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To cite this article: Mariah Knox , Jordan Skan , Neal L. Benowitz , Matthew Schnellbaecher & Judith J. Prochaska (2020) Recruitment best practices of a cardiovascular risk reduction randomised control trial in rural Alaska Native communities, International Journal of Circumpolar Health, 79:1, 1806639, DOI: [10.1080/22423982.2020.1806639](https://doi.org/10.1080/22423982.2020.1806639)

To link to this article: <https://doi.org/10.1080/22423982.2020.1806639>



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Published online: 12 Aug 2020.



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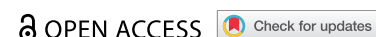


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ORIGINAL RESEARCH ARTICLE



## Recruitment best practices of a cardiovascular risk reduction randomised control trial in rural Alaska Native communities

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### ABSTRACT

Though not native to Alaska, tobacco use is common among Alaska Native people in the Norton Sound region, an area consisting of 16 communities with population size 107 to 3,695. We summarise best practices in recruiting Alaska Native adults who smoke for a randomised controlled tobacco treatment trial. Participants were Alaska Native, 19 years and older, smoking daily, with hypertension and/or high cholesterol, residing in the Norton Sound region of Alaska. Study staff travelled to the remote communities to recruit, typically staying 5 days. Screening and enrolment success was examined by day, season, and staffing level. From June 2015 – December 2018, the study team made 122 trips, screening 1089 individuals and enrolling 314 participants. In the field, days 2–3 (51%) were best for screening, while days 3–4 (53%) had the greatest enrolment. Community size correlated with enrolment ( $r = 0.83$ ,  $p < .001$ ). Recruitment was optimised in spring and with multiple staff in the field. Despite challenges (e.g., harsh weather, poor internet connectivity), with active outreach (e.g. tabling in busy areas, attending community events, utilising mixed media, collaborating with clinic staff), the project reached its recruitment goal. Study findings can inform community-based tobacco treatment research trials in remote areas.

### Abbreviations:

CVD: Cardiovascular disease; VTC: Video conferencing; ANMC: Alaska Native Medical Centre; HEALTHH: Healing and Empowering Alaskan Lives Towards Healthy Hearts; NSHC: Norton Sound Health Corporation; RERB: Research Ethics Review Board

### ARTICLE HISTORY

Received 22 April 2020  
Revised 30 June 2020  
Accepted 28 July 2020

### KEYWORDS



Recruitment strategies; rural; Alaska Native; cardiovascular health

## Introduction

Tobacco is not native to Alaska, and instead was introduced with colonisation. Yet today, nearly half of Alaska Native men and over a third of Alaska Native women smoke cigarettes [1]. In the Norton Sound region, the adult smoking prevalence is 48%, compared to a state smoking prevalence of 18% [2]. Indigenous peoples of Alaska are greatly affected by smoking-related illnesses and have a life expectancy that is about a decade shorter than Alaskan adults of other racial and ethnic groups [3]. Cardiovascular disease (CVD) is the leading cause of death for Alaska Native peoples [4], with cancer, and foremost, lung cancer, a close second [4–6]. Best practices for engaging rural residing Alaska Native peoples in tobacco cessation treatments warrant research, particularly in remote areas that may be under-resourced for preventive medicine services.

Historical problems with research conducted in rural indigenous communities have been widely

documented. In knowing this, improving the relationship between researchers and indigenous communities is integral. Past researchers have noted failure in properly communicating the purpose, risks, and benefits of research efforts to the communities from which data have been extracted [7]. Concern about inadequate dissemination of study findings also has been raised [8,9]. Research practices of this kind have been termed “helicopter research,” representing the at-a-distance relationship between a community and a research team [7]. This distance is in part physical, as researchers tend to travel large distances to reach these rural communities and only stay for a short period of time. Additionally, the distance is cultural, as there can be cultural clashes between styles of communication, knowledge acquisition, and general decorum. Prior research with indigenous communities has underscored the importance of honouring tribal governments,

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building trust, and offering incentives for compensation of participant time involvement [7,10–13].

In bridging the gap between researcher and indigenous participant, unique geographic obstacles should be considered. Alaska is vast. From north to south, the state measures approximately 1420 miles, west to east 2500 miles, and in landmass is twice the size of Texas [14]. The substantial time and financial cost of conducting a study such as this are important factors to recognise [15]. Many rural and remote Alaskan regions are only accessible by aircraft and subject to unsuitable weather conditions. Daily fluctuations in fog, wind, and snowy conditions can prevent an aircraft from reaching its destination, disable telephone networks, and interfere with internet connections. Furthermore, travel can be resource intensive and time taxing, which requires researchers to be flexible and develop new cost-effective strategies for interacting with participants. Treatment models must be similarly flexible.

