Approach Bias Retraining to Augment Smoking Cessation

NCT03325777

Last Revised: 4/8/2021

Consent to Participate in Research

Basic Study Information

Title of the Project: Approach Bias Retraining to Augment Smoking Cessation
Principal Investigator: Jasper Smits, PhD
Study Sponsor: National Institute on Drug Abuse (NIDA)

Invitation to be Part of a Research Study

You are invited to be part of a research study. This consent form will help you choose whether or not to participate in the study. Feel free to ask if anything is not clear in this consent form.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to investigate the effect of a brief computerized task on smoking cessation paired with counseling.
- In order to participate, you must be a daily smoker between ages 18-65.
- If you choose to participate, you will be asked to:
    - Participate in a 17-week protocol
    - Complete questionnaires about your smoking behaviors
    - Complete brief assessments with a computerized task involving a joystick.
    - Participate in cognitive behavioral therapy (CBT) for smoking cessation
    - Breathe into a carbon monoxide (CO) monitor
    - Make a quit attempt at week 5 of the protocol
    - Use nicotine patches to help with withdrawal symptoms
    - Provide saliva samples at the last two follow-ups if you have abstained from smoking
- Risks or discomforts from this research include temporary nicotine withdrawal symptoms after quitting. These symptoms are not harmful and you probably have already had numerous experiences with these sensations and feelings throughout your day-to-day life. Additionally, you may experience side effects from the nicotine patches. These will be minimized by providing you with the appropriate dosage based on the number of cigarettes you are smoking before your quit attempt.
- The possible benefits of this study include a reduction in your smoking rate or an increase in your confidence in making a quit attempt. Therefore, there is a potential direct benefit for improvements in your physical and psychological health.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

You have been asked to participate in a research study investigating the effect of a brief computerized task on smoking cessation paired with counselling. The purpose of this study is to

determine the effect of completing a computerized joystick task believed to increase control over substance-related cues. We are interested in whether or not participating in the study will lead to improved smoking outcomes.

The task utilizes a novel training protocol, emergent from a promising set of interventions, known as Cognitive Bias Modification (CBM). CBM interventions work to target automatic thoughts and tendencies that occur outside of our conscious control. Previous research suggests that these automatic tendencies may have a direct effect on various health behaviors (e.g. continued smoking despite previous quit attempts).

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to:

- Participate in a 17-week protocol. You will be asked to attend 7 weekly, 60 minute sessions and 4 follow-ups at weeks 8, 9, 13, and 17. Each follow-up session will last about 15-30 minutes.
- Complete questionnaires about your smoking behaviors.
- Complete brief assessments with a computerized task involving a joystick.
- Participate in cognitive behavioral therapy (CBT) for smoking cessation.
- You will breathe into a carbon monoxide (CO) monitor to determine the level of CO in your lungs and blood.
- You will be randomly assigned (like a flip of a coin) to one of two training groups. Both groups will consist of the same number of sessions and will be of equal length.
- Make a quit attempt at week 5 of the protocol.
- Use nicotine patches to help you with your withdrawal symptoms.
- Provide saliva samples at the last two follow-ups if you have abstained from smoking.
- All weekly sessions will be audio recorded, for clinical supervision purposes and to ensure the integrity of administered therapy.

This is a research study and, therefore, is not intended to provide a medical or therapeutic diagnosis or treatment. The training provided during the course of this study is not necessarily equivalent to the standard method of prevention, diagnosis, or treatment of a health condition.

How long will you be in this study and how many people will be in the study?

Participation in this study will 17 weeks, including the follow-up visits. The study will include approximately 100 total study participants.

What risks and discomforts might you experience from being in this study?

There are some risks you might experience from being in this study. This study may also involve risks that are currently unforeseeable.

There are no risks associated with the interviews or psychological tests other than possible discomfort involved in answering some of the questions. You may experience anxiety or frustration when completing the computer task, although this will be transient, occurring only during the task itself. You will not be forced to do anything you do not want to do, and you can terminate any of these procedures at any time. Research staff will be available to talk to you about any anxiety that you may experience.

Other potential risks include temporary nicotine withdrawal symptoms after quitting. These risks, though minimal, are likely and typical of nicotine withdrawal, resulting from the addictive nature of nicotine. Discomfort related to smoking cessation may include such symptoms as increased anxiety, irritability, difficulty concentrating, headaches, nausea, decreased heart rate, fatigue, increased hunger, and tobacco cravings. Although symptoms of nicotine withdrawal may be uncomfortable, they are not harmful to your health. As a smoker, you probably have already had numerous experiences with these sensations and feelings throughout your day-to-day life.

