

Alaska Native Family-Based, Financial
Incentives Intervention for Smoking Cessation
(Aniqsaaq)

NCT05413265

May 9, 2023



Alaska Native Tribal Health Consortium
Alaska Native Family-Based Financial Incentives Intervention
for Smoking Cessation
Participant Consent Form – Phase 2
Person Who Smokes

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.

Key Information

We are looking for your consent to join a research study. Your participation is voluntary. The purpose of the study is to help Alaska Native people quit smoking. The study will test a family-based financial incentives intervention that has cash rewards and family support to quit. The study will last about eight months. Everything is done remotely with no in-person visits. You will need to join the study with a family member. Both will fill out surveys. You will get resources for quitting smoking and family wellness. Both will take part in a 6-month financial incentive intervention. You will complete regular breath and saliva tests to see if you have quit smoking. You will upload digital photos of yourself doing these tests using an app on a phone or tablet. You will get text messages from study staff before and after each scheduled smoking test. You will get cash rewards for quitting smoking and your family member will get rewards at the same amount as you. Potential risks or discomforts of participation are loss of confidentiality and withdrawal symptoms due to quitting smoking. Other possible risks are the time and inconvenience to fill out online surveys, do the breath and saliva tests, use an app, upload digital photos of yourself, and get text messages from study staff. Some of the personal questions on the surveys might make you uncomfortable. You or your family member might experience some discomfort if your tests are positive for smoking. This would prevent you both from getting rewards. Study benefits are that it may help you to quit smoking. If you choose not to participate or wish to leave the study after you join, other treatments will still be available to you. These include Alaska's Tobacco Quitline and regional Tribal stop smoking programs. You will not lose any rewards earned if you decide to leave the study after you join.

What is the name of this research study?

The name of this research study is “Alaska Native Family Based Financial Incentives Intervention for Smoking Cessation.” The study is also called Aniqsaaq, which means “to breathe.”

Why is this study being done?

We are doing this research study to find better ways to help Alaska Native people quit smoking. We hope to learn more about how to use financial incentives to encourage Alaska Native people to quit and how family members can support them.

Consent Form for Alaska Native Family-Based Financial Incentives Intervention for Smoking Cessation**What is the goal of the study?**

The goal of this study is to develop and test a family-based financial incentive intervention to help Alaska Native people quit smoking. The study has three phases. In this second phase, we are asking Alaska Native people who smoke and family members to take part in a financial incentive intervention to help people quit smoking and give their feedback.

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 or American Indian person;
- 2) Live in Alaska;
- 3) Are 18 years or older;
- 4) Report that you smoke cigarettes (on average, at least 3 cigarettes per day over the past 3 months);
- 5) Are willing to complete a saliva (oral swab) test to confirm your smoking status;
- 6) Are considering or willing to make a quit attempt;
- 7) Are willing to nominate one adult family member who will join this study with you;
- 8) Are willing to complete saliva (oral swab) and breath tests throughout the study and to submit digital photos of yourself completing the tests and results;
- 9) Own or have access to a mobile phone that can receive text messages, or a tablet with Internet access, or you are willing and able to use a loaner iPad for the study duration;
- 10) Are willing to complete and sign an Internal Revenue Service Tax Identification Number and Certification (W-9) form.

Who should not be in the study?

Anyone who:

- 1) Used medicine or a program to quit smoking in the past 3 months;
- 2) Is already enrolled in the study with another family member;
- 3) Currently smokes marijuana more than once per week and is not willing to quit during the study.

Who has reviewed and approved this study?

The Alaska Area Institutional Review Board (IRB) and the Mayo Clinic IRB have approved this study. 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 Institutes of Health.

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. You will be asked to sign the last page of this form, which tells us you agree to take part.
2. You will be asked to complete a saliva (oral swab) test to see if you can take part. We will mail you a saliva test to complete at home. It takes about 10 minutes to complete the test. The results will be used to measure the amount of nicotine in your body to confirm your smoking status. You will be asked to upload digital photographs of yourself completing this test to a secure website. Only research

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staff will have access to the photos and screening test results. Right after the research staff records the result, the digital photographs will be deleted.

