LEVERAGING COMMUNITY PHARMACISTS TO OPTIMIZE SMOKING CESSATION SERVICES FOR RURAL SMOKERS IN APPALACHIA

STUDY INFORMATION LETTER

Leveraging Community Pharmacists to Optimize Smoking Cessation Services for Rural Smokers in Appalachia

What is the purpose of this form?

This form will provide you with information about this research study.

Who is funding this study?

This study is being funded by the National Institute of Health (NIH).

Key Information About This Research Study

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What problem is this study trying to solve?

Adult smoking rates in the United States are highest in areas such as rural Appalachia, specifically the Central and South-Central subregions of Appalachia, including parts of Virginia, Tennessee, Kentucky, and North Carolina. Smokers living in these areas are more likely to start smoking cigarettes earlier in life, daily and in great excess and consequently significantly affected by tobacco-related cancers. Rural smokers face increased financial barriers to obtaining therapies to stop smoking and have limited awareness of available smoking cessation/stopping programs and resources. Thus, more help is needed to reach and assist rural smokers to make a successful quit attempt. Quitting smoking is associated with decreased risk of both cancer and heart disease.

Nicotine is the main addictive substance in tobacco. When a person uses tobacco, many parts of the body get used to having nicotine in them. When a person quits tobacco, they also quit nicotine and will likely have withdrawal from it. This is because the body has to get used to not having nicotine.

The nicotine in tobacco leads to actual physical dependence. This can cause unpleasant withdrawal symptoms when a person tries to quit. Nicotine replacement therapy (NRT) gives you nicotine – in the form of gum, patches, sprays, inhalers, or lozenges – but not the other harmful chemicals in tobacco. NRT can help relieve some physical withdrawal symptoms so that you can focus on the psychological (emotional) aspects of quitting.

NRT is an over-the-counter drug proven safe and helpful for smokers attempting to quit smoking. It is approved by the U.S. Food and Drug Administration (FDA) and is widely available at pharmacies and retailers nationwide. In this study, NRT comes in the form of patches and lozenge.

The purpose of this study is to evaluate the effectiveness and implementation of a pharmacist-delivered medication therapy management intervention (QuitAid) to smoking cessation in rural Appalachia.

Medication therapy management (MTM) services, which have been used to manage chronic diseases, such as diabetes, generally consists of medication review, an individual medication record and medication-related action plan, and consistent follow-up with pharmacists.

There will be two groups of participants in this study:

1. Smokers will participate in a smoking cessation program that includes the use of nicotine replacement therapy (NRT) in the form of the patch and/or lozenge. The NRT treatment can last 4 or 8 weeks, depending on the group the participant is randomly assigned. This consent is for participants who are smokers.

2. Community pharmacists will participate in the study and recruit smokers in rural areas for participation. Pharmacists who agree to participate will sign a separate consent form.

You were asked to take part in this study because you had identified yourself as a smoker and are seeking treatment to stop smoking.

Up to 768 people who are identified as smokers will take part in this part of the study in the rural Appalachia of Virginia, West Virginia, Tennessee, Kentucky, and North Carolina.

What will you do in this study?

Full details of all the procedures are found later in this form. By agreeing to take part in this study, you will:

- Use nicotine replacement therapy in the form of the patch or patch and lozenge for 4 weeks or 8 weeks
- Complete five surveys
- Some participants will be randomized (like the flip of a coin) to take part in a 7-week text messaging program to help them quit smoking
- Some participants will be randomized to take part in a tobacco quitline program.
- Some participants will be randomized to take part in QuitAid, a medication therapy management intervention delivered by their local pharmacist or technician.

What is the difference between being in this study and getting usual care?

If you take part in this study, the following things will be done differently than if you do not take part in this study.

