

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

**PI: Sarah Hegyi, PhD, CCC-SLP**

**Protocol#00033331**

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### **1. Rationale for the study, area of current scientific concern and why the research is needed**

Although motor imagery (MI) has not yet been researched in the field of swallowing rehabilitation, the potential benefit is far reaching. Difficulty swallowing, or dysphagia, can occur in people who have a history of stroke, head injury, neurological disease (such as Parkinson's disease, ALS, etc.), and head/neck cancer. A person with dysphagia may have difficulty eating everyday foods and may require an altered diet, such as tube feedings or pureed foods. Because of this, having dysphagia is often associated with increased feelings of isolation and depression. Speech-language pathologists work with people with dysphagia to rehabilitate their swallow, with the goal of reducing their risk of choking and improving their ability to eat normal foods. The use of MI as a way to augment dysphagia rehabilitation has implications for patients who aren't safe to have any food by mouth as well as those who fatigue easily.

### **2. Background information, description of existing research and information that is already known**

Motor imagery (MI) is the mental rehearsal of physical movement without any body movement and can use various mental frameworks such as auditory, visual, tactile, gustatory, and kinesthetic imagery (Dickstein & Deutsch, 2007). MI has been used in sports science to improve speed, performance accuracy, strength, and movement dynamics of athletes (Taktek, 2004). It has also been used in rehabilitative medicine, specifically physical and occupational therapies, to improve upper and lower extremity function (Peters & Page, 2015). Target patient populations for research have included stroke, spinal cord injury, Parkinson's disease and other neurological disorders. Commonly MI is combined with actual physical practice for optimal rehabilitation outcomes and there is evidence for neural reorganization with MI. MI requires minimal direct supervision, minimal expense and no specialized equipment. Additionally it has no known risk, which is important for patients with high levels of impairment and fatigue.

### **3. The research questions, objectives and purpose**

This is a collaborative project between Dr. Sarah Hegyi at USF-Sarasota-Manatee, Dr. Erin Kamarunas at James Madison University (JMU), Dr. Christina Nobriga at Loma Linda University (LLU), and Dr. Teresa Drulia at Texas Christian University (TCU). Each study site will acquire IRB approval from each respective university IRB.

This research study is a six-week treatment pilot study to determine the effect of motor imagery for tongue strengthening exercises on measures of tongue strength and swallowing pressure in typically aging older adults. Typically-aging older adults represent a group "at risk" for dysphagia secondary to sarcopenia of striated musculature important to swallowing. Participants

at all study sites will be randomly selected into one of four groups: 1) placebo (active jaw open against resistance/close against resistance/lateralize/protrusion exercises with relaxation exercises), 2) active tongue exercises against resistance only, 3) active tongue exercises against resistance + motor imagery of tongue exercises against resistance, and 4) motor imagery of tongue exercises against resistance only. In some JMU participants we will also determine cortical activation patterns differences during motor execution and motor imagery of tongue exercises between the groups using near-infrared spectroscopy. The results of this study will inform refinement/further development of the mental practice protocol to use with patients with dysphagia in future studies.

The research questions are as follows:

1. Does a 6 week treatment of motor imagery tongue exercises with or without active tongue exercise improve tongue strength in healthy older adults compared to a 6 week treatment of placebo exercises and 6 week treatment of active tongue strengthening exercises?
2. Does a 6 week treatment of motor imagery tongue exercises with or without active tongue exercise improve swallowing pressures in healthy older adults compared to a 6 week treatment of placebo exercises and 6 week treatment of active tongue strengthening exercises?
3. Does a 6 week treatment of motor imagery tongue exercises with or without active tongue exercise alter cortical hemodynamic response patterns in healthy older adults compared to a 6 week treatment of placebo exercises and 6 week treatment of active tongue strengthening exercises? (JMU participants only)

Our hypothesis, based on previous research, is that the group receiving both active and MI treatment will make the most gains in all three measures, followed by the active only group, then the MI only group, then the placebo group (control).

#### **4. The study design including information that is needed to answer the research questions**

Subjects will be recruited by USFSM email blast, word of mouth, and community advertisements (local clubs, community centers, clinics, physician offices).