Video conferencing (VTC) programmes are helping to alleviate the aforementioned obstacles in both research and healthcare. These programmes can be thought of as aHIPAA compliant video chats. VTC programmes allow patients to come into their local or regional clinics and meet with a researcher or a doctor over a computer screen, who may be hundreds of miles away. VTC programmes are increasingly being adopted by tribal hospitals as they save time and costs associated with travel and enable more patients to access their providers. The Alaska Native Medical Centre (ANMC) has developed robust telemedicine clinics in more than 19 specialties including cardiology, dentistry, internal medicine, OB/GYN, neurosurgery, pain management, and palliative care.

In 2011, the National Heart, Lung and Blood Institute published a programme announcement (PAR-11-346) that requested applications for indigenous-health focused research on multiple health behaviour change for secondary prevention of CVD. The Healing and Empowering Alaskan Lives Towards Healthy Hearts (HEALTHH) project was funded as part of this initiative. With a focus on Alaska Native adults who smoke and treatment of multiple risk behaviours, the HEALTHH project seeks to translate advances in VTC for chronic disease prevention interventions among Alaska Native peoples [16].

The HEALTHH project was conducted at the invitation and approval of tribal leadership in the Norton Sound region, which is a geographically remote region of Alaska. The current study reports on outreach and recruitment efforts for the HEALTHH project with the goal of enrolling 300 Alaska Native men and women who smoke residing in Norton Sound. We report on

enrolment by days in the field, season, staffing, and community size. With broader applications, these findings can inform future community-based tobacco treatment research trials in remote regions. We believe this study is necessary as there is much literature examining how to interact with indigenous populations when conducting research; however, there is no literature examining detailed recruitment strategies across multiple time frames to our knowledge.

## Methods

### *Design and setting*

The HEALTHH project was a two-group randomised controlled trial conducted in the Norton Sound region of Alaska, which consists of 16 mainland and island communities, ranging in population size from 107 to 3,695 individuals (Figure 1). The HEALTHH Project evaluated two active treatment conditions, both targeting multiple CVD behaviours. Group 1 received VTC interventions on smoking and physical activity, while group 2 received VTC interventions on medication compliance and having a heart-healthy Alaska Native diet. Two active treatment conditions, rather than a no-treatment control group, were chosen for evaluation so that all study participants would receive an intervention programme. We considered this design to be most ethical and acceptable, particularly given the small size of the communities and the importance of building trust. The project design and procedures were reviewed and approved by the following institutional and tribal committees: the Alaska Area Institutional Review Board (IRB); the Stanford IRB; the University of California, San Francisco IRB; the Alaska Native Tribal Health Consortium (ANTHC) research review committee and Board of Directors; the Norton Sound Health Corporation (NSHC) Research Ethics Review Board, made up of Alaska Native community members; and the NSHC Board of Directors. Additionally, a data safety monitoring board (DSMB) was established for the study with independent experts in the fields of preventive cardiology, community-based interventions, Alaska Native health, and clinical and community psychology; two of the three DSMB members identified as Alaska Native/American Indian.

### *Participants*

Participation was restricted to Alaska Native men and women, aged 19 years or older, residing in the Norton Sound region, who smoked 5 or more cigarettes per day, were English literate, and were identified with



**Figure 1.** Norton Sound region map. This map was created by NSHC. The HEALTHH project was granted permission from their public relations specialist to use this figure in publication.

high blood pressure and/or high cholesterol. Exclusion criteria were having a body mass index of 50 or greater, currently pregnant, or currently participating in a tobacco cessation programme.

The HEALTHH project staff included indigenous (Tlingit, Athabascan, and Inupiaq tribal heritage), and non-indigenous members. All team members received training in Alaska Native indigenous cultures, in the history of government interactions with tribes when the land was purchased from Russia, and in research ethics violations with Alaska Native peoples in the not so distant past. Awareness of these topics was important in establishing best practices for community outreach. Study staff travelled from Anchorage, Alaska and California to the Norton Sound region with stays typically being 5 days long and lasting up to 2 weeks. Despite concerted efforts, the study was not successful in hiring a team member residing in the Norton Sound region. Recruitment occurred year-round. In the Norton Sound region of Alaska, summer is from July to August, autumn from September to early October, winter from late October to April, and spring from May to June.

