Official Title: Reducing distress and tobacco smoking in cancer survivors: a TDCS telehealth study (BREATHES)

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Wake Forest®
School of Medicine

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Department of Physiology and Pharmacology

REDUCING DISTRESS AND TOBACCO SMOKING IN CANCER SURVIVORS: A TDCS TELEHEALTH STUDY (BREATHES)

Informed Consent Form to Participate in Research
Dr. Merideth Addicott, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to evaluate a noninvasive form of brain stimulation (transcranial direct current stimulation (tDCS)) as a tool to help decrease anxiety and improve smoking cessation outcomes, especially in individuals with a cancer diagnosis that are trying to stop smoking. You are invited to be in this study because you are a smoker who has had a diagnosis of cancer, and you want to quit. Your participation in this research will involve 24 sessions (done in your own home) and will last about 10 weeks.

Participation in this study will involve the following: a remote screening/consent session, 20 sessions of remote-supervised tDCS (rs-tDCS) (real or sham) done in your home, and 2 remote follow-up sessions over 1 month. All research studies involve some risks. The largest risk associated with this study is minor discomfort during treatment such as warmth, itching or tingling sensation under the area of the electrodes on your forehead. You may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include other forms of treatment for nicotine dependence including counseling and medication. A national help line, 1-800- QUITNOW (1-800-784-8669) offers free assistance and referrals. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Merideth Addicott. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have received a cancer diagnosis, you smoke, and you would like to quit smoking. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to evaluate the feasibility of rs-tDCS as a therapeutic approach to smoking cessation in cancer survivors. We are evaluating this as a tool to decrease distress and decrease cigarette use.

In this study rs-tDCS will be compared to placebo. A placebo is a substance, like a sugar pill, that is not thought to have any effect on your disease or condition. In this study the placebo is called a "sham treatment". You will be randomized to receive either the active study treatment (rs-tDCS) or the sham treatment, which is not active. Sham controls are used in research studies to see if a device being studied has a true effect.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

46 people at this research site will take part in this study. In order to identify the 46 subjects needed, we may need to screen as many as 62 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. This study is using a 2:1 randomization, such that you are 2 times as likely to receive the active versus the sham/placebo condition.

Neither you nor the research coordinator will know which study treatment you are receiving. This is done so that a fair evaluation of results can be made.

If you take part in this study, you will have the following tests and procedures:

1. *Baseline Screening/Consent (Session 1)*: You will complete interviews and self-report screening measures (on a computer) designed to assess your smoking behaviors, your psychiatric history, and your mood. You will also be asked to report your daily cigarette consumption during the course of the study. You will also be asked about your employment history, past medical history, focusing on chronic (and current) medical problems, medications, quality of life, quality of sleep, and substance use. The research procedures, risks and benefits will be explained. This session lasts about 2 to 3 hours.

2. *rs-tDCS device training (Session 2):* If you qualify for the study and agree to continue, we will ship you the tDCS equipment, a tablet computer, a breath carbon monoxide (CO) reader, and other materials. When these have arrived, we will conduct an online session to show you how to use the equipment. You will be asked about the feasibility and tolerability of the tDCS procedure, as well as any side effects, throughout the study. You will be randomized to either sham rs-tDCS treatment or real rs-tDCS treatment. You will not be told which type of stimulation you are receiving during a treatment session. The real rs-tDCS and the sham rs-tDCS feel the same, so you will not be able to determine which you are receiving based on your experience. This session lasts about an hour.
3. *rs-tDCS treatment and mindfulness (Sessions 3-22):* For five days per week (at about the same time of day) for 4 consecutive weeks, you will complete online sessions with a study coordinator. These sessions last about 30 minutes each, and must be conducted while you are in a quiet room, free from distractions (such as pets, housemates, tv, or music on in the background). During these sessions, you will receive tDCS treatment and listen to an audiotrack on mindfulness in addition to some music. You will be asked to complete some questionnaires about once per week. At every session, you will be asked to report your breath CO and recent use of all drugs and medications. You are allowed to reschedule up to 3 sessions, but all sessions must be completed within 5 consecutive weeks, no more than 1 session per day.
4. *Smoking cessation.* During the first 5 tDCS sessions, the study coordinator will discuss your smoking cessation goals with you. You will be asked to make a quit attempt on the 6th tDCS session (Session 8).
5. *Follow-up Sessions (Sessions 23-24).* You will be asked to return the equipment and tablet computer following Session 22 in the prepaid shipping package we provide. You will have 2 additional online sessions with a study coordinator spread out over 1 month to report on your breath CO, mood, smoking, medication and drug use, and any side effects. These sessions will last about 1 hour.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. If you choose not to participate, it will not affect your relationship with any current treatment provider you may have or you're right to health care or other services to which you are otherwise entitled.

