UNIVERSITY OF SOUTH FLORIDA

Informed Consent to Participate in Research Involving Minimal Risk

Pro# 00033331

You are being asked to take part in a research study. Research studies include only people who choose to take part. This document is called an informed consent form. Please read this information carefully and take your time making your decision. Ask the researcher or study staff to discuss this consent form with you, please ask her to explain any words or information you do not clearly understand. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

We are asking you to take part in a research study called:

The effects of a motor imagery exercise program on tongue strength.

The person who is in charge of this research study is Dr. Sarah Hegyi**.** This person is called the Principal Investigator. However, other research staff may be involved and can act on behalf of the person in charge.

The research will be conducted at University of South Florida, Sarasota Manatee (USFSM) in Sarasota, Florida, in the participant's home, or in a private location at a community center.

Purpose of the study

The purpose of this study is to *compare the effects of different exercise types on tongue strength*. This study will contribute to the researcher's completion of pilot data on this subject.

Why are you being asked to take part?

We are asking you to take part in this research study because you are a generally healthy, typically aging adult between the age of 60 and 89. No person will be turned away from the study just because he/she is a specific ethnicity, race, gender, sex and/or socioeconomic level.

Study Procedures:

Any information you provided during the screening process or during the study will be kept confidential and only reported in group descriptive terms for research papers or presentations.

Should you decide to participate in this research study, you will be asked to sign this consent form once all your questions have been answered to your satisfaction.

Should you decide to participate, you will be randomly assigned to a treatment group and will be trained on how to complete a specific exercise regimen. You will be asked to complete the exercise regimen 3 times a day, for 3 days a week, for 6 weeks. The exercise regimen will be completed individually in your own home. You will be given an exercise log so you can document your exercise regimen.

Tongue strength measures will be taken at USFSM, in the participant's home, or in a private location at a community center during four separate visits: at baseline (week 0), week 2, week 4, and week 6. Tongue strength measures will be taken using an air-filled bulb held in the mouth. Two different strength measures will be taken and you'll complete six repetitions of both during these appointments.

Participation in this study will require approximately 3 hours of your time at your preferred study session location, in addition to the time you will spend completing the exercise regimen at home. Time commitment expectations during appointments are provided below:

- Week 0: 1 hour
- Week 2: 30 minutes
- Week 4: 30 minutes
- Week 6: 30-45 minutes

Total Number of Participants

Around 20-30 individuals will take part in this study.

Alternatives / Voluntary Participation / Withdrawal

You do not have to participate in this research study.

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study. If you are a USFSM employee, your decision to participate or not to participate will not affect your job status, employment record, employee evaluations, or advancement opportunities.

Benefits

Potential benefits from participation in this study include any benefits associated with the assigned exercise regimen, including improved tongue strength. However, not all group assignments may benefit.

The results from this research may benefit patients who have swallowing difficulty secondary to tongue weakness.

Risks or Discomfort

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

Compensation

Compensation for participation is available. You will be compensated $60 in Amazon gift cards if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be given Amazon gift cards in the amount planned through each study visit you completed. The compensation plan is this:

- Visit 1 (Recruitment Phase 2 + Baseline) - $20 Amazon gift card processed via email at end of session.
- Visit 2 (end of Week 2) No compensation provided.
- Visit 3 (end of Week 4) $20 Amazon gift card processed via email at end of session.
- Visit 4 (end of Week 6) $20 Amazon gift card processed via email at end of session.

Though we cannot refund costs associated with transportation to and from the study place, we will give you a free temporary parking pass to use on campus for the days of your in-person visits if USFSM is your preferred study session location.

Costs

It will cost you the amount required for either public transportation or gas money for private transportation to take part in the study at USFSM or a community center and complete 4 in-person visits if the USFSM campus or a private location in a community center is your preferred study session location.

Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

- The research team, including the Principal Investigator and other approved research staff (for example, Co-Investigator, graduate research assistants).
- Certain government and university people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
- Any agency of the federal, state, or local government that regulates this research.
- The USF Institutional Review Board (IRB) and related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance.

The results of this research will be presented at conferences. The results of this project will be coded in such a way that your identity will not be attached to the final form of this study. The researcher retains the right to use and publish non-identifiable data. While individual responses are confidential, aggregate data will be presented representing averages or generalizations about the responses as a whole. All data will be stored in a secure location accessible only to the researcher. Identifiable data with your name on it will be destroyed five years after this research is published. De-identified data will be kept on the Principal Investigator's secure laptop.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov 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 website at any time.

You can get the answers to your questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, or experience an unanticipated problem, call Dr. Sarah Hegyi at 941-359-4383 or by email at sehegyi@usf.edu.
If you have questions about your rights as a participant in this study, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638 or contact by email at RSCH-IRB@usf.edu.

You can refuse to sign this form. If you do not sign this form you will not be able to take part in this research study. If you do sign this form and start participation in this research study, you can withdraw at any time. If you choose to withdraw from this study:

- You will no longer be a participant in this research study;
- We will stop collecting new information about you;
- Amazon gift cards will only be provided in the amount planned through each study visit you completed up to the point of withdrawal;
- We will use the information collected prior to your withdrawal from the study.

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies. You will receive a signed copy of this form.

Consent to Take Part in this Research Study

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

_____ _____
Signature of Person Taking Part in Study Date

_____
Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

_____ _____
Signature of Person obtaining Informed Consent Date

_____
Printed Name of Person Obtaining Informed Consent