Identifying Effective Treatment for Veterans Unwilling to Quit Smoking

NCT04061720

July 6, 2021

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Title of Study: **Veterans Smokers Health Study**

Principal Investigator: **Jessica Cook, PhD** **VAMC:** Madison, WI

STUDY SPONSOR
This research is supported by a VA MERIT grant.

INVITATION/STUDY SUMMARY
You are invited to be in a research study that is funded by the VA. Participation in this research is voluntary. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about what we will ask you to do, the risks, the benefits, your rights as a volunteer, or anything else about the research or this form that is not clear. This process is called "informed consent." This copy of the form is for your records.

WHAT IS THE PURPOSE OF THE STUDY?
Most smokers in the VA healthcare system who are not ready to quit receive only brief provider advice to quit once a year. The purpose of this study is to test whether Enhanced Chronic Care improves the likelihood of quitting when compared to Standard Care (brief offer to quit once a year) in Veterans who are not interested in quitting smoking. Enhanced Chronic Care provides ongoing motivational coaching and support designed to: 1) increase motivation to make changes in your smoking, and 2) provide easier access to treatment for you smoking.

WHAT WILL MY PARTICIPATION INVOLVE?
If you decide to participate in the study, your participation will include an initial telephone call that includes screening for study eligibility, consent, and introduction to study procedures. If you qualify and would like to participate, you will be randomly assigned to receive either Standard Care or Enhanced Chronic Care and study visits will be scheduled. Randomization is like flipping a coin.

You will receive 4 telephone assessments over the two-year study period, scheduled approximately every 6 months. These calls will last about 15 minutes each. If you are randomly selected to receive Enhanced Chronic Care, you will receive additional brief, motivational phone calls every three months over the 2-year study period to discuss your smoking. Some of these calls will occur at the same time as your assessment calls. You do not need to quit smoking or use any treatment while you are in this study. Some participants will be invited to attend a single visit at the VA hospital to provide a breath sample to measure carbon monoxide and a saliva sample to measure nicotine after the 2-year follow up call. Participants who are invited but unable to attend this visit at the VA will be offered the option to provide a saliva sample via a mailed collection kit.

Phone assessments will include:

- All participants will receive an assessment call from study staff about every 6 months for 2 years after the initial screening phone call. During this call, you will be asked questions about

your motivation to quit smoking. You will also be asked questions about your mood, your confidence about your ability to quit smoking, and any nicotine withdrawal symptoms you might be having. You will also be asked about how much you smoke and drink alcohol, and how many quit attempts you have made or whether you plan to quit smoking. The assessment call will last about 15 minutes.

If you are assigned to Enhanced Chronic Care, you will also receive brief motivational calls scheduled every 3 months for the 2-year study period.

Motivational calls will include:

- Motivational calls involve discussing your thoughts and feelings about smoking as well as discussing treatment options if you become interested in making any change to your smoking. These calls may occur at the same time as assessment phone calls and last 10 minutes.

Tobacco treatment:

You do not have to quit smoking or use any treatment to be in this study. However, if you decide you would like to change your smoking, treatment will be provided by study staff following VA clinical care guidelines. Treatment includes an additional 4 – 7 telephone counseling calls and the nicotine patch, nicotine lozenge, and/or nicotine gum. These counseling calls will last about 10 – 20 minutes.

We will also collect the following information about you for this research study:

- Information from you: Name, address, phone number, and information about your smoking and other tobacco use.
- Information from the coaching calls: Whether you had a particular coaching call that you were assigned to have and the main topics covered.

ARE THERE ANY RISKS?

The questionnaires may produce distress. You should feel free to discuss any discomfort about the study procedures with the study staff. You are free not to answer any questions you don't want to answer.

If you choose to use tobacco treatment while in this study, you may experience symptoms of nicotine withdrawal or side effects from the nicotine patch, gum, or lozenge. These side effects will be discussed with you at the beginning of treatment as part of VA standard clinical care. The risks associated with nicotine patch, gum, and lozenge are the same in the research study as they are in VA clinical care.

