STRONG MEN, STRONG COMMUNITIES: REVISION OF A DIABETES PREVENTION INTERVENTION FOR AMERICAN INDIAN AND ALASKA NATIVE MEN DURING THE COVID-19 PANDEMIC

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Abstract: This paper describes the revision of the in-person Strong Men, Strong Communities (SMSC) study to a remote protocol and highlights key successes, challenges, and critical lessons learned applicable to remote trial implementation. The SMSC study is the first randomized controlled trial to exclusively recruit American Indian and Alaska Native men into a diabetes prevention intervention. The five-year randomized controlled trial was in its 42nd month with 99 subjects enrolled when the COVID-19 pandemic ceased all in-person research. The study protocol was revised to accommodate remote implementation which required multiple protocol and procedural changes, including the use of Facebook for national recruitment of participants; alteration of the informed consent process; use of REDCap for independent participant completion of informed consent; revised eligibility criteria; and use of Zoom to deliver intervention classes. The remote study protocol proved superior to the in-person protocol in terms of recruitment, retention, engagement in intervention classes, and efficiency of data collection. Challenges to participation and retention included competing demands of participant's jobs as essential workers and for some, the trauma of the losing a loved one(s) to COVID-19. Future studies are needed to evaluate the effectiveness of a remote protocol in the absence of a pandemic.

INTRODUCTION

American Indian and Alaska Native (AI/AN) men have striking health disparities compared to both men of other races/ethnicities and AI/AN women (Centers for Disease Control and Prevention [CDC], 2021). For example, life expectancy for AI/AN men is 5 years less than for AI/AN women (75.8 vs. 81.1 years) and nearly three years shorter compared to non-Hispanic White (NHW) men (U.S. Department of Health and Human Services, 2022). Diabetes and obesity

are major public health issues for AI/AN men and increases in diabetes are largely attributed to an increase in obesity (CDC, 2020). The prevalence of obesity is 48% in AI/AN men versus 31% in NHW men CDC, 2018; Zhao et al., 2022), and diabetes prevalence and diabetes-related mortality is twice that of NHW men (CDC, 2019, 2021).

Outcomes from Diabetes Prevention Program (DPP) randomized controlled trial (RCT) and the Special Diabetes Program for Indians Diabetes Prevention demonstration project (SDPI-DP) indicate that type 2 diabetes can be prevented or delayed with lifestyle interventions that improve modifiable risk factors such as diet, increased physical activity, and weight loss (Eriksson & Lindgarde, 1991; Jiang et al., 2013; Knowler et al., 2002; Lindstrom et al., 2003), yet few studies have included large numbers of minority male participants or AI/AN men in particular (Jiang et al., 2018; Jiang et al., 2013; The Diabetes Prevention Program Research Group, 1999). For example, among 3,234 DPP participants, only 171 were AI/AN, of which 32% were men (Knowler et al., 2002). Similarly, only 25% of 2,553 AI/AN SDPI-DP participants were men (Jiang et al., 2013).

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 in lifestyle interventions and diabetes risk reduction programs (Pagoto et al., 2012; Taylor et al., 2013). In particular, recruitment of men in clinic-based programs is difficult because they tend to seek clinical care less often than women (Galdas et al., 2004) and generally present with more advanced disease (Beckford-Ball, 2006; Holley-Mallo & Golden, 2021). AI/AN men's perceptions of normative health behaviors and gender roles may also discourage participation (Marak & Tuennerman, 2013; Sinclair, Gonzales, et al., 2020). These results suggest that existing efforts to recruit men, especially men of color, into lifestyle interventions are insufficient and that tailored recruitment efforts are necessary. Moreover, there is an urgent need for diabetes risk reduction programs tailored to the unique values and habits of AI/AN men. Therefore, the Strong Men, Strong Communities (SMSC) in-person RCT was developed to evaluate the effect of a community-based, culturally informed lifestyle intervention on modifiable diabetes-related risk factors among AI/AN men.

During the pandemic, clinical trials have faced unprecedented logistical barriers including social distancing protocols, study staff and participant's fears of potential exposure during study visits, reduction of in-person research staff, and policies deeming study visits non-essential, necessitating adoption of remote methods to sustain research (Loucks et al., 2021; Marra et al.,

2021; Omary et al., 2021; Valmorri et al., 2021). However, researchers have capitalized on the need to transform the landscape toward a more equitable and efficient future through implementation of remote study models (Izmailova et al., 2020; Loucks et al., 2021; Randell et al., 2021; Vogl et al., 2021). To date, there is minimal experience in defining best practices in this domain. Here, we present the methods used in launching and implementing a fully remote, longitudinal diabetes prevention study with AI/AN men. We describe the revision of the in-person SMSC study to a remote protocol and highlight key successes, challenges, and critical lessons learned applicable to remote trial implementation.

