

Title: Smartphone-based Financial Incentives to Promote Smoking Cessation Among Alaska Native Pregnant Women

NCT Number: not yet assigned

Document Date: July 29, 2021



## ALASKA NATIVE TRIBAL HEALTH CONSORTIUM AND THE UNIVERSITY OF VERMONT

### SMARTPHONE-BASED FINANCIAL INCENTIVES TO PROMOTE SMOKING CESSATION AMONG PREGNANT WOMEN

#### Adult Consent Form

#### Key Information

We are looking for your consent to join a research study. Your participation in the study is voluntary. The purpose of the study is to help you quit smoking. The study will last while you are pregnant and for six months after you have your baby. It will involve breath and saliva tests to see if you are smoking. You will also fill out surveys, and study staff will give you brief counseling to help you quit smoking. Potential risks or discomforts for participation may include feeling irritable and tired due to quitting smoking. Some of the personal questions on the surveys might make you feel uncomfortable or cause emotional upset. You can skip any questions that you do not want to answer. The benefits of the study are that it may help you to reduce or 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, such as the Alaska Tobacco Quit Line (1-800-784-8669).

#### **This form can be read to you if you ask.**

This form will tell you about a research study you can join. The Alaska Native Tribal Health Consortium and the University of Vermont (UVM) are partners in this study. Please ask us if you have questions. Take as much time as you need to decide. You will need to give us your verbal consent to join the study. We will note your verbal consent in our records and mail you a copy of this form.

#### **What is the name of this research study?**

Financial Incentives to Promote Smoking Cessation Among Pregnant Women

#### **Why is this study being done?**

We are doing this study to help Alaska Native (AN) women quit smoking while they are pregnant. We are using treatments that work well in other groups of pregnant women. This is the first time AN women are using them.

#### **What is the goal of the study?**

The goal of the study is to compare two different treatments for helping pregnant AN women quit smoking. Each treatment group will get support for quitting smoking. We will compare how well each treatment helps pregnant AN women quit smoking and stay quit after they have their baby.

#### **Why am I being asked to be in the study?**

We are asking you to join this study because you:

(1) are an AN women, (2) are pregnant, (3) report you smoke cigarettes (at least once in the past week), (4) are 18 years or older, (5) own a smartphone, and (6) want to join a study to help you quit smoking.

**Who should not be in the study?**

Anyone who (1) is not a current smoker or smoking is not their main tobacco source, (2) does not have a smartphone, (3) is exposed to carbon monoxide that cannot be avoided (such as a car mechanic), (4) smokes marijuana often and does not want to quit during the study, (5) has a behavioral or medical condition or other concern (such as legal) that may interfere with joining the study, or (6) does not want to join a study to quit smoking cannot join the study.

**Who has reviewed and approved this study?**

The Alaska Area Institutional Review Board (IRB) and the UVM IRB approved this study. IRBs review studies to make sure they follow federal rules that protect people who volunteer to be in research. The ANTHC Health Research Review Committee has also approved this study.

**Who is funding this study?**

Money for this study is coming from the National Institute of General Medical Sciences (NIGMS) and UVM.

**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. Download a smartphone app called DynamiCare Rewards.
2. Take a video of yourself doing a saliva test using the app.
3. Speak with a UVM researcher by phone to learn which treatment group you are in. There are two treatment groups in this study so there is a 50/50 chance you to be in either group.
4. Fill out online surveys while you are pregnant and after you have your baby that ask you questions about yourself and your tobacco use.
5. Take videos of yourself doing breath and saliva tests with the smartphone app when you are notified to take a test. In one of the treatment groups, you may be asked to take these tests more often.
6. Complete three phone calls where you receive brief counseling and a quit line referral.
7. Answer some questions at the end of the study about what you liked and didn't like about participating, so we can learn how to make the treatment better.

**Will specimens be taken or stored?**

You will take videos of yourself doing breath and saliva tests using the smartphone app. The videos that you send us are confidential. The video files are encrypted meaning that only authorized study staff can see them. They are destroyed seven days after you submit them. To protect the privacy of housemates or family members, we ask that you only record yourself. Saliva tests will be disposed of by you and not stored by the research team.

**How many people will be in the study?**

We will recruit up to a total of 60 Alaska Native pregnant women who smoke for this pilot study.

**How much of my time will this study take?**

The study will last for the duration of your pregnancy and six months after you have your baby.

