Smokeless Tobacco Cessation Intervention for Firefighters

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Duke University Health System

Consent to Participate in a Research Study
#Smokeless Tobacco Cessation Intervention for Firefighters

You are being asked to take part in this research study because you use smokeless tobacco and are interested in quitting. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

A grant from the National Cancer Institute will sponsor this study. Portions of Devon Noonan, PhD, FNP-BC and her research team's salaries will be paid by this grant.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to test whether a text messaging program is effective in helping people with careers as firefighters/EMS to reduce their use of smokeless tobacco.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 50 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will be asked questions about your tobacco use and where you live to make sure that you are eligible. If we change the study in any way that affects you, we will tell you about the changes. We might ask you to sign a new consent form if there are changes to the study.

Participants who own and are willing to use their personal phone that can send/receive text messages and have a free texting plan will be included in the study.

Randomization
You will be randomly assigned (like the flip of a coin) to one of the two groups after completing a baseline survey. You have a 50% of being in either Group 1, the tailored intervention or the RTQ (Reduction To Quit) group or Group 2, the control group.

Group 1: RTQ Program (Reduction To Quit)
If you are in the tailored intervention program: This program will last up to 10 weeks. Participants in this group will be given the choice to: 1) either follow a reduction program or 2) to set a quit date for themselves within two-four weeks. For those who choose to set their own quit date, you will receive 8 weeks of text-based support messages focusing on health benefits, confidence building, and helping in your quit plan. Messages coming past your quit date will provide support in dealing with craving, urges, and relapse prevention.

For those who choose to participate in the reduction program, you will reduce the daily amount of participants chew/dip use on a weekly basis. During the first week, you will be asked to use chew/dip as

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per your regular habit. You will be required to text us at the end of each day how many times you chewed/dipped that day. The text-intervention will calculate the number of times you used smokeless tobacco during your first week. For all weeks following, you will receive a text (on the 7th day) instructing you of your updated daily usage amount for your chew/dip for the coming week. This will decrease each week until you reduce to zero. During this time, we ask that you text us at the end of each day how many times you dipped. This will help us know if you have followed the schedule.

All participants in this group, no matter if they choose to follow the reduction program or not, will receive text-based cessation support messages to help you quit, along with interactive capabilities when participants text back key words when extra support is needed during cravings, post-call stress, and mood slips. In addition, participants will be given a four week supply of Nicotine Replacement Therapy (NRT) 4 mg lozenges.

Group 2: Control Group
If you are in the control group. you will be sent the Enough Snuff cessation booklet, which will be paired with support text-messages. The booklet will walk you through self-evaluation of readiness to quit, setting a quit date and a quit plan, and how to deal with craving and maintain your quit status. After the booklet is sent, you will then receive support text messages from the study team twice a week for eight weeks. In addition, participants will be given a four week supply of Nicotine Replacement Therapy (NRT) 4 mg lozenges. Instructions for proper use of NRT lozenges will be provided to you when you receive the lozenges in the mail.

End of Program- 1 month Follow-up Assessment
For both study groups, we will send a follow-up assessment 1 month after you have completed the intervention. In addition, all study participants will also be given the choice to participate in an interview at the end of the intervention, where you will be asked your opinion on the text messages you received or the intervention. The interview will be recorded on an encrypted audio device and will be transcribed for analysis. Your identity will not be revealed in the recordings and, once they are transcribed, will be coded with your participant record ID to protect your information.

If you have reported to the study team that you have quit using smokeless tobacco you will be asked to provide a saliva sample to check for nicotine. Providing the saliva sample is voluntary in this study. All saliva samples will be destroyed once the nicotine testing has been performed.

Participation is voluntary in this study. Refusal to participate will involve no penalty or loss of benefits to which you are entitled.

HOW LONG WILL I BE IN THIS STUDY?
The study will last for approximately 5 months. You will be contacted 1 month after intervention completion to complete assessments about your smokeless tobacco use. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first. The study

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doctor may also withdraw you from the study if they feel it is necessary for your health, such as if you have a reaction to the NRT.

WHAT ARE THE RISKS OF THE STUDY?

Risk of loss of confidentiality:
There a potential risk of loss of confidentiality by participating in a research study. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Physical risks of NRT:
Possible side effects of NRT lozenges include nausea/vomiting, light-headedness, headache, poor sleep or nightmares, mouth soreness or tingling, hiccups, throat irritation, rash and increased blood pressure.. While it is rare, NRT may cause changes in heart rhythm. If you believe you are experiencing severe side effects or vomiting as a result due to NRT use, we advise you to please call the study number at 919-613-9130 and ask to speak with our Principle Investigator, Dr. Devon Noonan.

Risk of allergic reaction to NRT:
Occasionally, people have allergic reactions to medications which may require medical treatment. A severe allergic reaction could be life-threatening. Examples of an allergic reaction include: a rash; shortness of breath; wheezing; difficulty breathing; sudden drop in blood pressure; swelling around the mouth, throat, or eye; fast pulse; and sweating. You should get immediate medical help and contact the study doctor if you have any of these or any other side effects during the study.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, you may quit using smokeless tobacco which is beneficial to your current health. We hope that in the future the information learned from this study will benefit other people and help them quit smokeless tobacco.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of NCI, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

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The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

We will use your phone number to send you text messages through a web service called Mosio. All text messages will go through the usual mobile phone carrier channels. Information sent to your mobile phone may be permanently kept by Mosio and their business associates. Information disclosed to Mosio or to outside reviewers for audit purposes may be further disclosed by them and not covered by the federal privacy regulations. Texting is not a secure form of communication and these messages like most text messages are unencrypted, so there is a small chance that someone could eavesdrop on them while being sent. The privacy policy for Mosio can be found here https://www.mosio.com/privacy/

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

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You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS TO YOU?
There are no costs to be in the study.

WHAT ABOUT COMPENSATION?
You will be reimbursed for your participation. All participants will receive up to $35 for expenses related to your participation. The payment will be prorated to $15 for the baseline survey and $20 for the 1-month follow-up assessment.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Devon Noonan at 919-613-9130 during regular business hours and at 617-543-5759 after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Devon Noonan, PhD, FNP-BC in writing and let her know that you are withdrawing from the study. Her mailing address is DUMC 3322 307 Trent Drive Durham NC 27710.

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

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Devon Noonan at 919-613-9130 during regular business hours and at 617-543-5759 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time