Potential risks also include nicotine patch side effects. Common side effects include local skin irritation at the site of the patch, and mild nausea if the participant continues to smoke at a high level while using the patch, and temporary vivid dreams. Less common are allergic skin reactions. This risk will be minimized by providing you with the appropriate dosage that corresponds with the number of cigarettes you are smoking before your quit attempt.

There are no known risks associated with saliva cotinine and carbon monoxide analyses. The procedures for obtaining these samples are brief, safe, and minimally uncomfortable. Some participants may experience minor, short-term discomfort with these procedures. For example, some individuals may find it slightly uncomfortable to hold their breath for 15 seconds, as required for the carbon monoxide analysis. In addition, some individuals may report brief dry mouth following the saliva cotinine procedure.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

The overall results of this research study may not benefit you directly. However, if through participating in this study, you reduce your smoking rate or increase your confidence in making a quit attempt, the potential direct benefits of your participation may be improvements to your physical and psychological health. The knowledge gained may additionally help researchers and others to understand how smoking-related cues may facilitate addiction and how practicing inhibiting automatic responses to these cues may help guide a successful quit attempt. The results may have implications for improving the success rates of future smoking cessation programs.

What will happen to the samples and/or data we collect from you?

As part of this study we will collect self-report data, such as responses from questionnaires about your smoking behaviors. This data will be kept in a confidential form within a secure database, such that your name will be assigned an ID number. We will also collect carbon monoxide (CO) breath samples which will be inputted into your participant record that contains no identifying information and is located within a secure database. Lastly, we will collect saliva samples at the follow-up visits if you have quit smoking in order to verify abstinence. Your saliva samples will be labeled with only a participant ID and will be destroyed after the conclusion of the study once they have been analyzed.

How will we protect your information?

The study is confidential. In order to protect your confidentiality, any information about you obtained as a result of participation in this research will be kept as confidential as legally possible. However, your research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities. A record of your participation

will be kept in a confidential form, such that your name will be assigned an ID number. By doing this, information you provide cannot be directly linked to your name. Furthermore, information with identifying information, such as the consent form, will be kept separately from data that has been assigned an ID number. All of the information you provide will be stored in password protected files at all times. If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. We may share your data or samples with other researchers for future research studies that may be similar to this study or may be very different. The data or samples shared with other researchers will not include information that can directly identify you

Information about you may be given to the following organizations:

- The study sponsor and/or representative of the sponsor
- Representatives of UT Austin and the UT Austin Institutional Review Board

A description of this study 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 will happen to the information we collect about you after the study is over?

All de-identified data will be kept indefinitely for research purposes. The data resulting from your participation may be used for future research or be made available to other researchers for research purposes not detailed within this consent form.

Identifying information will be destroyed five years after the publication of study results or seven years after the last patient contact (whichever is longer) in line with the guidelines of the American Psychological Association.

How will we compensate you for being part of the study?

You will receive $250 for your full participation in the study. You will be paid $50 at weeks 6 and 9, and $75 at weeks 13 and 17. You will be responsible for any taxes assessed on the compensation.

Who will pay if you are hurt during the study?

In the event of a research-related injury, it is important that you notify the Principal Investigator of the research-related injury immediately. You and/or your insurance company or health care plan may be responsible for any charges related to research-related injuries. Compensation for an injury resulting from your participation in this research is not available from The University of Texas at Austin.

You are not waiving any of your legal rights by participating in this study.

What are the costs to you to be part of the study?

To participate in the research, you will need to pay for transportation to The University of Texas at Austin campus for all study visits.

Who can profit from study results?

A researcher who is involved in this study, Dr. Richard Brown, is CEO and receives equity shares in Health Behavior Solutions, Inc., a company that promotes products and services for health behavior change, including smoking cessation. The business interests of Health Behavior Solutions, Inc. relate to the topic of this study.

Your samples may be used for commercial profit and there is no plan to share those profits with you.

What other choices do you have if you do not take part in this study?

You can receive a list of referrals containing a list of smoking cessation resources as an alternative to participating in this study.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer.

If you decide to withdraw before this study is completed, your de-identified data will be retained and analyzed unless we receive a written request to destroy or exclude the data from any analysis.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

Jasper Smits, PhD
Phone: 512-810-0375
Email: smits@utexas.edu

Or

Annabelle DiVita
Phone: 303-335-7834
Email: Annabelle.divita@utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
I agree to be audio recorded.

_____
I do not agree to be audio recorded.

_____
Signature Date

_____
Signature of person obtaining consent Date