A text-based reduction intervention for smokeless tobacco cessation
NCT04315506
01/28/2022

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
#EnufSnuf Study

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 reduce their use of smokeless tobacco.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 800 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 the baseline survey. You have a 50% of being in either the Scheduled Gradual Reduction (SGR) group or the control group. You will then be given a baseline survey and the intervention will be explained to you.

Group 1: SGR Program
If you are placed in the SGR program: This program will last up to 13 weeks. The program will reduce participants chew/dip use by a 1/4th each week down to zero by program completion, with an option to extend gradual reduction by one week. The intent of this program is to reduce the number of times you chew/dip to zero. You will also receive text-based cessation support messages to help you quit. During the first week, you will be asked to use chew/dip as per your regular habit. You will be required to text "s" every time you use. You may also be asked to text us about how you are feeling (e.g. your craving levels, your mood). The text-interventionwill calculate the number of times you used smokeless tobacco during that first week. You then will be texted the instructions to reduce the number of times you use

smokeless tobacco by a fourth each week, until you reduce to zero. You will have the option to extend a week if needed. During these weeks you will be instructed not to use smokeless tobacco unless you receive a text message to do so. Within 30 minutes after you receive the text message you will be required to respond to that message and text the study team "s" if you chewed/dipped. You also will be asked to let the study team know if you chew/dip at a different time than the time we text you. This will help usknow if you have followed the schedule or not. If this pattern continues then you will receive a text or call to reexamine your pattern or smokeless tobacco use and readjust your schedule.
Group 2: Control Group
If you are in the control you will be sent the Enough Snuff cessation booklet. After it is sent you will then receive a text message from the study team twice a week for ten weeks.

End of Intervention and 6 Month Follow-up Assessments
For both study groups, we will send follow-up assessments at 12 weeks from baseline, and 6 months from baseline If you have reported to the study team that you have quit using smokeless tobacco you may be asked to provide a saliva sample to check for nicotine. We will also contact you for a midpoint check in around 19 weeks post-baseline to see if you have quit and how much you are using smokeless tobacco.

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 8 months. You will be contacted at the end of the intervention and six months 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.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. 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.

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?

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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.

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).

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?
There are no costs to the subjects to be in the study.

WHAT ABOUT COMPENSATION?
You will be reimbursed for your participation. All participants will receive up to $40 for your expenses related to your participation. The payment will be prorated to $10 for baseline survey, $10 for end of intervention survey, $20 for 6 month survey.

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.

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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 Web site will include a summary of the results. You can search this Web site at any time.

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