Outreach for recruitment included the use of local media. For example, the HEALTHH project was featured in the regional newspaper (Nome Nugget), in interviews on local radio stations (e.g., KNOM), and in the NSHC newsletter. Continued coverage was maintained throughout recruitment via paid newspaper ads and brief radio announcements. Posting flyers was another

form of outreach. Flyers were posted, with permission, in community hospitals and clinics, post offices, banks, restaurants, senior centres, grocery stores, and in community government and multipurpose buildings. The flyers contained information on study eligibility requirements, the research goals, compensation, and study contact information. Language used in the local media is shown in Figure 2; the ads also included the study's contact information and dates the team was in town for enrolment. Additional forms of outreach included tabling in busy locations and health fairs, participating in community events (e.g., bingo, pull-tabs, cultural events), and collaborating with clinic staff.

Screening primarily took place at the NSHC hospital, outlying community clinics, and other community events. Features of the recruiting staff member were not recorded (e.g., race, gender, tribal affiliation). None of the indigenous staff members had tribal origins in the Norton Sound region. The screener consisted of 12 questions. The first screening question that disqualified the individual from enrolling was recorded as the "reason for ineligibility". Individuals were asked at the end of the screener how they learned about the project. This item was added mid-way into recruitment. Those eligible to participate were read an 8-page consent form and asked if they would like to voluntarily take part. Those who wished to decline were assured they would not lose their rights to medical care.

## Outcomes

The primary outcomes were screening and enrolment success by day, assessed after all recruitment travel was completed. Secondary outcomes examined participant self-reported demographics, tobacco use history, use of other tobacco products at least 100 times (i.e., established use), and diagnosed medical conditions recorded from the baseline interview after all baseline data were gathered.

## Sample size and randomisation

The HEALTHH project aimed to enrol and randomise a total of 300 participants into one of the two treatments. A computerised programme, REDCap, was used as the project's stratification randomisation tool based on three questions: Does the participant ... live in Nome or another Norton Sound town? smoke more or less than 8 cigarettes per day? seriously intend to quit cigarettes in the next 30 days? Project staff screened, consented/enrolled, and then randomised the participants.





**Take part in a study about healthy hearts**

The goal of the **HEALTHH Study** is to learn more about treating tobacco use and heart disease risks in Alaska Native adults.

You may eligible if you are:

- Of Alaska Native Heritage
- Live in the Norton Sound or Bering Strait Region
- Not currently pregnant
- A smoker

If eligible, you can receive up to \$200 upon completion of this study.

**Figure 2.** Study Recruitment Local Media Ad.

### Data analysis

We examined team flight itineraries against screening and enrolment activities by day in the field. Total counts and percentages were used to examine screening and enrolment success by day, season, and staffing level. We ran a correlation between enrolment numbers and community population size. We also calculated frequencies for recruitment referral source and the reasons for ineligibility. Lastly, we ran descriptive statistics (means, frequencies) to describe the sample on the baseline interview items.

## Results

### Project travel

From June 2015 through December 2018, the team made 122 outreach trips for recruitment with over 209,700 air miles travelled. The research team visited 15 of the 16 Norton Sound communities. We were unable to visit Little Diomedede, the smallest community, as it was only accessible by helicopter one day per week, weather permitting. The average number of recruitment trips for the 15 visited communities was

8.7 (range: 2–35). By season, 22% of the trips occurred in summer ( $n = 27$ ), 12% in autumn ( $n = 14$ ), 50% in winter ( $n = 61$ ), and 16% in spring ( $n = 20$ ).

### Screening and eligibility

In total, 1089 people were screened for eligibility. By day, screening rates were as follows: Day 1 (8%,  $n = 79$ ), Day 2 (25%,  $n = 259$ ), Day 3 (26%,  $n = 275$ ), Day 4 (23%,  $n = 239$ ), Day 5 (13%,  $n = 138$ ), and beyond Day 5 (5%,  $n = 58$ ). The number of community members screened per trip and per day in the field varied by the number of staff members in the field (Table 1). Out of necessity, most trips (80%) were conducted solo by a rotating staff member, although having two, three, or more team members in the field was found to optimise screening numbers; 20% of recruiting trips included a staff member with tribal affiliation. Most trips (63%) were 5 days in duration, spanning Monday through Friday (range: 1–13).