#### **Compensation Schedule**

- 4 in-person visits for a total of \$60 in Amazon gift cards should a participant complete the entire, 6-week research protocol.
  - Visit 1 (Recruitment Phase 2 & Baseline) - \$20 Amazon gift card provided at end of visit.
  - Visit 2 (end of Week 2 of 6-week exercise program).
  - Visit 3 (end of Week 4 of 6-week exercise program). \$20 Amazon gift card provided at end of visit.
  - Visit 4 (end of Week 6 of 6-week exercise program). \$20 Amazon gift card provided at end of visit.

## **Recruitment (Phases 1 & 2)**

### **Phase 1 Recruitment** (anticipated 20-25 minutes in length):

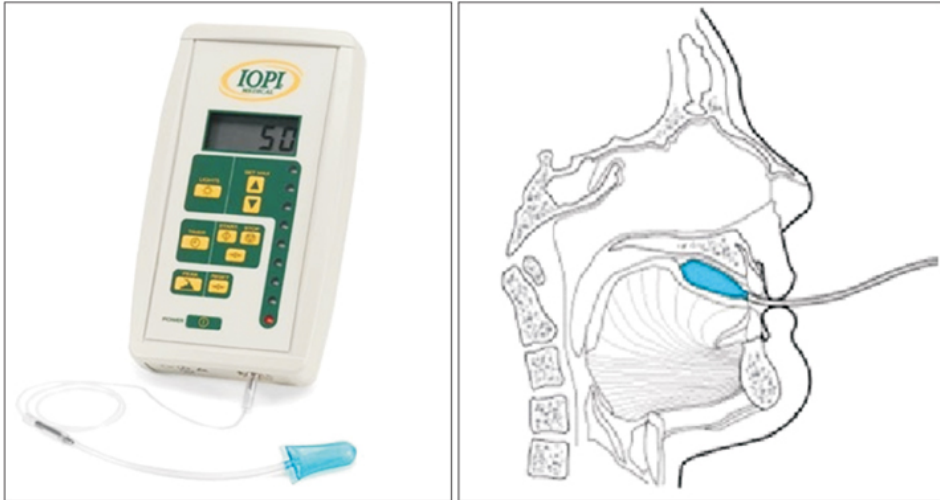
- Telephone pre-screen for verbal consent and inclusion/eligibility telephone screening (includes EAT-10 screening tool) completed with persons responding to advertisement.
  - If preferred by potential subject, a hard copy of the screening forms will be mailed to address provided, including a pre-stamped/labeled return envelope.
  - If preferred by potential subject, an electronic copy of the screening forms will be e-mailed to e-mail address provided and scanned completed screening forms accepted in return.
- Potential subjects meeting the screening forms criteria will be invited for Phase 2 of recruitment + baseline (if eligible) in-person visit at USFSM, participant's home, or private location at a community center (e.g., conference room at an independent living facility) if preferred

### **Phase 2 Recruitment + Baseline (if eligible) (Visit #1)** (Phase 2 Recruitment anticipated 30 minutes in length):

- Each in-person visit will be conducted confidentially and privately at USFSM, a the participant's home, or a private location at a community center.
- Intraoral examination will be completed to confirm absence of tongue piercings/oral apparatus that may interfere with tongue exercises.
- Investigator will administer the Kinesthetic and Visual Imagery Questionnaire (KVIQ-10) and Mini Mental State Examination (MMSE).
- Both the KVIQ-10 and MMSE must be passed to continue.
  - If fails KVIQ-10 or MMSE, the individual will be notified that he/she does not qualify to participate in the study and thanked for taking the time to complete the recruitment activities.
  - If passes both KVIQ-10 and MMSE, detailed study information and informed consent form will be reviewed, with time provided for potential subject to ask questions. Should the potential subject decide to voluntarily participate in the study, informed consent form will be signed and the baseline experimental session will begin.

### **The following equipment will be used to take measures at baseline and other follow up visits:**

1. **Iowa Oral Performance Instrument (IOPI)** - Uses an air filled bulb held in the mouth to measure oral pressures in kilopascals. Maximal isotonic tongue pressures as well as pressures generated from normal swallows will be measured at baseline and three follow up visits (described below). This equipment is portable.



