TITLE: Open Trial of Heart Rate Variability Biofeedback for Smoking Cessation

NCT05224050

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Open Trial of Breath Training for Smoking Cessation

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

STUDY SUMMARY: This consent form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to help smokers quit smoking. If you take part in the research, you will be asked to attend smoking cessation counseling, use nicotine replacement therapy, and participate in a breathing intervention. Your time in the study will take place over the course of 4 months, including 3 in-lab visits, and 5 remote sessions.

Possible harms or burdens of taking part in the study may be side effects from the Nicotine Transdermal Patch, discomfort related to quitting smoking, physical discomfort due to our breathing intervention requiring you to breath differently than is typical, slight emotional distress when completing questionnaires, interviews, and counseling services. Possible benefits of taking part may be access to high-quality, evidence-based smoking cessation treatment.

An alternative to taking part in the research study: 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.

The information in this consent form will provide you with more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Teresa M. Leyro, Ph.D. is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Other individuals working as co-investigators or study staff may assist or act for the Principal Investigator.

Teresa M. Leyro, Ph.D. may be reached at 732-659-4283 or teresa.leyro@rutgers.edu. Study staff can also be reached at abusa@psych.rutgers.edu .

The Principal Investigator or another 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.

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Sponsor of the Study: National Institute on Drug Abuse (NIDA).

Why is this study being done?

The purpose of this study is to help individuals who smoke cigarettes quit smoking. The research study will develop and test whether the inclusion of a breath training component with standard smoking cessation treatment is useful. The research study will also test whether the inclusion of this breath training component is particularly helpful for individuals who may struggle with elevated mood and anxiety symptoms in their attempt to quit. First, we aim to test whether the intervention is easy and useful to implement. Second, we hope to improve smoking cessation outcomes and 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. Individuals who smoke who also suffer from elevated emotional distress tend to smoke at greater rates, report greater cigarette 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. Breathing 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 breath training component to a smoking cessation program will provide smokers who want to quit with a cost-effective and efficient tool. We also hope that it will increase the likelihood that individuals who smoke are able to achieve prolonged abstinence and will also have a positive impact on emotional symptoms.

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

Who may take part in this study and who may not?

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
- Are proficient in reading and speaking English
- Are proficient in the use of a computer

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
- Have plans to leave the greater New Brunswick, NJ area in the next 6 months
- Have evidence of another current moderate or severe substance use disorder
- Have severe visual or hearing impairments
- Have a medical condition

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- Are taking a medication that may affect the utility of the breath training component for you or its potential benefit for you

Why have I been asked to take part in this study?
We hope that this study will help individuals who smoke cigarettes quit smoking, as well as test and develop a breathing based intervention as a treatment adjunct for smoking cessation.

How long will the study take and how many subjects will take part?
We expect 30 individuals who smoke daily to complete our study. Each participant will meet with the research team up to 8 times over the course of 4 months. Following your baseline session, you will receive 7 intervention sessions. This includes 2 intervention sessions before your quit date (one of which will be on the same day as the baseline session), and additional counseling sessions during weeks 2, 3, 4, 5, and 6. Your final appointment will be scheduled to occur 3 months after your quit date.

What will I be asked to do if I take part in this study?
If you agree to participate in the study, the following procedures will occur:

Screening: Phone Assessments: The phone assessments will last approximately 1 hour.
You will first speak with Dr. Leyro or another trained staff member over the phone who will go over several assessments with you. This will include an initial screening and a diagnostic interview to assess whether or not you are eligible for study participation.

- First, we will complete a phone screen. During this screening, you will be asked questions about your current and past medical and psychological history to determine basic eligibility.
- Second, you will complete a diagnostic interview. During the interview, you will be asked to provide details regarding current and prior thoughts, feelings, and behaviors, and fill in a few surveys, including contact information, information about your mood and emotions, and more detailed information on your medical history.
- Then, you'll be emailed and asked to complete a set of online questionnaires to obtain additional information about your current mood, personality characteristics, as well as tobacco use, withdrawal, craving, and urge.

If ***you are found to be eligible*** for participation in this study, you will be asked to come into the lab to complete physiological assessments before being enrolled in our study intervention, which include smoking cessation counseling, nicotine replacement therapy, and a breathing intervention.

