Heart Rate Variability Biofeedback for Smoking Cessation

Informed Consent Form

Date of approval: 10-3-2018

NCT03972137

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Rutgers University
Consent to Participate in a Research Study

Study Title: Biofeedback Smoking Cessation Treatment

Principal Investigator: Teresa M. Leyro, Ph.D.

Who is conducting the research study?
You are invited to participate in a research study that is being conducted by Teresa Leyro, Ph.D., a professor in the Department of Psychology at Rutgers University, and the Principal Investigator of this study. A Principal Investigator has the overall responsibility for the conduct of the study. However, there are often other individuals involved in the research project who are part of the research team.

The study Principal Investigator, Teresa Leyro, Ph.D., or a member of her laboratory, will go through the details of the study with you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

Why is this study being done?
The purpose of this study is to help smokers with elevated mood and anxiety symptoms quit smoking. The research study will develop and test whether the inclusion of respiratory biofeedback with standard smoking cessation treatment is useful. First, we aim to improve smoking cessation outcomes. Second, we hope to reduce mood and anxiety symptoms.

Cigarette smoking remains the leading cause of preventable death and poses an immense economic and health burden, in particular for those affected by comorbid anxiety and mood disorders. Cigarette smokers who suffer from elevated emotional distress smoke at greater rates, report greater dependence, and experience tremendous difficulty quitting.

Among these individuals, alterations to the autonomic nervous system have been observed, and may make it more difficult to cope with cigarette withdrawal and emotional distress. Biofeedback interventions are one strategy that may be used to improve autonomic nervous system functioning, and also improve how well individuals can regulate distressing experiences.

We hope that adding a respiratory biofeedback component to a smoking cessation program will increase the likelihood that smokers are able to achieve prolonged abstinence, and will also have a positive impact on emotional symptoms.

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The current researchers have no financial or propriety disclosures relevant to the current project.

Who may take part in this study?
You may participate in this study if you are between the ages of 21 and 50, have been smoking at least five cigarettes daily for the last two years, proficient in reading and speaking English, are proficient in the use of a computer and have an iPhone that is compatible with the respiratory biofeedback application used in this study. You will not be eligible to participate in this study if you are currently pregnant or lactating, using other tobacco or nicotine products, including those used to help you quit, currently receiving smoking cessation counseling or taking medication to help you quit, have evidence of experiencing current or past psychotic or manic symptoms, have current suicidal or homicidal thoughts or behaviors, have a self-reported pending legal issue which may result in incarceration OR have plans to leave the greater New Brunswick, NJ area in the next 6 months, have evidence of another current substance use disorder, have severe visual or hearing impairments, or if you have a medical condition, or are taking a medication that may affect the utility of respiratory biofeedback for you or its potential benefit for you.

How long will the study take and how many people will take part in this study?
We expect 10 daily smokers to complete our study. Each participant will meet with the research team twelve (12) times over the course of 4 months. Following your baseline session, you will receive ten (10) intervention sessions. These include five intervention sessions before your quit date, another visit on your quit date, and additional counseling sessions during weeks 4, 5, 6, and 7. Your final appointment will be scheduled to occur 3 months after your quit date.

What will happen if I take part in this research study?
If you agree to participate in the study, the following procedures will occur:
Baseline: Visit 1: The first visit will last approximately 2-3 hours.

- You will first meet with Dr. Leyro or another trained staff member assistant who will go over several assessments with you in a private research space. These will include a medical history form, carbon monoxide analysis of your breath to ensure your smoking status, questionnaire completion, and a diagnostic interview to assess whether or not you are eligible for study participation.
    - During the carbon monoxide analysis, you will be asked to blow air into a tube that is attached to a machine, which determines the amount of carbon monoxide in your lungs. This is used to determine whether you are currently smoking.
    - You'll then be asked to complete a battery of 'paper and pencil' questionnaires as well as several computerized tasks to obtain additional information about your current mood, personality characteristics, as well as tobacco use, withdrawal, craving, and urge.
    - Next, we will attach you to physiological monitoring equipment to assess autonomic nervous system, including how your blood flows in and out of your heart, heart rate, blood pressure, and sweat response. To do this, we will have to attach several electrodes to your body as well as blood pressure cuffs to your arm and fingers.
    - Finally, we will complete a diagnostic interview. During the interview, you will be asked to provide details regarding current and prior thoughts, feelings and behaviors.

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If ***you are found to be eligible*** for participation in this study you will be enrolled in our study intervention, including both smoking cessation counseling, nicotine replacement therapy, and a respiratory biofeedback intervention.

