VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Impact of preoperative respiratory strength training on postoperative health for heart transplant recipients
Version Date:	5/17/2024
PI:	Cara Donohue, Ph.D. CCC-SLP

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This research study is investigating whether completing breathing exercises before surgery helps heart transplant patients recover after surgery. Previous studies have shown that breathing exercises can improve breathing, cough, and swallow function in patients with other diseases/conditions. The current study will investigate the impact of respiratory muscle strength training on breathing and cough function, swallow function, frailty, patient-reported eating and swallowing fatigue, patient-reported quality of life, and health outcomes in individuals undergoing heart transplantation. This study will involve three in-person research evaluations (in our lab or the hospital) that will last 30 minutes- 1 hour and will consist of a screening, breathing and cough testing, swallow function testing, grip strength testing, and completion of questionnaires. Following the initial research evaluation, individuals will complete daily exercises of active or sham respiratory muscle strength training for several weeks with one telehealth or in-person session per week. The exercises will take 10-15 minutes to complete, and individuals will fill out training logs daily. A potential benefit of participating in this research study includes improving respiratory and cough function and strength. This study also has the potential to lead to better treatments for people undergoing heart transplantation who have impaired pulmonary, cough, or swallow function. Risks of participating in this study include dizziness/lightheadedness, fatigue, muscle soreness, boredom, fainting, spasm of your vocal cords, nosebleed, gagging, vomiting, food/liquids entering the lungs, and loss of confidentiality.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Study Title:	Impact of preoperative respiratory strength training on postoperative health for heart transplant recipients
Version Date:	5/17/2024
PI:	Cara Donohue, Ph.D. CCC-SLP

You are being asked to take part in this research study because you are an adult between the age of 18-90 years old who is undergoing heart transplantation. You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
This research study will involve breathing and cough testing, swallow function testing, grip strength testing, completion of breathing exercises, and completion of questionnaires. Possible side effects and risks of study procedures and treatments include:

- Dizziness/lightheadedness
- Fatigue
- Muscle soreness
- Boredom
- Discomfort of wearing nose clips
- Fainting
- Spasm of your vocal cords
- Nosebleed
- Gagging
- Vomiting
- Food/liquids going into the lungs

Good effects that might result from this study:
The benefits to science and humankind that <u>might</u> result from this study:
Undergoing the active treatment in this study will likely lead to improvements in breathing and cough function/strength. Additionally, we hope that the treatment will lead to improvements in postoperative swallow function and health outcomes in heart transplant patients. Importantly, the information obtained from this research study will inform clinical practice of heart transplant patients with impaired pulmonary, cough, and swallow function. Information gained from this study has the potential to illuminate a new, preventative, treatment to improve postoperative swallowing and health outcomes for heart transplant patients while they are recovering after heart transplantation.

Study Title:	Impact of preoperative respiratory strength training on postoperative health for heart transplant recipients
Version Date:	5/17/2024
PI:	Cara Donohue, Ph.D. CCC-SLP

Procedures to be followed:
This study will consist of an initial research visit that will involve breathing and cough testing, and grip strength testing, which will take approximately 30-45 minutes. After that we will teach you how to perform daily exercises of respiratory muscle strength training. You will be assigned to either the active or the sham treatment group. You will complete the exercises daily and will fill out training logs on MyCap. They will take approximately 15 minutes to perform. We will do a telehealth or in-person session with you once per week from the time of your first research visit until you undergo heart transplantation. Treatment sessions will take place via a secure version of Zoom or in a private room in person. After that, you will come back for a second research evaluation that will involve breathing and cough testing, grip strength testing, swallow function testing, and the completion of some questionnaires about the treatment you received and eating and swallowing related fatigue which will take approximately 60 minutes. The swallow function test will involve the insertion of a small camera through the nose and into the throat area. After this, you will have your heart transplant surgery. Following your heart transplant surgery and while you are still in the hospital, you will undergo another swallow function test and will complete questionnaires related to eating and swallowing related fatigue and quality of life related to your heart condition which will take approximately 45 minutes. We will also extract some data from the electronic medical records about your health following your heart transplantation.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:

Study Title:	Impact of preoperative respiratory strength training on postoperative health for heart transplant recipients
Version Date:	5/17/2024
PI:	Cara Donohue, Ph.D. CCC-SLP

If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Cara Donohue, Ph.D. CCC-SLP at 615-932-4709.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the Principal Investigator may take you out of this study:
Individuals may be withdrawn from the research study by the Principal Investigator if they experience adverse side effects that are believed to be associated with the treatments being explored in this study. If the Principal Investigator determines withdrawal from the study is necessary, they will contact you via phone/e-mail.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell the Principal Investigator (Cara Donohue, Ph.D., CCC-SLP). Deciding to not be part of the study will not change your regular medical care in any way.

Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov (NCT06190171) 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 Web site at any time.

Confidentiality:
Data collection will occur in a private room with the Principal Investigator or a trained research assistant. You will be assigned an alphanumeric code to protect your data from being identified. All your data will be stored in a locked file cabinet or entered/stored in REDCap or MyCap, secure web-based applications offered through Vanderbilt. Only approved research study personnel with HIPAA training and responsible conduct in research training will have access to your data.

Study Title:	Impact of preoperative respiratory strength training on postoperative health for heart transplant recipients
Version Date:	5/17/2024
PI:	Cara Donohue, Ph.D. CCC-SLP

This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
Research participants may indicate to the Principal Investigator if they are interested in results of this research study. This information will be tracked and deidentified data in the form of presentations and/or manuscripts will be shared with interested research participants once the study is complete.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by

Study Title:	Impact of preoperative respiratory strength training on postoperative health for heart transplant recipients
Version Date:	5/17/2024
PI:	Cara Donohue, Ph.D. CCC-SLP

the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Study Title:	Impact of preoperative respiratory strength training on postoperative health for heart transplant recipients
Version Date:	5/17/2024
PI:	Cara Donohue, Ph.D. CCC-SLP

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____