**Baseline Visit #1 Protocol: (anticipated 30 minutes)**

1. Investigator completes basic education and training about how the IOPI is used/protocol for collecting IOPI measurements.			
2. Investigator will measure subject's maximum/peak tongue pressure using IOPI device. <ul style="list-style-type: none"> <li>○ Six measurements will be taken, with 30-40 seconds between each.</li> <li>○ Mean value will be used as the subject's maximum tongue strength</li> </ul>			
3. Investigator will measure subject's regular swallowing pressures using the IOPI device. Swallows will be completed using the participant's saliva (no water or other liquid given during measurement). <ul style="list-style-type: none"> <li>○ Six measurements will be taken, with 30-40 seconds between each.</li> <li>○ Participants will be given 20-30 mL of water to swallow between each rep to help moisten the mouth.</li> <li>○ Mean value will be used as the subject's normal swallowing pressure</li> </ul>			
4. Investigator will randomly assign subject to one of four study groups:			
<b>(1) Placebo (control) exercise</b>	<b>(2) Active tongue exercise</b>	<b>(3) Active tongue exercise + Motor Imagery exercise</b>	<b>(4) Motor Imagery exercise</b>
5. Investigator completes jaw exercise training with subject, including basic education about physical strengthening exercise. <ul style="list-style-type: none"> <li>○ Instructions will be rehearsed verbally and written instructions will be provided to each subject to use in home environment.</li> <li>○ Limited practice opportunity provided to confirm subject's</li> </ul>	5. Investigator completes active tongue exercise training with subject, including basic education about physical strengthening exercise.	5. Investigator completes active tongue exercise training with subject, including basic education about physical strengthening exercise.	5. Investigator completes mental practice exercise training with subject, including basic education about motor imagery and mental practice.

<p>understanding of exercise instructions.</p> <ul style="list-style-type: none"> <li>○ A lightweight, portable counter clicker will be provided to the subject to keep track of active exercise repetitions.</li> </ul> <p><b>AND</b></p> <p>Investigator completes visualization relaxation training with subject.</p> <ul style="list-style-type: none"> <li>○ Instructions will be rehearsed verbally and written instructions will be provided to each subject to use in home environment.*</li> </ul>	<ul style="list-style-type: none"> <li>○ Instructions will be rehearsed verbally and written instructions will be provided to each subject to use in home environment.</li> <li>○ Limited practice opportunity provided to confirm subject's understanding of exercise instructions.</li> <li>○ Tongue depressors will be provided to the subject to use for resistance during active exercises.</li> <li>○ A lightweight, portable counter clicker will be provided to the subject to keep track of active exercise repetitions.</li> </ul>	<ul style="list-style-type: none"> <li>○ Instructions will be rehearsed verbally and written instructions will be provided to each subject to use in home environment.</li> <li>○ Limited practice opportunity provided to confirm subject's understanding of exercise instructions.</li> <li>○ Tongue depressors will be provided to the subject to use for resistance during active exercises.</li> <li>○ A lightweight, portable counter clicker will be provided to the subject to keep track of active exercise repetitions.</li> </ul> <p><b>AND</b></p> <p>Investigator completes mental practice exercise training with subject, including basic education</p>	<ul style="list-style-type: none"> <li>○ Instructions will be rehearsed verbally and written instructions will be provided to each subject to use in home environment.</li> <li>○ A lightweight, portable counter clicker will be provided to the subject to keep track of mental practice repetitions (to reduced cognitive load of counting repetitions while completing mental practice). Mental practice instructions are outlined below.**</li> <li>○ Limited practice opportunity provided to confirm subject's understanding of exercise instructions.</li> <li>○ Investigator observes to confirm no overt muscular activity in</li> </ul>
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		<p>about motor imagery and mental practice.</p> <ul style="list-style-type: none"> <li>○ Instructions will be rehearsed verbally and written instructions will be provided to each subject to use in home environment.</li> <li>○ A lightweight, portable counter clicker will be provided to the subject to keep track of mental practice repetitions (to reduced cognitive load of counting repetitions while completing mental practice). Mental practice instructions are outlined below.**</li> <li>○ Limited practice opportunity provided to confirm subject's understanding of exercise instructions.</li> <li>○ Investigator observes to</li> </ul>	<p>head/neck area during motor imagery tasks.</p>
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		confirm no overt muscular activity in head/neck area during motor imagery tasks.	
<p>6. Investigator instructs subject to complete 1 set (10 repetitions in each direction – open/close/lateralization/protrusion) of placebo exercise, 3x day, 3 days/week for two weeks.</p> <p><b>AND</b></p> <p>Following completion <u>of all reps of the active exercises in a given set</u> (10 reps per direction for 40 reps total), subject will find quiet spot (without distraction) to complete relaxation exercises*. This will be repeated 3x/day, 3 days a week for 2 weeks.</p>	<p>6. Investigator instructs subject to complete 1 set (10 repetitions) in each direction (protrusion, elevation, left, right), 3x day, 3 days/week for two weeks.</p>	<p>6. Investigator instructs subject to complete 1 set of active tongue exercise (10 repetitions) in each direction (protrusion, elevation, left, right). 3x day, 3 days/week for two weeks.</p> <p><b>AND</b></p> <p>Following completion <u>of all reps of the active exercises in a given set</u> (10 reps per direction for 40 reps total), subject will find quiet spot (without distraction) to complete mental practice exercises, including 10 repetitions per direction (40 reps) of mental practice tongue exercises. This will be repeated 3x/day, 3 days a week for 2 weeks.</p>	<p>6. Investigator instructs subject to complete 1 set of mental practice exercise (10 repetitions) in each direction (protrusion, elevation, left, right), 3x day, 3 days/week for two weeks.</p>
<p>7. A record form will be reviewed and provided to subject, with instructions to document each exercise set complete each week (date and time) and to note any applicable personal comments as warranted (e.g., fatigue, pain, technical difficulty, interruptions during a set). Only the subject's participant number will be recorded on the form.</p>			
<p>8. An appointment will be scheduled for Visit #2 around two weeks following Visit #1. Attempt to schedule subsequent visits at a consistent time of day, so that max measurements are taken around the same time of</p>			