METHODS

In-Person Study Protocol

The SMSC study protocol (Table 1) has been described in detail elsewhere (Sinclair, Carty, et al., 2020) and was approved by the Washington State University Institutional Review Board (IRB). Briefly, the specific aims of the SMSC study are to (1) refine the SMSC intervention in response to feedback from focus groups in three recruitment sites, (2) compare change in diabetes risk scores (primary outcome) and modifiable diabetes risk factors (secondary outcomes) between the intervention and wait list control groups, and (3) evaluate the ability of SMSC to retain 80% of 240 AI/AN male participants aged 18–75 years with no previous diagnosis of type 1 or type 2 diabetes.

The SMSC study is a blocked partially clustered RCT to compare the effects of the SMSC between two groups: intervention and waiting list control group. SMSC is a manualized intervention and group facilitation is guided by a peer educator manual. Peer educators, and other site staff who performed recruitment and data collection, attended a series of standardized in-person and virtual trainings led by the Principal Investigator and university data management team.

Recruitment

Men, ages 18-75 years, who self-identified as AI/AN race, were overweight or obese (BMI $\geq$25 kg/m^2), and who did not have a physician-diagnosis of type 1 or type 2 diabetes were recruited in Minneapolis, Minnesota; Portland, Oregon; and Phoenix, Arizona using the following strategies: local health fairs and powwows, Native-serving organizations and clinics, sporting events, local media releases (print, radio), and social media (i.e., Facebook). Men were screened at the events or scheduled an in-person screening appointment. Eligible and interested men

completed an in-person informed consent process and a 1.5-hour baseline data collection visit, after which time they were randomized using REDCap to either the intervention or wait list control group. After cohorts of 10 men completed their baseline assessment, they were block randomized into the two conditions using the cohort as a block.

Data Collection and Measures

Data collection for participants in both allocation groups occurred at baseline, 3 months (post lifestyle classes), and 6 months (post maintenance phase). Men randomly assigned to the immediate intervention group also completed a 12-month data collection visit to assess maintenance of weight loss during the 6-month no-contact period. Waitlist control group participants were offered the same classes after the 6-month data collection.

A survey and clinical measures were collected at each data collection visit. Survey data were collected in REDCap (REDCap, 2022). Sociodemographic data collected included age, educational attainment, marital status, health conditions, prescription medications, family history of chronic disease, annual household income, employment status, and alcohol and tobacco use. The survey also included questions about dietary and physical activity habits, healthy lifestyle support from family and friends, stress, discrimination, and resilience. The primary outcomes were weight and a 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 AI/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 was collected to assess A1C, glucose, and lipids. A urine sample was collected from each participant for the microalbumin/creatinine test. Systolic and diastolic blood pressure, height, weight, and waist circumference were also measured.

Previous research that engaged AI/ANs in an intervention with similar design and aims (Jiang et al., 2013) suggested that a sample size of 240 men would provide ~80% power to detect a difference of 0.40 in the primary outcome of change in Diabetes Risk Score. 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 would have excellent power (~94%) to detect a 0.5 *SD* difference in fasting glucose between the intervention and control groups.

Strong Men, Strong Communities Intervention

The SMSC intervention is a modified version of the Group Lifestyle Balance (GLB) curriculum (Kramer et al., 2009; Seidel et al., 2008) 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 151 AI/AN men in the three recruitment sites (Sinclair, Gonzales, et al., 2020). The impact of settler colonialism and resulting historical trauma (Brave Heart et al., 2011) in AI/AN males includes the challenge of defining their roles and position in contemporary society. An important goal of the pre-intervention focus groups was to understand how the collective traumatic history of AI/AN communities has contributed to the erosion of traditional roles and male identity development. In the focus groups, men described health-related values and norms and their roles as men in the context of hegemonic masculinity juxtaposed with traditional roles as AI/AN men (Sinclair, Gonzales, et al., 2020). Men recognized that individualism, economic success, material wealth and social class status are hegemonic masculine aspirations, but these were not mentioned as goals by most focus group participants. Instead, men discussed the importance of providing for family and community and the desire to perform acts that would first benefit the community rather than themselves. Men who put family and community first were considered warriors and physically, mentally, and spiritually healthy. For many participants, AI/AN culture, values, and expectations shaped their definitions of manhood, health, and the behaviors and goals they aspire to. Therefore, social cognitive theory constructs and GLB content were combined with selected cultural symbols and themes, cultural patterns and concepts, values, norms, and relationships identified in the focus groups to promote healthy eating, physical activity, and weight loss. For example, being healthy was linked to being a warrior throughout the SMSC intervention. Intervention activities were hypothesized to improve psychosocial variables of problem solving, behavioral capability, self-control procedures, emotional coping response, and self-efficacy for healthy lifestyle behaviors.