Baseline: In-Lab Visit 1: Visit 1 will last approximately 3-4 hours.
In the lab, you will speak with Dr. Leyro or another trained staff member who will go over additional assessments with you. This will include a carbon monoxide analysis of your breath to ensure your smoking status, questionnaires to learn more about your physical and mental health as well as your daily smoking patterns and health behaviors, a measurement of your height and weight, and physiological measures.

- 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.

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- Next, you will be attached to sensors on your arms, neck, torso, and fingers that will allow us to measure your heart rate, cardiac activity, blood pressure, and respiration. There are no known risks associated with this assessment. New sterile sensors are used for each participant. While you are attached to the equipment, you will be asked to complete a few computerized tasks.

If you are still deemed eligible, you will learn a breathing intervention and how to use a smartphone app to breathe at a certain rate. In addition, each participant will receive smoking cessation counseling and nicotine replacement therapy patches.

You will be asked to provide the names and contact information for three individuals who may be contacted if we are unable to reach you during your participation in this study. If we are unable to reach you, we will attempt to contact these individuals in order to reach you. We may also contact these individuals to learn whether or not you are currently smoking. You will be contacted for all assessments, independent of whether you continue treatment, and you will be compensated accordingly.

Intervention Overview: In-Lab and Remote: Sessions will last 60-90 minutes. You will work with a separate breath training counselor and smoking cessation counselor. You will complete a total of 7 breath training sessions. You will also complete a total of 6 smoking cessation sessions. Two breath training and two smoking cessation intervention sessions will occur face-to-face in the lab, with the remainder conducted remotely via Zoom.

During week 1, you will have two breath training and two smoking cessation sessions; the first session will be in the lab immediately following your baseline assessments, and the second will be conducted remotely through teletherapy. ***Your quit day will be scheduled for week 2 of treatment***.

You will then have once weekly treatment sessions. Weeks 2, 3, 4, and 5 will also be conducted remotely through teletherapy. Week 6 you will come back into the lab for an in-person session. Intervention sessions will include a combination of smoking cessation skills and breath training using the Inner Balance device, *with the exception of week 5 when you will only meet with your breathing therapist*. In-lab and remote sessions will also include taking a sample of your breath via carbon monoxide analysis to determine your current smoking status and completing a few questionnaires about your physical and mental health, as well as your current thoughts, urges, and cravings surrounding smoking. We will video and/or audio record therapy sessions to ensure that counseling is provided as intended. An overview of the intervention schedule is provided in Table 1.

Table 1. Overview of Intervention Schedule

Week	Treatment
Week 1 (Session 1)	In-person Baseline, Smoking Cessation, & Breath Training
Week 1 (Session 2)	Remote Smoking Cessation & Breath Training
Week 2 (Session 3, Quit Day)	Remote Smoking Cessation & Breath Training
Week 3 (Session 4)	Remote Smoking Cessation & Breath Training
Week 4 (Session 5)	Remote Smoking Cessation & Breath Training
Week 5 (Session 6)	Remote Breath Training
Week 6 (Session 7, 1 Month Follow Up)	In-person 1 Month Follow Up, Smoking Cessation, & Breath Training
Week 15 (3 Month Follow Up)	In-person 3 Month Follow Up

In addition, we will provide you with 8 weeks of nicotine replacement therapy patch. At week 1, we will provide you with the nicotine replacement therapy (NRT) patch and instructions for use. You will be asked to begin using

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the patch on the morning of your quit date. We will provide you with the patch 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 breath training using the Inner Balance app for at least 10 but ideally up to 20 minutes a day.

Follow-up Appointments:
Your 1-month and 3-month 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 and a measurement of your height and weight. We will also routinely assess your physiology to monitor any changes that occur throughout your quit attempt and use of your breathing intervention. You will be attached to sensors on your arms, neck, torso, and fingers that will allow us to measure your heart rate, cardiac activity, blood pressure, and respiration. There are no known risks associated with this assessment. New sterile sensors are used for each participant. While you are attached to the equipment, you will be asked to complete a few computerized tasks.