- You will receive 4 or 8 weeks of nicotine replacement therapy in the form of the nicotine patch and you may also receive the nicotine lozenge.
- You may also be selected to receive a medication therapy management intervention, QuitAid, for smoking cessation. QuitAid will include 1 in-person coaching session with a pharmacist from your pharmacy, and 5 follow-up telephone coaching sessions. All sessions will occur weekly within 4 to 6 weeks from the time of enrollment.
- Some participants will be randomized (like the flip of a coin) to take part in a 7-week text messaging program, SmokefreeTXT, to help them quit smoking
- Some participants will be randomized to take part in a tobacco quitline program.

How long will this study take?

Your participation in this study will last up to 6 months. Your participation in this study will require up to 15 study visits over a 6-month period of time. Only 2 of the 15 study visits will require you to travel to your local participating pharmacy for an in-person visit, and that is only if you receive the QuitAid intervention or report that you have quit smoking at the end of the study.

What will happen in the study?

In this study, some of your required visits will be done by telephone, via a web-based survey, or a mailed paper survey and others will be done at your pharmacy. Some of the treatments will be audio recorded for training purposes. You will be told prior to any recordings and provided the opportunity to decline. Also, audio recordings will not include names to further protect privacy.

BASELINE SURVEY:

You will be asked to complete the baseline survey which will take about 30 minutes to complete. This survey will ask about:

- your background such as age, race, education, annual income
- your tobacco use history
- your urge to smoke
- current medication use
- your general health and medical history
- your thoughts and feelings about quitting smoking
- how you feel about taking part in this study

RANDOMIZATION and STUDY TREATMENT

You will be randomly assigned (like the flip of a coin) to 1 of 32 study treatment groups. You have an equal chance of being assigned to any one of the groups. Neither you nor your pharmacist can

choose which treatment you are assigned to.

Each treatment component is described in more detail below.

- All participants will receive at least 4 weeks of the NRT patch
- You will also have an equal chance of receiving the following treatment components:
  - 8 weeks of NRT medication instead of 4 weeks
  - NRT lozenge in addition to receiving the NRT patch
  - The pharmacist-delivered intervention, QuitAid
  - The tobacco quitline intervention
  - The SmokefreeTXT intervention

STUDY PROCEDURES (weekly for 4 or 8 weeks)

All NRT will be provided by the study team. The NRT will be mailed directly to your home, delivered to your home by your local pharmacy, or available for pickup at your pharmacy with instructions for proper use unless you are randomly selected to participate in the medication therapy management intervention. If you receive the medication therapy management intervention you will pick up your first dose of NRT at your first visit with your pharmacist. You will use nicotine replacement therapy in form of patch or patch AND lozenge either for 4 weeks or 8 weeks, depending on the group you are assigned.

If you are randomly selected to participate in the QuitAid intervention, you will participate in one (1) in-person coaching session with a trained pharmacist or technician at your pharmacy and 5 follow-up coaching sessions over the telephone. All sessions will occur weekly within 4 to 6 weeks from the time of enrollment. The first session will occur in a private room at the pharmacy, and during this first session, you will receive the NRT you were randomly selected to receive.

In these sessions, the pharmacist will address any withdrawal symptoms you may have, discuss barriers to using nicotine replacement therapy, and provide alternative strategies to help you quit smoking cigarettes. Sessions will last between 5 to 30 minutes of your time. These strategies have previously been used to help people quit smoking.

If you are randomly selected to participate in the Tobacco Quitline intervention, you will receive a 4-session validated behavioral treatment delivered by trained specialists. The goal of this intervention is to help you set a quit date and quit smoking. Sessions will last between 20-30 minutes, and callers are encouraged to call back as often as they want for additional assistance and support. Some of the sessions will be audio recorded for training purposes. You will be told prior to any recordings and provided the opportunity to decline. Also, audio recordings will not include names to further protect privacy.

If you are randomly selected to participate in the SmokefreeTXT intervention, you will be enrolled into the program by study staff at the time of the study screening call. This is a nationally disseminated texting program distributed by the National Cancer Institute which provides smokers with up to 3-5 messages per day for 7 weeks. Standard text messages rates apply.

