Title: Evaluation of Learning-Theory-Based Smoking Cessation Strategies

NCT#: NCT01368653

Document date: 1/30/2013

Consent Form to Participate in a Research Study

Title of Study: Evaluation of Learning-Theory-Based Smoking Cessation Strategies

Principal Investigator: Danielle E. McCarthy, Ph.D.

INTRODUCTION

You are invited to participate in a research study. Before you agree to participate in this study, you should know enough about it to make an informed decision. If you have any questions, ask the investigator. You should be satisfied with the answers before you agree to be in the study.

BACKGROUND/PURPOSE

The purpose of this study is to test a treatment strategy designed to help smokers quit smoking by helping them prepare to quit and break the habit of smoking and to test a strategy to help people recover from smoking lapses (returns to smoking during an attempt to quit smoking permanently) by smoking cigarettes containing very low levels of nicotine. The study may identify new treatments that help smokers quit and stay smoke-free and may give researchers information about how best to combine distinct treatments to help smokers quit. A total of 200 smokers will take part in this research.

INFORMATION

Participation in this study will involve the following:

1. Telephone screening (15 minutes, you have already completed this). Over the phone, we (members of my research team) asked you to answer a series of questions to see if you might qualify for this study. We then invited you to come to this orientation session to learn more about the study.

2. Orientation session (1.5-2-hour session today). Today we introduced you to the study and asked you to participate. If you choose to sign this consent form and take part in the study, we will conduct additional screening and training today.

    a. Carbon monoxide testing (5 minutes). We will ask you to hold your breath for 15 seconds and then blow into a clean tube attached to a machine in order to test your carbon monoxide level. This test tells us how much carbon monoxide is in your blood and is a good sign of how much you smoke.

    b. Questionnaires (30 minutes). We will also ask you to complete a packet of questionnaires asking about your smoking history, past attempts to quit smoking, mood, personality, and personal characteristics. We will review some of these answers to make sure that you qualify for the study. If your answers show that you do not qualify, we will let you know and you will not be asked to do anything more in the study.

    c. Interactive Voice Response (IVR) System Training (30 minutes). At the end of the session today, we will show you how to use the Interactive Voice Response system to answer questions for the study using a cell phone. You may use your own cell phone

to answer these questions, and we will repay you for the cell phone minutes you use at the rate of 10 cents per minute at the end of the study. If you do not have a cell phone, we will give one to you that you may use only to receive calls for the study. During the study, we will ask you to carry a cell phone for a total of 24 days during the first phase of the study (and, for those who are eligible, for 14 days in the follow-up period). You will receive an automated phone call from us two times during your waking day and once at your bedtime (3 times total). At each phone call, you will be asked questions about what you are thinking, feeling, and doing. You will not be asked to answer sensitive questions. Today, we will ask you to practice using a cell phone to answer questions so you are familiar with how it works. We will start calling you at two random times during the day and your bedtime starting 16 days before your quit day. If you prefer to provide responses by computer, you may complete the interview items at an internet site we will provide. Each IVR call or internet survey should take about two to four minutes to complete.

3. IVR feedback call (10 minutes). We will call you to go over your use of the IVR system the day after you start using it. During this call, we will go over the records you have completed to see how many calls you missed, did not finish, or took a long time to answer. We will share this feedback with you and will answer any questions you have about the system.

4. Live telephone calls
   You will receive a total of 7 live, person-to-person calls lasting 2-5 minutes at wake-up (14, 12, 10, 8, 6, 4, and 2 days before your target quit day). You will receive one call on each of these days. These brief calls will take place at your typical wake-up time and will remind you whether you are supposed to smoke normally or stop smoking for a specific period of time each day. There is a 50% chance you will be asked to smoke normally, and a 50% chance you will be asked to stop smoking on each of the 7 days we call you at wake-up. If you are asked to stop smoking, we will offer support and advice about how to do this during the phone call. If you are asked to smoke normally, we will simply remind you to keep smoking and answer any questions you may have.

