NSU IRB APPROVED:
Approved: August 14, 2025
Expired: August 13, 2026
IRB#: 2025-299

INSTITUTIONAL REVIEW BOARD
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General Informed Consent Form
NSU Consent to be in a Research Study Entitled

The Impact of Dysphagia Exercises on Oropharyngeal Swallowing Function in Patients with ALS

Who is doing this research study?

College: NSU Health Neuroscience Institute, Center for Collaborative Research, College of Allopathic Medicine

Principal Investigator: Lauren Tabor Gray, PhD, CCC-SLP

Co-Investigator(s): Eduardo Locatelli, MD, MPH, Raquel Garcia, SLP.D, CCC-SLP, Olivia Lallouz,M.S., CF-SLP

Site Information: Center for Collaborative Research
NSU Neuroscience Institute
7595 SW 33rd Street
Davie, FL 33314

Funding: Internal Funding

Conflict of Interest Disclosure:
Your doctor, who is doing this research study, is interested in both your clinical care and the research study. You have the right to talk about this study with someone else who is not part of the research team before deciding if you want to be in this research study.

What is this study about?

You are invited to participate as a volunteer in this clinical research study funded by the Husman Research Fund. This document is called an informed consent form. Please read this information carefully and take your time making your decision. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. Please tell the study doctor or study staff if you are taking part in another research study.

This is a research study designed to see if tongue exercises are helpful for persons with amyotrophic lateral sclerosis (pALS). The purpose of this study is to see if a tongue exercise program improves tongue strength and swallowing in pALS.

Why are you asking me to be in this research study?

You are being asked to be in this research study because you have been diagnosed with ALS. pALS develop difficulty with tongue mobility, tongue strength, and swallowing. This study is looking at the effect of a tongue exercise program in pALS. We want to find out if the tongue exercises help to improve

tongue strength, speech production, and swallowing in pALS. This study will include about 25 participants with ALS from the NSU Health ALS Clinic.

What will I be doing if I agree to be in this research study?

You are being asked for your consent to take part in a research study. This document provides a summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. This document will provide all relevant details.

Participation in this research requires three in-person visits over 10 weeks. There will be four additional evaluations using telehealth during the 10-week time period. In-person visits will take about 90-120 minutes and telehealth appointments will take no more than 60 minutes. Following the 10-week study period, you will be asked to participate in a once monthly telehealth check-in for 6 months. All tongue exercises will be completed in your home. As part of the study, this is what you will be asked to do:

1. Five weeks of observation (no intervention, weeks 0-5)
2. Followed by five weeks of tongue exercises (intervention, weeks 5-10)
3. After the initial 10 weeks, monthly follow-up using for 6 months telehealth (no more in-person visits required)

Research Study Tests:

To make sure this study is a good fit for you, we will collect information about your tongue mobility, tongue strength, swallowing, and medical history during your routine ALS clinic appointment. This is called "Screening" period and will take about 60-90 minutes. If the study is a good fit for you and you want to participate, you will be "enrolled" in the study as a participant.

As a study participant, this is what you will be doing. During each visit, you will undergo tests to look at your breathing and cough using standard clinical exams. You will also be asked to fill out surveys on your ability to breathe, cough, the ability to complete activities of daily living, and your overall quality of life. You will complete the following tests at each in-person evaluation, which will take approximately 100-120 minutes.

All of the below procedures will be performed at in-person evaluations.

Swallowing Assessment: We will take measures of your tongue strength, tongue mobility, and swallowing at each in-person visit. You will be asked to sit in a chair for these tests. Each test will assess your tongue strength, tongue mobility, and swallowing. A tongue manometer will be used during the assessment of your tongue mobility and strength. A small air-filled bulb will be placed in your mouth and you will press the bulb with your tongue. It is an objective measure to assess tongue strength. A demonstration will be provided for each swallowing test. We will assess each swallowing test three times and give you plenty of rest between assessments. All of the swallowing tests will take about 30 minutes.

Speech Assessment: We will take measures of your speech intelligibility and speech rate at each visit. Speech rate is measured in words per minute and will be assessed by you reading a standardized passage called "Bamboo". Speech intelligibility is how well others can understand you when you are

speaking. This will be assessed via counting the number of syllables produced in a designated interval of time and the amount of time used to produce a given number of syllables.

