James Madison University

Human Research Review Request

FOR IRB USE ONLY:					
Exempt:	☐	**Protocol Number:**	**1st Review**: _____	**Reviewer:** _____	
Expedited:	☐	IRB: _____	**2nd Review:** _____	**Reviewer:** _____	
Full Board:	☐	Received: _____	**3rd Review:** _____		

PROJECT TITLE:	Study of the Use of the Passy Muir Swallowing Self Trainer by Persons with Dysphagia
PROJECT DATES (Not to exceed 1 year minus 1 day):	**From:** 07/29/13 MM/DD/YY **To:** 07/28/16 MM/DD/YY
MINIMUM # OF PARTICIPANTS:	
MAXIMUM # OF PARTICIPANTS:	
EXTERNAL FUNDING:	**Yes:** ☒ **No:** ☐ ☐ **If yes, Sponsor:** Passy Muir, cost of devices, patient travel and payment for participation
RESPONSIBLE RESEARCHER(S):	Christy L. Ludlow, PhD, Erin Kamarunas, PhD
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TELEPHONE:	
DEPARTMENT:	
ADDRESS (MSC):	
PLEASE SELECT:	☒ Faculty ☐ Undergraduate Student ☒ Administrator/Staff Member ☐ Graduate Student
(If Applicable):	
RESPONSIBLE ADVISOR:	
E-MAIL ADDRESS:	
TELEPHONE:	
DEPARTMENT:	
ADDRESS (MSC):	

Investigator: Please respond to the questions below. The IRB will utilize your responses to evaluate your protocol submission.

1. ☒ **YES** ☐ **NO** Does the James Madison University Institutional Review Board define the project as ***research?***
The James Madison University IRB defines "research" as a "systematic investigation designed to develop or contribute to generalizable *knowledge*." All research involving human participants conducted by James Madison University faculty, staff, and students is subject to IRB review.

2. ☒ **YES** ☐ **NO** Are the human participants in your study ***living*** individuals?
"Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains:
(1) data through intervention or interaction with the individual; or (2) identifiable private information."

3. ☒ **YES** ☐ **NO** Will you obtain data through ***intervention*** or ***interaction*** with these individuals?
"Intervention" includes both physical procedures by which data are gathered (*e.g.*, measurement of heart rate or venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between the investigator and participant (*e.g.*, surveying or interviewing).

4. ☒ **YES** ☐ **NO** Will you obtain ***identifiable private information*** about these individuals?
"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information provided for specific purposes which the individual can reasonably expect will not be made public (*e.g.*, a medical record or student record). "Identifiable" means that the identity of the participant may be ascertained by the investigator or associated with the information (*e.g.*, by name, code number, pattern of answers, etc.).

5. ☐ **YES** ☒ **NO** Does the study present ***more than minimal risk*** to the participants?

"Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. Note that the concept of risk goes beyond physical risk and includes psychological, emotional, or behavioral risk as well as risks to employability, economic well-being, social standing, and risks of civil and criminal liability.

CERTIFICATIONS:

For James Madison University to obtain a Federal Wide Assurance (FWA) with the Office of Human Research Protection (OHRP), U.S. Department of Health & Human Services, **all** research staff working with human participants must sign this form and receive training in ethical guidelines and regulations. "Research staff" is defined as persons who have direct and substantive involvement in proposing, performing, reviewing, or reporting research and includes students fulfilling these roles as well as their faculty advisors. The Office of Sponsored Programs maintains a roster of all researchers who have completed training within the past three years.

Test module at OSP website http://www.jmu.edu/sponsprog/irb/irbtraining.html

Name of Researcher(s)	Training Completion Date
Erin Kamarunas, PhD	09/02/2013
Christy Ludlow, PhD	08/06/2013
Seng Mun Wong	11/08/2013
Erin Staudt	5/28/15

For additional training interests visit the National Institutes of Health Web Tutorial at: *http://cme.nci.nih.gov/*

By signing below, the Responsible Researcher(s), and the Faculty Advisor (if applicable), certifies that he/she is familiar with the ethical guidelines and regulations regarding the protection of human research participants from research risks. In addition, he/she agrees to abide by all sponsor and university policies and procedures in conducting the research. He/she further certifies that he/she has completed training regarding human participant research ethics within the last three years.

