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A randomized controlled trial evaluation of a smoking cessation and physical activity intervention delivered via telemedicine in the Norton Sound region of Alaska

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ABSTRACT

Objectives: Tobacco use disproportionately affects Alaska Native people. Physical activity may aid quitting smoking and provides health benefits. We tested telemedicine-delivered heart health interventions in Alaska's Norton Sound region.

Methods: Alaska Native adults (N = 299, 51.5 % male, 60.5 % Inupiaq) with hypertension and/or hypercholesterolemia who smoked daily were randomized to intervention on smoking and physical activity (group 1) or traditional diet and medication adherence (group 2). Intention to change was not required for participation. Stage-tailored mailed workbooks and personalized reports were supported by telehealth counseling at baseline, 3, 6, and 12 months. Study outcomes were assessed at baseline, 3-, 6-, 12-, and 18-months (i.e., 6-months after the final counseling session). Smoking outcomes were self-reported 7-day point prevalence abstinence (7d-PPA),[1] bioconfirmed with urine anabasine; 24-hour quit attempts; and 50 % reduction in smoking. Self-reported physical activity outcomes were metabolic equivalent of task (MET) minutes and meeting moderate-to-vigorous physical activity (MVPA) guidelines.

Results: At baseline, participants averaged 12.4 (SD = 10.0) cigarettes/day, with 19.4 % prepared to quit smoking, and 81.6 % meeting MVPA guidelines. During the study, most (70.2 % group 1; 63.5 % group 2) reported a 24-hr quit attempt ($p = 0.219$), and Group 1 (53.6 %) was more likely than Group 2 (28.4 %) to use nicotine replacement therapy (NRT), OR = 2.92, $p < 0.001$. At 18-months, 40.5 % (group 1) and 32.5 % (group 2) had reduced their smoking by half or more ($p = 0.343$), and 10.8 % vs. 7.9 % (group 1 vs. 2) reported 7d-PPA with 4 % vs. 6 % (group 1 vs. 2) bioconfirmed. Time and baseline stage of change predicted 7d-PPA (p's$\leq$.015), with no group effect ($p = 0.325$). Activity levels did not significantly differ by group or time.

Conclusions: Telemedicine counseling supported NRT use but did not significantly affect behavioral outcomes.

1. Introduction

Tobacco is not native to Alaska, yet its use and health harms disproportionately affect Alaska Native people (Centers for Disease Control and Prevention [CDC], 2019). Over a third (36 %) of Alaska Native people smoke cigarettes compared to 16 % among non-Native adults in Alaska (Alaska Department of Health and Social Services [ADHSS], 2022). The higher smoking prevalence is due to a greater likelihood of ever use and lower rates of quitting. Among Alaska Native people, 64 % have ever smoked, of whom 44 % have quit; whereas, for

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[1] Abbreviations:7d-PPA: 7-day point prevalence abstinenceMET: Metabolic equivalent of taskMVPA: Moderate-to-vigorous physical activityNRT: Nicotine replacement therapy.

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non-Native adults, 42 % have ever smoked of whom 62 % have quit (ADHSS, 2022). Regional differences in tobacco product use and tobacco-related inequities also are apparent. State surveillance data indicate that cigarette smoking is more prevalent in the southern (39 %) and northern (38 %) parts of Alaska compared to other regions (≤21 %), and 49 % of Alaska Native adults in the Norton Sound region smoke (ADHSS, 2022).

The disproportionately higher rates of tobacco-related morbidity and mortality represent critical barriers to health equity for Alaska Native people (ADHSS, 2022; Nierkens et al., 2013). Cancer and heart disease are the leading causes of death among Alaska Native people, both of which can be caused by smoking (Alaska Native Tribal Health Consortium [ANTHC], 2021). Remote communities in Alaska may face increased challenges to tobacco prevention and cessation as well as early cancer or heart disease diagnosis and treatment. Health equity, community wellness, and tobacco cessation are tied to Alaska Native people's social determinants of health (Adler et al., 2016), in that socioenvironmental conditions directly affect behavioral risks and quality of life.

Physical activity may aid quitting smoking and provides health benefits (Ussher et al., 2019). Independent of smoking status, physical activity has been demonstrated to reduce cancer and cardiovascular disease (CVD[2]) risks (Zhang et al., 2015). Interventions that address multiple risk behaviors for change, such as smoking and physical activity, offer a more comprehensive approach to reducing health risks such as heart disease, stroke, cancer, and diabetes (Prochaska et al., 2010). However, reviews have identified mixed or weak intervention effects for achieving change in multiple behavioral risk factors (Ebrahim et al., 2011; Prochaska and Prochaska, 2011). More research is needed and specifically in understudied, high-risk communities (Atkins and Clancy, 2004; Orleans, 2004). For Alaska Native people residing in remote regions of Alaska, intervention strategies ought to be culturally targeted and accessible. In Alaska's Northwest region, for which Nome is a vital hub, in 2015, 44 % of adults met the guideline of 150 or more minutes per week of moderate-to-vigorous physical activity (MVPA), which was a decline from 2010 levels (ADHSS, 2020).

