Department of Veterans Affairs

INFORMATION SHEET

Version Date: 12-18-2020

Title of Study: Development of an e-Health Smoking Cessation Intervention for Low Income Veterans

Principal Investigator: Megan Kelly, Ph.D. VA Facility: Bedford VAMC

Sponsor of Study: National Cancer Institute

This information sheet will give you information about the study to help you decide whether you want to participate. Taking part in this study is completely voluntary.

SUMMARY OF IMPORTANT INFORMATION

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is focused on developing a web-based treatment to help Veterans with low incomes quit smoking. This treatment is called Vet Flexiquit. It is being funded by the National Cancer Institute. By doing this part of the study, we hope to compare this treatment with another web-based smoking cessation treatment and learn whether participants prefer one over the other.

2. WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

If you decide to participate in this study, you will be randomly assigned to one of the two web-based smoking cessation treatments. This process is like flipping a coin. The programs will send you 2-4 text messages and/or emails daily. The amount of time you use this program and what parts of the program you use is up to you. You will do this at home.

During the study, you will participate in 3 study visits. The first visit, held by telephone or VA-approved video conferencing software, will involve answering questions about your smoking habits and smoking history. This will take about 30 minutes. You will be given a $25 gift card for participating in this study visit. At the second study visit, we will call you after 1 month, and ask you similar, but fewer questions. This will take about 10 minutes. At the third study visit, which occurs after three months, we will contact you by either telephone or VA-approved video conferencing software. This visit will take about 30 minutes and involve answering questions about your smoking habits, opinion of the treatment and taking a saliva cotinine test. You will be given a $25 gift card for this study visit.

Pregnant women will not be able to participate.

3. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

We cannot and do not guarantee or promise that you will receive any benefits from this study.

Using the web-based programs may help you quit smoking.

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4. WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is the possibility that answering some questions may be emotionally upsetting. You have the choice to not answer any question that makes you feel uncomfortable.

5. DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation in this research study is voluntary. If you decide to take part in the study, it should be because you want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. You may also discontinue participation at any time.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Megan Kelly of the Edith Nourse Rogers Memorial Veterans Hospital. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: 781-687-3317.

MORE RESEARCH DETAILS

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you are assigned to Group A (25 participants), you will participate in one web-based treatment program for quitting smoking. This web-based program helps you to develop a quit plan. It teaches you about smoking triggers, medications to help you quit smoking, acceptance of thoughts and feelings related to smoking, mindfulness exercises, and exploring your personal values. You will be asked to input answers to questions on your smoking and skills learned through the program. The program will also ask you to track smoking and skills practice. You will receive 3-4 daily text messages and/or emails from the program. The amount of time you use this program and what parts of the program you use is up to you.

If you are assigned to Group B (25 participants), you will take part in another web-based treatment program for quitting smoking. This program includes a discussion of the following topics: preparation to quit smoking, building motivation to quit and identifying smoking triggers, information on the health effects of smoking, and advice about quitting smoking. You will receive 2-3 daily text messages and/or emails from the program. The amount of time you use this program and what parts of the program you use is up to you.

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If you are in Treatment Group A or Treatment Group B, you will be asked to complete the following procedures:

- Visit 1 (by telephone or VA-approved video conferencing software): We will ask questions, some of which will be repeated in other visits, including your amount of smoking, past history of smoking, and other treatments. You will be assigned group A or B by chance. Instructions for using the assigned web program will be provided, and study staff will assist you in logging in for the first time. You will have an equal chance of receiving either one of the two web-based treatment programs. This visit will take about 30 minutes of your time. You will be provided with a $25 gift card (by mail) for this visit.

- Telephone Appointment. You will be contacted by phone after one month in order to ask you questions about smoking, how you like the treatment, and use of the website. The telephone visit will take about 10 minutes of your time, and you will receive a $15 gift card (by mail) for your time.