_____ _____
Principal Investigator Signature Date

_____ _____
Principal Investigator Signature Date

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Principal Investigator Signature Date

_____ _____
Principal Investigator Signature Date

_____ _____
Faculty Advisor Signature Date

Submit an electronic version of your **ENTIRE** protocol to jmu_grants@jmu.edu.
Provide a **SIGNED** hard copy of the Research Review Request Form to:
Office of Sponsored Programs, MSC 5728, James Madison Administrative Complex, Bldg #6, Suite 26

Background:

Over 60% of patients who have a stroke will experience secondary problems with their swallowing (dysphagia) (Mann et al., 1999). However, at least half of acute stroke patients will discharge to home with limited follow up on their swallowing problem (Howrey et al., 2011), which can lead to severe consequences. Similar problems with need for continued access to swallowing therapy occur following treatment of head and neck cancer where patients usually experience swallowing difficulties following chemoradiation and surgery (Hutcheson et al., 2012; Hutcheson & Lewin, 2012). Patients with swallowing disorders following traumatic brain injury also usually require a prolonged period of rehabilitation (Hansen et al., 2008). Once patients are discharged to home, limited access and cost issues are often barriers to continuing swallowing rehabilitation and consequently the patient's swallowing problem is chronically untreated. This not only negatively impacts the patient's quality of life and their ability to eat an oral diet, it fails to address chronic aspiration that can lead to rehospitalization and death. Continuing dysphagia care immediately following discharge is extremely important as earlier treatment leads to better outcomes (Odderson et al., 1995).

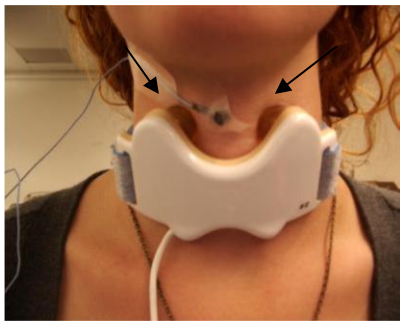


Figure 1. The Passy-Muir Swallowing Self-Training device is worn around the neck with the motors making contact with either side of the thyroid cartilage. These motors vibrate to stimulate the sensory nerves that induce swallowing.

We are currently developing the Passy Muir Swallowing Self-Trainer to continue treatment of dysphagia after the patient is discharged to home. The self-training device is worn around the neck with motors placed externally on the skin over the thyroid cartilage to provide vibratory stimulation to the larynx (Figure 1). The vibrations activate the sensory receptors inside the larynx which excite CNS control for swallowing (Chi-Fishman, 1994) and can help the patient to initiate swallowing. Patients can use the self-training device at home to promote swallowing rehabilitation during daily swallowing practice. The device can also be programmed to vibrate at regular intervals throughout the day to promote saliva swallows. Using this method, the patient can continue their swallowing therapy independently and in a manner that is cost effective. A previous Phase I trial compared the clinical outcomes of 8 patients with chronic dysphagia using either an intramuscular electrical stimulation implant device or an external vibratory stimulator to practice swallowing daily at home (FDA IDE G0G0153). Functional outcomes of oral intake improved with both devices. As the external vibratory stimulation has the advantage of being external and completely noninvasive, it has been selected for further development as a self-training device. A second pilot study (IRB-12-0057) examined the effect of different frequencies of vibration on the swallowing frequency of healthy participants and found swallowing significantly increased from baseline when using a vibration of 70 Hz on one side of the larynx and 110 Hz on the other side (Figure 2). Data is currently being collected on the effect of different vibration characteristics on swallowing in participants who have swallowing problems after stroke (IRB-13-0010).