If we detect a possible abnormal ECG during our in-person session, we will inform you in the event you might want to follow up with a physician. However, please note that our equipment is not medical grade. We will not provide the actual ECG or other physiological records because our procedures are not designed for clinical diagnosis.

You will come in for a final follow-up appointment approximately 3 months after your quit date. Your final follow-up appointment includes all of the above as well as a collecting a sample of your saliva. Saliva collection is a simple, painless procedure that takes approximately 3 minutes. This will help us determine your smoking status during your 3-month follow up appointment.

What are the risks of harm or discomforts I might experience if I take part in this 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. Individuals who smoke and 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 someone who smokes, you may 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.

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- You may also experience physical discomfort throughout the study. For example, the breathing 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. You may also refuse to answer any individual questions you are asked.

- You may find the use of study apps frustrating to learn. However, your breathing therapist will train you on how to use these apps and check in with you on your experience with the apps during your weekly sessions. You can also email or call us if you continue to experience problems with the apps.

- 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, only IRB approved software and devices will be used, and all teletherapy platforms will be HIPPA compliant. 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. This study has also been granted a Certificate of Confidentiality from the National Institutes of Health, the details of which are described below.

- Participation in this study may pose unknown and unforeseeable risks.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be access to high-quality, evidence-based smoking cessation treatment. In addition, indirect benefit from your participation includes contributing to research on smoking cessation and emotional distress. This research may have implications for smoking interventions. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not 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 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 I know if new information is learned that may affect whether I am willing to stay in the study? During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your followup is completed, you will be contacted.

Will there be any cost to me to take part in this study?
Aside from the time associated with coming to the New Brunswick Campuses of Rutgers University, there are no expected costs of participation. You have the option to request a prepaid Uber, Lyft, or taxi to cover travel costs.

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Will I be paid to take part in this study?

In return for your time and effort required to take part in this study, you will receive *up to* $755 for participation. You will accrue $35 for the completion of baseline assessments (even if ineligible for the remainder of the study), $10 for each week of intervention weeks 1, 2, 3, 4, and 5, $35 for week 6, $50 for completion of your 3-month follow-up appointment at week 15, and up to $105 weekly compensation for at-home breathing practice using the Inner Balance device provided to you. To facilitate your practice, we ask that you practice using a smartphone and provide us with several brief ratings of how you feel before and after each practice session. You will additionally receive a $50 bonus for making it to 6 out of 7 treatment session and returning all study-provided devices (e.g., the Inner Balance device, the iCOquit CO monitor, a smartphone or tablet if you borrowed one for the study, etc). If you withdraw from the study, we ask that you return any study-provided devices (e.g., smartphone or tablet), and then we will provide you with compensation for all study participation up to that point. Participants will receive partial compensation for partial completion of study appointment measures.

You will be compensated for your time via ClinCard, which is a specially designed debit card for clinical research. Greenphire, the company which developed the ClinCard, will act as an agent of Rutgers University to manage the payment. You will be given a Greenphire ClinCard, which is a debit card that your study payments are loaded onto following completion of study visits. When a study visit is completed, the payment will be approved and loaded onto your card. The funds will be available every Friday during the time of your participation, unless the study coordinator advises you that it may take a little longer. You may use the ClinCard as you choose, including at grocery stores, restaurants, and to retrieve cash from major banks. You will be issued one ClinCard for the duration of your study participation. If your card is lost or stolen, you can contact ClinCard support at (866) 952-3795. This phone number is also on the back of the card. If you do need a replacement card and you obtain it directly through the ClinCard customer support service, it will be mailed to your address. In that event, the balance from your lost card will be loaded onto your replacement card, minus a $7 replacement fee charged by the customer support service. Or, you may request a replacement card during your next visit with your study coordinator, who will provide you with a replacement card for a fee of $3.50, which will be subtracted from your ClinCard balance.

In order to participate in this ClinCard program, as a part of the study, Greenphire will collect information about you, including your name, address, telephone number, next appointment date, date of birth, social security number, email address, if applicable, and your study subject ID. All information is stored in a secure fashion and will be deleted from Greenphire's system once the study has been completed and the funds on your ClinCard have been exhausted. Your information will not be shared with any third parties and will be kept confidential.

