

Social Media Intervention to Promote
Smoking Treatment Utilization and
Cessation Among Alaska Native Smokers

NCT03645941

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**Alaska Native Tribal Health Consortium
Social Media Intervention to Promote Smoking Treatment Utilization
and Cessation among Alaska Native Smokers
Participant Consent Form – Phase 4**

This form can be read to you if you ask.

This form will tell you about a research study you can join. This study is being done by the Alaska Native Tribal Health Consortium (ANTHC) and Mayo Clinic. If you have questions please ask us. Take as much time as you need to decide. If you choose to be in the study, you will need to sign this form.

What is the name of this research study?

Social Media Intervention to Promote Smoking Treatment Utilization and Cessation among Alaska Native Smokers

Why is this study being done?

We are doing this research study to find a better way to stop tobacco use among Alaska Native (AN) people. Social media has promise as an approach to help AN people quit using tobacco.

What is the goal of the study?

The goal of the study is to develop and test a culturally appropriate Facebook (FB) delivered intervention to help AN people quit using tobacco. The study has 4 phases. In this fourth phase, we are testing the FB group as a way to help Alaska Native people quit smoking.

Why am I being asked to be in the study?

You are being asked to be in this study because you:

(1) are an Alaska Native person, (2) reside in Alaska, (3) are 19 years of age or older, (4) are a current smoker (smoked at least 1 cigarette per day over the past 7 day period) (5) are considering or willing to make a quit attempt.

Who should not be in the study?

Anyone who: (1) is not a current smoker or smoking is not their primary tobacco source, (2) is not considering or willing to make a quit attempt, (3) does not have access to Internet on mobile phone, at home, work, or other location, (4) does not have an existing Facebook they are willing to use or not willing to set up an account prior to study enrollment, (5) was enrolled in a stop smoking program or used medication for smoking cessation in the past 3 months.

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Who has reviewed and approved this study?

This study has been approved by the Alaska Area Institutional Review Board (IRB) and the Mayo Clinic IRB. IRBs review proposed studies to make sure they follow federal regulations for the protection of human participants in research. This study has also received tribal approval.

Who is funding this study?

Money for this study is coming from the National Institute on Drug Abuse.

If I agree to be in this study, what will I be asked to do?

If you decide to be in this study we will ask you to do several things:

1. Sign the last page of this form, which tells us you agree to take part.
2. Answer some questions about your socio-demographics and tobacco use history.
3. You will receive some print and/or on-line materials about quitting tobacco.
4. You will be assigned by the flip of a coin to one of two groups.
5. You may be asked to participate in a Facebook group for 3 months.
6. At 1 month, 3 months, and 6 months after you enroll you will be asked to answer some questions online.
7. At 1 month, 3 months, and 6 months after you enroll you will be mailed a saliva kit. You will be asked to mail back a saliva sample in the collection tube.

Will specimens be taken or stored?

Saliva samples will be collected. The saliva samples will be shipped directly to Mayo Clinic for analysis of cotinine, a measure of the nicotine in your saliva. These will be labeled with a subject ID number only. Once the specimen sample is processed the sample will be destroyed.

How many people will be in the study?

We will recruit up to a total of 60 Alaska Native people who smoke for this randomized pilot trial.

How much of my time will this study take?

6 months.

How much time will the whole study take?

We are in Phase 4 of this research; this phase will last less than a year. The study began in 2018 and is expected to end in 2021. If this study is successful, we hope to conduct a larger study. Our long-term goal is to develop interventions for Alaska Native people who use tobacco to quit so they will decrease their risk of disease and death from tobacco use.

Is there any risk or discomfort from the study?

Risks are minimal and include those associated with the inconvenience of participating in a Facebook Group, of providing saliva samples, and answering some questions online. There are also some minimal risks with respect to confidentiality. As a member of a secret Facebook group, participants will be asked to talk about their own tobacco use and others' use of tobacco, and

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participate in discussions about tobacco use among Alaska Native people, readiness to quit tobacco, and tobacco treatment resources, among others. It is possible that health information or other personal information about study participants or other AN members could be disclosed on Facebook postings.

What are the possible risks of this study to my community?

Risks of a study to a community are not always known. The people involved in this study have worked closely with ANTHC, a Community Advisory Board, and other community members to make a plan to lessen the risk of community harm. This plan says all presentations or publications must be approved by the ANTHC Health Research Review Committee.

How will I benefit from this study?

There will be no direct benefits to you, but the study will help us learn more about helping people to quit tobacco.

Will I be paid to be in the study?

No. You will receive a \$25 gift card for completing each assessment for a total of \$100 as a thank you for your time. You will also receive a \$25 gift card for each saliva specimen sent in for a total of \$75.

Who will be able to see my records?

We will not be reviewing your medical records for this study.

How will you protect my confidentiality?

All information will be kept confidential to the extent that is legally possible. Information we collect from you will be stored with your study identification number and will not contain your name or other information that would identify you. Consent forms and any information collected on paper will be stored in locked cabinets and electronic data in password-protected secure computer files. Data will be kept for at least 6 years after the study ends and all reports are published. It may be kept longer, but all protections of the data must stay in place. Data will be completely destroyed when it is no longer needed.

Government staff persons sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

What happens to the findings from the study?

Names will not appear in any report or papers resulting from this study. All results that are made public will be summary results, they will not report anything that would identify a person. Summary results will be shared with participants and Tribal leadership. Papers will be written for publication in scientific literature. These papers will be reviewed and approved by the ANTHC Health Research Review Committee before being published.

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Can I refuse to be in the study?

Yes, taking part in this study is your choice. If you do decide to join the study, you can leave it at any time. Your decision will have no impact on your medical care provided through the Alaska Tribal Health System or any other place where you get health care.

Who do I call if I have questions later or I decide to leave the study?

If you have any questions or study-related injuries or complaints, you may contact the Principal Investigator(s):

In Alaska:

ANTHC: Kathryn Koller, PhD, RN
(907) 729-3644

In Minnesota:

Mayo Clinic: Christi Patten, Ph.D
(507) 538-7370

If you have questions about *your rights as a study participant*, you may call the Alaska Area Institutional Review Board (AAIRB):

Terry Powell, AAIRB Administrator
907-729-3924 (collect calls accepted) akaalaskaareairb@anthc.org

Dr. Shanda Lohse, AAIRB Chairperson
slohse@southcentralfoundation.com

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To be in this study, please sign your initials in the appropriate box and then sign the statement below.

	<u>I agree</u> <i>Please initial</i>	<u>I disagree</u> <i>Please initial</i>
1. <u>CONSENT FOR FUTURE CONTACT</u> <u>IF APPLICABLE</u>		

I have read or been told about this research study and all of my questions have been answered to my satisfaction. I have been offered a copy of this consent. **I agree to be in the study.**

Name of participant: _____ DOB: ___ / ___ / ___

Signature of Participant: X _____ **Date:** _____

Study Personnel Receiving Consent: _____

For non-English speaking participants only: The participant is non-English speaking. I have translated the details of the study into the participant's Native language and have indicated their wishes in the boxes above. Signature of Interpreter: _____ Name of Translator (please print): _____
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