- Visit 2 (by telephone or VA-approved video conferencing software). After 3 months, you will have a study visit to answer questions about smoking, side effects, other treatment, and your opinion of the treatment. You will also complete a saliva cotinine test to verify whether you have been smoking or not. A saliva cotinine test is a test that measures the amount of saliva cotinine in your body by using a test strip. Saliva cotinine is a measure of your level of cigarette smoking. This visit will take about 30 minutes of your time and you will receive a $25 gift card (by mail).

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS OF TAKING PART IN THIS STUDY?

There is the possibility that answering some questions may be emotionally upsetting. You have the choice to not answer any question that makes you feel uncomfortable. If you quit smoking, you may experience some nicotine withdrawal symptoms, including irritability and restlessness. Pharmacotherapy for smoking cessation will substantially reduce these symptoms. We can provide a referral to you to help you obtain this medication.

There may be unanticipated risks. If you have any unusual or uncomfortable feelings during the study, contact the research staff. You can reach a study staff by calling a member of the

research team during normal business hours. You can also come in to the Mental Health Clinic (Hours: Monday-Friday, 8:00 am-4:00 pm; Building 78, 2nd Floor; 781-687-4333). You may also come in to the Bedford VAMC Urgent Care Center during their main hours (Monday-Friday, 8:00 am-4:00 pm; Building 78, 1st Floor; 781-687-2654) or after hours. You may also call the doctor on call after hours (781-275-7500). If you become suicidal, hospitalization is possible.

Since we are concerned about your health and safety, there are some situations when we will contact your primary care physician or other clinical professional that is providing care for you, such as to inform him/her that:

- You need to be taken to Urgent Care for medical reasons
- You report suicidal thoughts or homicidal thoughts
- You are hospitalized
- You experience serious side effects that are a concern to you and/or the study team
- You experience an adverse event or reaction that occurs in the course of the study where the PCP or mental health provider has not already been informed.
- You may be potentially harmed by continued participation in the study.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

If you do not want to join this study, you may obtain another smoking cessation treatment, use a medication or use another web-based smoking cessation program. We can provide information about these to you. Smoking Cessation treatments at the VA include individual and group counseling, telephone counseling, , smoking cessation medications and the VA quitline (1-855-QUIT-VET). Similar treatments are available through programs in the community.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

This study is being done together by researchers at the Bedford VA Medical Center and the Fred Hutchinson Cancer Research Center in Seattle, Washington, and some data without identifiers will be sent to them.

Participation in this research may involve a loss of privacy. However, numerous safeguards will keep electronic and hard copy data secure. Your research records will be kept as confidential as possible. All research information will be kept in locked files at all times. Your identity will not be revealed in any reports or publications resulting from this study. Only a code number will identify

your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.)
Only authorized persons will have access to the information gathered in this study. Federal Agencies such as the Office for Human Research Protection (OHRP) and the Government Accountability Office (GAO) may have access to the records.

Identifiers might be removed from the identifiable private information collected. After the removal, the information could be used for future research studies without additional consent from you.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of certain communicable diseases, physical or sexual abuse, child or elder abuse or neglect, or harm or risk of imminent harm to self or others. The Certificate does not protect you if you, someone in your family, or someone you know voluntarily releases information about you.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You, or your insurance, will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

The study team will inform you of any important information about your participation that may affect you or your willingness to be in this study.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call **Dr. Megan Kelly at 781-687-3317 during the day or have the doctor on call (781-687-2000) paged after hours.**

VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures.

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No money has been set aside for compensation in case of injury as a result of participating in this study however I have been told that I would still have the right to file any legal action.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions about the research, you may contact Dr. Megan Kelly at 781-687-3317.

If you have any questions, concerns, or complaints about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board Coordinator, Denise Carr at 781-687-2839, and the information will be given to the Institutional Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Kelly or study staff will explain the research study to you and obtain your verbal consent. You will be told of the risks or discomforts and possible benefits of the study. You will be told of other choices of treatment available to you. You will be given the chance to ask questions and obtain answers.