The current study reports on a telemedicine-delivered, motivationally-tailored counseling intervention to treat tobacco use and promote physical activity in the Norton Sound region of Alaska. Telemedicine is an outreaching, flexible modality for delivering disease prevention counseling with the potential to promote health equity in remote locations. The Healing and Empowering Alaskan Lives Toward Healthy-Hearts (HEALTHH) Project was designed in response to the National Heart, Lung, and Blood Institute's (PAR-11-346) request for applications for Indigenous health-focused research on multiple health behavior change for secondary prevention of CVD. The HEALTHH study aimed to test two culturally-tailored, telemedicine-delivered interventions, based on the transtheoretical model (TTM) of behavior change (Prochaska and DiClemente, 1983), each focused on changing two CVD risk behaviors to improve heart health. The TTM assesses individuals' readiness for behavior change and tailors interventions. The TTM does not assume people are ready to take action immediately, and instead encourages manageable stage progressions, thereby reducing resistance to change (DiClemente et al., 1991; Prochaska and DiClemente, 1983). TTM interventions typically are delivered over a year with four touch points to support behavior change (e.g., Johnson et al., 2008; Prochaska et al., 1993, 2001a, 2001b, 2004, 2006, 2008; Velicer et al., 1999).

In the current study, one condition promoted tobacco cessation and regular physical activity (group 1), and the other condition promoted traditional, heart-healthy food intake and adherence to cholesterol-lowering and antihypertensive medications (group 2; outcomes reported elsewhere (Oppezzo et al., 2022). Designed to be feasibly integrated within a preventive cardiology service, the interventions offered telehealth counseling sessions every 3- to 6-months for a year with motivational encouragement and medication support; four mailed personalized reports linking to a stage-tailored participant-completed workbook; and behavior-specific add-ons to support adherence (e.g., wearable to promote daily physical activity). The current paper compares changes over time in smoking and physical activity outcomes between the two study groups. We hypothesized that those randomized to the smoking and physical activity condition would be more likely to reduce their smoking, make a 24-hour quit attempt, remain quit, and increase their physical activity.

2. Methods

2.1. Sample

Participants were 299 Alaska Native men and women, ages 19 or older, smoking 5 or more cigarettes daily, and residing in 1 of 16 communities in Alaska's Norton Sound region, with population sizes ranging from 150 to 3598 (the population size of Nome). Approximately 76 % of the region's population is of Alaska Native heritage, with the largest Tribal representation being Inupiaq and Yup'ik. Many residents live traditional lifestyles and rely on land, river, and sea for subsistence (Norton Sound Health Corporation, 2022). Study recruitment ran from 2015 to 2018 with community outreach (e.g., local media, flyers, tabling) (Knox et al., 2020). Additional inclusion criteria were: English proficiency and elevated blood pressure (systolic/diastolic BP $\geq$ 140 mmHg/90 mmHg) or cholesterol (LDL $\geq$ 160) or taking antihypertensives or cholesterol lowering medication (Prochaska et al., 2018). Exclusion criteria were BMI $>$ 40 (raised to BMI $>$ 50 to be more inclusive), active pregnancy, or currently in smoking cessation treatment. Intention to change was not required to participate.

Participant enrollment and allocation are summarized in Fig. 1. Leading reasons for study exclusion were not having hypertension or high cholesterol or smoking $<$ 5 cigarettes daily. Given the linguistically diverse region, intervention materials were in English, which is spoken across tribal groups (Emmett et al., 2019). One person was excluded due to the English proficiency requirement.

2.2. Study design

Following baseline assessment, a computer-generated, stratified randomization program individually assigned participants based on their village size (Nome vs. other), cigarettes per day (cut-point of 8 (Renner et al., 2013)), and smoking stage of change. Randomization was to: Group 1, targeting tobacco cessation and physical activity or Group 2, promoting traditional diet and medication adherence. To avoid cross-group contamination, participants in the same household were randomized to the same condition. Counseling sessions occurred at baseline, after randomization, and at 3-, 6-, and 12-months. Assessments occurred at baseline, 3-, 6-, 12-, and 18-months, the final assessment occurring 6-months after the last counseling session. The protocol has been described in detail previously (Prochaska et al., 2018). Institutional review board (IRB) approvals were obtained from Stanford University; the University of California, San Francisco; the Alaska Area IRB; the ANTHC Board and its manuscript and proposal review committee; and the Norton Sound Board of Directors and its Research Ethics Review Board, the latter of which has closely guided the HEALTHH project.

[2] Abbreviations:7d-PPA: 7-day point prevalence abstinenceADHSS: Alaska Department of Health and Social ServicesANTHC: Alaska Native Tribal Health ConsortiumCDC: Centers for Disease Control and PreventionCVD: Cardiovascular diseaseHEALTHH: Healing and Empowering Alaskan Lives Toward Healthy-HeartsIPAQ: International Physical Activity QuestionnaireLDL: Low-density lipoprotein cholesterolMET: Metabolic equivalent of taskMVPA: Moderate-to-vigorous physical activityNRT: Nicotine replacement therapyTTM: Transtheoretical model.

