Safety, Feasibility, and Impact of Preoperative Respiratory Strength Training in Cardiac Surgical Patients

ClinicalTrials.org NCT04887415

University of Florida IRB202100993

Principal Investigator: Emily K Plowman, Ph.D. CCC-SLP

Co-Investigator: Cara Donohue, Ph.D. CCC-SLP

Informed Consent Form, 5/17/2022

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM to Participate in Research, and

AUTHORIZATION

to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Safety, Feasibility, and Impact of Preoperative Respiratory Strength Training in Cardiac Surgical Patients

3. Whom do you call if you have questions about this Research Study?

Principal Investigator:
Emily Plowman, Ph.D. CCC-SLP
352-273-9215

Co-principal investigator/Research Study Coordinator:
Cara Donohue, Ph.D. CCC-SLP
352-273-8632

4. Who is paying for this Research Study?

This study is funded by an ASHFoundation Mentored Clinical Research Grant and by an American Heart Association Post-doctoral Fellowship Award.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research

subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The purpose of this research study is to investigate the safety, feasibility, and effects of a breathing exercise program (respiratory strength training) on breathing, swallowing, and cough function in patients who will be undergoing a cardiac surgical procedure. If you choose to participate in this research study, you will actively participate for approximately one month before your surgery and until the time of your hospital discharge.

b) What is involved with your participation, and what are the procedures to be followed in the research?

If you are eligible and agree to participate in this research study, you will undergo three research examinations that consist of tests of breathing, cough, and swallowing. Two examinations will take place before you have surgery at the preoperative clinic and one examination will take place after you have surgery on Unit 77 of the UF Heart and Vascular hospital. Each examination will take approximately 30-45 minutes. We will also review your medical records to see if you have previously had any swallowing problems or heart surgeries as this information will be helpful to understand who this treatment works best for. Test results from research visits can also be made available, if you desire, to your medical care team.

After your first examination and before your surgery, you will complete at-home breathing exercises five days per week. We will aim to have you complete breathing exercises for 4 weeks before your operation, however the exact time will depend on your surgery date. You will have the option to complete any of these exercise sessions with a study team member using zoom (called a telehealth session) as much as you would like and be asked to complete a training log after each session. You will also have one in-person visit within your home or at our research laboratory at the mid-point of the training program. It will take you approximately 30 minutes per day to complete the breathing exercises. After you have surgery, we will monitor your health related outcomes (e.g., pneumonia, hospital length of stay, etc.).

c) What are the likely risks or discomforts to you?

- Although rare, there is a possibility that completing the breathing/coughing tests or the breathing exercises could result in dizziness, lightheadedness, soreness, or fatigue.
- While uncommon, the swallowing test we will perform can result in gagging, discomfort, vomiting, fainting, a muscle spasm in the vocal cords,

or a nosebleed. There is also a chance that aspiration (food or liquid going into the lungs) could occur during the swallowing exam.

- Risks of opting to have the numbing agent applied during the endoscopy are rare but may include allergic reaction, transient redness, cardiovascular or neurological response.

d) What are the likely benefits to you or to others from the research?

You may or may not benefit from participating in this research study. Completing these breathing exercises may improve your breathing, cough function, and swallow function after you have surgery. If this study shows that breathing exercises are helpful, it may also help other patients who are undergoing cardiac surgery in the future.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

There are no established breathing or swallowing treatments for patients undergoing cardiac surgical procedures.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care?

Your normal clinical care will not be affected in any way by participating in this research study.

7. What will be done only because you are in this Research Study?

Examinations: You will have two preoperative evaluations (one prior to the start of your training, and another after you complete your breathing exercise program) at the University of Florida Heart and Vascular hospital preoperative clinic and one postoperative evaluation on Unit 77 of the Heart and Vascular hospital. Each evaluation will take approximately 30-45 minutes. During the first research evaluation, you will undergo tests of breathing, cough, and speech. During the second research evaluation, you will undergo tests of breathing, cough, speech, and swallowing. The third research evaluation will consist of a swallowing evaluation only.

For the swallowing evaluation, you will be seated in a comfortable position. We will put a lubricant on the inside of your nose and then we will insert a small camera through your nose and into the throat area. This is called a Fiberoptic Endoscopic Evaluation of Swallowing (FEES). The fiberoptic test is often well tolerated using only a waterbased lubricating gel. However, for additional comfort with the exam you may choose to have a numbing agent (i.e., lidocaine spray or gel) applied to the inside of your nose. We will have you talk so we can see how your vocal cords and other structures in the throat area move. We will watch how structures move and where food and liquid goes as you eat and drink things such as Gatorade, pudding, crackers, and M&Ms. The swallowing evaluation will take approximately 10-15 minutes.