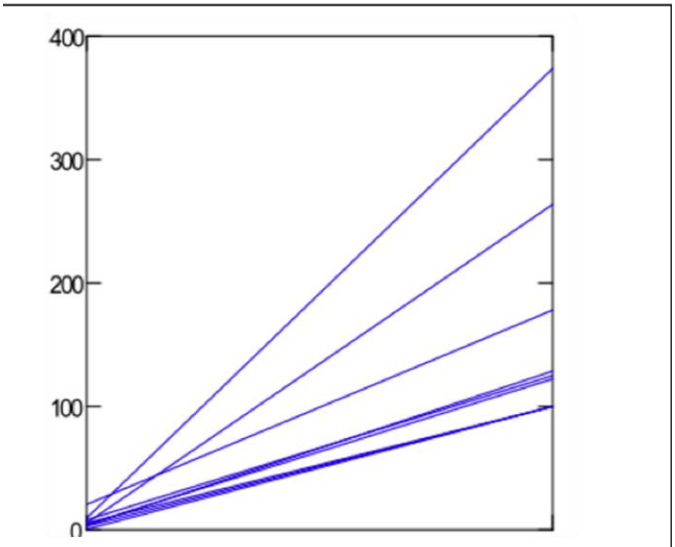


Figure 2: the 70/110 Hz motor increased swallowing by 100% or more in all healthy

Purpose: The purpose of this study is to allow patients with chronic dysphagia to use the Self-Trainer for daily swallowing practice in their home and collect feedback on device use and satisfaction and use. Objective information on the effectiveness of self-training for swallowing rehabilitation will also be gathered.

Objectives:

1. To develop and evaluate training for participants and caregivers to use the self-trainer.

2. To gather participant feedback on the use of the device after 3 months of daily practice.
3. To determine how 3 months of daily practice with the Passy Muir Swallowing Self-Trainer affects swallowing physiology, brain activation, oral intake, and quality of life in participants with chronic dysphagia.

Procedures/Research Design/Methodology/Timeframe

Design: This study is a case series study of participants using the device to evaluate patient preferences such as frequency of device use, compliance with training guidelines, patient and caregiver training required for appropriate use, and patient and caregiver feedback on satisfaction with the device. All participants will continue any outpatient rehabilitation they are receiving during this time period. This research will determine device training and use parameters before designing a Phase II controlled trial of the degree of benefit from device use. All participants and their caregivers will be trained on correct use of the Swallowing Self-Trainer and will use the device to practice swallowing in their home environment for 3 months (months 1-3). Each participant will complete the outcomes measures at baseline and immediately after the 3 months of device use.

Subjects: Between 12 and 20 participants with oropharyngeal swallowing problems will be recruited from the local area for participation. Participants must be 13 years of age or older. Parental consent will be obtained simultaneous to participant consent if the participant is under 18. Recently the principle investigator was contacted by the speech pathologist of a minor who has had a stroke and dysphagia and is interested in participating in this study.

Recruitment: Participants will be recruited from community hospitals, rehabilitation centers, and home health services in the local area. Participants who have previously participated in the protocol, The Passy Muir Swallowing Self Training Device to Enhance Recovery Post Stroke (13-0010), and have documented during the consent process that they will wish to be contacted with information on future studies will also be recruited to participate in this study.

Each participant will be given $20 for each visit they attend at Sentara RMH Medical Center (SRMH) for training or data collection purposes and $100 upon completion of the study. Travel mileage will also be reimbursed. All study compensation will be given in the form of a check mailed to the participant to the address they have specified by the study sponsor, Passy Muir. Hotel stay can be arranged and paid for if the participant is required to stay in Harrisonburg overnight. Hotel stay will also be paid for by the study sponsor, Passy Muir.

Documentation of Dysphagia: Participants will be identified as having swallowing difficulties for admittance into the study by obtaining medical records. Swallowing difficulty will be verified during the modified barium swallow completed as a baseline outcome measure.