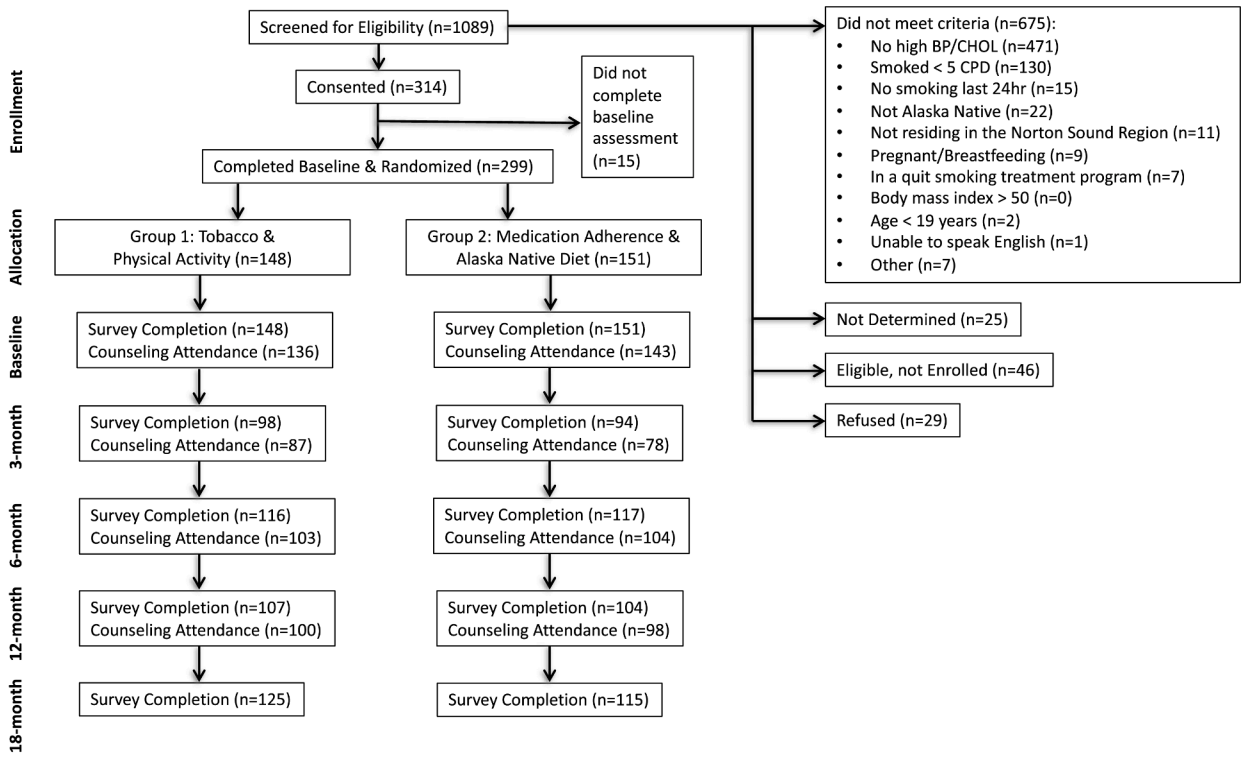

Fig. 1. CONSORT diagram. Recruitment and retention by condition at 3-, 6, 12-, and 18-months.

2.3. Study interventions

The multi-component interventions provided four telehealth counseling sessions; four mailed personalized reports linking to a stage-tailored workbook; and behavior-specific add-ons to support adherence. Given the remote region, the study computer-driven interventions were delivered via video telemedicine (Vidyo, a HIPAA compliant video telemedicine platform) to participants in their local community clinics by study health coaches who were guided by a computer program that tailored counseling messages based on the TTM (Prochaska and DiClemente, 1983). All study team members received extensive training in: motivational interviewing; Alaska Native Indigenous cultures; history of ethics violations against Alaska Native peoples; tobacco, physical activity, dietary, and medication adherence guidelines; stage-tailored interventions; and the use of the TTM-guided computer-counseling program (Knox et al., 2020; Prochaska et al., 2018). Counseling promoted smoking cessation and physical activity or a heart-healthy Native diet and heart medication adherence, depending on study randomization. Counseling sessions and the resulting printed reports were tailored to participants, thereby minimizing contamination across groups.

Participants were mailed their personalized behavior-specific reports and stage-tailored workbooks. The workbooks emphasized motivational, cognitive-behavioral, and relapse prevention strategies with written exercises and photos of Alaska Native traditional people, land, activities, and foods. The physical activity workbook included subsistence activities (e.g., food gathering or harvesting, fishing, trapping) and community celebrations and gatherings, in addition to standard intentional physical activities (e.g., walking in town, participating in an exercise program or sport) (Brooks-Cleator and Lewis, 2020; Redwood et al., 2008).

The interventions were informed by the research team's prior fieldwork in Alaska and continued community partnership (Benowitz et al., 2012; Binnington et al., 2012; Renner et al., 2013). The interventions were culturally targeted to reflect traditional Alaska Native values such as respect for elders, land, and family. Intervention materials were reviewed by team members of Alaska Native heritage; data safety monitoring board members of American Indian or Alaska Native heritage; the Norton Sound Research Ethics Review Board, comprised of Tribal stakeholders; and the Alaska Area IRB. Feedback informed enhancements, including incorporating local photos, language and cultural terms, and Alaska Native stories.

All participants had access to nicotine replacement therapy (NRT) from the Norton Sound Health Corporation. The tobacco cessation and physical activity intervention proactively encouraged and provided guidance on the use of combination NRT (patch plus gum or lozenge) for 12-weeks duration and provided a pedometer for daily tracking of physical activity. The traditional diet and heart medication adherence intervention provided a cookbook with heart-healthy Alaska Native recipes (ANTHC, 2015) and a bag to organize medications. For this paper, the traditional diet and heart medication adherence condition will be referred to as the comparison group or group 2. Table 1 summarizes the intervention treatment components, which included behavior-specific counseling, personalized printed feedback, and workbooks plus NRT and pedometer (Group 1) or Native cookbook and medication bag (Group 2).

2.4. Measures

Study measures were collected at the village clinics at baseline and 3-, 6-, 12-, and 18-months. For their time, participants received $30 at baseline; $40 at months 3, 6, and 12; and $50 at 18-months, for a total possible stipend of $200 via gift cards. Contact information was collected and confirmed at each assessment for study retention.

2.4.1. Demographic characteristics

Participants reported their age, gender, highest level of education, and Alaska Native Tribal group (Aleut, Athabascan, Inupiat, Yup'ik, another Tribal group). Participants identifying more than one Tribal group (n = 18) were classified as another Tribal group. Residence was dichotomized as Nome versus another Norton Sound community given

Table 1
Comparison of intervention components and time schedule.