   You will receive a total of 7 live, person-to-person calls lasting roughly 20 minutes on the same days you receive wake-up calls (14, 12, 10, 8, 6, 4, and 2 days before your quit date). If you are in the group asked to stop smoking on these days, your second call that day (after the wake-up call) will be at the end of the period you were asked to stop smoking for that day (e.g., if you woke up at 6 AM and were asked to stop smoking for 4 hours, we would call you at 10 AM). If you are in the group asked to continue smoking normally, these calls will be 2, 4, 6, 8, 10, or 12 hours after you wake-up. We will schedule the second call of the day with you during the wake-up call earlier that same day. During these 20-30-minute calls, you will be asked to complete an interview about your feelings, smoking behavior, thoughts, and emotions.

   At the seventh call (2 days before your quit date), we will start one-on-one smoking cessation counseling with you. We will go over quit-smoking materials that we will send

to you by mail before this call, and will describe how to use the 21-mg nicotine patches we will send you as well.

We will call you on your quit day (the day you are to stop smoking cigarettes and begin wearing a nicotine patch) and again 2 days later. These calls will take place at times that are convenient for you during our normal business hours (9 AM-7 PM). During these calls, we will again interview you regarding your feelings, smoking behavior, and thoughts. We will also offer additional counseling to help you quit smoking and stay quit during these calls.

5. Post-quit smoking cessation visit (1 visit, 30-minutes). At this visit 7 days after your quit day, you will be asked to complete a carbon monoxide test and a brief questionnaire about your feelings, smoking behavior, and thoughts. You will receive a final counseling session at this visit, as well. If we gave you a cell phone for the study, you will return it at this visit.

6. Treatment conditions You will be randomly (by chance, like flipping a coin) assigned to one of two groups in the quitting preparation phase of the study. You will have a 50% chance of being assigned to each of 2 treatment conditions:

    a. If you are assigned to the first treatment condition, you will receive a 6-week supply of 21-mg nicotine patches to be used starting on the quit day and will receive 4 one-on-one, 15-minute counseling sessions based on a Clinical Practice Guideline. Both of these treatments have been shown to help people stop smoking.

    b. If you are assigned to the second treatment condition, you will receive the patches and counseling offered in the first treatment group, plus an experimental treatment that involves 7 practice quitting sessions in the 2 weeks before a quit day. Practice quitting session duration will be tailored to your smoking pattern. The periods of time that you are asked to stop smoking will increase as you get more practice quitting. You will receive tips about ways to maintain abstinence at the phone call when you wake up on your practice quitting days.

7. Follow-up (two 10-15-minute telephone interviews). We will contact you over the telephone 4 weeks post-quit for a 10-15-minute interview. At this interview, we will ask you about your thoughts, emotions, and behaviors. At this telephone call, you may also be randomized to a second treatment condition designed to help smokers break the routine of smoking. If you are eligible for this phase of the study, you will be randomly assigned (like flipping a coin) to one of two conditions. You will have a 50% chance of being in each of the two groups below, if you are eligible for this phase of the study, as determined by your follow-up telephone interview responses.

    a. If you are eligible and assigned to the first treatment condition, you will receive advice, encouragement, and support regarding quitting smoking over the telephone.

b. If you are eligible and assigned to the second treatment condition, you will receive a 6-week supply of cigarettes containing very low levels of nicotine to begin smoking while still using the nicotine patch to help break the habit of smoking. These cigarettes contain tobacco, and look and smell like regular cigarettes, but deliver very little nicotine.

Everyone who is eligible for this phase of the study will be asked to complete additional IVR calls, similar to those described above. If you are in this group, you will be asked to complete 3 calls lasting 2-4 minutes per day for 2 weeks. These calls will ask about your thoughts, feelings, and behavior, as before.

We will call you again 6 weeks after the first follow-up interview to conduct a similar interview 10-weeks post-quit. This 10-15-minute interview will also ask about your thoughts, emotions, and behaviors. If you report at the 10-week interview that you have not smoked for a week or more, we will ask you to return to the office for an office visit. At that visit, we will conduct a carbon monoxide test. The study will end after the 10-week follow-up interview and visit.