Added late to the screening form,  $n = 198$  people were asked how they had heard about the study. This was only asked of those who enrolled. Nearly one in four (24%) stated word-of-mouth from a family member or friend. Few reported seeing a study flyer posted in the community (5%), being referred by an NSHC employee (3%), or learning of the study via some form of media (1.5% radio, 0% newspaper, 0.5% social). Most (66%) stated “other source”, which was largely interactions with staff members in the field.

Of the 1089 people screened, 360 (33%) met eligibility criteria, 25 (2%) were not determined (e.g., no cholesterol results), 29 (3%) refused to participate, and 675 (62%) were ineligible. Of the 675 ineligible individuals, 70% ( $n = 471$ ) had normal blood pressure or cholesterol. The second leading reason for exclusion was smoking less than 5 cigarettes per day (see Figure 3).

**Table 1.** Screening and Enrolment Success by Staffing Numbers and Overall.

	1 staff	2 staff	3 or more staff	Overall
Number of Trips	97	21	4	122
Total # of Days in the Field	440	109	30	579
Total # of People Screened	675	258	115	1048
Range of # Screened per Trip	0–35	0–37	7–38	0–38
Average # Screened per Day	1.53	2.37	3.83	1.64
Average # Screened per Trip	6.69	12.29	28.75	8.59
Total # of People Enrolled	211	85	17	313
Range of # Enrolled per Trip	0–10	0–13	0–10	0–13
Average # Enrolled per Day	0.48	0.78	0.57	.51
Average Enrolled per Trip	2.18	4.05	4.25	3

Note: People who screened over the phone not included in these totals and one additional participant from the Norton Sound region enrolled while on a doctor visit to Anchorage.

## Project enrolment

Of the 360 people who met eligibility criteria, 314 (87%) provided consent to enrol into the study. By day, enrolment rates were as follows: Day 1 (5%,  $n = 15$ ), Day 2 (15%,  $n = 48$ ), Day 3 (26%,  $n = 81$ ), Day 4 (27%,  $n = 86$ ), Day 5 (20%,  $n = 61$ ), and beyond Day 5 (7%,  $n = 22$ ). By season, the number of community members enrolled per trip was highest for spring ( $M = 3.45$ ,  $SD = 2.76$  per trip), followed by winter ( $M = 2.61$ ,  $SD = 2.71$ ), autumn ( $M = 2.29$ ,  $SD = 2.67$ ), and then summer ( $M = 2.00$ ,  $SD = 1.71$ ). Community size was significantly correlated with enrolment ( $r = 0.83$ ,  $p < .001$ ), with a third of the sample enrolled from the two largest communities.

## Sample description

Of the 314 individuals who consented to participate in the study, 15 did not complete the baseline assessment and were unable to be re-contacted, and 299 were randomised to a study condition. The randomised sample is 48.5% women and 51.5% men with an average age of 46 years ( $SD = 14$ , range: 19 to 81). Identified tribal affiliation was 61% Inupiat, 28% Yup'ik, and 11% other/refused. At baseline, the sample averaged 12 cigarettes per day ( $SD = 10$ ) and 30 years of smoking ( $SD = 14$ , range: 1–64). In addition to cigarettes, 23% of participants reported using chew or snuff at least 100 times in their lifetime, 7% cigars, 3% electronic cigarettes, and 2% iqmik (i.e., masticated tobacco leaf mixed

with punk fungus ash). Most (65%) reported using a tobacco product within 30 minutes of waking, which is an indicator of addiction. Details on tobacco-related medical conditions for the sample are summarised in Table 2.

## Discussion

Establishing a team presence in the remote Norton Sound region of Alaska was crucial to success with recruitment for the HEALTHH research project, a telemedicine-delivered CVD prevention counselling intervention trial conducted with Alaska Native adults who smoke. Most recruitment trips were completed over the course of 5 days. Day 1 focused on engagement with the clinic staff and efforts in the community to get the word out about the project. Days 2 and 3 were most successful for screening. Enrolment success increased by days 3 and 4. After 5 days, both screening and enrolment tapered. There was a greater success with recruitment in communities with larger populations and greater infrastructure. Spring was the most successful season for recruitment. Winter brought weather challenges, and in summer, populations declined as community members travelled for subsistence activities (e.g., berry picking, fishing, hunting).