For the breathing and coughing evaluations, we will have you cough hard into equipment to measure your cough strength and have you breathe in and out forcefully to measure your breathing function. You will also fill out a questionnaire to measure how out of breath you get. The breathing and coughing evaluations will take approximately 15 minutes.

For the speech evaluation, you will read a short paragraph while wearing a microphone headset.

Breathing exercises: After completing your initial preoperative evaluation, the study coordinator will teach you how to use two handheld respiratory trainers. You will complete breathing exercises five days per week for a targeted duration of 4 weeks, however the exact duration will depend on when your surgery is scheduled. It will take you approximately 30 minutes per day to complete the breathing exercises from home. You will be given a training log to fill out each training session. At least once per week (depending on your desired number), you will have a telehealth session (video conference call over the internet) with a study team member to check in with you, ensure you are completing the breathing exercises correctly, and to provide you with an opportunity to ask questions. You will also have one in-person visit within your home or at our research laboratory at the mid-point of the training program and to retest your breathing function and to adjust your respiratory trainers. In addition, you will complete a speech test and fill out a brief survey (the same as in first research visit).

As part of this Research Study, we will collect information on your past medical history such as any previous heart surgeries or swallowing problems, and we will monitor your health-related outcomes following surgery (for example length of hospital stay or pneumonia) from your medical records for up to 90 days following your surgery; however, we will not perform any additional research testing sessions with you. Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you

or your legally authorized representative. Paper and electronic data (including videos) will be stored for 5 years after completion of the research study and then will be destroyed.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The Research Team will collect and use private information about you and your health, which is referred to as protected health information (PHI). The following information may be collected, used, and, shared with others.

- Your entire research records (swallowing tests, breathing/cough tests, training logs)
- Name and contact information (home/email addresses, phone number)

All PHI will be stored within a locked file cabinet, on a secure computer server, or on encrypted storage devices.

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide studyrelated care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.

The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information <u>may</u> be shared with:

- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies which are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

You will actively participate in this research study for approximately one month before your surgery and until the time of your hospital discharge. We will also continue to monitor your health-related outcomes (for example length of hospital stay or pneumonia) from your medical records for up to 90 days following your surgery.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11.How many people are expected to take part in this Research Study?

30 patients who are planning to undergo cardiac surgical procedures will participate in this research study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12.What are the possible discomforts and risks from taking part in this Research Study?

- Although rare, there is a possibility that completing the breathing/coughing tests or the breathing exercises could result in dizziness, lightheadedness, soreness, or fatigue.
- While uncommon, the swallowing test we will perform can result in gagging, discomfort, vomiting, fainting, a muscle spasm in the vocal cords, or a nosebleed.
- Risks of opting to have the numbing agent applied during the endoscopy are rare but may include allergic reaction, transient redness, cardiovascular or neurological response.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a

release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

You may or may not benefit from participating in this research study. Completing these breathing exercises may improve your breathing, cough function, and swallow function after you have surgery.

13b. How could others possibly benefit from this Research Study?

If this study shows that breathing exercises are helpful, it may also help other patients who are undergoing cardiac surgery in the future.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals. None of the study team members have a financial interest or a conflict of interest.

14.What other choices do you have if you do not want to be in this study?

Participating in this research study is optional. Declining to participate will not impact your medical treatment.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a.Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let

them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b.Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- If study team members believe study participation is negatively impacting your health.
- If you are unable to perform the breathing exercises for this study.
- If you are diagnosed with another medical illness during the study that could impact the study results.
- The study is canceled.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

Neither you, nor your insurance provider will be charged for any of the tests or procedures performed for the purposes of this research study (e.g. swallowing tests, breathing tests, breathing exercises). The respiratory trainers will be provided to you at no cost and will be yours to keep. Please contact Dr. Donohue 352-273-8632 or Dr. Plowman 352-273-9215 if you receive a bill related to this study.

17.Will you be paid for taking part in this Research Study?

There will be no compensation offered for study participation.

18.What if you are injured while in this Research Study?

If you believe you have been injured as a result of your participation in this research study, the professional services that you receive from any University of Florida Health Science healthcare providers will be provided without charge, while other expenses (e.g., Shands hospital expenses) will be billed to you or your insurance company.

The research study team will determine whether your injury is related to your participation in the research study.

Please contact one of the Research Team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

Consent to be Video and/or Audio Recorded

With your permission, we would like to record parts of the research session via a stand-alone camcorder. This is optional and is not required to participate in the study. You will have the following done during this research visit (check all that apply):

☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on video or audio recordings, and confidentiality will be strictly maintained. However, when these video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Dr. Plowman, or her successor, will keep the video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These video and/or audio recordings will be shown under her direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Plowman has your permission to use the video and/or audio recordings, and sign and date below.

☐ I do not wish to have the optional camcorder recording during the research visit (initial next to all that apply):

_____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of education at the University of Florida Health Science Center. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

_____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

_____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date