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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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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





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