Videofluoroscopic Swallow Study (VFSS) is a specialized X-ray procedure used to evaluate how a person swallows different types of food and liquids. During the test, the individual consumes substances mixed with a barium, which allows the swallowing process to be viewed in real-time on a fluoroscopy screen. In this research, the VFSS helps identify any difficulties or abnormalities in swallowing function. The procedure is non-invasive and typically lasts about 3-10 minutes. While VFSS is considered safe, it does involve exposure to a small amount of radiation, similar to that of other diagnostic X-rays. The ALARA principles for a (VFSS) are safety guidelines designed to minimize radiation exposure. ALARA stands for "As Low As Reasonably Achievable," and it emphasizes using the minimum amount of radiation necessary to achieve quality diagnostic results. Participation in this study involving VFSS is voluntary. All findings will be used to advance knowledge about swallowing disorders and will be handled with strict confidentiality.

The radiation dose associated with a Videofluoroscopic Swallow Study (VFSS) is measured in millisieverts (mSv). On average, the effective dose from a VFSS ranges from 0.2 to 0.32 mSv, which is considered low and remains well below the average annual exposure from natural background radiation. For context, the radiation exposure from a single VFSS is comparable to that of a roundtrip commercial flight between Miami, Florida, and Tokyo, Japan, which is estimated at approximately 0.28 to 0.32 mSv.

Surveys: You will also be asked to complete surveys at each visit. The surveys will take about 25 minutes total. They are listed here:

1. The ALS Functional Rating Scale-Revised is a survey assessing ALS symptoms.
2. Eating Assessment Tool -10 is a 10 item questionnaire about assessing swallowing difficulties.
3. The Exercise Therapy Burden Questionnaire is a 10-item questionnaire about exercise burden in chronic health conditions.

All of the below procedures will be completed only during weekly telehealth appointments (Week 5 -10):

Isometric Lingual Exercise During Telehealth: During your home telehealth evaluations you will be asked to perform isometric lingual exercises. You will be provided with a device to take home with you so we can assess your lingual strength during the telehealth visits.

Surveys: You will also be asked to complete surveys at each visit. The surveys will take about 25 minutes total. They are listed here:

1. The ALS Functional Rating Scale-Revised is a survey assessing ALS symptoms.
2. Eating Assessment Tool -10 is a 10 item questionnaire about assessing swallowing difficulties.
3. The Exercise Therapy Burden Questionnaire is a 10-item questionnaire about exercise burden in chronic health conditions.

After your initial evaluation appointment, you will be monitored for five weeks (weeks 0-5). After five weeks, you will have an online virtual evaluation via telehealth. During this online virtual evaluation, we will

provide you with the lingual manometer training equipment and teach you how to use the trainers (weeks 5-10). Everyone in the study will be provided with the lingual manometer training equipment. There is no control or "placebo" group that does not get the training equipment. The research therapist will instruct and train you on how to perform the isometric lingual strength training at home and how often to perform the exercises. The exercises will be performed five days per week with 25 repetitions per day. You will be provided with the lingual manometer equipment and a home training log to keep track of your training. The home therapist will meet with you weekly using telehealth to answer any questions.

At the end of the research study, we will review the results of the tongue strength, speech measures, swallowing measurements and compare them to your first visit. You can continue the tongue strength training after the study is completed. After the first 10-weeks of the study, we will follow up with you monthly on a telehealth visit that will last about 30-60 minutes (10 weeks to 6-months).

Could I be removed from the study early by the research team? There are several reasons why the researchers may need to remove you from the study early. Some reasons are:

- If you do not complete the respiratory training exercises
- If it is discovered that you do not meet the study requirements
- If it appears to be medically harmful to you

Are there possible risks and discomforts to me?

This study involves minimal risk to you. To the best of our knowledge, the tests you will be doing have no more risk of harm than you would have during routine clinical care. The Videofluroscopic Swallow Study (VFSS) uses Barium Sulfate, a radio-opaque contrast material. Barium Sulfate poses a minimum risk to patients. Barium is not absorbed into the body nor bloodstream. In rare cases, it can cause constipation and/or a patient can have an allergic reaction. Allergic reactions are uncommon and pose minimal risk to patients.

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

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.

What if a research-related injury occurs?