3. You will be asked to sign an IRS Tax Identification and Certification (W-9) form online or by mail. This is needed for research staff to report to the IRS any cash payments you may earn as part of the study.
4. You will be asked to answer some questions (online, by phone, or by mail) (baseline survey) that will take about 10 minutes to complete. The questions ask about your age, race, ethnicity, gender, education, marital status, employment, cultural identity, the closeness of your relationship with your family member, and tobacco use.
5. Your family member will also be asked to answer questions about themselves to see if they can take part. They will also sign a consent form.
6. You and your family member will receive some print and/or online resources about family wellness and quitting smoking. Your family member will also receive social support tips.
7. If both you and your family member consent to take part, you both will take part in a 6-month financial incentive intervention. The study includes the following:
 - a. Complete six (6) smoking status check-ins. These will be done at Weeks 1, 2, 3, and 4, then at 3 and 6 Months. You will be mailed an iCOquit® monitor to complete breath tests and oral swab (saliva) tests to use at the check-ins. The iCOquit® monitor measures the level of carbon monoxide on your breath. The saliva test measures the amount of nicotine in your body. Each check-in will take up to 20 minutes to complete.
 - b. Download a secure app called Vincere Health on your phone or tablet. You will use the app to send photos of your breath and saliva tests and to answer questions about your tobacco use. The research staff will review the photos and test results when you send these in the app.
 - c. Complete an orientation session with study staff to go over how to do the breath and saliva tests and use the app.
 - d. You and your family member will each receive a \$25 cash gift card for each of the six check-ins that you complete.
 - e. In addition, if your tests are negative for smoking at the check-ins, you will earn cash payments of up to \$750 maximum. Your family member will also earn rewards at the same amount you earn.
 - f. After each check-in, you and your family member will receive text messages from study staff to note the completion of the check-ins and rewards earned.
8. After the 6-month intervention, you will be asked to complete a follow-up survey (online, by phone, or by mail) that will take about 15 minutes to complete. The survey will ask for your feedback on the study.

Will specimens be taken or stored?

At each of the six scheduled check-ins, you will take digital photographs of yourself doing the breath and saliva tests using the Vincere Health app. The photographs you send us using the app are confidential. The photo files are encrypted and only authorized study staff can see them. These will be destroyed after the study ends. Saliva tests (oral swabs) will be disposed of by you and not stored by the research team.

How many people will be in the study?

We will enroll up to a total of 20 people: 10 Alaska Native people who smoke and 10 family members.

Consent Form for Alaska Native Family-Based Financial Incentives Intervention for Smoking Cessation**How much of my time will this study take?**

You will be in the study for about 8 months. The six check-ins will each take about 20 minutes of your time. This includes the time to complete the breath and saliva tests and answer questions about your tobacco use. The surveys you are asked to complete twice during the study will take about 10 to 15 minutes of your time.

How much time will the whole study take?

The whole study began in 2022 and will end in 2027. This phase of the research (Phase 2) will last about a year.

There may be future related studies. We will ask you at the end of this form if you are interested in being contacted in the future about receiving the results of this study and about future related studies.

Is there any risk or discomfort from the study?

Risks are minimal. Potential risks include:

(1) The time and inconvenience to fill out online surveys, use an app, do regular breath and saliva tests, upload digital photos of yourself doing the smoking tests, and get text messages from study staff. You can fill in the surveys online, or using a paper form that can be mailed to you, or with study staff over the phone. You can contact the study staff any time if you have questions on how to do the smoking tests or use the app.

(2) You might be uncomfortable answering some of the personal questions on the surveys. You can skip any questions that you do not want to answer.

(3) You might be uncomfortable or upset if your saliva screening test result is negative. This would prevent you from taking part in the study. If you are not eligible to take part, we will provide you with resources to quit smoking. This includes information about other treatments like Alaska's Tobacco Quitline and regional Tribal stop smoking programs.

(4) You might have nicotine withdrawal symptoms if you quit smoking. Symptoms may include cravings for cigarettes; feeling restless, tense, or irritable; difficulty concentrating, increased hunger and drowsiness, and depressed mood. Although uncomfortable, these symptoms usually go away within a week or two. The study provides resources to quit smoking that may help you manage these symptoms.

(5) You might be uncomfortable or upset if your smoking test results at the check-ins are positive for smoking. This would prevent you from getting rewards. The study staff will encourage you to try again at the next check-in. You will not lose any rewards earned to that point.

