**Official Title:** A Text-based Reduction Intervention for Smokeless Tobacco Cessation- Pilot Study

**NCT:** NCT06637358

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**Consent to Participate in a Research Study**
Pilot-A text-based reduction intervention for smokeless tobacco cessation

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. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. 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 and will be reviewed with you by the study team.

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

Please tell the study doctor or study staff if you are taking part in another research study.

**Why is this study being done?**
The purpose of this study is to test whether a quit coach and extended supporting text messaging program is effective in helping people reduce their use of smokeless tobacco.

Approximately 70 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.

Scheduled Gradual Reduction (SGR) Program
All participants will begin the study in this program, which will last up to 7 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

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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 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-intervention will calculate the number of times you used smokeless tobacco during that first week. You then will be texted instructions to reduce the number of times you use smokeless tobacco by a fourth each week until you reduce to zero. 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 us know 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.

End of Intervention and 7 Month Follow-up Assessments
At the end of your initial 7 weeks of intervention, we will reach out to you via text to ask if you have been successful in quitting your use of smokeless tobacco.

If you have successfully quit, we will send follow-up assessments at 19 weeks from baseline, and 7 months from baseline.

If you have not quit your use of tobacco after the first 7 weeks, we will provide you with next steps as described below.

Extension of Study & Randomization
If you respond that you have not yet been able to quit your use of smokeless tobacco, you will be randomly assigned (like the flip of a coin) to one of two groups. You have a 50% chance of being in either Group 1, the Extended SGR (Scheduled Gradual Reduction) group or Group 2, the Quit Coach Group.

Group 1: Extended Scheduled Gradual Reduction (SGR)
Participants placed in this group will receive an additional 8 weeks of the gradual reduction text program. 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 chew/dip as

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Group 2: Quit Coach
Participants placed in this group will receive the Extended SGR intervention (as described above) for an additional 8 weeks. In addition, participants will receive support from a text-based quit coach for the eight-week period. The quit coach will be available for real-time support and questions. Coaches will reach out up to 3 times per week during the intervention period.

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 may last up to 7 months. You will be contacted at the end of the intervention and 7 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.

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that you are taking before you start the study and before starting to take any of these products while you are on 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?**
Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept securely at DUHS. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the sponsor, the National Institutes of Health (NIH), and representatives of Duke University Health System Institutional Review Board. If any of these groups review your research record, they may
also need to review your entire medical record.

This information may be further disclosed by the sponsor of this study, NIH. If disclosed by the sponsor, the information is no longer covered by the 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 the federal privacy regulations.

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 will 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.

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

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.

**Will it cost me anything to be in the study?**
There are no anticipated costs to you for participating in this study.

**Will I be paid to be in the study?**
You will be compensated 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 program survey, $20 for 7-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.

**What if I want to withdraw from the study?**
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.

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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 Dr. 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 should 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.

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**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 Participant | Date | Time |
| _____ | _____ | _____ |
| Signature of Person Obtaining Consent | Date | Time |