Respiratory Muscle Strength and Function in Patients With Neuromuscular Disease

NCT01555905

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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)

If you are a parent, as you read the information in this Consent Form, you should put yourself in your child's place to decide whether or not to allow your child to take part in this study. Therefore, for the rest of the form, the word "you" refers to your child.

If you are an adult, child, or adolescent reading this form, the word "you" refers to you.

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. 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.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Respiratory Muscle Strength and Function in Patients with Neuromuscular Disorders

3. Who do you call if you have questions about this research study?

Principal Investigator: Barbara K. Smith, PhD, PT 352-294-5315

Other research staff: Jessica Ehrbar, Study Coordinator, 352-273-6855

24-hour emergency line: 352-575-0852

4. Who is paying for this research study?

The sponsor of this study is University of Florida.

5. Why is this research study being done?

The purpose of this research study is to evaluate whether individuals with neuromuscular diseases and symptomatic breathing will respond to strength training for the breathing muscles.

You are being asked to be in this research study because you have been diagnosed with a neuromuscular disease and have reported that you have difficulty with breathing.

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 (even if you did not participate in this research study)?

You will see your doctors regularly for check-ups, laboratory work, x-rays, and breathing functions tests.

7. What will be done only because you are in this research study?

Respiratory testing: Respiratory testing will be completed before you start the first exercise sessions. Once you complete the exercise training, you will be tested again. We will measure your breathing using a small sensor and breathing mask. All of the tests can be done while you are resting in a chair. You will wear a nose clip and breathe through a tube with a sensor inside of it. The sensor measures the air that moves through the tube when you breathe, as well as the gas levels in your exhaled breath. We may apply some recording stickers to measure the activity of your breathing muscles. These electrodes simply record when your breathing muscles are active. The following tests will be completed:

Pulmonary Function Tests: The pulmonary function tests measure how much air you breathe, and how quickly you can do it. You will wear a nose clip and breathe in through a tube. You will be tested while you breathe normally and also when you take forceful breaths. During forceful breaths, we will ask you to take a very deep breath into your lungs, and then force out the air as quickly as you can. The tests may be repeated up to 5 times to get a consistent reading. Between tests, you will rest until you do not feel tired. You will be tested before and after each training period.

Breathing against Small Resistances: We will ask you to take ten breaths in a row, five different times. During each set of 10 breaths, a small resistance will be attached to the breathing tube. Some people notice that it feels more strenuous to breathe through the resistances. After each set of 10 breaths, we will ask you how hard you had to work to breathe, and whether or not the work was uncomfortable. Between trials you will be given opportunity to rest for as long as you like, until you do not feel tired. You will be tested before and after training.

Maximal Respiratory Pressures: We need to know how strong your breathing muscles are. To test this, you will wear a nose clip and breathe through a tube or mask. We will ask you to breathe out fully, and then take a large, forceful breath and hold the tension for a few seconds. The test will be repeated up to 5 times to get a consistent reading between tests; you will have plenty of time to rest. You will be tested before and after each training period.

These tests will take up to two hours to complete.

Respiratory Muscle Training: You will receive inspiratory training for up to three months in this study. We will show you and/or a caregiver how to use the training device. You will breathe directly into the training device. You may notice that the trainer provides some resistance when you breathe. We regulate the setting on the device to make sure that you can successfully complete the exercises without feeling fatigued.

With the training device in place, you will take in 8-15 deep breaths against a moderate resistance. A moderate resistance means you will feel that you are working more than normal, but that it can be completed without difficulty. Then you will rest for approximately 3 minutes. The process will be repeated 3 more times for a total of 4 sets of 8-15 breaths. Training will be completed three to five days per week. While you are working with our study team during your initial respiratory testing, an investigator will familiarize you with the training device and assist you or your caregiver with the exercises to help you feel comfortable with the routine. For the first two weeks, the investigator will monitor every training session over the telephone. After the first two weeks, the investigator will continue to assist you by telephone at least once per week, and more often if you have questions. By this time, most patients feel very comfortable with the training exercises. The investigator will help you or your caregiver determine when you are ready to increase the intensity of your training exercises. During these training sessions, we will ask you to keep a diary of the training, including how many sets, at what intensity, and how many breaths you complete each day.