Group	Targeted Behaviors	Behavior Specific Treatment Components	Baseline	3 mo	6 mo	12 mo
1	Smoking & Physical Activity	• 30-min telemedicine, motivational counseling to support engagement with other treatment components	X	X	X	X
		• Workbook & personal report [a]	X	X	X	X
		• Pedometer	X			
		• Script for 12-wks NRT	X	X	X	X
2	Diet & Medication Adherence	• 30-min telemedicine, motivational counseling to support engagement with other treatment components	X	X	X	X
		• Workbook & personal report [a]	X	X	X	X
		• Native Cookbook	X			
		• Medication bag	X			

[a] Note: Printed workbooks and personal reports mailed to participants were behavior-specific, based on the transtheoretical model of behavior change (Prochaska et al., 2018; Prochaska and DiClemente, 1983), and tailored with suggested strategies and imagery for the region.

Nome's larger population size and to prevent potential identification of participants in the smaller individual communities. BMI (kg/m^2) was measured at baseline at the clinic.

2.4.2. Smoking measures

The primary outcome was 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 (7d-PPA) in cessation-induction studies with participants initially unmotivated to quit smoking and who thus will be quitting at different time points within the trial (Hughes et al., 2003). Participants reporting 7d-PPA provided a urine sample at the clinic for evaluation of anabasine, a biomarker of tobacco exposure with a half-life of 8 h that is not present in NRT. Liquid chromatography mass spectrometry determined concentrations of anabasine in urine, corrected for urine creatinine concentration. Values < 2 ng/ml are considered confirmed for nonsmoking (Jacob et al., 2002). Smoking reduction was calculated as the change in cigarettes per week from baseline and categorized to reflect 50 % reduction or greater. Participants were asked if they made a quit attempt that lasted 24-hours or longer and whether they had used NRT since the last assessment, reported as yes or no. Counselors encouraged Group 1 participants to use NRT assessing side effects and barriers to use. Smoking stage of change was categorized as in precontemplation (not intending to quit in the next 6 months), contemplation (intending to quit in the next 6 months), or preparation (prepared to quit in the next month and made a 24-hour quit attempt within the past year) (DiClemente et al., 1991).

2.4.3. Physical activity measure

Participants self-reported their physical activity with the 7-item International Physical Activity Questionnaire (IPAQ) – short form (Craig et al., 2003; Lee et al., 2011). Prior intervention research within Indigenous communities has used the IPAQ to quantify physical activity levels over time (Gittelsohn et al., 2014; Gittelsohn et al., 2017). In line with standard IPAQ scoring, minutes of walking, moderate, and vigorous physical activity were calculated and combined into a dichotomous measure indicating meeting of MVPA guidelines of 150 min or more per week (U.S. Department of Health and Human Services, 2018). Participants reporting 16 or more hours of walking, moderate, and vigorous time combined were excluded as outliers. Meeting of MVPA guidelines was determined by multiplying vigorous minutes of activity per week by 2 and adding that to moderate minutes of activity per week. Values of 150 min or more of MVPA per week met the guideline. Additionally, a continuous summative measure, MET (metabolic equivalent of task) minutes, was calculated consistent with IPAQ scoring guidelines, applying weights of 8 for vigorous, 4 for moderate, and 3.3 for walking.

2.4.4. Season

Consultation with local advisors in the region encouraged attention to season in the analyses since temperature and hours of sunlight in Alaska can influence time spent outdoors and active. Based on Nome's calendar and local advisors, the season when participants completed the study measures was coded as winter (October – April) or another season (May – September).

2.4.5. Counseling satisfaction

At the 3-, 6-, 12-, and 18-month assessments, participants were asked to indicate how helpful or unhelpful they found the individual telehealth counseling session conducted at their prior visit (i.e., baseline thru 12-months). Response options were unhelpful, neither helpful or unhelpful, somewhat helpful, pretty helpful, and very helpful.

2.5. Data management & analyses.

2.5.1. Power calculation

The study sample size requirement was based on a Type I error rate of 0.05, two-tailed testing, and a minimal power level of 0.80. The identified primary outcome was biochemically-verified abstinence from tobacco. The other targets (e.g., physical activity) are all continuous outcomes more sensitive to detecting changes over time. A combination of sources informed the projected treatment effect on tobacco abstinence between the intervention groups including our prior clinical trials (Hall et al., 2006; Prochaska et al., 2014), reviews of CVD cessation trials (Barth et al., 2008), and research with the TTM computer system in the general population. With TTM-tailored computerized cessation interventions, repeated evaluations have demonstrated abstinence rates in a narrow range of 22 %-to-26 % point prevalence abstinence at 18- to 24-months with nearly 15,000 participants in 10 trials recruited from a variety of settings (Prochaska et al., 2006, 1993, 2001a, 2001b, 2004; Velicer et al., 1999). Given these estimates, the cultural and regional characteristics of our target population, and inclusion of participants initially unmotivated to quit smoking, we anticipated quit rates of 5 % to 7 % in the comparison group across assessment time points. For the tobacco and physical activity group, we anticipated increasing quit rates of 13 %, 15 %, 17 %, and 19 % at 3, 6, 12 and 18 months, respectively, as the proportion of individuals reaching the action or maintenance stages of change increased over time. The projected difference in quit rates between the two conditions reflected a meaningful clinical difference (2.5-fold increase in abstinence) that could have large health impacts at a population level.

Using Rochon's SAS program (Rochon, 1998), required sample size estimates ranged from 140 to 148 per group to assure minimum statistical power of 0.80 to test the primary hypothesis of differences between groups in tobacco abstinence. Power calculations were based on analysis of multiple time points and adjusted for 25 % projected attrition (our prior retention rates $>$ 80 % at 18-months). For the continuous behavioral outcome of physical activity, a *t*-test with 2 groups of 112 each had 80 % power to detect a moderately sized effect of 0.376, which we

anticipated was adequate based on prior studies of TTM-tailored computerized interventions targeting these risk behaviors (Johnson et al., 2008; Prochaska et al., 2008).

