REDUCING ANXIETY IN LUNG CANCER SURVIVORS

WFU 01213 - REDUCING LUNG CANCER SURVIVORS’ ANXIETY (RELAX)

Informed Consent Form to Participate in Research
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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 had lung cancer and are experiencing anxiety and possibly shortness of breath. 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.

WHAT IS THE USUAL APPROACH TO MY ANXIETY FROM SHORTNESS OF BREATH RELATED TO MY LUNG CANCER?
Treatments for anxiety caused by shortness of breath may include different levels of medications to help decrease anxiety and shortness of breath. People who do not take part in this study should talk to their doctor about all of the choices you may have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Seventy-five people will take part in this study.

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to determine our ability to recruit early-stage lung cancer survivors who have completed cancer treatment to a study of a device that may decrease anxiety. We then will determine how many will complete the sessions using the study device as well as all study questionnaires. We will also compare effects of device-guided breathing on anxiety and shortness of breath in lung cancer survivors.
WHAT ARE THE STUDY GROUPS?
If you take part in this study, you will be randomized into one of the three study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.

You agree to take part in the study  
Randomize (The computer will randomly put you in a study group)

Group A  
Breathing Device Low Dose  
15 minutes, once a day, at least 5 days a week for 12 weeks

Group B  
Breathing Device High Dose  
15 minutes, twice a day, at least 5 days a week for 12 weeks

Group C  
Breathing Control Device  
15 minutes, once a day, at least 5 days a week for 12 weeks

- Group A: Will receive a device that will gradually slow down breathing rate. It plays music through headphones and has a sensor that attaches to your abdomen or chest. You will be asked to use it **once** per day for 15 minutes, at least 5 days per week, for 12 weeks.

- Group B: Will receive a device that will gradually slow down breathing rate. It plays music through headphones and has a sensor that attaches to your abdomen or chest. You will be asked to use it **twice** per day for 15 minutes, at least 5 days per week, for 12 weeks.

- Group C: Will receive a device that will leave your breathing rate at a similar rate that you usually breathe. It plays chimes through headphones and has a sensor that attaches to your abdomen or chest. You will be asked to use it **once** per day for 15 minutes, at least 5 days a week for 12 weeks.

HOW LONG WILL I BE IN THE STUDY?
You will be in the study for about 12 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 to learn about any potential health or safety consequences. After you finish, your cancer doctor or family doctor will continue to watch you for side effects and follow your condition.
WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?
Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra tests that you will need to have if you take part in this study.

At the Beginning of the Study:

We will ask you to answer a set of questions about yourself, including things like your age and marital status, your mood, and your breathing.

- Blood work to be sure your hemoglobin level is acceptable. Hemoglobin is a blood particle that carries oxygen. One (1) teaspoon of blood will be withdrawn from a vein or currently placed central line (port-a-cath) once at baseline to be sure that your oxygen level is acceptable. This is the total amount of blood drawn during the study. If a hemoglobin level obtained within the past 60 days is in your clinical record, there will be no need to draw blood for this study.
- At your first visit, a research staff member will give you a device and instruct you in how to use it. You will also receive written instructions and be able to use the device at home or at any other location that is convenient, private, and quiet.
- We will also ask you to complete additional questionnaires and do 2 short tests. One of them is a breathing test to check how your lungs are working, and the other one requires you to walk for 6 minutes to measure your physical function. This whole visit should take less than 1 hour.
- Some participants will be asked to obtain a saliva sample three times per day for three days to measure your cortisol levels.

During the study:

- Over the next 12 weeks of using your study device, follow the instructions we gave you at your first visit.
- Every time you use your device, you will be asked to complete 3 brief ratings about your mood and breathing just before and after you use it.
- The Research Coordinator will call you on a weekly basis to ask if you are having any problems with using the device and to collect breathing data (stored in the device) for the prior 7 days. The research staff will instruct you on how to view the data.

After you have been using the device for 6 weeks, we will mail you another set of questionnaires about your mood and your breathing. This questionnaire is brief and should take less than 20 minutes to complete. We will provide a postage-paid envelope for you to return this form to us.

End of the study:

- At the end of the 12-week study period, we will ask you to come back to the study office to turn in your equipment and to answer questions again about your mood and your breathing.
- Some participants will be asked to obtain a saliva sample three times per day for three
days to measure your cortisol levels.
- You will also do another breathing test and 6-minute walk. This final study visit should also take less than 1 hour.

Before and after the study, we will also ask you questions like how helpful you think the study activities are.

WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
Being in this study involves very little risk to you. You should discuss the risk of being in this study with the study staff.

There are no known risks or side effects related to using the Breathing device. Risks from using the study devices are highly unlikely.