Staff engagement in these activities, paired with other pastimes was vital (e.g. four-wheeling, boating, hiking, pull-tabs, basketball, sharing of traditional food). Interest and participation in community events proved

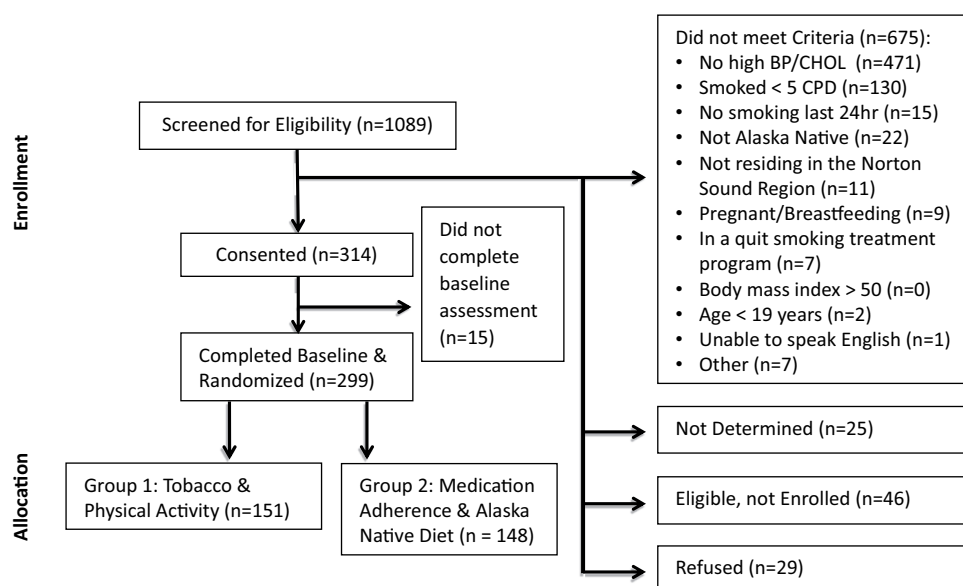


Figure 3. HEALTHH Consort Diagram.

**Table 2.** Self-Reported Ever and Current Tobacco-Related Medical Conditions of HEALTHH Participants (N = 299) at Baseline.

Medical Condition	Ever		Current	
High Blood Pressure	235	79%	202	68%
High Cholesterol	114	38%	83	28%
Myocardial Infarction	20	7%	n/a	n/a
Cancer	22	7%	3	1%
Diabetes	26	9%	22	7%
Asthma	43	14%	23	8%
Emphysema/COPD	n/a	n/a	21	7%

Note: COPD is chronic obstructive pulmonary disease

a success, in that one of our staff was “adopted” by an Alaska Native family and given an Alaska Native name. Moreover, community members developed a comfort with asking the team more detailed questions about the project, which supported word-of-mouth referrals. Critically important were multiple trips to revisit communities, enabling staff to form friendships, particularly with the community health aides working in the clinics. The gain in knowledge was bidirectional with community members learning more about heart health research and staff gaining an appreciation for the people, their communities, and indigenous cultures.

Leveraging multi-strategy recruitment efforts, we identified best practices to be: tabling in busy areas, attending community events (e.g., bingo, pull tabs, open gym, basketball games), offering flexible appointment times and locations, walking around town and talking with locals, and collaborating with clinic and hospital staff. Our proactive effort of building a connection between the project and the community was key. Growing a positive reputation of the team and project led to word-of-mouth referrals over time. Had we relied upon reactive methods of earned and paid media and posted flyers, we would not have met our enrolment goal. In the largest community of Nome, we had the greatest success recruiting at the NSHC hospital with a table outside of the pharmacy, combined with tabling at the local grocery store and screening potential participants while walking around the community.

The team made multiple unsuccessful efforts to hire staff based in the Norton Sound region, to reduce travel and increase onsite study presence. We also found it was unrealistic to engage the busy community health aides in recruitment efforts for the project. Other project enrolment challenges included travel delays and cancellations due to weather, interruptions in online and cellular connectivity, late and missed appointments, competing demands for clinic space, distrust of outsiders and the research process, and the time needed to complete project activities, which could extend to 3 hours at baseline.

Conducting research in rural Alaska provided unique experiences and required thoughtful consideration, growth, and adaptation. For instance, to show respect, travel was adjusted if an elder passed to provide time for the community to honour their loss. With extended stays in the villages, the research team needed to be flexible and resourceful. On several occasions, the tap water had to be boiled or filtered to be suitable for drinking. Thus, the team carried water bottles with built-in filtration systems. When there was no water available, staff showered at community buildings, known as washeterias, and used honey buckets as toilets. When schedules overlapped with travelling healthcare providers, research staff stayed in school libraries, government or city buildings, or in the homes of clinic staff. Safety protocols were established for the wellbeing of staff while travelling. Study travel boxes were equipped with universal door locks and self-defence instruments.