2.5.2. Missing data

Fig. 1 shows survey and counseling session completion totals at each timepoint. Retention for the full sample at the 18-month assessment was 80 %. Survey completion did not differ between groups at any timepoint (p's > 0.05). Older participants and those residing outside of Nome were more likely to complete assessments at all timepoints (p's < 0.01).

2.5.3. Data analyses

Analyses were run to determine the effect of condition over time (3, 6, 12, and 18 months) on the smoking and physical activity outcomes. For dichotomous outcomes (7-day-PPA, 50 % reduced smoking, meeting MVPA guidelines), generalized estimating equation (GEE) models were run with a binomial distribution fit with maximum likelihood, with ID as the random effect. For the MET minutes model, a GEE model with normal distribution and a log link was used. The MET minutes model required complete cases, while the other models permitted inclusion with missing data. Model covariates were: age, season (winter versus other season), residence (Nome versus other community), and baseline smoking stage of change (preparation versus contemplation or pre-contemplation), selected due to possible influence on smoking and physical activity outcomes and relationship to retention. A common set of covariates was tested for smoking and physical activity outcomes, because the behaviors were targeted in the same intervention and for parallel interpretation. Logistic regression models were run to examine group differences in making a 24-hour quit attempt and using NRT during the study period.

3. Results

3.1. Sample characteristics

Enrolled were 299 Alaska Native adults (51.5 % male, 48.5 % female), identifying as 60.5 % Inupiaq and 31.1 % Yup'ik, with a mean age of 46.3 years (SD = 14.0). Most participants had graduated high school (79.6 %) and 23.1 % resided in Nome. At baseline, the sample averaged 12.4 cigarettes/day (SD = 10.0), with 19.4 % prepared to quit smoking in the next 30 days, and 81.6 % reporting meeting MVPA guidelines. BMI averaged 28.1 (SD = 7.0), in the overweight range. Participant demographic and baseline characteristics were similar by study group (all comparisons, p > 0.05) (Table 2).

Table 2
HEALTHH sample baseline characteristics (N = 299).

	Tobacco + Physical Activity (N = 148)	Diet + Medication Adherence (N = 151)
	M (SD) / N (%)	M (SD) / N (%)
Age (M/SD)	45.5 (14.7)	47.0 (13.4)
Gender		
Male	77 (52.0 %)	77 (51.0 %)
Female	71 (48.0 %)	74 (49.0 %)
Highest Education Level		
Elementary / some high school	23 (15.5 %)	38 (25.2 %)
High school graduate	95 (64.2 %)	83 (55.0 %)
Some college	26 (17.2 %)	26 (17.2 %)
College degree or higher	4 (2.7 %)	3 (2.0 %)
Alaska Native Tribal Group		
Inupiat	90 (61.2 %)	86 (57.3 %)
Yup'ik	39 (26.5 %)	44 (29.3 %)
Another Tribal Group	18 (12.2 %)	20 (12.8 %)
Residence		
Nome	38 (25.7 %)	31 (20.5 %)
Other Norton Sound community	110 (74.4 %)	120 (79.5 %)
Smoking Measures		
Cigarettes per day (M/SD)	12.2 (9.8)	12.6 (10.3)
Prepared to quit in the next 30 days (%)	33 (21.9 %)	26 (17.6 %)
Physical Activity Measures*		
Meeting MVPA guidelines	123 (89.1 %)	121 (82.9 %)
Walking hours per day (M/SD)	0.87 (2.17)	0.67 (1.63)
Moderate hours per day (M/SD)	2.19 (2.78)	2.18 (2.91)
Vigorous hours per day (M/SD)	2.70 (2.78)	2.50 (3.35)
MET minutes per week (M/SD)	7253 (5861)	5776 (4875)
Body Mass Index (kg/m^2)*	28.21 (7.10)	28.05 (6.89)

* Missing IPAQ data on 10 group 1 and 5 group 2 participants and BMI data on 1 group 1 and 2 group 2 participants.

3.2. Smoking outcomes

Group 1 (53.6 %) was more likely than Group 2 (28.4 %) to use NRT during the trial, OR = 2.92, p < 0.001. By 18-months, 40.5 % (group 1) and 32.5 % (group 2) of participants reduced their smoking by half or more from baseline; significant by time and age (p's≤.018), but not group (p = 0.343) (see Fig. 2 for visualization of the time trend). Most participants (70.2 % group 1; 63.5 % group 2) reported a 24-hr quit attempt during the trial, with no significant difference by group (p = 0.219). By 18-months, 10.8 % (group 1) and 7.9 % (group 2) reported 7d-PPA (Fig. 3) and 4 % (group 1) and 6 % (group 2) were bio-confirmed as abstinent. Time and baseline stage of change predicted 7d-PPA (p's≤.015), with no group effect (p = 0.325) (Table 3).

3.3. Physical activity outcomes

In the model for meeting MVPA guidelines, the only significant predictor was residence. Participants residing in smaller communities were more likely to report meeting MVPA guidelines than participants residing in Nome (p = 0.031). In the model of MET minutes, only age was significant (p = 0.010) and indicated younger participants reported more MET minutes than older participants (Table 3).

3.4. Counseling satisfaction

Over 90 % of participants in both groups rated the counseling as somewhat to very helpful at all timepoints without indication of a decline in satisfaction over time (Fig. 4). Counseling satisfaction did not differ by gender (all p's > 0.390) and was not significantly correlated with age (all p's > 0.150).