(6) Being exposed to other sources of carbon monoxide (CO) may inflate your breath CO test even if you have quit smoking. This could prevent you from earning rewards. Other sources of CO include other people smoking in your home or smoking marijuana. You will receive information on avoiding other

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sources of CO.

(7) You might be uncomfortable or upset if the oral swab test shows a positive result if you have quit smoking. Some nicotine products like the nicotine patch may cause a positive result. We will ask about your use of other products at each check-in so that we can tell if a positive saliva test is due to cigarette smoking or the use of another product.

(8) Potential loss of privacy of others when you take digital photographs during the smoking tests. We ask that photos be taken only of yourself and not include anyone else.

(9) Your family member may be uncomfortable or upset if your smoking test results are positive for smoking at the check-ins during the intervention. This would prevent them from getting rewards. Your family member will not lose any rewards earned to that point. When you choose a family member to join the study with you, think about someone who is trusted and safe and will support you during the ups and downs of quitting smoking.

(10) Minimal risks related to loss of confidentiality. This includes when you upload photographs and share other information about yourself using the Vincere Health app. Below we cover how we will protect your confidentiality.

This list tries to anticipate any potential risks the study has. However, there may be some risks that are currently unknown.

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 harm to your community. This plan says all presentations or publications must be approved by the ANTHC Health Research Review Committee.

How will I benefit from this study?

You may benefit from quitting smoking. There are no other direct benefits to you from this study. You will be contributing to a better understanding of how to help Alaska Native people quit smoking.

Will I be paid to be in the study?

You will receive cash payments (your choice of mailed cash gift cards, a mailed reloadable debit card, or direct deposits to your bank) as you complete parts of the study as a thank you for your time:

- \$25 for completing the baseline survey
- \$25 for completing each of the six smoking status check-ins (up to \$150 total)
- \$25 for completing the follow-up survey

In addition, if your tests are negative at all the check-ins, you can earn cash payments up to \$750 maximum:

- \$50 at week 1
- \$75 at week 2
- \$100 at week 3

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- \$125 at week 4
- \$175 at 3 months
- \$225 at 6 months

Depending on the total amount of money you get in a calendar year, the income may be taxable. The research team must report giving participants \$600 or more in a calendar year. The report will show up as income for you and may affect income-based benefits.

If your test is positive for smoking or you miss a check-in at any time, you and your family member will still receive the \$25 just for your time in doing the test. You won't earn a reward that time, but you can try again the next time. You won't lose any rewards you have already earned. However, the next time your test is negative for smoking, the reward value will be reset (go back) to the same amount that you earned the last time your test was negative.

Who will be able to see my records?

The research team will not access any of 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. Only authorized research staff will have access to your information. Summary data that can no longer be connected to you (de-identified) will not be used for future research without your additional informed consent.

Vincere Health will have access to the digital photos you upload of yourself and other information you share through the Vincere Health app. The digital photograph files you upload using the App are secure. Authorized research staff will have access to review the research data collected through the App. The data will not be accessed by or shared with anyone else. The photos you upload and all other research data you provide using the Vincere Health app will be completely destroyed after your participation in the study ends.

Other research data will be stored at Mayo Clinic. Consent forms and any information collected on paper will be stored in locked cabinets and electronic data in password-protected secure computer files. It will be kept for at least 5 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. All data will be completely destroyed when it is no longer needed.

Government staff 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?

Study results will not be given back to individual participants. Names will not appear in any report or papers resulting from this study. All results that are made public will be summary results. We will not report anything that could identify a single person. We will share summary results with participants and

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Tribal leadership. If any significant new information about quitting smoking comes out and is related to your willingness to participate in this research, research staff will inform you.

Your de-identified data will not be used in any future research.

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.

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 by 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):

Christi Patten, PhD – Primary Contact for the Study
Mayo Clinic
(507) 261-0718

Timothy Thomas, MD – Alaska Site Principal Investigator
Alaska Native Tribal Health Consortium
(907) 729-3095

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

Yvonne R. Tanape-Druce, AAIRB Administrator
907-729-3924 (collect calls accepted)
akaalaskaareaIRB@anthc.org

Dr. Shanda Lohse, AAIRB Chairperson
akaalaskaareaIRB@anthc.org

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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>		

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: _____ Date of birth: ____ / ____ / ____

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

Study Personnel Receiving Consent: _____ **Date:** _____

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): _____