OFFICIAL TITLE:
Adaptation and Implementation of a Cherokee-based Participatory Research Project to Reduce CVD Risk

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STUDY PROTOCOL

Overview. *The goal of this study is to develop and then test the feasibility and acceptability of a culturally grounded intervention of CVD in CN citizens.* Based on community-based participatory research methods, a program developed by and for Cherokee people will best address the unique values, expectations, and needs of this population for CVD prevention. This proposal builds on over 3 years of well-established, trusting, and collaborative partnership between the PI and the CN. Aim 1 of the proposed project will lead to the development of the intervention while Aim 2 will test the intervention for feasibility and acceptability.

Table 4. Steps for fulfilling ***Aim 2 goals*** (Years 2-4)
1. Recruit, determine eligibility, and enroll JOC participants 2. Initiate intervention 3. Complete data collection 3a. Pre- and post-surveys; health information, satisfaction with program 4. Data Analysis

Eligibility, recruitment and informed consent. To participant in JOC, participants must be at least 18 years old, enrolled members of the CN, and express an interest in participating in the JOC. Participants will be recruited through a number of channels via 1) follow-up contact information from the online survey; 2) flyers at key CN buildings, including health centers and tribal complex buildings, recruitment at community center meetings; and 3) Online recruiting. Participants can contact PI by phone or email. If they meet eligibility criteria, she will complete the informed consent process with potential participants by appointment.

Baseline data collection. Baseline data will be obtained after each eligible person enrolls in the study and provides informed consent. PI will administer an online survey to all eligible participants to collect self-report data within the Cherokee Nation, Tahlequah, OK. The questionnaire will include information that will be used to contact participants when the cohort is assembled and ready to begin. Research staff will measure height, weight, and blood pressure using the same equipment for all participants (see C.8.1). We anticipate baseline data collection will require 60 minutes for each participant. After data collection is completed, participants will receive a gift card worth $50 as compensation for their time. They will be provided with a packet of study information, including information they can use to contact PI with questions.

Intervention. Participants will be given a schedule of events at the time of recruitment to determine if they can attend all sessions. There will be approximately one scheduled meeting with a facilitator a month, as well as one meeting a month that the group scheduled. There will also be assignments between group meetings that include reading and homework. Participants must agree to the schedule at the time of recruitment, including group and individual activities, to be eligible to participate. Note that although participants will agree up front to attend all sessions, we recognize that obstacles come up and that not everyone can have perfect attendance. Therefore, the intervention will be designed so that benefits can be experienced even if 1 or 2 of the sessions are missed; dose and attendance will be assessed as part of the feasibility study. Participants will be asked to meet at the Cherokee Nation, Tahlequah, Oklahoma for start of the group intervention. Participants (n=50) will be assorted into groups of ten and each will have a leader for primary contact. All participants will meet for key learning sessions, such as lectures, but will break out for experiential activities. This will allow for increased team building and peer relationships to develop, as well as ensuring safety for groups as they complete their group activities.

Follow-up data collection. For all participants, follow-up data collection will occur within two-four weeks of the final JOC session—approximately five months after the first session—in a computer lab at the CN, Tahlequah, OK. Follow-up will re-assess all measures collected at baseline that have the potential to change over time. After completing follow-up data collection, all participants will receive a $50 gift card and a meal as compensation.

***Measures*.** Study measures (**Table 5**) were selected based on the results of a pilot test and focus groups with RTR participants and alumni and feedback from our CN partners. The purpose of data collection is to establish if the measures we have chosen are acceptable to this population. Compared to the original program, we are adding additional demographic and CVD risk factor measures including blood pressure, and we plan to assess if these additions are acceptable to this community.

Table 5. Measures and collection times

Variable construct	**Collection times**
Demographics	Baseline
Anthropometrics	Baseline, follow-up
Physical health	Baseline, follow-up
Emotional health	Baseline, follow-up
Social well-being	Baseline, follow-up
Stress	Baseline, follow-up
Cherokee culture	Baseline, follow-up
Program satisfaction	Follow-up

Statistical Analysis

First, descriptive analyses will be conducted for all study variables, including means with ranges and standard deviations for continuous variables, and frequencies and proportions for categorical variables. Second, in order to assess change in participant outcomes between the two data collection periods (pre, post), paired sample t-tests will be utilized. Paired t-tests work well when the underlying distribution is symmetric, unimodal, and continuous. If the values are highly skewed or the sample is smaller than anticipated, it might be more appropriate to use a non-parametric procedure such as the Wilcoxon signed-rank test. All statistical analyses will be conducted using SAS 9.4 for Windows (SAS Institute Inc., Cary, NC.).