RUTGERS
Robert Wood Johnson
Medical School

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title Of Study: Persist to Quit: Telehealth Counseling for Smokers with Serious Mental Illness

Principal Investigator: Marc L. Steinberg, Ph.D.

This form is part of an informed consent process for a research study that will give information to help you decide if you wish to volunteer for this research study. It will help you understand what the study is about and what will happen during the study.

If you have questions at any time, you should feel free to ask. We will give you answers that you completely understand. After all your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Who is conducting this research study?
Dr. Marc Steinberg is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the study. There are other individuals who are also part of the research team.

Dr. Steinberg may be reached at 732-235-4341 and/or 317 George Street, Suite 105, New Brunswick, NJ 08901 and/or rusmoking@rwjms.rutgers.edu.

A member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

This study is sponsored by the National Institute on Drug Abuse.
The principal investigator is being paid to conduct this study according to a budget that will cover the costs of the study, including the costs of collecting all of the information required by the study.

Why is this study being done?
We want to learn how to best help smokers with serious mental illness to quit smoking. We are examining a new counseling approach based on cognitive behavior therapy. Cognitive behavioral therapy is a commonly accepted treatment for smoking cessation.

Why have you been asked to take part in this study?
You have been asked to take part because you are an adult smoker with schizophrenia, schizoaffective disorder, or bipolar disorder who is motivated to quit.

Who may take part in this study? And who may not?
You may take part in this study if:

- You are between 18 and 70 years old
- You are willing to make a quit in the next 30 days
- You report being a daily cigarette smoker (including those labeled "little cigars")
- You have a diagnosis of Schizophrenia, Schizoaffective Disorder, or Bipolar Disorder based on a semi-structured interview called the SCID-V
- You have not been hospitalized for a psychiatric illness in the last 8 weeks
- You have been taking the same medications for Schizophrenia, Schizoaffective Disorder, or Bipolar Disorder for the past 8 weeks
- You have access to a smartphone, tablet, or computer to attend telehealth video appointments with ability to download apps
- Must be receiving mental health treatment
- Must sign release of information for currently mental health treatment providers

You *may not* take part in this study if you:

- Have been taking varenicline (Chantix) daily for the past 10 days
- Have been taking bupropion (Zyban/Wellbutrin) to quit smoking daily for the past 10 days
- Have been taking any nicotine preparations (gum, lozenge, patch, spray, inhaler) daily over the last 10 days
- Are currently receiving tobacco dependence treatment counseling
- Report myocardial infarction, unstable angina pectoris, or significant cardiac arrhythmia (including atrial fibrillation) in the past 30 days
- Report that you are pregnant or nursing, planning on becoming pregnant in the next three months, or not using effective birth control if you are sexually active
- Have pending legal matters with potential to result in jail time
- Are planning on moving outside of New Jersey in next 3-months
- Report problematic substance use in the past 3 months (as measured by validated measures, AUDIT-C and DAST-10)
- Are at risk for suicide based on a semi-structured interview called the SCID-V

How long will the study take and how many subjects will participate?
We expect 61 subjects to participate. This study will take 4-years to complete. Participation in this study will last for 4-months and all appointments will be conducted through secure video. You will meet with a therapist through secure video for eight (8) weekly individual counseling sessions. You will also meet with the research team through secure video for an initial assessment, a post-counseling assessment, and a final assessment 3-months after your quit date.

What will you be asked to do if you take part in this research study?

- Attend 8 individual smoking cessation counseling sessions (lasting up to 50 minutes)
- Attend an initial research assessment (lasting up to 90 minutes)
- Attend a post-counseling research assessment (lasting up to 90 minutes)
- Attend a final research assessment (lasting up to 90 minutes)

Appointments will be completed using a HIPAA compatible video-conference platform for telehealth services (i.e. Microsoft Teams, Doxy.me, or zoom). We will provide you with assistance to set up applications used for study appointments. If necessary, we may complete assessments over the phone. You must be in the state of New Jersey during your counseling appointments.

Our research team may set up a google email account for you if you do not already an email that you use. We will not use email to discuss any personally identifying information. The

email address itself will only include your research ID number and the letters ptscs. This email will be used for communication throughout the research study. We ask that you do not use this email address for any communication outside of the research study to protect your confidentiality.

At your initial assessment you will complete standard questionnaires about tobacco use and mental and physical health. Women will complete a form indicating they are not currently pregnant, are not planning to become pregnant in the next 4-months, and are using birth control if sexually active. You will also answer questions about your age, gender, race, and other similar information. You will also complete tasks that measure something called "persistence," such as breath-holding endurance at your initial assessment session, after your final counseling session, and at the final 3-month assessment.

Between sessions, we will ask you to record your cigarette use each day. You may be asked to provide a carbon monoxide reading prior to appointments. This involves breathing into a machine called an "iCO Smokerlyzer" (which we will provide to you at no cost) and sending us the results through your email account.

We will give you nicotine patches for 10 weeks and weekly, individual counseling will last for 8 weeks. You will begin using the nicotine patches two weeks before your target quit date.

We will videorecord therapy sessions to ensure that counseling is provided as intended.

What are the risks and/or discomforts you might experience if you take part in this study?

The Nicotine Transdermal Patch ("the patch") has few side effects and is sold over the counter in the United States. Potential side effects include dizziness, headache, nausea, vomiting, diarrhea, or redness or swelling at the patch site. In addition, smokers who have serious arrhythmias (a disorder of the heart rate (pulse) or heart rhythm, such as beating too fast, too slow, or irregularly) or have chest pains due to coronary artery disease should use the patch with caution.