The researchers have taken steps to minimize the known or expected risks. However, you may still have problems or get side effects of the respiratory training, even though the researchers are careful to avoid them. In the event of a research-related injury, please contact Principal Investigator right away. See the contact section at the end of this form for phone numbers and more information.

Nova Southeastern University does not have a program to pay you if you are hurt or have other bad results from being in this study. However, medical care at Nova Southeastern University is open to you as it is to all sick or injured people. If you have health insurance, the costs for any treatment or hospital care you receive as result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you. If you do not have health insurance, you will be billed for the costs of any treatment or hospital care you receive because of a study-related injury.

What if there is new information learned during the study that may affect my decision to remain in the study?

If significant new information relating to the study becomes available, which may relate to whether you want to remain in this study, this information will be given to you by the investigators. You may be asked to sign a new Informed Consent Form, if the information is given to you after you have joined the study.

Will being in this research benefit me?

The possible benefits that you may expect from taking part in this research include improvements in breathing and cough function and shortness of breath. There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this research study will benefit other people with ALS in the future.

What happens if I do not want to be in this research study?

You have the right to leave this research study at any time or refuse to be in it. If you decide to leave or you do not want to be in the study anymore, you will not get any penalty or lose any services you have a right to get. If you choose to stop being in the study before it is over, any information about you that was collected **before** the date you leave the study will be kept in the research records for 36 months from the end of the study and may be used as a part of the research.

Will I be paid or be given compensation for being in the study?

Participants will receive compensation of $20 following each in-person study visit for a possible total of $40 following the Final Evaluation study visit. Compensation will be provided following each visit and is does not require the participant to complete all study visits. Participant compensation is provided to cover the costs of travel to the appointment and meals. This will be provided in the form of a Visa gift card.

Will it cost me anything?

There are no costs to you for being in this research study. All tests, treatment sessions and respiratory trainers will be provided at free of charge. Ask the researchers if you have any questions about what it will cost you to take part in this research study (for example bills, fees, or other costs related to the research).

Will clinically relevant research results be shared with me?

The study investigators plan to share certain research results with people who are in the study if they think they are important for you to know. The results will be shared with you in an individualized, format, meaning that the results apply only to you. The study team will share these results by providing you will a summary report of your individual tongue strength and swallowing results following training. This will help you decide if you would like to continue doing the tongue strength exercises after the research study.

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How will you keep my information private?

Information we learn about you in this research study will be handled in a confidential manner, within the limits of the law and will be limited to people who have a need to review this information. You will be assigned a specific patient number and all data collected will be associated to that number. This data will be available to the researchers, grant consultants, the Institutional Review Board and other representatives of this institution, and the David and Cathy Husman Research Fund (funding agency for this project). If we publish the results of the study in a scientific journal or book, we will not identify you. All confidential data will be kept securely stored in the research office within your specific research binder. All data will be kept for 36 months from the end of the study and destroyed after that time by shredding. 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.

Will there be any Audio or Video Recording?

This research study involves audio and/or video recording. This recording will be available to the researcher, the Institutional Review Board and other representatives of this institution, and the organization that funded the study (the Department of Defense). The recording will be kept, stored, and destroyed as stated in the section above. Because what is in the recording could be used to find out that it is you, it is not possible to be sure that the recording will always be kept confidential. The researcher will try to keep anyone not working on the research from listening to or viewing the recording.

Whom can I contact if I have questions, concerns, comments, or complaints?

If you have questions now, feel free to ask us. If you have more questions about the research, your research rights, or have a research-related injury, please contact:

Primary contact:
Lauren Tabor Gray, PhD, CCC-SLP
954-914-5447

If primary is not available, then please contact:
Raquel Garcia, SLP.D., CCC-SLP, BCS-S
954-914-5447

Research Participants Rights
For questions/concerns regarding your research rights, please contact:

Institutional Review Board
Nova Southeastern University

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You may also visit the NSU IRB website at www.nova.edu/irb/information-for-research-participants for further information regarding your rights as a research participant.

Research Consent & Authorization Signature Section

Voluntary Participation - You are not required to participate in this study. In the event you do participate, you may leave this research study at any time. If you leave this research study before it is completed, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you agree to participate in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction about the research

Adult Signature Section

I have voluntarily decided to take part in this research study.

Printed Name of Participant	Signature of Participant	Date
Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent & Authorization	Date