1, 2, 3, and 6-month FOLLOW-UP SURVEYS (each survey will last about 30 minutes):

This study visit will occur remotely (at your home), where you will be asked to complete the same type of survey that you completed at baseline. These surveys will give us updates on your progress and allow you to document any health problems you have. You will also be given the option to complete this survey by phone, through a secured website, or by a mailed paper survey sent directly to your home.

Quit Status Verification (this visit will take about 30 minutes to complete):

Only if you report that you no longer smoke cigarettes on the follow-up survey will you be asked to go to your pharmacy and have your breath tested to verify your smoking status. Your breath will be tested for carbon monoxide, a substance in your system when you use nicotine. You will be asked to blow into a machine that will analyze your breath.

Study Schedule

	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12
Study Week	-1	0	1	2	3	4	5	6	7	8	12	24
Screening	x											
Informed Consent		x										
Baseline Survey		x										
NRT Distributed[a]			x		x		x		x			
QuitAid Intervention[b]			x	x	x	x	x			x	x	x
Quitline Intervention			x	x	x	x						
SmokefreeTxt Intervention			x	x	x	x	x	x	x			
Follow-up Surveys						x				x	x	x
Quit Status Verification[c]												x

All visits are completed by telephone unless otherwise noted.

[a]NRT will be provided to you in doses based on your prescription drug benefits and the amount of NRT you were randomly assigned to receive. Your NRT will be mailed to your home, delivered by your local pharmacy, or you can pick it up in person at your local pharmacy.

[b]The first QuitAid visit will be on-site at your local pharmacy; the remaining visits will be by telephone.

[c]If you report that you quit smoking at the 6-month follow-up, you will be asked to go to your local pharmacy and blow into a machine that tests for carbon monoxide.

END OF STUDY:

After you have completed all required study visits, your participation in the study will end, and you will no longer receive nicotine replacement therapy provided by the study. If you feel that you still need nicotine replacement therapy, you will be referred to your primary care provider or a quitline or a web-based program so that they may assist you in receiving nicotine replacement therapy at a reduced cost. You may also purchase more nicotine replacement therapy yourself.

What are the risks of being in this study?

Risks and side effects related to quitting smoking include:

Quitting smoking is associated with a variety of nicotine withdrawal symptoms including:

Likely

- Depressed mood
- Difficulty sleeping
- Irritability
- Anxiety
- Difficulty concentrating
- Restlessness
- Increased appetite or weight gain

These symptoms typically are not severe and dissipate within a few weeks of cessation. Study staff will be available to discuss these symptoms with you and provide appropriate strategies to cope with them.

Risks and side effects related to nicotine replacement therapy include:

Risks from nicotine patches

Less Likely:

- Local skin irritation or rash where you place the patch
- Dizziness
- Dry mouth
- Joint, muscle, or back pain
- Headaches
- Stomach problems such as constipation, diarrhea, or nausea

- Trouble concentrating
- Trouble with mood such as depression or nervousness
- Difficulty sleeping or abnormal dreams
- Cough or sinus problems
- Cardiovascular problems such as irregular or fast heartbeat and elevated blood pressure

Although these side effects have been reported in those who use nicotine replacement therapy, they are uncommon and are less likely to be observed in persons who are regular cigarette smokers. In addition, many of these same symptoms are reported by persons who quit smoking without nicotine replacement therapy and have been attributed to nicotine withdrawal from smoking cessation. These symptoms frequently resolve on their own with continued or decreased use.

Allergic reactions are also a possibility. If you develop an allergy to the nicotine patches, the patches should be discontinued.

Risks from Nicotine Lozenge

The side effects of nicotine lozenge include:

Less Likely:

- Headache
- Heartburn
- Hiccups
- Mouth sores
- Dizziness

Risks of Sharing the NRT

Do not share the nicotine patch or lozenge with anyone. It is prescribed only for you and could hurt someone else. Keep it out of reach of children and people unable to read or understand the label.