4. Discussion

The telemedicine counseling intervention was feasible, rated high on satisfaction, and supported NRT use, but did not significantly affect smoking and physical activity behaviors. Older participants and those prepared to quit at baseline were more likely to reduce their smoking or quit. The significant time effect for 7d-PPA was at 18-months, when retention and reported quit rates were greatest for both groups. Increasing 7d-PPA over time is anticipated with samples not recruited as ready to quit, especially with TTM-based interventions that extend for a year, reflecting movement through the stages of change; however, the jump at 18-months was notable. Only 37 % (group 1) and 76 % (group 2) of self-reported quit rates were bioconfirmed. Discrepancy may be due to other tobacco product use (Epperson et al., 2020) or a wish to please the counselor. Although counseling occurred remotely, rapport likely

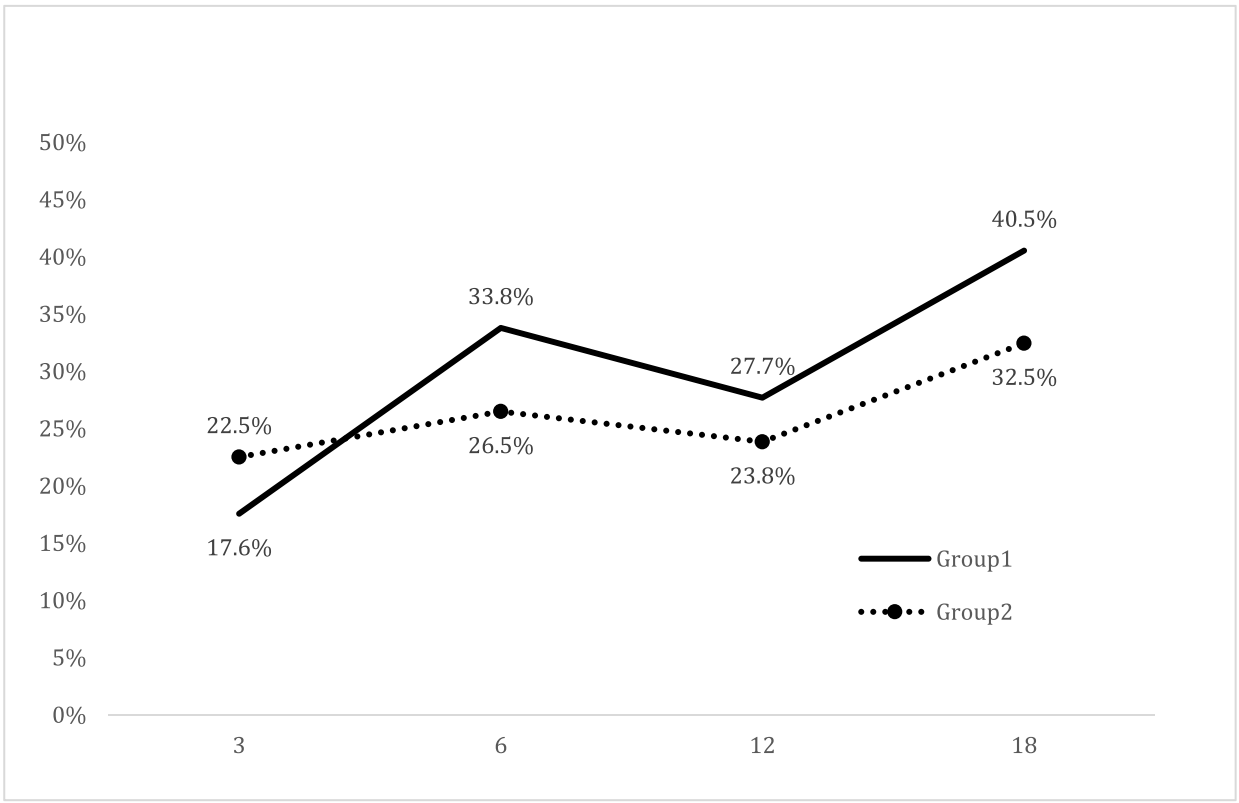

Fig. 2. 50% or Greater Cigarette per Day Reduction from Baseline by Group over Time.

