Enhancing Smoking Cessation in Homeless Populations
Consent Form
NCT01932996

You are invited to participate in a smoking cessation study. You were selected as a possible participant because you indicated that you smoke cigarettes and that you do not have a permanent residence. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Dr. Rebekah Pratt, PhD in the Program for Health Disparities Research at the University of Minnesota, Twin Cities. It is funded by the National Institutes of Health.

Study Purpose

The purpose of the study is to test which therapies are most effective in helping homeless people quit smoking. This study will look at two different treatments: 1) Counseling to help quit smoking and drinking alcohol using Cognitive Behavioral Therapy, and 2) Brief counseling on quitting smoking and alcohol. Cognitive Behavioral Therapy is a type of therapy that focuses on understanding the thoughts and feelings that influence behaviors. It is commonly used to treat a wide range of disorders including addictions such as smoking cigarettes. Trying the two treatments will show if using Cognitive Behavioral Therapy is helpful, and if trying to quit smoking at the same time as drinking proves to be beneficial. All participants will additionally receive 12-week treatment with nicotine patch plus nicotine gum/lozenge (nicotine replacement therapy).

Study Procedures

If you agree to participate in this study, you will be assigned by chance (like flipping a coin) to one of the two groups that are currently open for study participants:

- **Group A will receive brief smoking and alcohol counseling**
- ~~Group B will receive brief alcohol counseling plus smoking counseling using Cognitive Behavioral Therapy~~ (closed for enrollment)
- **Group C will receive smoking and alcohol counseling using Cognitive Behavioral Therapy**

No matter what group you are in, you will be asked to meet individually with research staff for a total of 17 times over the 6 months that the study will last. These meetings will take place at homeless shelters in the Twin Cities metro area. Efforts will be made to have the meetings in shelters that would be convenient for you. The first visit at week 0 will last up to 90 minutes while most other visits will last 30-60 minutes depending on which group you are assigned to. At weeks 16 and 26, the visits will also be 90 minutes long. Additionally, you may be asked to participate in an interview at week 26 to answers questions about your study experience. A study calendar is located on the last page of this form.

Screening Visit

At the first individual session you will be asked questions about your smoking and drinking history, your living situation, and background. If you are a woman who is able to get pregnant, you will be asked to take a pregnancy test. A saliva sample which tests for cotinine, a substance in your system when you use nicotine, will also be collected to verify your smoking status. You will be asked to use a cotton swab to collect saliva in your mouth; the swab will be placed in a study tube and carefully stored in the study freezer.

Baseline Visit

You will return for a visit where you will be assigned to one of the two groups listed above. You will then answer questions about your smoking and drinking history, as well as the following topics:

- Your height and weight
- Your recent history of substance abuse
- Your urges to smoke and drink
- Your motivation and confidence to quit
- Groups A & C will receive a complimentary package of nicotine patches

Individual Sessions

At all individual sessions you will be asked to take an alcohol breathalyzer test. If your result is greater than the legal limit, 0.08%, we will be unable to complete the study visit and will need to reschedule. At these visits you will also be asked to answer questions about your cigarette smoking and use of alcohol and other drugs. Several questions will be asked about your mental health history and current thoughts and feelings.

At every session you will take a carbon monoxide test. Carbon monoxide is a gas in cigarette smoke that is also in the air smokers breathe out from their lungs. To do this test, you will need to blow into a cardboard tube that is attached to a handheld device and portable machine. The machine will measure the amount of carbon monoxide in the air that you exhale.

Additionally, you will be asked questions about your smoking and drinking patterns and cravings at each visit, as well as your health beliefs and behaviors. You may be asked to keep a log, to help you remember when you had urges to smoke or drink, and what you did to address those urges.

At some visits, trained health professionals will conduct interviews, to see how your quitting process is going. They will ask you about:

- Your withdrawal symptoms
- Your urge to smoke
- Your urge to drink alcohol

You also agree to be audio-recorded during counseling sessions for supervision and education of staff, as well as ongoing quality control and improvement purposes. The audio recordings will be destroyed 5 years after the end of the study.

A member of the research staff will also be in contact with you regularly to remind you of your appointments, replace lost nicotine patches, gum or lozenge, or answer questions you may have between sessions. In order to remind you of appointments, to make sure you get refills on the nicotine replacement therapy, and that you are using the patch correctly, program staff may need to talk with other homeless service providers, such as a case worker or shelter director, about your current contact information.

If you do not follow the instructions outlined above, you may be asked to withdraw from this study. By signing this form you agree to return any unused patches, gum or lozenges at the end of the treatment phase of the study.

Week 26 Interview
If you are contacted to participate in the additional interview about your study experience at week 26, you have the option to decline the interview. If you chose to do the interview, your interview will be audio-recorded. The audio recording will not contain any personally identifying information and will be destroyed 5 years after the end of the study. You will be compensated with a $20 Visa gift card.

