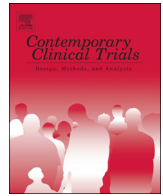




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The Healing and Empowering Alaskan Lives Toward Healthy-Hearts (HEALTHH) Project: Study protocol for a randomized controlled trial of an intervention for tobacco use and other cardiovascular risk behaviors for Alaska Native People

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ABSTRACT

Background: Tobacco use and tobacco-related diseases disproportionately affect Alaska Native (AN) people. Using telemedicine, this study aims to identify culturally-tailored, theoretically-driven, efficacious interventions for tobacco use and other cardiovascular disease (CVD) risk behaviors among AN people in remote areas.

Design: Randomized clinical trial with two intervention arms: 1) tobacco and physical activity; 2) medication adherence and a heart-healthy AN diet.

Participants: Participants are $N = 300$ AN men and women current smokers with high blood pressure or high cholesterol.

Interventions: All participants receive motivational, stage-tailored, telemedicine-delivered counseling sessions at baseline and 3, 6, and 12 months follow-up; an individualized behavior change plan that is updated at each contact; and a behavior change manual. In Group 1, the focus is on tobacco and physical activity; a pedometer is provided and nicotine replacement therapy is offered. In Group 2, the focus is on medication adherence for treating hypertension and/or hypercholesterolemia; a medication bag and traditional food guide are provided.

Measurements: With assessments at baseline, 3, 6, 12, and 18 months, the primary outcome is smoking status, assessed as 7-day point prevalence abstinence, biochemically verified with urine anabasine. Secondary outcomes include physical activity, blood pressure and cholesterol, medication compliance, diet, multiple risk behavior change indices, and cost-effectiveness.

Comments: The current study has the potential to identify novel, feasible, acceptable, and efficacious interventions for treating the co-occurrence of CVD risk factors in AN people. Findings may inform personalized treatment and the development of effective and cost-effective intervention strategies for use in remote indigenous communities more broadly.

Clinical Trial Registration # NCT02137902

1. Introduction

Tobacco use remains the leading preventable cause of morbidity and mortality and contributes to significant racial/ethnic group health disparities [1]. Alaska Native (AN) people have high smoking

prevalence and an increased risk for cardiovascular disease (CVD) and early death [2, 3]. The smoking prevalence in Alaska is 18% overall [4]. In contrast, 1 in 2 AN men and 1 in 3 AN women smoke cigarettes [5]. Effectively, the smoking prevalence among AN adults today is what the smoking prevalence was for US adults in the 1960s [1]. Efforts and

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progress in addressing the US tobacco epidemic have not been equitably distributed.

Tobacco use clusters with additional CVD risk behaviors, and attention to multiple risks is recommended to optimize health and well-being [6–8]. Previous research has identified smoking, obesity, lipids, and psychosocial factors as accounting for 90% of the population-attributable risks for myocardial infarction [9, 10]. Lower education and racial/ethnic minority status predict engagement in multiple risks; struggling with multiple risks is related to greater nicotine dependence; and clustering of behavioral risks is associated with CVD treatment noncompliance. National data on AN/American Indian adults indicated that 79% had at least one CVD behavioral risk factor and 46% had two or more [11]. Existing research to date has been largely cross-sectional and limited in the behaviors assessed. Greater understanding of the co-occurrence of multiple risks in AN people and effective intervention strategies are needed.

In the literature, multibehavioral intervention trials have mixed evidence. A 2011 review reported a nonsignificant reduction in smoking; change in other behaviors (e.g., physical activity) was unreported [12]. A separate review indicated secondary prevention and interventions with a thematic focus on a disease state (e.g., cancer) achieved greater success on multiple risks [13]. More research is needed to examine multi-behavioral interventions and with a focus on understudied and high-risk communities [13–15].