If child or elder abuse or neglect is reported during a visit or call, members of the study team may be

required by law to report this to the appropriate authorities. This may include reporting to the local law enforcement or protective service agencies, resulting in legal or social risks to you or other members of your household. Your confidentiality cannot be guaranteed in cases of child or elder abuse.

We will be collecting data that you fill out on questionnaires. This information is collected for research purposes only. There is a risk of loss of confidentiality in the event of unauthorized access to the answers you fill out on the questionnaires. Since some of the data is sensitive, including personal information about your mental health, a breach of confidentiality could have negative effects. To minimize this risk, hard copies of questionnaires will be stored in a locked filing cabinet and electronic questionnaires will be stored on secure servers. Only study researchers have access to these questionnaires.

Some of your coaching sessions may be audio recorded. These recordings will be used to ensure that treatment is consistent for everyone. These recordings will be kept confidential and will only be used for supervision of study personnel.

ARE THERE ANY BENEFITS?

No direct benefit to you can be guaranteed. Frequent contact with study staff may increase your motivation to change your smoking as well as provide you with easier access to tobacco treatment. In addition, you may feel you gain benefit from a sense of contributing to a better understanding of health care issues facing your fellow Veterans. You may experience a sense of purpose from helping improve how the VHA addresses the health care needs of other Veterans who smoke cigarettes.

ARE THERE ANY COSTS?

Participants will not be required to pay for care received as a subject in a VA research project. Some Veterans are required to pay co-payments for medical care and services provided at the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are *not* part of this study.

ARE THERE ANY ALTERNATIVES?

You do not have to participate in this study. If you are interested in quitting smoking, there are programs and treatments you may choose (both medication and non-medication) instead of participating in this study.

WILL I RECEIVE THE RESULTS OF RESEARCH TESTS?

Some participants will be invited to attend a single visit at the VA hospital to provide a breath sample to measure carbon monoxide and a saliva sample to measure nicotine after the 2-year follow up call. Participants who are invited but unable to attend this visit at the VA will be offered the option to provide a saliva sample via a mailed collection kit. If you attend this visit, you will receive the results

of your carbon monoxide breath test during this visit. If you provide a saliva sample in person or in the mail, you will not receive the results of your saliva test. These results measure only the presence and concentration of carbon monoxide in the breath and nicotine in the saliva and are not used for diagnostic purposes. Saliva samples will be sent to a lab for analysis and disposed of immediately. Samples will not be stored for future analysis.

WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?

To receive payment for your participation in this study, you may be required to provide your social security number and bank account information. This information will be used by the VA to pay you for this study and will not be kept by the study team.

You will receive $40 for completing the initial screening phone call. You will receive up to $140 for completing all of the assessment calls. Some participants will be invited to attend a single in-person visit to the VA Hospital or clinic to provide a breath sample to measure carbon monoxide and a saliva sample to measure cotinine following the 2-year assessment call. Participants who are invited but unable to attend this visit at the VA will be offered the option to provide a saliva sample via a collection kit sent in the mail. These participants will receive $75 for completing this visit or sending a saliva sample in the mail.

If you decide to engage in tobacco treatment through the study, you will receive $40 for completing the additional phone calls.

WILL THERE BE COMPENSATION FOR INJURY?

In the event you sustain injury as a result of participation in this investigation, all necessary and appropriate care will be provided. However, the VA may not pay for the costs of treatment for injuries that result from your non-compliance with study procedures.

IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND?

If you decide to participate in this study, you are free to withdraw your consent at any time. If you choose to withdraw from the study, no new information that might identify you will be gathered after that date, but the laws let investigators use information that has already been gathered in order to keep the research accurate. If you decide to terminate your participation in this study, you should notify Jessica Cook at [redacted].