You may experience some nicotine withdrawal when you quit smoking. If symptoms arise, they will be addressed as part of your treatment.

There is a risk that your confidentiality could be violated. To reduce the risk of violating confidentiality, several steps will be taken. Only IRB approved members of the research team will have access to the data. All computers used by research staff with be password protected with complex passwords. Data will only be accessed when coded, entered, or audited. The PI will maintain responsibility for safe data storage. All data will be stored in locked cabinets within locked rooms. The google email account will only be linked to your research ID number and ask that you do not use this account for communication outside of the research study to protect your confidentiality. Based on these procedures, we anticipate that the risk to confidentiality is very low.

There is also a slight risk of feeling distress and frustration when completing our questionnaires and participating in counseling sessions; however, this is minimal and can be addressed by our addiction psychiatrist or clinical psychologist at any time.

Please call 911 if you have a medical emergency or Acute Psychiatric Services (APS) at 855-515-5700 if you experience a psychiatric emergency.

Are there any benefits for you if you choose to take part in this research study?
The benefits of taking part in this study include access to high-quality, evidence-based smoking cessation treatment. If you quit smoking you are likely to experience improvements in health, social, and economic areas of your life. However, you might receive no direct benefit from taking part in this study.

What are your alternatives if you don't want to take part in this study?
Clinical practice guidelines for smoking cessation recommend getting behavioral support plus at least one of the seven FDA approved medications for smoking cessation. If you choose not to take part in this study, we will provide you with information regarding other options that can help you receive these treatments.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to continue with the study. If we learn of information that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?
There is no cost to you to take part in this study.

Will you be paid to take part in this study?
You will receive reimbursement for your time for completing assessment measures of up to $100 based on the following schedule:

- $35 for the initial research assessment. We may divide the baseline assessment battery into two sessions to minimize participant fatigue if necessary.
- $30 for the post-counseling research assessment (after session 8)
- $35 at the final research assessment (3-month post-quit date)

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. Only IRB approved members of the research team will have access to the data. All data will be stored in locked cabinets within locked rooms.

All computer files will be kept on computers requiring login and complex passwords for entry. Computer files may also be kept stored on the Rutgers Box cloud storage system which requires complex passwords for entry. All files with identifying information will have the extra protection of a password to open that individual file. Your personal information will be kept separate from your study data and linked only by a study number. Your name will not be used in any publications or papers derived from this study.

Your participant email address will only include information related to your assigned ID number and short title of our study "ptscs". This email address will not identify your name and to protect for confidentiality we ask that you do not use this email for any purpose outside of the research study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or

local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to Dr. Marc L. Steinberg; Division of Addiction Psychiatry; 317 George Street; Suite 105; New Brunswick, NJ 08901.

What will happen if I am injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which can be found above in the section, "What are the risks and/or discomforts you might experience if you take part in this study?"

In addition, it is possible that during the course of this study, new adverse effects of the nicotine patch that result in personal injury may be discovered. The University will make appropriate referrals for medical treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

Who can you call if you have any questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study principal investigator:

Marc L. Steinberg, Ph.D., Department of Psychiatry, **732-235-4341**
If you have any questions about your rights as a research subject, you can call the Institutional Review Board (IRB) Director at **(732)-235-9806** and Human Subject Protection Program at **(732)-235-8578.**

What are your rights if you decide to take part in this research study?
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions

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PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Information about you and your health is personal and private, so this information generally cannot be used in research without your written permission. The next few paragraphs tell you about how researchers want to use and share your health information in this research study. Your information will only be used as described here or as allowed or required by law. Ask questions if you do not understand any part of the research or the use of your health information. If you sign this consent form, you agree to let the researchers use your information in the research and share it with others as described below.

What is the purpose of the research and how will my information be used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help researchers answer the questions that are being asked in the research.

What information about me will be used?
- Medical history or treatment
- Medications
- Psychological testing, surveys or questionnaires

Who may use, share or receive my information?
The research team may use or share your information collected or created for this study with the following people and institutions:
- Rutgers University researchers involved in the study;
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- A data safety monitoring board (DSMB)
- National Institute on Drug Abuse (NIDA)
- Federal Drug Administration (FDA)

Those persons or organizations that receive your information may not be required by federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I be able to review my research record while the research is ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this research study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study).

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell him or her of your decision: Dr. Marc Steinberg, 317 George St., Suite 105, New Brunswick, NJ 08901.

How long will my permission last?
Your permission for the use and sharing of your health information will last until the end of the research study.

Rutgers, The State University of New Jersey IRB
Audio/Videotape Addendum to Consent form

By signing below, you are agreeing to participate in a research study conducted by Marc L. Steinberg, Ph.D. We are asking for your permission to allow us to video record your sessions as part of that research study. The recording(s) will be used for analysis by the research team and for training clinicians. The recording(s) will include your ID number and date of your counseling session.

Videorecordings will automatically be stored within the Microsoft Teams environment (i.e.,Microsoft Streams). If using Doxy.me or zoom as a backup, recordings would be stored on password protected local computers, and the files would then be encrypted and moved to a HIPAA compatible network storage. The files themselves will be password protected and encrypted using the Advanced Encryption Standard 256 method (AES-256). Files will be linked with each participant's ID number. Files will be destroyed 6 years after the protocol is closed.

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

AGREEMENT TO PARTICIPATE

1. Subject consent:
I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

2. Signature of Investigator/Individual Obtaining Consent:
To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legally authorized representative have been accurately answered.

Investigator/Person Obtaining Consent (printed name):_____

Signature:_____ Date: _____