Engagement in one behavior may support change in another. Specifically, physical activity may reduce cravings to smoke, withdrawal symptoms, and cessation-related weight gain [16]. Changing two or more behaviors at once, however, may be overwhelming. In a review of 20 randomized controlled trials of physical activity as an adjunct to tobacco treatment, nearly half the studies had under 30 participants per group; interventions varied in intensity, duration, format, and setting [17]; only 4 trials significantly increased fitness at end of treatment. Greater tobacco abstinence in the physical activity condition was reported in 4 of 20 studies at posttreatment, and only 1 study at 12 months. Notably, the study with the sustained effect tailored the intervention to participants' stage of change, informed by the transtheoretical model (TTM). Other research, targeting safe sun practices and healthy diet, found that TTM interventions can successfully support changes in multiple behaviors while aiding tobacco cessation [18, 19].

In 2011, the National Heart, Lung and Blood Institute requested applications for indigenous-health focused research on multiple health behavior change for secondary prevention of CVD. [20] With a focus on AN smokers and treatment of multiple risk behaviors, the current trial seeks to translate advances in telemedicine, personalized medicine, and computerized chronic disease interventions for the prevention of CVD among AN people.

2. Methods

Our interdisciplinary team brings expertise in cardiology, psychology, public health, nutrition, health economics, statistics, and pharmacogenomics. Investing in local capacity and fostering bidirectional learning, two team members, both of AN descent, received diversity supplements to support their dissertation projects linked to the main award. Notable study features include: (i) use of video telemedicine, at the invitation of tribal leadership, to address leading risk behaviors for CVD in AN people in the rural clinics they own and operate; (ii) application of culturally-tailored, theoretically-driven, TTM computer-assisted interventions to guide provider counseling for efficient and systematic attention to multiple risk behaviors for change (Table 1); (iii) comparing interventions on health behaviors (tobacco/physical activity) versus health factors (hypertension and high cholesterol); (iv) evaluation of effectiveness using objective measures (urine anabasine to biochemically confirm tobacco abstinence, lipid profile, blood pressure); (v) examination of cost-effectiveness of the

Table 1
Example Alaska Native (AN)-tailored intervention counseling activities by behavior and stage of change.

Intervention topic	Stage of change			
	Pre-contemplation	Contemplation	Preparation	Action
G 1 Smoking cessation	Sharing the facts: Tobacco is not native to Alaska and was not involved in any traditional practices; Tobacco accounts for 20% of Alaskan deaths; Heart benefits of quitting smoking are immediate	Comebacks for cons: Assesses key concerns and highlights strategies for treating nicotine withdrawal and the stress of quitting	Action plan: Selecting a quit date, sharing commitment with family/friends, identifying change strategies and medications	Avoid relapse: Identifying triggers and developing a plan to avoid relapse; identifying smoke-free environments
Physical activity	Exercise in nature: Participant identifies natural opportunities for physical activity in the environment (e.g., fishing, berry picking, hunting)	Behavior awareness: Encourages use of study-provided pedometer to see that each step counts for health	Family activities: References AN respect for family and encourages exercising with others	Reaping rewards: Outlines a contract for success with goals, target dates, and self-identified rewards
G 2 AN heart-healthy diet	Food in nature: Highlights AN foods such as seal and salmon as rich in heart healthy fats with contrast to highly processed, high-sodium commercialized food options	Return to AN dietary ways: "Traditional Food Guide" provides simple, heart-healthy meal and snack ideas; encourages connecting with elders to learn more about AN traditional diets	Family activities: Encourages family engagement in AN traditional cooking practices to continue heart-healthy traditions across generations	Eat this not that: Identifies common unhealthy food choices (e.g. Spam), with heart healthier AN food substitutes, (e.g. Mukluk)
Medication adherence	Stories like me: Letters from AN people sharing their stories about managing their heart health with medications	Behavior awareness: Guides tracking of current medication adherence to identify best change practices	Finding inspiration: Offers 10 creative ideas for supporting adherence, such as the study medication bag	Connecting to care: Encourages seeking additional support from community health aides and providers
				Maintain motivation: Encourages engagement in pleasant activities (AN dance, connecting with friends/family) to reward self for staying smoke-free Slipup recovery: Reframes setbacks as part of the process; helps identify situational and seasonal challenges to exercising and strategies for the future Check your thinking: Provides testimonials from AN people sharing how they maintained their motivation to sustain heart healthy dietary practices Staying on track: Encourages forward thinking to sustain attention and motivation to heart health adherence

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