using the Cholestech LDX System, which measures a complete lipid profile plus glucose in 5 min from a simple fingerstick. The DCA 2000 measures A1C and the microalbumin/creatinine assay measures albumin, creatinine, and the ratio of the two values. Results of the DCA 2000 tests are available in about 6 min. Systolic and diastolic blood pressure are measured twice using an automatic blood pressure cuff and the results are averaged for analysis. Waist circumference is measured and recorded twice using a cloth tape measure. The waist is defined as the midpoint between the highest point of the iliac crest and the lowest point of the costal margin at the midaxillary line. Body weight (kg) and height (cm) are measured using an electronic scale (Tanita BWB800AS) and a stadiometer (Seca 222), respectively. At each timepoint, body weight is measured twice to the nearest 0.1 kg with the participant fully clothed and shoes off using a calibrated balance scale and the two results are averaged. Height is be measured twice to the nearest 0.5 cm with shoes off using a standardized stadiometer and the two results are averaged.

Secondary outcomes measures are change in the individual modifiable Diabetes Risk Score components (i.e., waist circumference, hypertension medication [yes/no], blood pressure, fasting glucose, A1C, triglycerides, and ratio of urinary albumin to creatinine). In addition, the National Cancer Institute's Fat Screener (National Cancer Institute, 1996) and Fruit and Vegetable Screener (National Cancer Institute, 1998) are used to assess dietary fat and consumption of fruits and vegetables.

Both instruments are one to three pages and include food types, frequency of consumption, and quantity. Change in body mass index (BMI) is assessed and computed as body weight in kilograms divided by height in meters squared. Physical activity is assessed with the Modifiable Activity Questionnaire (Pereira et al., 1997), which has previously been used in AI/AN communities (Kriska et al., 1990). Stages of change for diet and exercise and perceived benefits of and barriers to exercise and healthy eating are measured. A 22-item conformity to masculine norms questionnaire (Owen, 2011) is also included in the survey. A social support questionnaire is used to assess family and community support for healthy eating and exercise (Sallis et al., 1987).

Covariates include sociodemographic data such as age, educational attainment, marital status, health conditions, prescription medications, family history of chronic disease, annual household income, employment status, support for healthy eating and physical activity, and alcohol and tobacco use.

Retention is measured as total number of SMSC sessions and data collection visits attended in Months 1–3 (range = 0–12) and Months 4–6 (range = 0–6). Because SDPI-DP found that full participation in all sessions strongly predicted reduced diabetes incidence compared to anything less than full participation (Jiang et al., 2013), binary indicators of full participation in the intervention and maintenance phases will also be calculated. Study retention will be measured as the total number of follow-up data collection visits completed (range = 0–4 for intervention; 0–3 for control) and as binary indicators of completing each individual follow-up visit.

Enrollment Procedures

Interested AI/AN men are given an explanation of the SMSC study in person or over the phone. If still interested, men are screened for eligibility using a study eligibility form. Eligible men complete a written informed consent process and proceed to data collection procedures. Upon completion of data collection, men are randomized to either the intervention or waiting list control study arm. A cohort of 8–12 men are assigned to each condition.

Data Management

Tracking participants across multiple recruitment sites is complex and a very important component of this study. A REDCap database has been created to monitor and manage data collection and recruitment efforts. Participant data is collected via laptop computers through secure wireless internet connection directly into the password-protected REDCap database. If missing data is noted within a participant's study record, the data collection staff complete an interview correction form to capture the missing data. Monthly audits of data are performed by the university data manager.

Data Analytic Plan

For Aim 2, analyses will be based on the intent-to-treat principle. For the SMSC randomized controlled trial, the bivariate relationship between the intervention and all primary and secondary outcomes, as well as all potential covariates, will be examined using simple *t* tests for continuous measures and chi-square for categorical variables, in order to identify variables that may be unbalanced between treatment arms due to chance alone. Next, the diabetes risk score will be plotted according to time points separately in the intervention and control arms. This step will allow visualization of the data and help inform how best to model variables for inferential analyses. The study design in which the intervention is delivered as sessions to small groups of participants is an individually randomized group treatment design, also known as a partially clustered design. As such, there is the potential for correlation between participant outcomes to occur in the intervention group, but not in the waiting list control group since there is no corresponding session experience (Flight et al., 2016). Randomization to the intervention or waiting list control will occur independently at each site; thus the study is a blocked partially clustered design. Given this study design, a mixed effects model will be implemented with random intercept that allows for intra-cluster-level variance in the intervention group, but not in the control group. Restricted maximum likelihood (REML) will be used to estimate the covariance parameters. To estimate intervention effects at each of the 3-, 6-, and 12-month time points, the Diabetes Risk Score will be used at the time point as the model outcome and adjust for the baseline Diabetes Risk Score value. Models will include study site and participant age as covariates. If imbalances in other covariates are observed between the intervention and control groups, they may also be added to the models.