**How much time will the whole study take?**

The study is expected to begin in 2021 and end in 2023. If this study is successful, we hope to conduct a larger study. Our long-term goal is to develop interventions to help Alaska Native pregnant women who use tobacco to quit. This is our long-term goal because we want to help these women have healthy pregnancies and babies, and also 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 related with the trouble of using a smartphone app, of providing breath and saliva samples, and answering questions online. The online surveys will ask you about yourself, your tobacco use, and your mental health including thoughts of depression or suicide. Some questions may make you uncomfortable or emotionally upset. You can skip any questions that you do not want to answer. The information you provide will be kept confidential. No identifiable information about you will ever be shared without your consent.

The only situation where we would need to break confidentiality is if you are in danger of hurting yourself or others. Should you share thoughts of self-harm, we ethically have to complete a suicidality questionnaire with you. If you express any suicidal intent, we ethically have to call crisis services or your regional hospital immediately in order to protect your safety. Other than this, the only other circumstance where we would break our confidentiality agreement with you is if you shared with us a plan to seriously harm others. That is not an item we ask about in any of our questionnaires, but we would be ethically obligated to act if that happened to occur.

Since both of the treatment groups in this study will try to help you quit smoking, one risk is that you may experience nicotine withdrawal. Nicotine withdrawal symptoms include things like craving cigarettes, restlessness, irritability, difficulty concentrating, and depressed mood. These symptoms usually go away within a week or two.

Women in one of the treatment groups will be asked to provide frequent breath and saliva tests to monitor smoking status. If these tests show that participants are not smoking, they can earn incentives. However, there is a risk that women might be exposed to other sources of carbon monoxide (e.g., cigars, hookah) or nicotine (e.g., e-cigarettes, nicotine gum) that could show up in the breath and saliva tests. If so, they may prevent women from earning incentives.

**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 the ANTHC Health Research Review Committee must approve all presentations or publications before they are available to the public.

**How will I benefit from this study?**

One benefit to you is that either of the two treatments in this study may help you to reduce or quit smoking. Quitting smoking can have many positive health benefits for you and your baby. Joining the study may also help us figure out better ways to help other AN women quit using tobacco.

**Will I be paid to be in the study?**

Women in both treatments can earn up to \$350 (check or electronic gift card) as a thank you for completing online surveys, breath and saliva tests, and brief phone calls with study staff. Women in

one of the two treatment groups can earn up to another \$1,620 in incentives for giving breath and saliva samples that show they have not smoked.

Depending on the total amount of gift money you get in a calendar year, the income may be taxable. We 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.

We will ask you to give us your social security number over the phone once you collect \$100 from the study. UVM requires us to collect social security numbers of participants we pay \$100 or more and we only need to collect it one time. Your social security number will be listed separately from any of your participant data and will be stored in locked filing cabinets.

**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?**

We will keep all information as confidential as possible according to the law. Information we collect from you will be stored with your study identification number only. The study number will not contain anything that could identify you. We will store all consent forms and anything we collect on paper in locked file cabinets. All electronic data will be collected through secure web-based applications and stored in password-protected secure computer files. Thus, the risk of a breaking confidentiality is very low.

We will keep data for at least seven years after we publish the last study paper. We will protect all data as we describe above until they we no longer need them and destroy them.

Government staff sometimes reviews studies such as this one to make sure researchers are doing the study safely and legally. A government staff may review your study records for this kind of review. 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 will be summary results. We will not report anything that could identify a single person. We will share summary results with participants and Tribal leaders. We will write papers with the results of this study for science journals. The ANTHC Health Research Review Committee will review and approve all papers before they are published.

**Can I refuse to be in the study?**

Yes, you can refuse to join the study. Joining 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 health 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, contact information is below:

Kaitlyn Browning, PhD – Primary Contact Person for the Study  
University of Vermont  
(802) 391-4244

Diann Gaalema, PhD – UVM Principal Investigator  
University of Vermont  
(802) 656-9874

Kathryn Koller, PhD – Site Principal Investigator  
Alaska Native Tribal Health Consortium  
(907) 729-3644

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)  
[akaalaskaarealRB@anthc.org](mailto:akaalaskaarealRB@anthc.org)

Dr. Shanda Lohse, AAIRB Chairperson  
[akaalaskaarealRB@anthc.org](mailto:akaalaskaarealRB@anthc.org)

Statement of Consent

You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given above. Your participation is voluntary, and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and understand that your verbal consent to take part will be documented. Please keep a copy of this form for your reference.

If you agree to take part in this study, you are not giving up any of your legal rights.