The total duration of the study from today will be 12.5 weeks and will take less than 17 hours of your time, not including travel time to and from our office. If we have difficulty scheduling with you, the total duration of the study may be slightly longer, particularly if the final follow-up visit for carbon monoxide testing is delayed.

ALTERNATIVES TO PARTICIPATION

Participation in this study is voluntary. You may choose not to participate, and you may withdraw at any time during the study procedures without any penalty to you. In addition, you may choose not to answer any questions with which you are not comfortable.

You should know that there are many ways to get help quitting smoking outside of this study. You do not need to take part in this study in order to obtain evidence-based stop-smoking treatment at no cost to you. You can seek smoking cessation counseling by telephone (through toll-free quitline services) or the internet (through governmental and non-governmental sites), and from your health care providers. Some employers and insurance programs also offer quit smoking programs or reimburse costs associated with quitting smoking. You can get stop-smoking medications, including the nicotine patch, at most drug stores and pharmacies. Nicotine patches, gum, and lozenges are available over-the-counter. In addition, you can discuss prescription medications that have been approved for use with smokers trying to quit with your health care provider.

RISKS

Participation in this study is associated with the following risks: breach of confidentiality, emotional distress, and medication side effects.

Breach of confidentiality. Although we take many measures to protect your privacy, we cannot guarantee that we will be able to maintain complete confidentiality of the information you share

with us. If your answers to our questions were disclosed, the disclosure could potentially affect your employment or insurability. To prevent any breach of confidentiality, we store the information you share with us (both electronic and paper records) securely. Your answers are not stored directly with your name. Your name and your answers to questions are stored separately and linked by a numeric code.

Emotional distress. Both answering questions and trying to quit smoking may cause distress for you. Although we do not ask about sensitive topics, our questions about your emotions, thoughts, and behaviors may be upsetting to you or cause you embarrassment. In addition, quitting smoking is linked to increases in anxiety, sadness, frustration, irritability, difficulty concentrating, hunger, and disrupted sleep for many people. If you become distressed during the study, we will refer you to services that may help you. In addition, if I, as the principal investigator, believe that continuing participation would put your safety or wellbeing at risk, I may decide to end your participation and refer you to treatment resources that can help you with your distress.

Medication side effects. Use of nicotine patch has been known to cause the following side effects: possible skin irritation at the site of application, sleep disturbance, rapid heartbeat, headache, and muscle or joint aches and stiffness. You will be advised to reduce smoking if these symptoms occur, or to remove the patch before, during, or just after smoking. In addition, nicotine overdose symptoms, including dizziness, nausea, weakness, vomiting, and rapid heartbeat, may occur, particularly if people continue smoking nicotine-delivering cigarettes while wearing the patch. Using the patches as directed reduces the risk of these side effects. If you develop side effects, reduce your use of the nicotine patch.

Smoking non-nicotine cigarettes. Smoking is harmful and carries significant health risks. In this study, we may ask you to smoke cigarettes containing very low levels of nicotine for up to 6 weeks. Smoking these cigarettes for up to 6 weeks should not increase your risk of health problems beyond the risks associated with daily smoking. We will encourage you to use these non-nicotine cigarettes as substitutes for regular cigarettes and will advise you to use only as many of the non-nicotine cigarettes as you would normally smoke your usual brand. We will not advise you to smoke these non-nicotine cigarettes in addition to your usual brand.

This study is not for people with a history of heart problems and negative reactions to the patch, including skin irritation. This study is not for women who are pregnant. Using the patch while pregnant may pose a risk to the embryo/fetus. The extent of these risks is not completely known. For this reason, we require women who could possibly become pregnant to agree to use one or more reliable forms of birth control throughout treatment (up to 10 weeks after the quit day). Women of child-bearing age should discuss birth control methods with their health care provider to make sure they are protected. If you become pregnant during the study, contact your health care provider and stop using the nicotine patch.

You should promptly report any problems that develop during the study. We will ask you if you experience any changes in your health at each office visit and at the follow-up telephone calls. You will be told of any changes in the way the study will be done and any new risks to which you may be exposed.

