

**Title: The effects of a motor imagery exercise program on tongue strength**

**Statistical Analysis Information**

**01/30/2019**

**Please note: the USF IRB did not require a separate Statistical Analysis Plan. All information required by the USF IRB for review is included in the Study Protocol document that was IRB-approved.**

## **Statistical Analysis Information**

### ***Motor Imagery Exercise and Tongue Strength***

#### **1. Brief review of study design**

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) [Placebo Comparator], 2) active tongue exercises against resistance only [Active Comparator], 3) active tongue exercises against resistance + motor imagery of tongue exercises against resistance [Experimental], and 4) motor imagery of tongue exercises against resistance only [Experimental]. In some JMU participants the investigators will also explore 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? (Primary outcome)
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? (Primary outcome)
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) (secondary outcome)

#### **2. Description of Participants**

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.

### **3. Sample size**

It is anticipated that around 40 participants will be recruited to participate in this study across all study sites (around 10 per study group total). As this is a novel pilot study, a power analysis will be conducted using data collected from this investigation when 10 participants have completed the study.

### **4. Primary Analysis/Results**

The investigators hypothesize, based on previous research in the area of motor imagery, 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).

Tongue strength means (max and during swallowing) will be analyzed using SPSS in a three way mixed ANOVA. The significance level will be set at  $\alpha = .05$ .

## **5. Other Pre-specified Analysis/Results**

The investigators will also be looking at cortical hemodynamic response patterns to motor imagery and physical execution of active tongue strengthening exercise between groups with JMU participants only. As this is exploratory in nature, the current investigators are not including a specific hypothesis. Rather, observational/descriptive/proof of concept factors will be explored. If sufficient data is available, a three-way mixed ANOVA will be used to understand effects on percent change in oxygenation during hemodynamic response.