day each visit, preferably at the time of day the subject feels strongest.
9. Investigator will process subject's first \$20 participation incentive.

\*Visualization Relaxation Exercise Instructions:

1. Find a comfortable and quiet spot where you will not be distracted.
2. Set a timer for three to five minutes.
3. Choose a place or situation that you find peaceful and calming (e.g., the beach or favorite vacation spot).
4. When ready, start the timer and close your eyes.
5. Imagine yourself in your peaceful and calm place or situation.
6. Try to imagine the smells, sights, sounds, and touch when you are there (e.g., the smell of sunscreen, the sound of water, the sight of children building sand castles, and the feel of the sand between your toes at the beach).
7. Focus on positive thoughts associated with your peaceful and calming place or situation.
8. When your timer rings, open your eyes and count out-loud to 5 to bring yourself back to the present.

Adapted from: Mayo Foundation for Medical Education and Research. (2017). *Stress management: Types of relaxation techniques*. Retrieved from <https://www.mayoclinic.org/healthy-lifestyle/stress-management/in-depth/relaxation-technique/art-20045368?pg=2>

\*\*Mental Practice Exercise Instructions:

1. Set the counter clicker to zero.
2. Assume a comfortable sitting position: seated upright (90°), both feet on the floor, arms resting comfortably in lap, and holding the counter clicker in one hand.
3. Imagine the tongue exercise movements (protrusion, left, right, elevation): use the first-person perspective, as if you were actually executing the exercise.
4. Avoid actually moving or contracting muscles from your tongue, face, head, or neck. Keep a relaxed position.
5. Remember to imagine seeing and feeling the movements from within – imagining completing each repetition as if you are pushing against a tongue depressor.
6. When ready, imagine performing one tongue exercise at a time, using the counter clicker to keep track of each mental exercise repetition completed. Keep breathing normally.
7. If you lose your concentration during a set (10 repetitions in each of the four directions), relax for a few moments and then start the exercise set again, re-setting the counter clicker to zero.
8. Try to make as few errors as possible with each imagined tongue exercise movement.