BENEFITS
As a participant in this study, you will receive two stop-smoking (patch and counseling) treatments that have been shown to increase the odds of quitting successfully, at no cost to you. We cannot guarantee that you will quit smoking successfully, however. In addition, the knowledge that we gain from your participation, and the participation of other volunteers, may help us to identify new treatments that may help other smokers quit smoking.

CONFIDENTIALITY
This research is confidential. *Confidential* means that the research records will include some information about you and this information will be stored in such a manner that some linkage between your identity and the response in the research exists. Some of the information collected about you includes your name, telephone number, address, and social security number. I will keep this information confidential by limiting access to the research data and keeping it in a secure location. The research team and the Institutional Review Board at Rutgers University are the only parties that will be allowed to see the data, except as may be required by law. If a report of this study is published, or the results are presented at a professional conference, only group results will be stated, unless you have agreed otherwise.

COMPENSATION
You will receive up to $465 for completing study activities, according to the following payment schedule:

- $40 for the 1.5-2-hour orientation session
- $10 for the 5-10-minute IVR feedback call
- $180 for calls, at the rate of $20 per day, on the following days: 14, 12, 10, 8, 6, 4, and 2 days before your quit day; on your quit day, and 2 days after your quit day .
- $50 for completing the 30-minute office visit 7 days after your quit day.
- $50 bonus for answering at least 80% of 3 scheduled, automated IVR calls per day over 24 days during the first phase of IVR calls
- $25 bonus for answering at least 80% of 3 scheduled, automated IVR calls per day over 14 days in the follow-up period, if you are eligible for this phase of the study
- $20, at the rate of $10 per call, for the 10-15-minute follow-up interviews 4 and 10 weeks after your target quit day
- $20 for the final 5-minute office visit after the 10-week telephone interview, if needed.
- Up to $70 in compensation for cell phone minutes used (if you use your own cell phone for study calls), at the rate of 10 cents per minute (if you complete all possible telephone activities totaling roughly 700 minutes of your time).

Compensation will be provided by check after the office visit 7 days post-quit (for all money earned up to that point), and by separate check after the follow-up interview 4 weeks post-quit, after the IVR feedback period in the follow-up phase of the study, and again after the final, 10-week post-quit follow-up. Rutgers employees who take part in this research will be paid through payroll in their regular departments.

If you use our cell phone and do not return it, we will deduct $50 from your compensation to cover the cost of replacing the equipment. If you withdraw from the study prior to its completion,

you will still receive compensation for any phone minutes used and all activities that you complete prior to leaving the study.

EMERGENCY MEDICAL TREATMENT
In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment by Rutgers University to provide any compensation for research-related injury. Please contact the investigator, Dr. Danielle McCarthy, at 848-932-5870, if you are injured for further information.

RESEARCH RESULTS
If you are interested in the results of this study, let me know by writing to me, Danielle E. McCarthy, Ph.D., at Department of Psychology and Institute for Health, Health Care Policy, and Aging Research, Rutgers University, 112 Paterson Street, NJ 08901, or by calling me at 848-932-5870. I will share results only after the study is completed and data are analyzed. I will then send you a summary of the group results in the mail.

CONTACT
If you have questions at any time about the research or the procedures, you may contact the researcher**,** Danielle E. McCarthy, Ph.D., at Department of Psychology and Institute for Health, Health Care Policy, and Aging Research, Rutgers University, 112 Paterson Street, NJ 08901, 848-932-5870, or demccart@rci.rutgers.edu.

If you have any questions about your rights as a research subject, you may contact the IRB Administrator at

Rutgers University Institutional Review Board for the Protection of Human Subjects
Office of Research and Sponsored Programs
3 Rutgers Plaza
New Brunswick, NJ 08901-8559
Tel: 848-932-0150
Email: humansubjects@orsp.rutgers.edu

PARTICIPATION
Your participation in this study is voluntary; you may decline to participate at any time without penalty to you. If you decide to participate, you may withdraw from the study at any time without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be removed from the data set and destroyed.

Sign below if you agree to participate in this research study. You will be given a copy of this form to keep.

Subject's signature_____ Date _____

Investigator's signature_____Date_____