Risks of Study Participation

There are some risks related to quitting smoking that you may experience while in the study. These may include headaches, being uncomfortable, changes in mood, weight gain, and the possibility of going back to smoking. The nicotine replacement therapy used in this study may include the nicotine patch, nicotine gum or nicotine lozenge. You should not use the nicotine patch if you have irregular heartbeats, or have had a heart attack of stroke in the previous month. Possible side effects of the nicotine patch may include skin irritation or rash, problems with sleeping, feeling/being sick, headache and dizziness. You may also experience nervousness, trembling, shortness of breath, cough, sore or swollen throat, indigestion, stomach pains, diarrhea, constipation, sweating, dry mouth, sore muscles, chest and limb pain, tiredness, weakness, or palpitations (feeling your heart beat). These are generally mild and stop after a few days of using the patch. Possible side effects of the nicotine gum or lozenge may include: mouth/teeth/jaw problems, sore throat, coughing, nausea, gas or stomach discomfort, headache, heartburn, sweating, or diarrhea.

Abruptly reducing or stopping alcohol use may result in alcohol withdrawal symptoms. Withdrawal symptoms could be mild, including insomnia (inadequate sleep), tremors (shaking of hands), anxiety (nerves), stomach upset, headache, excessive sweating, or feeling rapid heartbeat (palpitations). These mild symptoms may happen within 6-12 hours of stopping alcohol use. Abruptly stopping alcohol use may also lead to more moderate or serious symptoms including hallucinations (seeing or hearing things that are not real), seizures, delirium (confusion or loss of awareness of self, others, and environment), fever, and high blood pressure. More serious alcohol withdrawal symptoms may happen up to three days after stopping alcohol use. If these serious withdrawal symptoms are not treated, they could lead to death. The timing and severity of

withdrawal symptoms vary from person to person depending on the heaviness of alcohol use as well as past history of withdrawal symptoms.

You will be asked by staff at every individual session about side effects from the nicotine replacement therapy, alcohol-cessation and tobacco-cessation withdrawal symptoms, and any health problem that may interfere with your ability to use the nicotine replacement therapy. You can call the study phone number, which is (612) 625-1850, to report serious side effects and be advised on what to do if the patch, gum, lozenge, or anything related to the study makes you uncomfortable.

Pregnancy Risks
If a woman is pregnant or breastfeeding, she will not be allowed to take part in this study because the nicotine patch could harm her baby. Every woman who is able to get pregnant must have a urine test to see if she is pregnant. You agree to this test if needed in your case. If you are not pregnant and agree to use an effective method of preventing pregnancy while using the nicotine patch, you will be allowed to take part in the study. If you become pregnant while in the study and using nicotine patch, you should tell the staff and immediately stop using the patch.

Benefits of Study Participation

The benefits to study participation are that quitting smoking is one of the best things you can do for your health, even if you decide not to be in this study. Your chances of quitting successfully may be improved by using nicotine patch. About 1 in 3 people who use the patch are able to quit smoking. However, about half of those who quit smoking start again in a year. Your chances of quitting and staying quit may be enhanced through counseling. If you quit smoking permanently, within 7 years your risk of heart disease will return to the level of a non-smoker. In about 15 years your risk of lung cancer will be close to that of a non-smoker. Those who do not quit smoking completely may not benefit from being in this study.

Alternatives to Study Participation

You do not have to participate in this study. Alternatives to participating in this study are to continue smoking, to quit "cold turkey," to use other quit smoking programs, to buy nicotine replacement programs over-the-counter, or to get a prescription for the nicotine inhaler, nicotine nasal spray, bupropion (also called Zyban, Wellbutrin) or Varenicline from a doctor.

Study Costs/Compensation

There will be no direct costs to you associated with participating in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or any insurance company. In return for your time and effort, you will receive compensation with a total value of approximately $380 during the study or approximately $400 if you are asked and agree to be interviewed about your study experience at week 26.You will also be able to draw a prize in a

weekly raffle for attending specific study visits. Compensation may include pre-paid gift cards to be used at local clothing, shoe or drug stores. Additionally, bus tokens will be available for you to use to get to and from your appointments. Please see the Study Calendar for more information. You will also receive a 12 week supply of the nicotine patch plus nicotine gum or lozenge.

Research Related Injury

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by the National Institutes of Health, representatives of the Food and Drug Administration (FDA), and by departments at the University with appropriate regulatory oversight. Study information will not be recorded in your medical records. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality.

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 could identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

Finally, if we have information indicating you are at risk for harming yourself or others, or you tell us about a specific child who is being abused, we will have to report this information to the proper authorities to keep you and others safe.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota, the University of Minnesota Medical Center, Fairview, any shelters or social service providers. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researchers conducting this study are Drs. Kolawole Okuyemi, Anne Joseph, Janet Thomas, Susan Everson-Rose, Nancy Raymond, and Rebekah Pratt. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at (612) 625-1654.

To share feedback privately about your research experience, including any concerns about the study, call the Research Participants Advocate Line: 612-625-1650or give feedback online at www.irb.umn.edu/report.html. You may also contact the Human Research Protection Program in writing at D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

_____
Printed name of study participant

_____ _____ _____
Signature of study participant Date of signature Time (if needed)*

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____ _____
Signature of the Person Conducting the Consent Discussion† Date of signature Time (if needed)*

* Time is needed only if information was provided and consent is given on the same day, or if consent is given and any study-specific activities will be performed on the same day.

†The investigator, or a suitably qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the form at the same time as the subject.