For Aim 3, participant retention will be examined in three ways: (a) The proportion of men who returned for all follow-up visits will be calculated, (b) the proportion of men in the intervention group who attended all intervention sessions will be computed, and (c) baseline characteristics associated with study completion and high rates of attendance will be evaluated. In the first step, the point estimate and 95% confidence interval will be calculated for the proportion of men who return for the 3-, 6-, and 12-month visits. All participants combined will be examined, and then the intervention and control groups will be examined separately. It is anticipated that the lower bound of the 95% confidence interval for the

intervention group will be higher than 80%, showing that most men in the intervention group were retained for the entire study. A chi-square test will be used to determine if retention differed between the intervention and control groups. In addition, the mean number of follow-up visits in the intervention and control groups will be calculated and compared using a *t* test.

Similar statistics for the 3-, 6-, and 12-month visits will be examined separately to see if a particular follow-up visit had lower attendance. The point estimate and 95% confidence interval will be computed for the proportion of men in the intervention group who attended all sessions. Similar statistics for the proportion of men who attended all sessions during the intervention (Months 1–3) and the maintenance phase (Months 4–6) will be examined. The mean number of intervention sessions attended will be computed. Finally, regression methods will be used to determine the association between study completion and baseline participant characteristics. Study completion will be defined in two ways: as number of completed follow-up visits (or binary indicator for completing all visits) when looking at men in the intervention and waiting list control groups and as number of intervention sessions attended (or binary indicator for attending all sessions) by men in the intervention group only. Models will be fit using baseline characteristics such as demographic and diabetes risk factors as independent variables. When examining the number of completed follow-up visits among all participants, a limited number of interaction terms will be included with treatment arm in the model to determine if baseline BMI, for example, has a larger impact on study completion in the intervention group than in the control group. Although the latter analyses will be considered exploratory, they will inform retention efforts in future studies.

Discussion

SMSC is the first study to exclusively recruit AI/AN men to participate in a culturally and contextually tailored diabetes prevention randomized controlled trial. The purpose of SMSC is not only to reduce the risk of developing type 2 diabetes but also to create a culturally safe environment for AI/AN men to work together in a contemporary reality to regenerate positive masculinities that may contribute to the restoration of health, well-being, and purpose.

During five centuries of settler colonial oppression, AI/AN men have faced disenfranchisement from society and self and been cut off from the traditional focus on community life (Krech, 2002). Settler colonialism remains in a position of power within the context of AI/AN health because it is a structure that largely remains invisible. Settler society creates and imposes narratives that are positioned to satisfy the needs of colonial settlers and the systems that keep settler colonialism protected and ongoing (Tuck & Yang, 2012). As a structure, settler colonialism is upheld through formal oppressive systems founded on capitalism, White superiority, competition, ownership, possession, and individualism. Like all systems of oppression that require denial of benefits to some, settler colonialism keeps AIs/ANs in a consistent cycle of trauma, abuse, and turmoil through policies, practices, and social norms that serve to position AIs/ANs as inferior and unworthy of investment.

Colonizing strategies, such as genocide, assimilation, forced removal, and termination, strip AIs/ANs *out* of the land and strip away the Indian *within them* (Simpson, 2014). Historical and intergenerational trauma resulting from the legacy of such colonizing strategies has eroded cultural systems by disrupting transmission of AI/AN knowledge and cultural practices from one generation to the next (Jacob, 2013). The impact of colonialism on the transmission of cultural knowledge is evident in the forced transformation of masculinity constructs within AI/AN culture (Norgaard, 2019). Forced gender construction based on Western values and maintained by land and cultural disruptions are powerful processes that continue to negatively impact AI/AN men's health (Norgaard, 2019).

Hence, pathways to health and thriving AI/AN communities, including chronic disease prevention, emerge from reclaiming traditional cultural understanding and practices related to becoming, and being, a strong AI/AN man. The processes of AI/AN resistance and resurgence are powerful responses to colonial violence and act to promote cultural resilience and sustain a cycle of strong AI/AN communities far into future generations. Such focus may provide positive impacts within the field of health research by addressing the limitations of current strategies for recruitment, retention, and outcomes related to the health and well-being of AI/AN men. Acknowledgment and understanding of the effects of settler colonialism, and implementation of strengths-based approaches that respond to colonial trauma and promote cultural resilience, can inform more effective strategies for recruitment and retention of AI/AN men in health research. Indeed, improving AI/AN health requires interventions that take into account the profound nature of settler colonialism and the importance of programs concerned with "making power" to reclaim AI/AN traditions and cultural practices (Jacob, 2013).