**Visit #2 (end of Week 2)** (anticipated 30 minutes in length):

<p>1. Investigator will measure subject's maximum/peak tongue pressure using IOPI device.</p> <ul style="list-style-type: none"> <li>○ Six measurements will be taken, with 30-40 seconds between each.</li> <li>○ Mean value will be used as the subject's maximum tongue strength</li> </ul>			
<p>2. Investigator will measure subject's regular swallowing pressures using the IOPI device. Swallows will be completed using the participant's saliva (no water or other liquid given during measurement).</p> <ul style="list-style-type: none"> <li>○ Six measurements will be taken, with 30-40 seconds between each.</li> <li>○ Participants will be given 20-30 mL of water to swallow between each rep to help moisten the mouth.</li> <li>○ Mean value will be used as the subject's normal swallowing pressure</li> </ul>			
<p>3. Subject's exercise protocol instructions (as indicated) will briefly be reviewed to confirm subject's understanding/correct completion of assigned exercise protocol.</p>			
<p><b>(1) No exercise</b></p>	<p><b>(2) Active tongue exercise</b></p>	<p><b>(3) Active tongue exercise + Mental practice exercise</b></p>	<p><b>(4) Mental practice exercise</b></p>
<p>4. Investigator instructs subject to complete 1 set (10 repetitions in each direction – open/close/lateralization/protrusion) of placebo exercise, 3x day, 3 days/week for two weeks.</p>	<p>4. Investigator instructs subject to complete 1 set (10 repetitions) in each direction (protrusion, elevation, left, right), 3x day, 3 days/week for two weeks.</p> <ul style="list-style-type: none"> <li>○ Additional tongue depressors will be provided to subject as needed.</li> </ul>	<p>4. Investigator instructs subject to complete 1 set of active tongue exercise (10 repetitions) in each direction (protrusion, elevation, left, right), 3x day, 3 days/week for two weeks.</p> <ul style="list-style-type: none"> <li>○ Additional tongue depressors will be provided to subject as needed.</li> </ul> <p><b>AND</b></p> <p>Following completion of <u>all reps of the active exercises in a given set</u> (10 reps per direction for 40 reps total), subject will find quiet spot (without distraction)</p>	<p>4. Investigator instructs subject to complete 1 set of mental practice exercise (10 repetitions) in each direction (protrusion, elevation, left, right), 3x day, 3 days/week for two weeks.</p>

		to complete mental practice exercises, including 10 repetitions per direction (40 reps) of mental practice tongue exercises. This will be repeated 3x/day, 3 days a week for 2 weeks.	
5. Investigator reminds subject to continue to complete the record form each week.			
6. An appointment will be scheduled for Visit #3 around two weeks following Visit #2. Attempt to schedule subsequent visits at a consistent time of day, so that max measurements are taken around the same time of day each visit, preferably at the time of day the subject feels strongest.			

**Visit #3 (end of Week 4) (anticipated 30 minutes in length):**

1. Investigator will measure subject's maximum/peak tongue pressure using IOPI device. <ul style="list-style-type: none"> <li>o Six measurements will be taken, with 30-40 seconds between each.</li> <li>o Mean value will be used as the subject's maximum tongue strength</li> </ul>			
2. Investigator will measure subject's regular swallowing pressures using the IOPI device. Swallows will be completed using the participant's saliva (no water or other liquid given during measurement). <ul style="list-style-type: none"> <li>o Six measurements will be taken, with 30-40 seconds between each.</li> <li>o Participants will be given 20-30 mL of water to swallow between each rep to help moisten the mouth.</li> <li>o Mean value will be used as the subject's normal swallowing pressure</li> </ul>			
<b>(1) No exercise</b>	<b>(2) Active tongue exercise</b>	<b>(3) Active tongue exercise + Mental practice exercise</b>	<b>(4) Mental practice exercise</b>
3. Investigator instructs subject to complete 1 set (10 repetitions in each direction – open/close/lateralization/protrusion) of placebo exercise, 3x day, 3 days/week for two weeks.	3. Investigator instructs subject to complete 1 set (10 repetitions) in each direction (protrusion, elevation, left, right), 3x day, 3 days/week for two weeks. <ul style="list-style-type: none"> <li>o Additional tongue depressors</li> </ul>	3. Investigator instructs subject to complete 1 set of active tongue exercise (10 repetitions) in each direction (protrusion, elevation, left, right), 3x day, 3 days/week for two weeks. <ul style="list-style-type: none"> <li>o Additional tongue depressors will be</li> </ul>	3. Investigator instructs subject to complete 1 set of mental practice exercise (10 repetitions) in each direction (protrusion, elevation, left, right), 3x day, 3 days/week for two weeks.

	will be provided to subject as needed.	provided to subject as needed.  <b>AND</b>  Following completion of all reps of the <u>active exercises in a given set</u> (10 reps per direction for 40 reps total), subject will find quiet spot (without distraction) to complete mental practice exercises, including 10 repetitions per direction (40 reps) of mental practice tongue exercises. This will be repeated 3x/day, 3 days a week for 2 weeks.	
4. Investigator reminds subject to continue to complete the record form each week and to bring completed record form to next, final visit (#4).			
5. An appointment will be scheduled for Visit #4 around two weeks following Visit #3. Attempt to schedule subsequent visits at a consistent time of day, so that max measurements are taken around the same time of day each visit, preferably at the time of day the subject feels strongest.			
6. Investigator will process subject's second \$20 participation incentive.			