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

8. How long will you be in this research study?

You will be in this research study for up to 16 weeks, including 12 weeks of training and respiratory function testing before and afterward.

9. How many people are expected to take part in this research study?

Up to 30 people are expected to participate in this study.

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

10. What are the possible discomforts and risks from taking part in this research study?

Although each breathing test lasts for a very short time, the testing may feel strenuous. The breathing tests are associated with a very low risk of difficulty, even for sick, hospitalized patients on a breathing machine. Your breathing and heart function will be monitored during the testing sessions, You can stop any test at any time, and you will be provided with plenty of rest, whether you feel tired or not.

The inspiratory training sessions may make you feel tired and or short of breath. In our experience, these sensations subside within one minute of stopping the exercises. We will regulate the intensity of the exercises to minimize your tiredness or exertion feelings. The exercises are generally considered to be safe, even for people with chronic heart or respiratory diseases. We always provide you with long periods of rest during your training, whether or not you feel tired.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another 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.

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

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.

11a. 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. The potential benefits may include increased strength and endurance of the breathing muscles.

11b. How could others possibly benefit from this study?

The results from this study will help the researchers understand how the breathing muscles respond to training. This information may lead to rehabilitation in treatments to help treat breathing difficulties for patients with neuromuscular diseases, in conjunction with medical therapies.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

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

Your participatation in this study is entirely voluntary. You may decline to take part in this study.Your decision will not affect any current or future health care you receive at this institution. If you do not want to volunteer for this study, tell the Principal Investigator or her assistant, and do not sign this informed consent form.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from this study, no other information about you can be collected. Depending upon how long you have been in the study, some of the data collected prior to your withdrawal may still be able to be included in the study, with your permission.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- You do not qualify to be in the study because you do not meet eligibility requirements.
- You are unable to tolerate the breathing exercises or complete the training sessions regularly with the investigator.
- You are unable to follow the instructions provided by the investigator or cannot attend your scheduled follow-up appointments.
- The investigators determine that continuing in the study may be harmful to you.
- The study is cancelled for administrative or other unforeseen reasons.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

The training device will be provided at no cost to you.

The sponsor will provide all medical services required as part of your participation in this study. If you receive a bill for these services, please contact Barbara Smith PhD, PT at (352) 294-5315 or the study coordinator at (352) 273-6855.

All other medical services provided that were not directly related to the study will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, and/or co-payments for these services, an any non-covered or out-of-network services.

Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.

15. Will you be paid for taking part in this study?

You will not be paid for taking part in this study.

16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center health care provider will be provided without charge. These healthcare

providers include physicians, physician assistants, nurse practitioners, dentisits or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employess. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Barbara Smith, PhD, PT at (352) 294-5315 if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Name
- Address
- Telephone number
- Information about the strength of your breathing muscles obtained from performance tests
- Pulmonary function and arterial blood gases laboratory tests and x-rays
- Exercise training diaries
- Type and dose of medications
- Use of assisted breathing devices (i.e. BiPAP, oxygen, ventilator) and settings

- Height, Weight, and Age

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. Once this information is collected, it becomes part of the research record for this study. More specifically, your PHI may be collecrted, used, and shared with others for the following study-related purpose(s):

- To evaluate the effectiveness of respiratory muscle strength training in training weakness of the breathing muscles in adults with neuromuscular disease
- To study changes in breathing timing and performance following respiratory muscle strength training
- To compare how patterns of muscular weakness affect breathing pattern in individuals with neuromuscular disease

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- Other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (University of Florida).
- United States governmental agencies who 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 who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until the end of the study. This information will be disclosed forever since it will be stored for an infinite period of time in a secure database. If you withdraw your permission for the use and sharing of your PHI, then your information will be removed from the database.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

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 & Authorization Date

Consenting Adults. 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 other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

_____ _____
Signature of Adult Consenting & Authorizing for Self Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-21 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____
Print: Name of Subject:

_____ _____
Consent & Authorization Signature Date
of 1st Parent /Legal Representative

_____ _____
Print: Name of 1st Legal Representative Print: Relationship to Participant:

_____ _____
Consent & Authorization Signature Date
of 2nd Parent/Legal Representative

_____ _____
Print: Name of 2nd Legal Representative Print: Relationship to Participant:

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

_____ _____
Assent Signature of Participant Date