How Long Will I Be in the Study?

You will be in the study for about 10 weeks.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study

with the study staff. Risks and side effects related to the treatment we are studying include: warmth, itching or tingling sensation under the area of the electrodes. There could also be mild discomfort from wearing the headgear.

Further risks include the following:

1. *Randomization risk*: The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.
2. *Security of confidentiality and privacy risk*: Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.
3. *Potential Risk of Psychiatric Interviewing (minimal risk):* As part of this study, you will be asked questions about sensitive personal information. You may feel anxiety about disclosing your substance use history and reporting some aspects of your demographics. Some questionnaires include questions on suicidal ideation. In the event that you endorse suicidal ideation, the staff present with you will be authorized to contact the PI or one of the Co-I's on the study who will then assess the situation to see whether further intervention is required. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.
4. *Risk of tobacco withdrawal symptoms:* Quitting smoking can cause symptoms of tobacco withdrawal. These include cravings, urges to smoke, irritability, difficulty concentrating, restlessness, increased appetite, anxiety, and depressed mood.

Reproductive Risks and Other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be the following: the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot

be guaranteed. From a biological perspective, you may benefit from the positive effects of real rs-tDCS if you are randomized to the active groups. You may be able to stop smoking from your participation in this study although this cannot be guaranteed. From a psychological perspective you will likely benefit from the additional time you will spend in contact with the study team when you will be surrounded by educational materials on smoking cessation and an environment that is generally supportive and encouraging despite your struggle with nicotine use. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have a number of options. If you should choose to seek treatment either before or after your participation in this study, there are a number of options. Most types of treatment for nicotine dependence involve some form of counseling and medication. A national help line, 1-800- QUITNOW (1-800-784-8669) offers free assistance and referrals. If you would like to receive additional information on nicotine dependence, this will be provided to you by the study personnel.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid up to $320 if you complete all the scheduled study sessions. You will not be paid for the initial phone screen. If you withdraw for any reason from the study before completion you will be paid for each complete study session. The money will be credited to a ClinCard after each session. To receive payment, you must provide your social security number, name, and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to supply this information you can still take part in the study but you will not be paid.

Table outlining session and compensation information is shown below:

SESSION	AMOUNT ($)
Consent/Screening SESSION1	$20
Training SESSION2	$10
rs-tDCS SESSION3	$10
rs-tDCS SESSION4	$10
rs-tDCS SESSION5	$10
rs-tDCS SESSION6	$10
rs-tDCS SESSION7	$10
rs-tDCS SESSION8	$10
rs-tDCS SESSION9	$10
rs-tDCS SESSION10	$10
rs-tDCS SESSION11	$10
rs-tDCS SESSION12	$10
rs-tDCS SESSION13	$10
rs-tDCS SESSION14	$10
rs-tDCS SESSION15	$10
rs-tDCS SESSION16	$10
rs-tDCS SESSION17	$10
rs-tDCS SESSION18	$10
rs-tDCS SESSION19	$10
rs-tDCS SESSION20	$10
rs-tDCS SESSION21	$10
rs-tDCS SESSION22	$10
Follow-up 1 SESSION 23	$10
Follow-up 2 SESSION 24	$10
Return Equipment	$50
Study Completion bonus	$20
TOTAL	**$320**

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institutes of Health (NIH). The sponsor is providing money or other support to Wake Forest University of Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied. Portions of Dr. Addicott and her research team's salaries will be paid by this grant.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy

the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Merideth Addicott at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** Names, all elements of date (except year) for dates directly related to an individual (e.g. DOB, telephone numbers, electronic mail addresses, and self-reported diagnosis of cancer).

Information collected from you during this study will not be placed in your medical record.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Wake Forest Baptist Health; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and other agencies if required.

Some of these people, agencies and businesses may further disclose your health information. If

disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Merideth Addicott that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Merideth Addicott
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

A description of this clinical trial will be 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.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or

safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Merideth Addicott at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this consent.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ (Docusign date/time stamp)

Person Obtaining Consent (Printed):_____

Person Obtaining Consent: _____ (Docusign date/time stamp)