



Contents lists available at [ScienceDirect](#)

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial



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

Judith J. Prochaska^{a,*}, Anna Epperson^a, Jordan Skan^b

intervention to inform clinical practice, health care policy, and dissemination; and (vi) evaluation of theoretical mediators and moderators of treatment outcome including village size and individuals' rate of nicotine metabolism. The trial will be the first to test a biomarker of the rate of nicotine metabolism as a moderator of treatment outcome in

village), public eateries (e.g., the Norton Sound Health Corporation Hospital cafeteria in Nome serves traditional foods such as reindeer or fish), and community celebrations/gatherings. Participants in group 2 receive support on blood pressure and cholesterol medication management, a medication bag to organize their medications, and a cookbook with heart-healthy AN recipes. [Table 1](#) provides examples of intervention strategies by behavioral target and stage of change. The online TTM computer intervention tracks completed research sessions with time duration and flags sessions due but not yet completed, allowing for process monitoring from a distance and in real-time.

2.4. Assessments

Assessments are at baseline and 3, 6, 12, and 18-month's follow-up, conducted at the village clinics or via a toll-free phone line ([Table 2](#)). For their time, participants are paid \$30 at baseline; \$40 at months 3, 6, and 12; and \$50 at 18-months, for a total possible stipend of \$200 provided via gift cards. A comprehensive contact form collects information for tracking participants, used in longitudinal studies with long-term follow-up rates exceeding 80%. At each follow-up, changes in contact information are elicited.

The primary outcome is smoking status, assessed as number of cigarettes smoked in the last 7 days, coded as abstinent only for participants reporting "no tobacco, not even a puff." Consensus guidelines from the Society for Research on Nicotine and Tobacco recommend use of 7-day point prevalence abstinence in cessation-induction studies with smokers unmotivated to quit, who will be quitting at different time points within the trial [34]. For participants reporting 7-day abstinence at follow-up assessments, biochemical verification involves a urine sample for evaluation of anabasine, a biomarker of tobacco exposure with half-life of 8-h that is not present in NRT. Liquid chromatography-mass spectrometry will determine concentrations of anabasine in urine, corrected for urine creatinine concentration. Values < 2 ng/ml will be considered a confi

- [9] F. Lanas, A. Avezum, L.E. Bautista, et al., Risk factors for acute myocardial infarction in Latin America: the INTERHEART Latin American study, *Circulation* 115 (9) (2007) 1067–1074.
- [10] S. Yusuf, S. Hawken, S. Ounpuu, et al., Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study, *Lancet* 364 (9438) (2004) 937–952.
- [11] V.B. Jernigan, B. Duran, D. Ahn, M. Winkleby, Changing patterns in health behaviors and risk factors related to cardiovascular disease among American Indians and Alaska Natives, *Am. J. Public Health* 100 (4) (2010) 677–683.
- [12] S. Ebrahim, F. Taylor, K. Ward, A. Beswick, M. Burke, G. Davey Smith, Multiple risk factor interventions for primary prevention of coronary heart disease, *Cochrane Database Syst. Rev.* 1 (2011), <http://dx.doi.org/10.1002/14651858.CD001561.pub3>.
- [13] J.J. Prochaska, J.O. Prochaska, A review of multiple health behavior change interventions for primary prevention, *Am. J. Lifestyle Med.* 5 (2011) 208–221.
- [14] C.T. Orleans, Addressing multiple behavioral health risks in primary care. Broadening the focus of health behavior change research and practice, *Am. J. Prev. Med.* 27 (2) (2004) 1–3.
- [15] D. Atkins, C. Clancy, Multiple risk factors interventions. Are we up to the challenge? *Am. J. Prev. Med.* 27 (2) (2004) 102–103.
- [16] A.H. Taylor, M.H. Ussher, G. Faulkner, The acute effects of exercise on cigarette cravings, withdrawal symptoms, affect and smoking behaviour: a systematic review, *Addiction* 102 (4) (2007) 534–543.
- [17] M.H. Ussher, A.H. Taylor, G.E.J. Faulkner, Exercise interventions for smoking cessation, *Cochrane Database Syst. Rev.* 8 (2014), <http://dx.doi.org/10.1002/14651858.CD002295.pub5>.
- [18] J.O. Prochaska, S. Butterworth, C.A. Redding, et al., Initial efficacy of MI, TTM tailoring and HRI's with multiple behaviors for employee health promotion, *Prev. Med.* 46 (3) (2008) 226–231.
- [19] J.J. Prochaska, W.F. Velicer, J.O. Prochaska, K. Delucchi, S.M. Hall, Comparing intervention outcomes in smokers treated for single versus multiple behavioral risks, *Health Psychol.* 25 (3) (2006) 380–388.
- [20] National Heart, Lung, and Blood Institute, PAR-11-346. Interventions for Health Promotion and Disease Prevention in Native American Populations (R01), Retrieved from <https://grants.nih.gov/grants/guide/pa-files/PAR-11-346.html>.
- [21] C. Renner, A. Lanier, B. Lindgren, et al., Tobacco use among South Western Alaska Native people: products, patterns, of use and dependence, *Nicotine Tob. Res.* 15 (2) (2013) 401–406.
- [22] N.L. Benowitz, C.C. Renner, A.P. Lanier, et al., Exposure to nicotine and carcinogens among southwestern Alaskan native cigarette smokers and smokeless tobacco users, *Cancer Epidemiol. Biomark. Prev.* 21 (2012) 934–942.
- [23] M. Binnington, A. Zhu, C. Renner, et al., CYP2A6 and CYP2B6 genetic variation and its association with nicotine metabolism in South Western Alaska Native people, *Pharmacogenet. Genomics* 60 (4) (2012) 429–440.
- [24] A.S. Go, D. Mozaffarian, V.L. Roger, E.J. Benjamin, J.D. Berry, W.B. Borden, et al., on behalf of the American Heart Association Statistics committee and stroke statistics subcommittee, Heart disease and stroke statistics-2013 update: a report from the American Heart Association, *Circulation* 127 (2013) e6–