Smoking Cessation Intervention Sessions:
You will attend a total of ten intervention sessions that will last between 30 minutes and one hour. During weeks 1 through 3, you will have two sessions each. Your quit day will be scheduled for week 3 of treatment. You will then have one treatment session during weeks 4, 5, 6, and 7. Intervention sessions will include a combination of smoking cessation skills and biofeedback training. We will video and audio record therapy sessions to ensure that counseling is provided as intended.

In addition, we will provide you with 8 weeks of nicotine replacement therapy patch. At week 3, we will provide you with the nicotine replacement therapy (NRT) patch and instructions for use. You will be asked to begin using the patch on the morning of your quit date. We will provide you with NRT for 8 weeks. Throughout this period, we will help you step down, or decrease, the amount of nicotine in the patches you are using. After 8 weeks of using the NRT patch, we will ask that you refrain from all nicotine use.

Study staff will go over the details of your treatment schedule prior to your leaving. You will also receive text, phone and email reminders of all study appointments.

At-home Practice:
All participants will be asked to complete at-home practice as part of their intervention. This will include planning for your quit date, practicing skills that will help you be successful in quitting, and practicing your respiratory biofeedback training using a smartphone app, twice daily.

Follow-up Appointment:
Follow-up sessions will include an analysis of your breath to determine whether or not you are currently smoking via your self-report and carbon monoxide analysis. We will also routinely assess your physiology to monitor any changes that occur throughout your quit attempt and use of biofeedback. You will come in for a final follow-up appointment 3 months after your quit date.

You will be asked to complete a tracking form including names, phone numbers, and home and email addresses, of three individuals who may be contacted if we are unable to reach you. If we are unable to reach you, we will attempt to obtain smoking data by telephone verification from contacts and encourage completion of questionnaire data via online survey link or mail. You will be contacted for all assessments, independent of whether you continue treatment, and you will be compensated accordingly.

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Study location: All these procedures will be completed at 1 Spring Street, New Brunswick NJ 08901 or Tillett Hall 53 Avenue E, Piscataway, New Jersey 08854.

What side effects or risks can I expect from being in the study?

Overall, the risks in this study are very minimal and may include the following:

- The Nicotine Transdermal Patch ("the patch") has few side effects and is sold over the counter in the United States. Potential side effects of the nicotine patch 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.

- Discomfort related to quitting smoking during the study may include increased anxiety, irritability, difficulty concentrating, headaches, upset stomach, and tobacco cravings. These symptoms are typical of short-term nicotine withdrawal and result from the addictive nature of nicotine. 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. In addition, these symptoms will be directly addressed as part of your treatment.

- You may also experience physical discomfort throughout the study. For example, the respiratory biofeedback intervention requires you to breath differently than is typical. Because it may seem unusual, participants may occasionally report some discomfort. Also, attachment of electrodes, although passive, may result in some discomfort upon removal. However, removal is no more painful than removing an adhesive bandage.

- There is a slight risk of feeling emotional distress and frustration when completing our questionnaires, interviews, and counseling sessions; however, this is minimal and can be addressed by Dr. Leyro, who is a licensed clinical psychologist, if necessary.

- Finally, 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. Data will only be accessed when coded, entered, or audited. All data will be stored in locked cabinets within locked rooms. Based on these procedures, we anticipate that the risk to confidentiality is very low.

Are there benefits to taking part in the study?
The benefits of taking part in this study includes access to high-quality, evidence-based smoking cessation treatment. If you quit smoking you will experience health benefits, however, it is possible that you will receive no direct benefit from taking part in this study.

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Can I stop being in the study?
Yes. Study participation is completely voluntary. You can discontinue participation at any time without penalty and regardless of whether or not you complete both visits. Just tell the study researcher or staff person right away if you wish to stop.

Also, the study staff may stop you from taking part in the study at any time if he or she believes it is in your best interest. For example, based upon changes in your personal inclusion/exclusion or study inclusion/exclusion criteria, or in the case that you fail to complete study procedures, do not follow study rules, if the study has stopped.

In addition, participants will be considered withdrawn from the study if they fail to return three calls if when messages are left, fail to attend three appointments, and refuse an outreach visit by staff.

What other choices do I have if I do not 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 and express interest in another cessation program, we will provide you with information regarding other treatment options. Examples include a free telephone QuitLine or a local smoking cessation clinic.

How will information about me be kept private?
Your participation in this research is confidential. Private health information including data regarding physical health, mental health, and substance use will be linked to an arbitrary study identification number. However, a limited amount of information will be stored in a password-protected file in such a manner that will link your identity and your responses. The information in this file is limited to your assigned study ID, first and last name, your contact information (phone number and email address), and date of participation. Please note that this information will be stored separately from study data coded by your arbitrary study number.