Intervention participants attended 12 weekly one hour in-person lifestyle classes with a male AI facilitator to learn strategies for healthy eating, physical activity, and stress reduction, and engaged in facilitator-led physical activity. Following the 6-month data collection, six maintenance phase classes were delivered every other week over 3 months. Maintenance phase classes were delivered by the same peer educator and focused on providing 1) continued support for lifestyle changes and 2) opportunities for peer-led physical activity in a small group setting. Brief text messages of one to two sentences were also sent to intervention participants twice each week (n=24) during the 3-month maintenance phase to reinforce and encourage healthy eating and physical activity. Waitlist participants were offered the same intervention after completion of the 6-month data collection.

Retention

A store gift card was 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 was served at each intervention session, and when available, wild game, salmon, trout, wild rice, or other traditional AI/AN foods were offered. Public transportation vouchers for travel to and from the study sites were offered to participants who requested 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.) were offered at intervention sessions.

Multiple methods were used to maintain contact with participants including documentation of work, home, and cell phone numbers, home and email addresses, confirming whether text messages would be accepted, and obtaining contact information of friends, relatives, or coworkers who would know how to contact them if their phone service was terminated, or mailing address changed. Participants received 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 missed a session received a phone call from the peer educator; the peer educator let them know they were missed, asked why the session was missed for tracking purposes and provided a reminder for the next session.

Retention was 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 would also be calculated. Study retention was to 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.

Table 1
Strong Men, Strong Communities revised protocol

Study Activity	Pre-COVID-19 Protocol	Revised Protocol
Recruitment	Local face-to-face recruitment in each site	National recruitment through geographically targeted Facebook posts, study website, listservs, virtual Native events, snowball sampling methods, local and regional newspapers, existing networks throughout the U.S.
Eligibility Criteria	• Self-reported American Indian or Alaska Native men • 18-75 years of age • Reside in or near the identified recruitment sites • BMI ≥25 kg/m^2 • No prior diabetes diagnosis	• Self-reported American Indian or Alaska Native men • 18-75 years of age • Reliable residential internet access • Computer or smartphone • Active email account • BMI ≥25 kg/m^2 • No prior diabetes diagnosis
Enrollment with Informed Consent	In-person	REDCap with participant electronic signature
Study Intervention	• In-person small cohorts of men • Lifestyle classes - 12 weekly classes • Maintenance phase - 3 months in duration, every other week • 2 motivational text messages each week	• On Zoom small cohorts of men • Lifestyle classes - 12 weekly classes • Maintenance phase - 2 months in duration, every other week • 3 motivational text messages each week
Data Collection	In-person	REDCap and Zoom
Primary Outcome	Diabetes risk score calculated with: • Gender • Age • Taking hypertension medications for high blood pressure? • Do you have any brothers or sisters who have diabetes? • Hemoglobin A1c (A1C) • Fasting blood glucose • Triglycerides • Urinary albumin and creatinine ratio • Systolic and diastolic blood pressure • Waist circumference	• Weight – goal of 7.5% weight loss from baseline weight • Dietary habits and consumption • Physical activity habits and frequency

Study Pause Period Due to COVID-19

On March 16, 2020, all in-person recruitment and enrollment activities were suspended. The five-year RCT was in its 42nd month with 99 subjects enrolled. Following discussion with the Washington State IRB, follow-up visits with previously enrolled subjects were conducted by phone. As the pandemic's severity became clearer and the timeline to return to in-person contact was unknown, the study protocol modification from in-person to fully remote recruitment, data collection, and implementation was developed. The revised protocol was approved by the Washington State IRB in June 2020 and the National Institutes of Health in July 2020. However, the Minneapolis and Portland sites decided not to continue with the study because of demands of the pandemic, leaving the Phoenix site as the sole partner in the remote study protocol.