If you receive $600 or more in a calendar year in total stipend payments from this study, or from other Rutgers's studies or programs, Rutgers University will issue to you an IRS Miscellaneous Income Form 1099, indicating the total amount of the payments you received in that tax year. Your decision to receive the stipend payments through ClinCard or in another payment form will not affect Rutgers University's issuance of the Form 1099.

You may opt to receive cash instead of signing up for ClinCard. If you choose to receive cash, you will be paid during your in-person visits which will occur at the end of Session 1, 1 Month Follow Up, and 3 Month Follow Up.

How will information about me be kept private or confidential?

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,

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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.

Five years after the conclusion of the study, any source linking your data to your personal identity will be destroyed and only the de-identified data will be kept.

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.

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 is available on http://www.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

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Apps are used to store data in a secure and encrypted form. Although every reasonable effort has been taken, confidentiality during internet communication procedures cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with the study.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study? It is your choice whether to take part in the research. You may choose to take part, not to take part, or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, 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 data already collected about you, but you must do this in writing to Teresa M. Leyro, Ph.D. at 848-445-2090 or teresa.leyro@rutgers.edu.

Additionally, we have the right to withdraw you from the study at any time in such cases as:

If we determine that you gave us incorrect data that fall under exclusion criteria.

You are not able to fill out required questionnaires or obey study requirements.

You become pregnant.

Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Teresa M. Leyro, Ph.D., Psychology Department, at 848-445-2090 or teresa.leyro@rutgers.edu.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB Office at: (973) 972-3608 or (732) 235-9806 or (732) 235-2866, or email us at IRBOffice@research.rutgers.edu, or write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

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AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent 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 and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature: Date:_____

Subject Compensation:

I am choosing the following as my form of compensation throughout the study:

_____ClinCard _____Cash

Subject Name (Print):_____

Subject Signature: Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature: Date: _____

ADDENDUM: CONSENT TO AUDIO/VISUALLY RECORD OR PHOTOGRAPH SUBJECTS

You have already agreed to take part in a research study entitled: Open Trial of Breath Training for Smoking Cessation conducted by Teresa M. Leyro, Ph.D. We are asking your consent to allow us to audiotape your diagnostic interview and video and/or audio record your intervention sessions you as part of the research. You do not have to consent to be recorded to take part in the main research.

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 recordings of your intervention sessions will be used to ensure accurate delivery of the intervention and to provide feedback to study clinicians.

The recording(s) may include the following information that can identify you: 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 either remove

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that portion of the recording, rewind the recording and record over such information if the virtual platform that is being used allows, 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. The recording(s) will not be used by us or distributed to investigators for other research.

Your signature on this form permits the investigator named above 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 consent.

AGREEMENT TO BE RECORDED

Subject Name (Print):_____

Subject Signature _____ Date _____

Investigator/Person Obtaining Consent Name (Printed):_____

Signature _____ Date _____

SMART PHONE, TABLET, OR COMPUTER LENDING ADDENDUM TO CONSENT FORM

You have already agreed to participate in a research study entitled Open Trial of Breath Training for Smoking Cessation conducted by Teresa M. Leyro, Ph.D. Please sign below to acknowledge that you understand the terms of the smartphone, tablet, or computer lending agreement below.

1) If you do not own a smartphone or computer which supports the Inner Balance application and video conferencing applications (i.e., Zoom) used in this study, we may lend you a device for use during remote teletherapy and at-home practice for the duration of the study.

2) You agree to return the device at the conclusion of the study (15 week follow-up visit) or if/when you withdraw from the study, whichever comes earlier.

3) If you withdraw from the study prior to full completion (15 weeks), you will receive full compensation for all research participation up to the point of the device's return. If you do not return the smartphone, tablet, or computer, you will not receive further compensation. If you do not return the device, you will

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not receive the final compensation, as we will be unable to retrieve study data—an integral part of your study participation.

4) If you complete the study, you will receive the $50 attendance compensation and up to $50-100 attendance bonus based on whether you attended 6/7 sessions or every session, contingent upon return of the borrowed smartphone, tablet, or computer.

Your signature on this form indicates that you understand the terms of the lending agreement for the smartphone, tablet, or computer to be used in the above-referenced study. The investigator will not use the data retrieved from the device 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