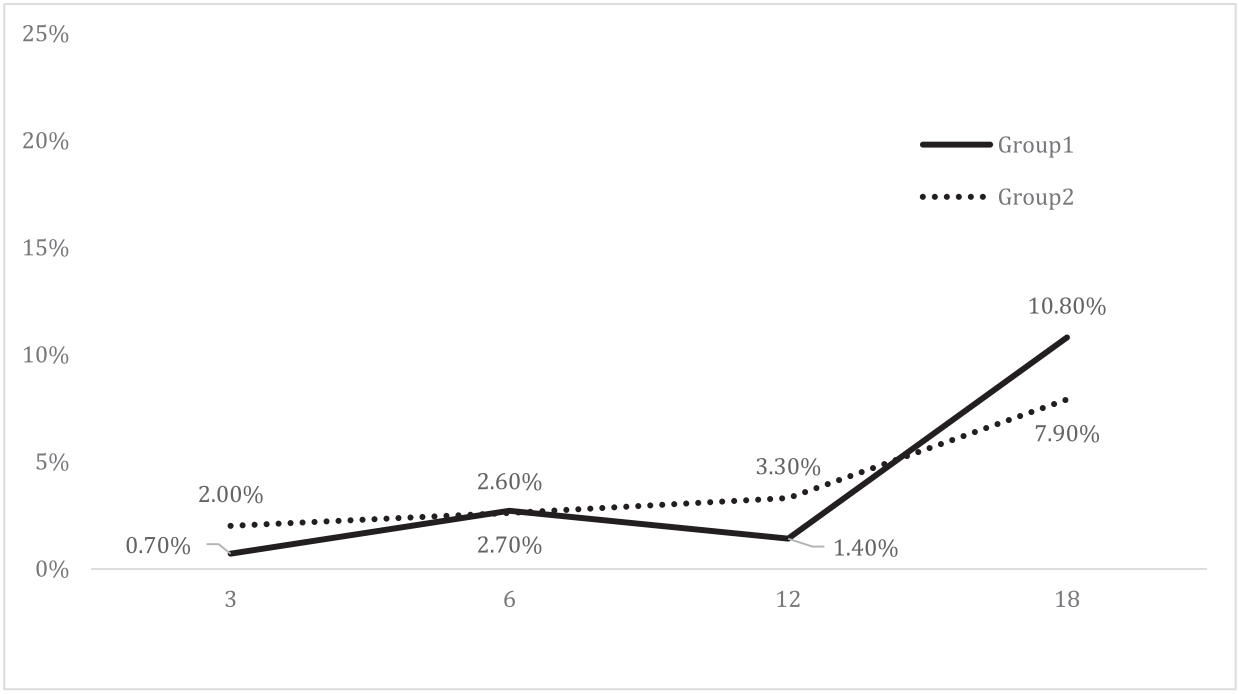

Fig. 3. Self-Reported 7-Day Point Prevalence Abstinence by Group over Time.

developed.

Physical activity levels were high to start relative to state reported levels for the region (ADHSS, 2020) and remained high over time. Younger participants reported greater MET minutes, and participants residing in the smaller communities were more likely to meet MVPA guidelines than those living in Nome.

Delivering innovative, culturally targeted, remotely deliverable interventions for CVD prevention is an important and needed endeavor. The study was novel in delivering CVD prevention counseling via telemedicine to remote regions of Alaska; tailoring the intervention for

Table 3
Intervention outcomes over time: adjusted and unadjusted models.

	Reported Abstinence (ref: no)				**Reduced cigarettes per week by ≥ 50 % from Baseline (ref: no)**			
	Adjusted (N = 292)		*Unadjusted (N = 299)*		*Adjusted (N = 292)*		*Unadjusted (N = 299)*	
	B	p	B	p	B	p	B	p
Group (ref: 1)	1.35	0.325	1.57	0.291	0.25	0.343	0.27	0.337
SOC (ref: not in prep)	**1.00**	**0.015**			0.28	0.199		
Residence (ref: Nome)	−0.15	0.748			−0.14	0.539		
Winter (ref: no)	0.03	0.913			0.20	0.126		
Age	0.02	0.229			**0.02**	**0.018**		
Time	**0.96**	**0<.001**	**1.02**	**0<.001**	**0.61**	**0<.001**	**0.55**	**0<.001**
Group X Time	−0.28	0.321	−0.36	0.241	−0.10	0.184	−0.13	0.064
	Meeting Physical Activity Guidelines (ref: no)				**MET minutes**			
	Adjusted (N = 292)		*Unadjusted (N = 299)*		*Adjusted (N = 282)*		*Unadjusted (N = 289)*	
	B	p	B	p	B	p	B	p
Group (ref: 1)	−0.09	0.784	0.01	0.975	−0.13	0.265	−0.15	0.219
SOC (ref: not in prep)	0.16	0.432			−0.01	0.936		
Residence (ref: Nome)	**0.41**	**0.031**			0.05	0.602		
Winter (ref: no)	0.06	0.661			0<.01	0.988		
Age	−0.01	0.252			**−0.01**	**0.010**		
Time	−0.08	0.223	**−0.13**	**0.006**	−0.04	0.187	−0.04	0.161
Group × Time	0.03	0.745	−0.04	0.582	0.04	0.262	0.04	0.221