Pandemic Study Protocol

The specific aims of the study remained relatively intact. Aim 1 had been completed prior to the COVID-19 pandemic. For Aim 2, the primary outcome was revised to weight loss with secondary outcomes of dietary habits and consumption and physical activity habits. It was no longer feasible or affordable to collect the data needed to calculate the Diabetes Risk Score. Aim 3 was revised to evaluate the ability of SMSC to retain 80% of 150 participants rather than 240 participants as originally planned. The SMSC study design remained a blocked partially clustered RCT to compare the effects of the SMSC between two groups: intervention and waiting list control group.

In transitioning to an all-remote data collection process, several changes were made to both protocol and standard operating procedures. Phoenix and Washington State University staff developed the revised study protocol and coordinated and conducted all study procedures. The peer educator and other staff who performed recruitment and data collection attended standardized remote trainings via Zoom which were led by the Principal Investigator and university data management team.

Recruitment

To ensure completion of data collection and access to the intervention classes, three additional eligibility criteria were added to the original criteria: ownership or access to a computer, tablet, or smartphone; reliable internet access; and an active email account. Laptops, tablets, and smart phones were not provided to participants. Due to social distancing restrictions, a study website and Facebook page were created for national recruitment of AI/AN men. Other

recruitment strategies included posting the recruitment flyer to listservs, joining virtual Native events to advertise the study, snowball sampling methods, and advertisements in local and regional newspapers and with existing AI/AN networks throughout the United States. Facebook advertisements were focused on geographic regions where large populations of AI/AN people reside such as Washington, Oklahoma, New York, North and South Dakota, Oregon, Montana, Alaska, California, New Mexico, Nevada, Colorado, and Arizona. Men who were interested in the study could either contact study staff directly through the phone number or email listed on the recruitment flyer or enter their contact information on a secure study website. SMSC staff would call the person to describe the study and complete the eligibility screening over the telephone or via Zoom.

Data Collection and Measures

Eligible and interested men were emailed a REDCap (REDCap, 2022) link to independently read and electronically sign the study consent form but were encouraged to contact study staff if they had any questions about the study before signing. After REDCap notified staff that a consent form was signed, another REDCap link was sent to the participant to independently complete the study survey which remained the same as the pre-pandemic survey. Staff also contacted the participant to schedule a HIPAA-compliant Zoom data collection meeting and let him know that a data collection kit would arrive in the mail within a few days of their call. Participants were instructed to open the kit but not to collect any of the data until instructed to do so during the Zoom data collection meeting with study staff. The data collection kit included a body weight scale; a tape measure to collect height, waist, and hip measurements; and a blood glucose monitoring system that included an instruction booklet, glucose meter, lancing pen and lancets, 10 testing strips, several band aids, sterile alcohol prep pads, gauze, chux (i.e., disposable absorbent pads), and a pen. Also included in the data collection kit was a folder with detailed instructions to prepare for the Zoom data collection meeting, a page to record the date and time of each scheduled Zoom data collection meeting, instructions for collection of a fasting blood glucose, and detailed and illustrated instructions for the collection of fasting blood glucose, height, weight, and waist and hip circumference. There was also a section in the folder where participants could record their individual values for each measurement.

The single data collection kit had all the supplies each participant needed for three data collection meetings, and they were instructed to keep everything in the kit for the 3- and 6-month data collection meetings. The 12-month data collection with participants randomized to the

immediate intervention group was discontinued due to the short remaining funding period. Incentives included a store gift card for each data collection visit: $25 for baseline, $50 for 3-month follow-up, and $100 for the final follow-up.

During the Zoom data collection meeting, study staff asked if the participant had any questions regarding the informed consent and reviewed any unanswered REDCap survey questions with participants to obtain responses and reduce missing data. Study staff then guided the participant through the contents of the kit, instructions provided in the kit, and how to use the glucose meter and accurately measure height and waist and hip circumference. Participants completed all measures with their Zoom camera turned on so study staff could ensure accurate measurements and verify measurements. After 10 men completed their baseline assessment, typically after 2 weeks, they were randomized into the two conditions using the cohort as a block as in the in-person protocol and provided group-specific instructions.

Sample Size

Assuming a within subject correlation of 0.7, a within group correlation of 0.1, and an intraclass correlation of 0.3, a sample size of 150 men (75 wait list control and 75 among 15 intervention groups) will provide at least 80% power to detect a standardized difference of 0.39 in weight. With potential 20% attrition, this effect size increases to 0.43.