Our project goal was 300 participants. We were successful in consenting 314 community members for the project and randomising 299 participants to a treatment condition over a three-and-a-half-year recruitment period. The resulting sample was diverse with respect to demographics, tobacco use, and health profiles. Due to the research goals, we turned away 62% of screened individuals. Addressing the funding agency’s interest in multiple CVD risk factor interventions for secondary prevention, our recruitment criteria narrowed the pool of smokers eligible to participate. Those excluded were smokers without high blood pressure or high cholesterol. Also excluded were non-daily and light smokers. Given the high prevalence of tobacco use in the region – both cigarette smoking and dual use with smokeless tobacco – further tobacco treatment intervention research in this area is warranted. Additionally, Alaska Native cultures vary largely depending on the tribe and region. Future research on recruitment and enrolment strategies involving other Alaska Native tribes and regions is encouraged.

## Conclusion

Herein, we reviewed our experiences recruiting Alaska Native adults in the Norton Sound region of Alaska for a heart health project. Study findings suggest it is not necessary for research staff to remain in a remote Alaska Native community for more than 5 days to adequately screen and enrol participants. The findings may inform travel planning for future research involving Alaska Native peoples in remote areas of Alaska, and further other diverse groups. Having this knowledge affords researchers the ability to properly allocate funds and time.

Developing a community presence, paired with establishing rapport and trust was identified as key, and the bidirectional learning that resulted was central to the project's success. Both of these increased word-of-mouth referrals, and familiarity with research staff, which were our best referral sources. In a project such as this, with many miles flown to achieve our enrolment goal, it has been vital to manage team resources and to support team members' wellbeing. Future research could benefit from similar methods of analysing recruitment strategies with other communities and in different regions of Alaska. Additionally, focus on research strategies paying particular attention to outreach, time, and cost considerations may be beneficial.

## Acknowledgments

We acknowledge with great appreciation the tribal representatives who make up the Norton Sound Health Corporation's (NSHC) Research Ethics Review Board (RERB). The RERB has been central in approving, guiding, and overseeing this research. In addition, we appreciate Reba Lean, NSHC CEO Angela Gorn, RD, MBA, and Steven Daniel, MD for their support with study recruitment and study presence in the community. We recognize the dedicated efforts of the HEALTHH recruitment and counselling team members including Nicole Anzai, Amy Chieng, Dr. Maria Crouch, Nicole Jeffery, Colleen Johnson, Anne Michalek, Derek Searcy, Adrienne Lazaro, Dr. Anna Epperson, and Sarah Stinson; and our Data Safety Monitoring Board members Drs. Tina Woods, Teresa LaFromboise, and Andrew Pipe. The stage-tailored computer interventions and treatment manuals were developed by Pro-Change Behavior Systems. VIDYO has provided the telemedicine platform for intervention delivery. We also appreciate Amy Chieng's assistance with manuscript formatting and submission.

## Disclosure statement

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

## Funding

This study was funded by the National Heart, Lung, and Blood Institute #R01HL117736 both in a parent award and three Diversity Supplement awards.

## Ethical approval and consent to participate

The manuscript has undergone tribal review and received approval for submission. All procedures performed in studies involving human participants were in accordance with the

ethical standards of the Alaska Area Institutional Review Board (reference # 2014-05-023), Stanford Institutional Review Board (IRB #2,638), and University of California San Francisco Institutional Review Board (UCSF IRB #14-13,83) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## Informed consent and permissions

Written informed consent was obtained from all participants in the study.

## Authors' contributions

MK analyzed and interpreted the data present in this paper, as well as composed the manuscript. JS assisted with data analysis and editing of the manuscript. NB and JP conceptualized the study design for HEALTHH. JP also oversaw the creation and editing of the manuscript. MS provided medical guidance to staff if questions arose. All authors have read and approved the manuscript.

## Consort guidelines

We acknowledge that this study adheres to the CONSORT guidelines.

## Disclaimers

The views expressed in this submission are solely the authors', and do not reflect NHLBI nor any institutional views.

## Data availability

The datasets generated and/or analyzed in the current study are not publicly available per community request. Inquiries should be sent to the corresponding author.

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