However, if you express suicidal thoughts or plans of any type, or if you express intent to seriously harm others, in the answers to our questions, we will do all that we can to maintain your safety and the safety of others, in which case the confidentiality limits described may be broken. To the best of our ability, we will seek your cooperation in making the report and provide you with referral information to local providers in the community with expertise in the treatment of problems related to your expression of intent to harm yourself or others.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The research team and the Institutional Review Board at Rutgers University, who is responsible for supervising our research, are the only parties that will be allowed to see the data. If a report of this study is published, or the results are presented at a professional conference, data will be presented anonymously. Per Federal Regulations, study data will be retained for three years at which point the file linking participant names to arbitrary study IDs will be destroyed and remaining data will be anonymized.

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This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Drug Abuse, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others as well as reports of child and elderly abuse and neglect.

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 are the costs of taking part in this study?
Aside from the time and travel associated with coming to the Livingston and/or New Brunswick Campuses of Rutgers University, there are no expected costs of participation.

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Will I be paid for taking part in this study?
In return for your time, effort, and travel expenses required to take part in this study, you will receive *up to* $230 for participation. You will receive $10 during intervention weeks 3, 4, and 6; $25 during intervention weeks 1, 2, 5, and 7, which will include measurement of your physiology, $50 for completion of your 3-month follow-up appointment at week 16, and a $50 bonus for making it to each of your treatment and follow-up sessions.

Participants will receive partial compensation for partial completion of study appointment measures.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. Your relationship with the study staff will not change, and you will not be penalized or lose benefits to which are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to Dr. Teresa M. Leyro, Department of Psychology, Tillett Hall, 53 Avenue E, Piscataway, NJ, 08854.

Who can answer my questions about the study?
You can talk to the researcher(s) about any questions, concerns, or complaints you have about this study. Contact Teresa. Leyro, Ph.D. at 848-445-2090.

If you wish to discuss questions about the study or your rights as a research participant with someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please contact an IRB Administrator at the Rutgers University, Arts and Sciences IRB:

Institutional Review Board
Rutgers University, the State University of New Jersey
Liberty Plaza / Suite 3200
335 George Street, 3rd Floor
New Brunswick, NJ 08901
Phone: 732-235-9806
Email: humansubjects@orsp.rutgers.edu

CONSENT
You have been given and have read, or have had read to you, a summary of this research study. It has been explained to your full satisfaction.

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You understand the procedures you will undergo, including any potential benefits, risks, or discomforts.

You acknowledge that PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline participation in this study, or to withdraw from it at any point without penalty, prejudice, or loss of compensation to which you are otherwise entitled. Furthermore, you understand that the investigator has the right to terminate the experiment at any time for any reason.

You realize the results of this study may eventually be published or presented at scientific meetings, but that the confidentiality of all research data associated with this study will be maintained to the maximum extent allowable by law.

Finally, you have been provided with a copy of this consent form to keep.

If you wish to participate in this study, please sign below.

_____	_____	_____
Date	Participant's Printed Name	Participant's Signature for Consent
_____	_____	_____
Date	ABUSA Investigator's Printed Name	ABUSA Investigator's Signature

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Audio/Visual Addendum to Consent Form

You have already agreed to participate in a research study entitled Biofeedback Smoking Cessation Treatment conducted by Teresa M. Leyro, Ph.D. We are asking for your permission to allow us to audiotape your diagnostic interview and videotape your intervention sessions as part of that research study. You do not have to agree to be recorded in order to participate in the main part of the study.

The audio recording(s) of your diagnostic interview will be used to ensure reliability of diagnoses by the research team and as a teaching tool for new members of the team receiving training in the administration of diagnostic interviews. The video recording of your intervention sessions will be used to ensure accurate delivery of the intervention and to provide feedback to study clinicians.

The recording(s) will include the arbitrary number that will be assigned to your data in order to ensure confidentiality. If you say anything that you believe at a later point may be hurtful and/or damage your reputation, then you can ask the interviewer to rewind the recording and record over such information OR you can ask that certain text be removed from the dataset/transcripts.

The recording(s) will be stored in password protected files, on password protected computers kept in locked rooms belonging to the lab. The recordings will be kept until reliability analyses have been completed and destroyed upon termination of data analytic procedures for the current investigation.

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.

_____	_____	_____
Date	Participant's Printed Name	Participant's Signature for Consent
_____	_____	_____
Date	ABUSA Investigator's Printed Name	ABUSA Investigator's Signature