

Electronic Proactive Outreach for Smokers with COPD: Engaging patients to quit (CDA 19-081)

NCT04462289

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DEPARTMENT OF VETERANS AFFAIRS

Medical Center
One Veterans Drive
Minneapolis, MN 55417

[Date]

Dear [Mr./Ms.] [Subject's Last Name]:

I am writing to ask for your help in a research study that we are conducting through the pulmonary department at the Minneapolis VA Medical Center. Our goal is to find ways to better use technology, like text messaging, to help Veterans improve their health. You are being invited to participate in this study because our records show that you have some lung disease related to smoking and you currently use tobacco.

You will be asked to complete a short baseline survey by phone about your current smoking and any recent quit tries, which will confirm eligibility for the study. You will then randomly receive one of two ways to offer help for stopping smoking either through your usual clinic or a text messaging program offered through the VA's text messaging service called the "Annie App." You do *not* need to be planning on stopping smoking to participate. About six months after that, we will contact you again to ask a few questions regarding your experiences with the outreach and any stop smoking support you have used or quit attempts you have made. You will be paid \$20 for each survey to be paid at the end of the study. We will also pull information from your medical record to confirm your medical diagnoses and what quit resources you may have used. Some participants will be invited to complete a short interview to tell us more about their experiences, which will be paid \$30. Some participants will be asked to do a "breath test" using a device we mail to you and your own phone, which will also be paid \$30 for completing that test.

Your contribution is *very important* to this project—we cannot do it without you. Your choice to participate is voluntary and will have absolutely no bearing on your medical care at the VA. You can decline further participation at any time, and we will use only information provided up to that point. Be assured that the records of this research study will be kept completely confidential. We will not include anything that will make it possible to identify you in any report we publish, and we will not disclose your information to any person or entity except as required by federal law.

It is very important for us to hear from you because we need the perspective of Veterans like you. Completing any of the research study is voluntary and you can skip any questions you prefer not to answer.

If you prefer not to be contacted by us again about this study, please call our study coordinator at **612-629-7225**. We will make no further attempts to contact you. Please use the same number if you have any questions regarding this opportunity.

Sincerely,

Dr. Anne Melzer

Minneapolis VA Medical Center

Megan Campbell, MPH

Project Coordinator

Eligibility Assessment and Consent Script:

Hello I am {name} and I am calling from the Pulmonary research department. I am calling about the study that we recently sent you a letter about. Would you be willing to chat for a few minutes?

First, I want to see if you might be eligible to participate:

Have you smoked cigarettes, even a puff in the past 30 days?

yes no

If yes, continue if no: Thank you. We are looking for participants who currently smoke cigarettes.

Do you have a text-capable phone?

yes no

If yes, continue if no: Thank you, our program requires us to text participants.

Are you currently trying to quit smoking and are participating in a tobacco treatment program? If you are trying to quit on your own or using some nicotine replacement products, like the gum, patches or e-cigarettes on your own without working with a counselor, that's ok.

yes no

If no, continue. If yes: Thank you, that is wonderful you are working on quitting, however we are looking for participants who are not already in a program to quit smoking.

Consent Script:

Our study is looking at better ways we can help Veterans who smoke to quit, focusing on Veterans with smoking-related lung problems. You would be in our study for about 6 months and can opt out of participation at any time. You do not need to be interested in stopping smoking to participate. We will ask you just a few questions today. You will then be randomly assigned to either receive motivational text messages from the VA's "Annie" text messaging program about ways to work towards quitting smoking or continue your usual medical care. The program will text you up to once a day over three months with tips and information on treatment options. You can opt out at any time. We will call you at the end of 6 months to ask a few questions about how it went and whether you have made any changes to your tobacco use. We will also ask for feedback on the texting program. We will also pull information from your medical record to confirm your medical diagnoses and what quit resources you may have used during the study. We will pay \$20 for completing the survey today and \$20 for completing a survey in 6 months at the end of participation. For some participants, we will ask them to do a short interview at the end to give us some more feedback on the program and we will pay them \$30. Some participants who stop smoking will be asked to provide a "breath test" to confirm they have quit smoking using a device that connects to their smartphone, which we will send in the mail. They will be paid \$30 for completing the breath test. Any information that we gather will be kept strictly confidential and stored securely within the VA. Participation in the study has no impact on your VA benefits and we will never share your personal information except as required by federal law. You can opt out of the study at any time or skip any questions you prefer not to answer. Does that sound like something you would be interested in participating?

(If yes, continue). If no: Thank you for your time. Can I ask why you are not interested in participating?

Not interested in quitting (if they say this: You do not need to be interested in quitting to participate.)

Not interested in text message programs

Other _____

Great! In preparation we need your permission to enroll you in the Annie program, the VA's text messaging platform for education and self-management of medical conditions. The platform is an automated system that will send text messages at pre-specified intervals. While you do have the ability to text back to the study team, these are not monitored in real-time, and it may take a few days for us to get back to you. If you have time-sensitive health concerns, you should always contact your care team directly rather than using the Annie system. We will provide you the direct line to our study staff if you have questions related to our study or about smoking cessation. If you leave a message, we will get back to you as quickly as possible.

Please be aware that SMS text messaging are not secure and could cost you something depending on your texting plan. Collection of a patient's information by Annie is subject to VA privacy rules. Any information you send using the Annie program will not be shared with anyone outside the program. Participation in the Annie program is voluntary, and you are welcome to stop the messages at any time. If you feel you would no longer wish to participate and receive text messages, you can text "STOP" to the Annie text message, or call us and we can stop your enrollment.

Does that sound okay to you? Great. We also need to tell you a little about the tobacco cessation program for our study. The goal of it is to help people who aren't quite ready to quit smoking become more motivated, learn new techniques to quit or cut down, or get them in touch with help when they are ready. There are about 30 messages over the course of 3 months and you can always opt out of further messages. Do you have any questions or concerns I can address right now?

Ok, great!

I have just a few more questions for you today. (Start baseline survey).