Risks from Completing Questionnaires

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Risks for women:

Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you are pregnant or breastfeeding. You must use an effective method of birth control during the study. If you have questions about birth control, please ask the study leader or your primary care physician. If you are pregnant now, or get pregnant during the study, please tell us right away. Please wait at least 3 days after quitting smoking and nicotine replacement therapy use before getting pregnant or breastfeeding as nicotine can stay in your system for up to 3 days.

IMPORTANT: *Smoking during pregnancy increases the risk of health problems for developing babies, including pre-term birth, low birth weight, and birth defects of the mouth and lip. Smoking during and after pregnancy also increases the risk of sudden infant death syndrome (SIDS).*

Risk for potential loss of privacy:

One risk of allowing us to collect information about you is a potential loss of privacy. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot guarantee it will be safe.

Risk of Breath Test:

There are no known risks from the breath test.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Risks of audio taping:

Those who are randomized to receive the Quitline intervention may be asked to be audio recorded during randomly selected sessions. At no time will this procedure include video recording. The recordings will be stored on secure servers. Only the study team will be able to access these files. The audio recordings will be destroyed after the completion of this study.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include quitting smoking.

Quitting smoking:

- Improves your health status and quality of life
- Improves your life expectancy
- Reduces your risk of diseases such as chronic obstructive pulmonary disease (COPD), cardiovascular diseases, and cancer.
- Improves outcomes for people diagnosed with coronary heart disease, cancer, or COPD.
- Improves reproductive health and the health of pregnant women, their fetuses, and children.
- Lessens the financial burden associated with smoking on smokers, the healthcare system, and society.

In addition, the information researchers get from this study may help others in the future.

Payment for this study:

You will receive up to $100 in Walmart gift cards for finishing this study by gift card. You will be paid for the surveys you complete during the course of your study participation. You will receive a $5 gift card for completing the baseline survey, a $10 gift card for completing the 1-month follow-up survey, a $15 gift card for completing the 2-month follow-up survey, a $20 gift card for completing the 3-month follow-up survey, and a $25 gift card for completing the 6-month follow-up survey. If you quit smoking, you will also receive a $25 gift card for completing the breath test.

You should get your payment about 7 days after finishing each study survey, and should you leave the study early, you will be paid for each survey you complete.

If you do not finish the study, you will be paid for the specific study related activities that you complete (e.g., $15 for completing the baseline survey and the 1-month follow-up survey).

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: medication management therapy for smoking cessation, quitline treatment, SmokefreeTXT messages and carbon monoxide breath test.

Your insurance will be billed for the NRT prescription. Whatever amount the insurance does not pay, the study will cover. Therefore, you will have no out of pocket expenses related to participating in this study. If you do not have insurance or your insurance does not cover the NRT, the study will cover all costs of the NRT.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study at any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at your pharmacy.

Even if you do not change your mind, the study team can take you out of the study.

If you decide to stop being in the study, we will ask you to call the study coordinator at (434) 260-9517 or email at quitaid@virginia.edu. There is no penalty for withdrawing, and withdrawing will not affect your experience as a customer at your local independent pharmacy.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular care at your pharmacy.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address, and date of birth

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Information about you and/or samples from you may be given to other researchers outside of the University of Virginia after all identifiers such as name, address, phone # have been removed.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information and samples obtained from you during this study will not be used in future research.

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.

What if you decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVA will not use it in the following cases:

- You have agreed in writing to allow UVA to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the study team to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

QuitAid Study Team

University of Virginia, School of Medicine

Associate Professor, Department of Public Health Sciences

PO Box 800765, Charlottesville, VA, 22908

Phone: 434-260-9517

Email: QuitAid@virginia.edu

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research

PO Box 800483

Charlottesville, Virginia 22903 Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

The study team will communicate with you by email or text message:

In communication with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy, but we want to tell you about this possible risk.

You do have to agree to communicate with the study team by email in this study. If you agree to emailing, the study team will collect your email address from you that you would like them to use to contact you. Please note, this study may require you to receive text messages. If you agree to text messaging, charges may apply depending on your data/text plan with your phone provider. If you choose not to agree to text messaging, you cannot be in the study.