Strong Men, Strong Communities Intervention

The SMSC curriculum was mailed to each intervention participant prior to the first Zoom delivered class. The content, duration, and frequency of intervention classes (i.e., 12 weekly, 1-hour classes) remained the same but were delivered using Zoom. The AI male peer educator continued to lead the lifestyle classes using the same SMSC curriculum and facilitated physical activities that could be performed in a home setting with no equipment including push-ups, sit ups, squat jumps, lunges, and yoga. A PowerPoint presentation was developed that mirrored the curriculum content and was presented in each class. Incentives such as stretch bands, yoga mats, and pedometers were mailed to participants to support their physical activity.

The maintenance phase was reduced to twice monthly meetings over 2 months rather than 3 months to accommodate the remaining funding period. The peer educator facilitated physical activity during four Zoom classes delivered every other week. The frequency of text messages to reinforce curriculum content was increased to three per week (n=36) rather than two per week (n=24) in the in-person study protocol. The final data collection occurred at the end of the maintenance phase, and waitlist control group participants were offered the same Zoom-delivered

classes and curriculum. Strategies used for the in-person protocol were retained to maintain contact with participants for the COVID-19-adapted protocol.

RESULTS

During the 6-month recruitment period, 285 men completed the eligibility screening. A total of 180 men were eligible and 172 completed the informed consent process. Reasons for ineligibility included BMI < 25 kg/m^2, existing physician-diagnosis of type 2 diabetes, lack of internet access, and unavailable for, or no interest in attending, intervention classes. Only 158 of 172 (92%) individuals completed all data collection activities and were randomized. The mean age among participants was 39 years (*SD* = 10) and ranged from 18 – 70 years; mean BMI was 36 kg/m^2 (*SD* = 8) and ranged from 25.1 to 63 kg/m^2; mean fasting blood glucose was 103.5 mg/dL (*SD* = 15) and ranged from 60 to 174 mg/dL. The final data collection for the remaining cohorts and analyses are underway.

DISCUSSION

The COVID-19 pandemic has caused unprecedented disruptions affecting nearly every aspect of research. This paper provides the description of an in-person diabetes prevention intervention for AI/AN men and the study protocol revisions during the COVID-19 pandemic. As devastating as the pandemic has been, it has also provided an opportunity to identify effective strategies to recruit a historically excluded population and test differing implementation modalities.

The SMSC remote protocol revealed that recruitment through Facebook and the internet could reach AI/AN men of all ages across the United States and proved more effective than in-person recruitment. For example, during the three and a half year in-person study across three sites, we were only able to recruit and randomize 99 AI/AN men compared to the remote recruitment in which 158 AI/AN men were recruited and randomized in 6 months with only one partner site. However, engagement in new social media platforms took time and daily posts and audience relevant content were required to keep viewers engaged. It took nearly 4 months before the SMSC Facebook page produced a significant increase in recruitment. The SMSC AI social media staff person created multiple posts each day that were intended to emphasize the strength, roles, and importance of men in AI/AN communities and to motivate men to be healthy for their family and community. Participants who gave permission were frequently featured on the SMSC Facebook

page wearing their SMSC t-shirt and being physically active. Some participants provided testimonials on Facebook by describing the impact of the SMSC study on their health and well-being and encouraged other AI/AN men to join the study. The AI male facilitator also posted content on the SMSC Facebook page to recruit AI/AN men and to offer exercises men could perform in their homes or yards that did not require exercise equipment.

Retention was higher using the remote protocol. For example, retention in the pre-pandemic study was 62% compared to 87% in the current remote study. Reasons for loss to follow-up in the in-person study included movement of participants from the city to their reservation making them unable to attend in-person classes, disconnected phones, limited hours of operation by the site partners, and lack of interest in attending in-person classes.