Current Challenges and Lessons Learned

Sociodemographic data indicate that the AI/AN population in the three recruitment sites experience significant inequities in education, employment, and income. For example, more than 30,000 AIs/ANs reside in Minneapolis

where almost one third live below the federal poverty level, 21% aged ≥25 years lack a high school degree or GED, and 19% of those aged ≥16 years are unemployed compared to 6.5% of the general population in the same area. The average poverty rate for AIs/ANs in Portland is 34% compared to 12% among Whites. More than half of AI/AN students do not graduate high school and the unemployment rate is 70% higher for AIs/ANs than for Whites in Portland (Coalition of Communities of Color & Portland State University). In Phoenix, 24% of AIs/ANs live below poverty level compared to 13% of the overall Phoenix population. AIs/ANs experience the lowest high school graduation rates (67%) compared to high school students of all other races/ethnicities in Arizona (80%; Arizona Department of Education, 2018). Data reporting unemployment for AIs/ANs in Phoenix are limited but unemployment is as high as 60% in some tribal communities in Arizona (Walter Cronkite School of Journalism and Mass Communication, 2018).

These social determinants of health affect participation and retention in research and health outcomes. Lack of money for transportation and continuous phone service and lack of stable housing and unemployment have limited the ability to recruit and retain many AI/AN men in the SMSC intervention. Vouchers for transportation are offered to men who request them. However, the study budget lacks enough funding to provide cell phones to participants. Recruitment staff often direct men to resources for housing and employment, but outcomes are variable. Some men travel from the city to their reservation and remain there for several months, making it impossible for them to attend the in-person intervention sessions.

In the early stages of the study, there was also significant loss to follow-up for data collection visits. The original plan provided a $25 gift card for each data collection visit. To reduce dropout and entice men to return for the follow-up data collection visits, the compensation for data collection visits was revised to $25 for baseline, $50 for 3 months, $75 for 6 months, and $100 for 12 months. The revised compensation has been more effective in getting men to return for data collection visits, particularly since some of the men are unemployed. Finally, the limited hours in which the intervention sessions are offered also impact participation and retention. For example, two partner organizations' regular business hours are 8:00 a.m. to 5:00 p.m. Monday through Friday, with no weekend days available. These hours are not convenient for men who work during this time.

Study Limitations

There are several limitations of this study. The methods used in this study may not be generalizable to AIs/ANs outside of the three recruitment sites or in rural tribal communities. The use of monetary incentives offered in the SMSC intervention are likely not sustainable in "real world" settings. Those who want to implement methods from this study may consider nonmonetary incentives or raffles to increase recruitment or improve retention. This study does not specifically address social determinants of health, such as education and employment, that recognizably affect AI/AN men's health and well-being. Unmet basic needs, that is, a steady income and stable housing, may limit interest in participating in a lifestyle intervention for some men. The SMSC study also does not address the limited infrastructure of men's health programs and services. However, peer educators offer information regarding needed resources, and implementation of SMSC provides the study's partner organizations the opportunity to create men's health programs.

In conclusion, this article describes the first randomized controlled trial that rigorously evaluates a diabetes prevention intervention designed specifically for AI/AN men. Given the disproportionate burden of type 2 diabetes among AI/AN men, it is essential to identify methods for their successful recruitment and retention in health research. The SMSC intervention supports positive behavior change in a culturally safe environment where healing from settler colonial practices may begin, and from it, strong and healthy AI/AN men can emerge. Despite several limitations, this study will illuminate the health needs of AI/AN men and effective approaches to engage them in health research.

Implications for Men's Health Equity

AI/AN men experience health as a socially racialized and oppressed group in which health is rooted in the enduring legacy of colonization. Historical and ongoing colonial settler practices have led to present-day social and health inequities, which are shamefully apparent in health data. These inequities have become normalized and accepted and essentially made AI/AN men "invisible" and unworthy of investment. AI/AN men have been habitually underrepresented in health research, and there is a paucity of literature that explains the disparity in participation in research or strategies to increase participation of AI/AN men. However, participation in health research is key to ameliorating health inequities and the impact of settler colonialism on the health trajectory of AI/AN men. The SMSC study will fill the void in knowledge about recruitment and retention approaches for AI/AN men from urban communities where more than 70% of AIs/ANs reside (U.S. Census Bureau, 2010). If effective, the study design and implementation have important implications for recruitment and retention of AI/AN men in health research. Broader and deliberate inclusion of AI/AN men in research may increase health equity by reducing premature morbidity and mortality and healthcare costs, thereby improving the quality of life of men

and their families. The SMSC intervention is only the first step toward health equity for AI/AN men and the responsibility to ensure inclusion of AI/AN men lies with the research community.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was made possible with support from the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) grant number R01DK102728.

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