You may experience discomfort, bruising and/or bleeding where the needle is inserted for the blood test. Occasionally some people feel dizzy, lightheaded, or faint. Infection may occur on rare occasions.

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.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This information may help you to avoid side effects, interactions and other risks.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research every six months.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?
If you decide not to take part in this study, you have other choices. For example:
- You may choose to receive therapy or take medications for anxiety symptoms without participation in this study.
- You may choose to take part in a different study, if one is available.
- Or you may choose not to be treated for anxiety symptoms.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
If you agree to take part in the study, there may or may not be direct benefit to you. We hope that use of the device will help your anxiety and shortness of breath, but there is not yet definite proof of benefit. We hope the information from this study will benefit other people in the future. By
being in this study, you will help to increase knowledge about how use of different breathing rates affects your mood, symptoms, and quality of life.

**CAN I STOP TAKING PART IN THIS STUDY?**
Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the research staff know as soon as possible. If you stop, you can decide whether or not to talk to the investigators or study staff to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB, or FDA.

**WHAT ARE MY RIGHTS IN THIS STUDY?**
Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the Wake Forest School of Medicine Institutional Review Board at (336) 716-4542.

**WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**
The device will be supplied at no charge while you take part in this study. All study costs, including any 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 YOU BE PAID FOR PARTICIPATING?**
You will receive no payment or other compensation for taking part in this study.

**WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART 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 (336) 716-3467.

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 Dr. Suzanne C. Danhauer at (336) 716-7402, or after hours, call (336) 716-2011.

**WHO WILL SEE MY MEDICAL 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: type of lung cancer, diagnosis date, type and date of cancer treatment(s), name and dosage of medications used in the past month.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

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. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

3) The National Cancer Institute.

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.
Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished.

You can tell Dr. Suzanne C. Danhauer 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:

Suzanne C. Danhauer, Ph.D.
Department of Social Sciences & Health Policy
Division of Public Health Sciences
Wake Forest School of Medicine
Medical Center Boulevard
Winston-Salem, NC 27157

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.

If you choose to participate in this study, your medical record at Wake Forest Baptist Health will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

WHERE CAN I GET MORE INFORMATION?
You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?
For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Suzanne C. Danhauer at (336) 716-7402, or after hours, call (336) 716-2011.
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 (336) 716-4542.

You will be given a copy of this signed consent form.

**BLOOD COLLECTION FOR RNA/DNA**

As part of this study, a blood sample will be obtained so that DNA and RNA from your blood sample will be purified. DNA, or deoxyribonucleic acid, stores and transmits inherited traits, such as eye color or blood type. RNA, or ribonucleic acid, works with DNA to help express these traits. As part of this research project, your DNA and RNA will be studied in an effort to find out if there are genes that contribute to medical conditions that are part of this study. Because we do not know how the results of this DNA/RNA study relate to your individual health, the results of the research will not be given to you or your doctor without your permission. These results will also not be placed in your medical records.

Researchers are trying to learn more about mental health and mood disorders. Much of this research is done using samples from your blood. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

If you choose to take part in this study, the main study doctor would like to collect an additional 2 teaspoons of blood at baseline and 12 weeks. RNA/DNA blood samples are being drawn to test connections between your cells and mental health and mood disorders.

The researchers ask your permission to use your samples and related health information (for example, your use of the device) for medical research. Your sample will be obtained and stored at Wake Forest University Baptist Medical Center. It will be given only to researchers approved by Dr. Suzanne Danhauer, the primary investigator of this study. An Institutional Review Board (IRB) must also approve any future research study using your blood sample.

**WHAT IS INVOLVED?**

If you agree to take part, here is what will happen next:

1) If you agree to participate in the blood sample for RNA/DNA testing, you will have approximately 2 additional teaspoon of blood drawn at baseline and 12 weeks for a total of 4 teaspoons of additional blood drawn during the study.

2) Researchers will not be given your name or any other information that could directly identify you.

3) You will not be notified of results from this RNA/DNA testing.
FOR RNA/DNA STUDIES:
My blood and related information may be used for health research. If I do not choose to have my additional blood drawn, I am still eligible to participate in the study.

Please circle your answer to show whether or not you would like to take part in the additional RNA/DNA blood draw.

YES       NO

MY SIGNATURE AGREEING TO TAKE PART IN THE STUDY
I have read this consent form or had it read to me. I have discussed it with the research staff and my questions have been answered. I will be given a signed copy of this form. I agree to take part in this study.

Participant’s Signature (Printed): __________________________

Participant’s Signature: __________________________ Date: _____ Time:____ am   pm

Signature of person(s) conducting Informed Consent Discussion: __________________________

Date:_______ Time:_______ am   pm