In the remote study, the convenience of joining classes from one's home and the AI male peer educator were instrumental in retention and engagement during classes. The process during classes was similar for the in-person and remote protocols. However, the level of personal information that participants shared differed between the in-person and remote classes. For both protocols, the peer educators began the first class with each cohort by sharing the story of his own journey to wellness and personal challenges he had faced in his life, and he assured participants that he was there to support them in their wellness journey. This level of relationship building and accountability to one another is critical in AI/AN communities (Wilson, 2008). Subsequently, men felt comfortable sharing personal stories; life challenges with stress, anxiety, and depression; and how being overweight or obese affected their personal relationships and physical abilities. Sharing stories is an integral part of AI/AN culture. Stories allow listeners to draw their own conclusions and to gain life lessons from a more personal perspective (Wilson, 2008). Stories allow us to see others' life experience through our own eyes. This information may then be internalized in a way that is difficult for abstract discussion to achieve (Wilson, 2008). Weekly debriefing sessions were conducted with peer educators from both protocols to monitor implementation and make corrections and revisions as needed. Discussions with peer educators indicated that men seemed much more comfortable sharing intimate details of their health journey during remote classes compared to the in-person classes. For example, a participant in the remote protocol described his difficulty with personal hygiene due to his weight and the negative impact his weight had on intimacy with his partner. This level of sharing did not occur in the in-person classes. This could, in part, be attributed to the remote nature of Zoom meetings where individuals may feel less

inhibited because they are not sharing a physical space with others and can easily choose to never see other individuals on the Zoom call again.

There was higher retention of participants in the remote protocol (70%) compared to the in-person study (40%). Reasons for attrition during the in-person protocol included the transient nature of many urban AI/AN men's lives where frequent movement between their reservations and the city is common; competing daily demands that made in-person class attendance difficult; and the limited operating hours of one of the recruitment sites. The remote protocol also experienced challenges to participation and retention, including competing demands of participant's jobs as essential workers and for some, the trauma of the losing a loved one(s) and community members to COVID-19. However, despite the impact of COVID-19, participants said they appreciated the remote delivery of the SMSC study because they could join from the safety of their homes; the small group meetings provided a space for men to discuss the impact of the pandemic on their lives and talk and learn together; and for some, it allowed their children to participate in the peer-led physical activities, which was only possible with the virtual adaptation. Men expressed a desire to keep the SMSC Facebook page active and to continue offering online workouts for AI/AN men to join after their participation in the study ended. Several AI/AN male guest speakers have performed Facebook Live events for participants and shared their challenges, successes, strength, and words of encouragement. Overall, remote processes proved to be more efficient and effective for AI/AN men because they could participate in the study from their homes and felt less inhibited in a remote environment.

The participant support team was equally critical to the success of the remote intervention. First, they reduced barriers to enrollment by guiding participants in the use of Zoom and through the enrollment process via Zoom and made certain that participants received their data collection kit and SMSC class materials. Second, the team promoted retention by sending multiple reminders to participants about scheduled classes and data collection meetings, made sure participants received their incentives and study t-shirt, and were always available to talk with participants. Finally, they ensured scientific rigor and data quality by following the revised study protocol and meeting face-to-face on Zoom for all data collection visits.

Limitations

Despite the many strengths of the remote study protocol, there were limitations and challenges. For example, eligibility criteria required participants to have internet access, a computer or smart phone, and an email address. The technology related criteria limited the study

to individuals who had income to support these requirements and the knowledge to use email and Zoom. The remote protocol also experienced challenges to participation and retention, including competing demands of participant's jobs as essential workers and for some, the trauma of the losing a loved one(s) and community members to COVID-19.

CONCLUSION

Disparities in clinical trial enrollment, particularly among AI/AN communities, are well-documented (Hodge et al., 2000; Vigil et al., 2021). Barriers to participation range from structural factors including required time commitments, distance and transportation to research sites, hidden costs, and a legacy of fear and mistrust stemming from historical atrocities in biomedical research (Carpio, 2004; Hodge, 2012; Pacheco et al., 2013). Remote models may provide greater efficiency, increased scale, wider geographic catchment areas, and the ability to reach a more representative population, including those unable or unwilling to travel for in-person study visits (Cheema et al., 2021; Greenberg et al., 2021; Loucks et al., 2021; Randell et al., 2021).

The pandemic has provided the opportunity to test a remote study protocol and identify best practices to recruit AI/AN men into a RCT. Remote clinical trials may reduce barriers to research engagement resulting in more representative samples. A critical evaluation of this approach is imperative to optimize a paradigm shift in research (Naz-McLean et al., 2021). SMSC fills a striking gap in approaches to increase AI/AN male recruitment and participation in lifestyle programs that reduce diabetes risk. Now that multiple vaccines are available and people are returning to work and in-person interaction, it will be important to continue research with AI/AN men to evaluate the effectiveness of a remote study protocol after the pandemic.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interests.

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