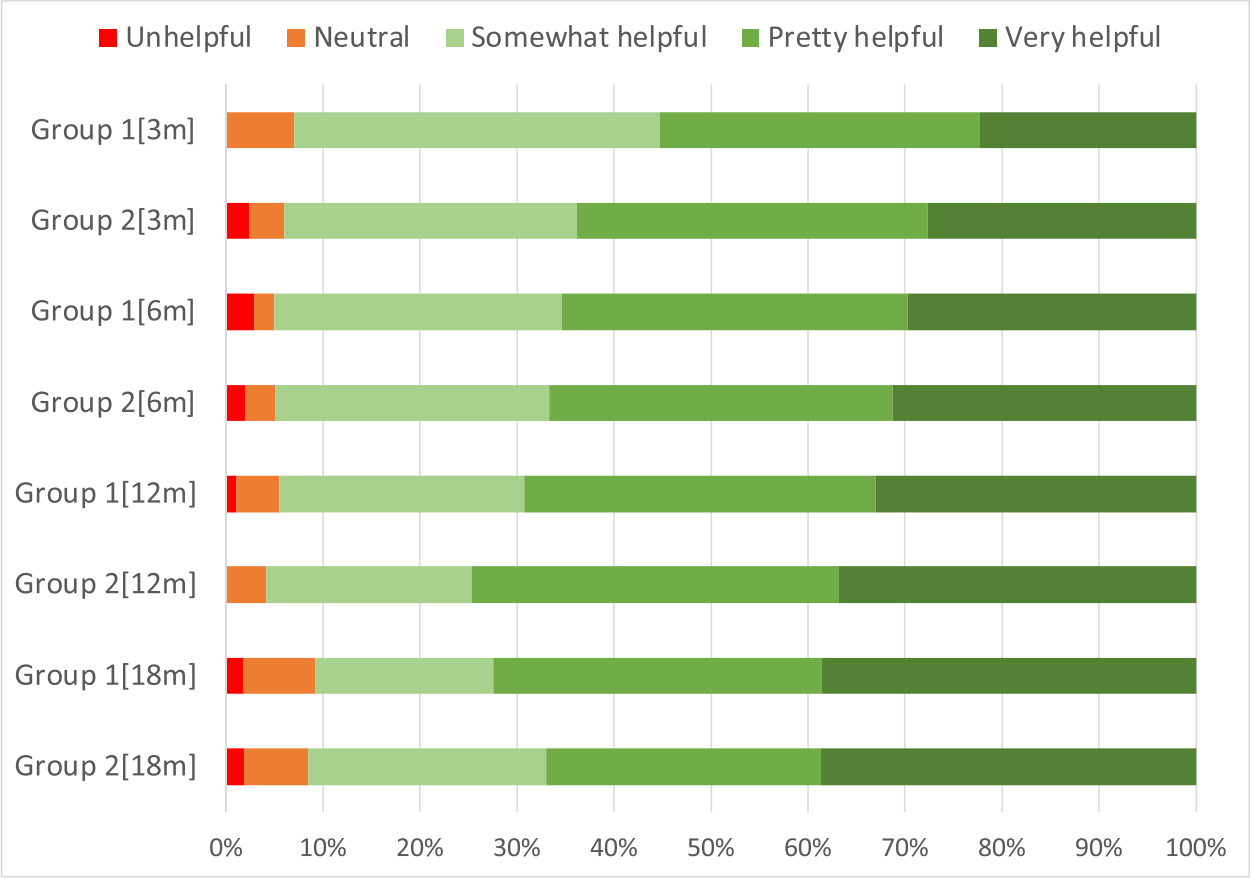

Fig. 4. Satisfaction with Individual Telehealth Counseling by Group over Time.

relevance to the region and Alaska Native culture; and comparing two multiple risk behavior interventions so that all participants received counseling on CVD risks. Satisfaction with the telehealth counseling was high overall and did not differ by gender or age or decline over time. While a viable channel for intervention delivery, greater intensity and duration of telemedicine services appears needed to support quitting smoking. More intensive pharmacotherapy also may be needed, such as varenicline, and worth investigation is cytisine, a naturally occurring plant-based alkaloid used for decades for quitting smoking in Central and Eastern Europe and with developing evidence in the US (Rigotti et al., 2023). An incentives-based model for smoking cessation in Alaska Native communities also has interest and with novelty for engaging family support (Patten et al., 2023).

Notably, in the current study, the relatively high retention of 80 % at

18 months exceeded the CDC guidance of 70 % retention or higher (CDC, 2011). To adhere to evidence-based guidelines for behavior change and to target multiple behaviors, the two interventions were similar in structure, though focused on very different behavioral targets for which co-action was not anticipated. Nevertheless, testing of two active interventions of similar format may have limited our ability to detect significant differences. Missing data were due to various and sometimes unspecified reasons (e.g., internet connectivity issues, assessment fatigue), which weakens the dose of the intervention and statistical power to detect treatment effects. Being sedentary was not a requirement for study participation, and the sample reported high levels of physical activity engagement at baseline. Future investigations may broaden inclusion to the American Heart Association's 2017 stage 1 hypertension criterion (Whelton et al., 2018) and definition of hypercholesterolemia that considers the presence of 2 + risk factors. Study measurement limitations included reliance on self-reported physical activity and a binary measure of NRT use. Though the IPAQ-short form has been widely used, including internationally and with Indigenous communities, over-reporting of active minutes is common and likely contributed to the ceiling effects in calculated physical activity outcomes observed here. Efforts to include an objective measure of physical activity (e.g., accelerometer) were discouraged by the community due to concerns about privacy and surveillance. Surveys did not assess consistency, timing, or amount of NRT use; however, counselors and group 1 participants discussed NRT use.

Tobacco use contributes to significant morbidity and mortality among Alaska Native people. More intensive and extended interventions may be needed to impact behavior long-term. Nevertheless, the study is novel in testing a telemedicine-delivered, culturally targeted tobacco and physical activity interventions in a remote region of Alaska, meeting enrollment goals, and retaining study participation over 18-months.

Disclosures

Drs. Prochaska and Benowitz have served as expert witnesses against the tobacco companies in lawsuits for which they have received fees for the work and have provided consultation to pharmaceutical and technology companies that make medications and other treatments for quitting smoking. No other authors have any disclosures to report related to this work.

Participant Consent

All participants provided written informed consent.

Ethics Statement

The authors designed the study, gathered and analyzed the data according to the Helsinki Declaration guidelines on human research. Institutional review board (IRB) approvals were obtained from Stanford University; the University of California, San Francisco; the Alaska Area IRB; the Alaska Native Tribal Health Consortium Board and its manuscript and proposal review committee; and the Norton Sound Board of Directors and its Research Ethics Review Board, the latter which has closely guided the HEALTHH project.

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CRediT authorship contribution statement

Judith J. Prochaska: Writing – review & editing, Writing – original draft, Validation, Supervision, Resources, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Erin A. Vogel:** Writing – review & editing, Writing – original draft, Validation, Formal analysis, Data curation. **Marily Oppezzo:** Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Formal analysis, Data curation. **Jordan Skan:** Writing – review & editing, Project administration, Investigation. **Mariah Knox:** Writing – review & editing, Investigation. **Amy Chieng:** Writing – review & editing, Investigation. **Maria C. Crouch:** Writing – review & editing, Investigation. **Rachael C. Aikens:** Writing – review & editing, Visualization, Validation, Formal analysis. **Matthew Schnellbaecher:** Supervision, Methodology, Funding acquisition, Conceptualization. **Neal L. Benowitz:** Supervision, Resources, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The authors do not have permission to share data.

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