WILL INFORMATION FROM THIS STUDY GO INTO MY MEDICAL RECORD?

Assessment and treatment phone calls with study staff are considered clinical contacts. Progress notes will be written in your VA medical record for each call and will outline the assessments and basic topics discussed.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Any information obtained about you in this study will be treated as confidential as required by law. Neither your name, initials, or other identifying data will be released or published without your permission unless we are required to do so by law (such as if you are at risk of imminent harm to others or to yourself). Data entered into a computer will be stored using a study identification code that does not identify you by name, and only selected researchers associated with the study will have access to this information. Current VA regulations require us to keep study records for 7 years.

There are some instances when your health information related to this study may be disclosed in connection with this research study. Specifically, the following people or groups may ask to look at our records to make sure that we are following all the regulations and may know that you are in the study:

- The VA committees (VA site 607-Madison VA) that oversee research, including the VA Research and Development Committee that oversees the safety and ethics of VA studies.
- University of Wisconsin Institutional Review Board.
- Other government oversight agencies that oversee research, such as the Department of Veterans Affairs, the Office for Human Research Protections in the Department of Health and Human Services, National Institutes of Health, National Institute of Drug Abuse, and US Food and Drug Administration.

Your data, recordings, and samples will be shared with researchers at the University of Wisconsin-Madison who are working on this study with us. By providing verbal consent you gave us permission to share your data, recordings, and samples with these researchers.

In addition, the results of this study may be used for medical and scientific publication, but you will not personally be identified. For safety reasons, confidentiality may need to be broken if it is found that you are an imminent harm to yourself or others. If an imminent harm is found, study personnel will contact the VA mental health triage team.

Information about you and your participation in this study will be collected and stored on a web-based computer program called REDCap. VA REDCap servers are housed at the VA Informatics and Computing Infrastructure (VINCI), physically located at the VA Austin Information Technology Center (AITC) in Austin, Texas. Your information will be entered directly into a password-protected computer and will be encrypted. Information will then be stored on a secure server in a locked room. Only individuals with appropriate permission can look at information about you in REDCap and no data is identifiable. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT IF I HAVE QUESTIONS?

If you have questions or concerns about this research, please contact the VA study investigator, Jessica Cook at [redacted]. For information on the rights of research subjects, please contact the VA hospital patient relations representative at (608) 280-7182. If you want to confirm this is a valid VA study, please call the VA Research Office at (608) 280-7007.

In case there are medical problems or questions, call study personnel at [redacted] during the day and VA medical triage at 608-280-7066 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

VOLUNTARY STATEMENT OF INTENT TO AVOID PREGNANCY

According to the FDA and the manufacturer of the nicotine patch, gum, and mini-lozenge, these medications should not be used by pregnant women. The risks of these medications to an unborn child are not fully known. We ask female study participants who are able to get pregnant or who believe that it is possible to get pregnant (for example, women who have gone through menopause but a year has not passed since the last menstrual period) to agree to the statement below about avoiding pregnancy while receiving study medication. Women who have had tubal ligation ("tubes tied") to prevent pregnancy do not have to agree to this statement if the tubal ligation occurred more than a year ago and no pregnancy has occurred.

By providing verbal consent, I agree to attempt to avoid pregnancy while taking study medication. I will continue to employ medically acceptable means of contraception that have been approved by study staff. These methods include IUD, oral contraceptive, barrier methods, or abstinence. I will immediately contact study personnel if pregnancy is suspected. I am aware that I may decline to agree to this statement and my refusal to do so will have no effect on my further treatment; however, I cannot participate in the treatment portion of this research study. If this occurs, I understand I can still receive tobacco treatment through the VA Tobacco Treatment Clinic.

AUTHORIZATION SECTION

Study staff will orally go over this consent form in full, review any questions, and ask for oral consent to enroll in the research study. You will receive a printed copy of this form for your records.