**Visit #4 (end of Week 6/Final session)** (anticipated 30-45 minutes in length):

1. Investigator will measure subject's maximum/peak tongue pressure using IOPI device. <ul style="list-style-type: none"> <li>○ Six measurements will be taken, with 30-40 seconds between each.</li> <li>○ Mean value will be used as the subject's maximum tongue strength</li> </ul>
2. Investigator will measure subject's regular swallowing pressures using the IOPI device. Swallows will be completed using the participant's saliva (no water or other liquid given during measurement). <ul style="list-style-type: none"> <li>○ Six measurements will be taken, with 30-40 seconds between each.</li> <li>○ Participants will be given 20-30 mL of water to swallow between each rep to help moisten the mouth.</li> <li>○ Mean value will be used as the subject's normal swallowing pressure</li> </ul>
3. Investigator will collect subject's completed record form for review and storage.
4. Investigator will process subject's third (final) \$20 participation incentive.

4. Thank you letter/email will be sent to subject.

### **Statistical Analysis**

Tongue strength means (max and during swallowing) will be analyzed using SPSS in a three way mixed ANOVA.

### **5. Sample size**

It is anticipated that around 20-30 subjects will be recruited to participate in this study at USFSM.

### **6. Study Population or inclusion and exclusion criteria**

Participants will be healthy older adults without a history of swallowing problems or neurological disorders. Inclusion/exclusion criteria are stated below.

Inclusion criteria include:

- Adults aged 60-89
- < 3 on EAT-10 (part of health questionnaire)
- Mean of  $\geq 2.5$  on the KVIQ-10 questions (Kinesthetic and Visual Imagery Questionnaire, short version), a screening questionnaire that assesses a person's motor imagery abilities
- $\geq 24$  on MMSE (Mini Mental State Examination), a screening questionnaire that assesses cognitive abilities.
- Availability to complete a consecutive 6-week exercise regimen
- There are certain conditions that are common to the aging study population we are recruiting which will be acceptable: controlled hypertension and controlled diabetes mellitus

Exclusion criteria include:

- History of diagnosed dysphagia (swallowing disorder)
- History of a seizure(s)
- Current or past problem with pain disorders involving the jaw muscles or joint of the mandible (e.g., TMJ disorder or myofascial pain disorder) – these are contraindicated for tongue strengthening exercises
- Presence of oral piercings/oral apparatus that may interfere with tongue exercises
- Medical conditions that would affect oral motor performance (e.g., history of acute or degenerative neurological condition, head/neck cancer), as determined by investigator
- History of a diagnosed dementia or other cognitive impairment
- Uncontrolled high blood pressure
- Visual impairment that would prevent the subject from independently viewing written mental exercise instructions and visual images, corrected contacts or lenses are acceptable

- Hearing impairment that would prevent the subject from receiving verbal instruction from investigators
- Motor impairment or injury that would interfere with subject's ability to independently manipulate a lightweight, portable counter clicker tool or perform jaw exercises.
- English is not the person's primary language

No potential subject will be disqualified based on information regarding ethnicity, race, gender, sex, or socioeconomic status information.

## **7. The expected results of the research, such as reports, papers, and contributions to theory**

It is anticipated that the results of the proposed research study will significantly contribute to the field of speech-language pathology, both in its pioneered innovation as an approach not yet explored for muscles important to swallowing and as a potential therapeutic intervention technique that may advance patient care. Further, the results of the study may also inform preventative wellness and care in speech-language pathology, as the normal aging process can include lingual weakening and dysphagia in the typical aging population, in those without a contributing disease process. Data may be presented at national/international conferences. Data may be published in peer-reviewed journals. Data may be used as pilot data for grant applications. The audience interested in our reported work will include speech-language pathologists, rehabilitation specialists, neuropsychologists, and neurologists.

## **8. Name of the Principal Investigator and Faculty Advisor if applicable**

The Principal Investigator is Dr. Sarah Hegyi, an Assistant Professor of Communication Sciences & Disorders at University of South Florida Sarasota-Manatee and a licensed/certified Speech-Language Pathologist.

## **9. Any potential risks to the subjects**

There is no known risk for motor imagery exercises. There are no known risks for oral motor exercises (tongue strengthening exercises).

## **10. Any experimental procedures or interventions that will be implemented**

Study groups will include: 1) placebo (jaw exercises with relaxation exercises), 2) active tongue exercises only, 3) active tongue exercise + motor imagery of tongue exercises, and 4) motor imagery of tongue exercises only. Experimental interventions include groups 3 and 4.

## **11. Any potential benefits to subjects**

Depending on group assignment, participants will be participating in a tongue strengthening protocol, which may have specific swallowing related benefits; however, this will not be directly measured and there is no guarantee of any swallow related benefit.

## **12. Human subjects considerations including · description of the informed consent process; · discussion of how the privacy and confidentiality of the subjects will be maintained.**

Participation will be entirely voluntary and an extensive inclusion/eligibility screening process will be completed prior to the informed consent process. Consent will be obtained prior to the screening process (both over the phone and/or via email/mail prior to obtaining the Screening Inclusion-Eligibility and EAT-10 screening forms completion and prior to beginning the in-person screening session). Should a participant qualify for the study, the informed consent form will be reviewed with the subject, providing ample time as needed to answer subject questions prior to voluntary signature. The privacy and confidentiality of the participants will be maintained. Telephone screenings and in-person visits will be completed in private and confidential locations. All data will be stored on Dr. Hegyi's password-protected USFSM laptop. Study files on this laptop will also be password-protected. The data on the laptop will be encrypted for protection, in case the laptop is lost or stolen. Each subject's identity will be disassociated from the subject's personal data - a subject number will be assigned to each subject upon signing of the informed consent. Physical data (e.g., subject record forms) will be identified according to subject number as much as possible. All physical data will be stored in a locked desk cabinet in the secure and locked office of the investigator. Only Dr. Hegyi will have access to the desk cabinet key.

Tongue strength measures from each of the four sessions will be recorded on paper forms for convenience and transferred to a digital spreadsheet after each session. Participant record forms for weeks of practice will be in paper format. All paper forms will be identified only by participant ID. Tongue strength measures (kPa) will be transferred to a digital spreadsheet (de-identified). Participant record forms (de-identified) will be scanned into digital format. De-identified paper forms will be stored in a locked file cabinet in Dr. Hegyi's office, which requires lock/key access. Spreadsheets of tongue strength measures will be stored on Dr. Hegyi's USFSM laptop, which is password protected and requires permission by Dr. Hegyi to access. Non-USFSM researchers at JMU and LLU will have access to de-identified digital data in spreadsheet format. De-identified data will be shared between universities using a password protected Dropbox account. The only identifiable information that will be shared between study sites will include participants' first/last names and email addresses so that the USFSM study site can process participant incentives in the form of Amazon gift cards. The JMU, LLU, and TCU study site principal investigators will send Dr. Hegyi individual participant names and emails included in an encrypted Word document, which will be used to generate an Amazon gift card as payment for the completed session, according to the compensation schedule above. As participants get paid in three installments, this will be done three times for each participant. Dr. Hegyi will delete the encrypted file as soon as the gift card is sent by email. All other study data will remain shared in de-identifiable form only.

Only de-identified data will be kept after the project ends. Consent forms will be destroyed five years after publication.

**13. If the study is greater than minimal risk, describe the data and safety monitoring plan, whether or not there is a data and safety monitoring board, how often data will be reviewed for safety, early stopping criteria, etc.**

We do not anticipate the study involving greater than minimal risk. Participation will be entirely voluntary and subjects will be allowed to opt-out of the study at any time.

**14. Research references**

- Dickstein, R., & Deutsch, J. E. (2007). Motor imagery in physical therapist practice. *Physical Therapy, 87*(7), 942-953.
- Peters, H. T., & Page, S. J. (2015). Integrating mental practice with task-specific training and behavioral supports in poststroke rehabilitation: Evidence, components, and augmentative opportunities. *Phys Med Rehabil Clin N Am., 26*(4), 715-727.
- Taktek, K. (2004). The effects of mental imagery on the acquisition of motor skills and performance: A literature review with theoretical implications. *Journal of Mental Imagery, 29*, 79-114.