Exclusion criteria: Exclusion from this study is contingent on participant self-report of one of the following:

- Ongoing psychiatric disorder for which the patient is receiving medication and is under the care of a psychiatrist
- Epileptic seizure
- Severe speech or language problems affecting communication and reading comprehension
- Cognitive impairment limiting understanding of the consent process and ability to follow directions as assessed by the Folstein Mini-mental State Examination (Folstein et al. 1975) with a score of less than 23.
- Diagnosis of esophageal disorders interfering with the ingestion of food and/or liquid.
- Inability to tolerate a nasal endoscopic exam.
- Rapidly progressive neurological disease such as amyotrophic lateral sclerosis, myasthenia gravis, and progressive supranuclear palsy.

Inclusion criteria:

- Participant must be 13 years old or older
- If the participant is under 18, parental consent must be given

- Stable medical condition
- Diagnosis of oropharyngeal dysphagia confirmed by MBS baseline measure of the follow two scales:
    - Penetration-Aspiration Scale score of 2 or greater verified by modified barium swallow (Rosenbek et al., 1996; Appendix I) and/or
    - Functional Oral Intake Scale score of 5 or lower (Crary et al., 2005; Appendix P)
- Folstein Mini-Mental State Examination (MMSE) score of 23 or greater indicating cognitive ability to follow directions and communicate preferences (Appendix H)
- Willingness to travel SRMH2 or more times to undergo initial evaluation, device use training and checkup at 3 months.

Exclusionary Criteria for Participants Who Agree to Undergo MRI and fNIRS:

- Pregnancy
- Cardiac problems
    - history of cardiac rhythm condition (including heart murmur or cardiac arrhythmia)
    - cardiac pacemaker in place
- Highly-pigmented (dark) skin color is an exclusion criterion because near-infrared spectroscopy requires the measurement of the degree of absorption of different wavelengths of light after being reflected back through the scalp. Highly pigmented skin interferes with wavelength transmission, making the measurement of changes in absorption inaccurate.
- Lack of a primary care physician who can be contacted if there are findings on the MRI.
- Presence of metal in the body (prostheses, electrodes, shrapnel, aneurism clips, other medical hardware)
- Presence of certain tattoos with ferromagnetic metal or permanent makeup, due to the exposure to high magnetic force through MRI procedures.
- Subjects who were metal workers as a previous occupation will also be excluded due to the possibility of unknown/undetected metal in their body.
- Volunteers with broken skin in the area that the fNIRS probes will be placed on the scalp
- Claustrophobia
- Previous surgery that used surgical staples
- Artificial joints

Will data be collected from or about any of the following populations?

___X___ Minors (under 18 years of age); Specify Age: 13 and over
_____ Prisoners
_____ Pregnant Women
_____ Fetuses
_____ Cognitively impaired persons
___X___ Other protected or potentially vulnerable population
_____ Not Applicable

Passy-Muir Swallowing Self-Trainer

The Self-Trainer is designed to be used in either automatic or manual mode. The mode can be easily set using a switch on the side of the controller. When the controller is in automatic mode, the device will vibrate up to 15 seconds every 3-5 minutes. These specifications are set by connecting the Self-Trainer to a computer terminal by the investigators. When the controller is in manual mode, the device operates in a momentary manner, specifically the device only vibrates when the button is pushed.

Swallow Practice

The participant will practice swallowing with the Self-Trainer daily in their home environment for 3 months. The Self-Trainer device will be set to vibrate at a vibration rate and pressure that is ideal for each participant based on testing (see Procedures Part B, section g). The participant will wear the Self-Trainer during waking hours with the device in automatic mode. In automatic mode the Self-Trainer will be programmed to vibrate up to 15 seconds every 3-5 minutes to stimulate saliva swallows and promote swallowing practice. In this manner the participant will complete approximately 180-300 saliva swallows per day.

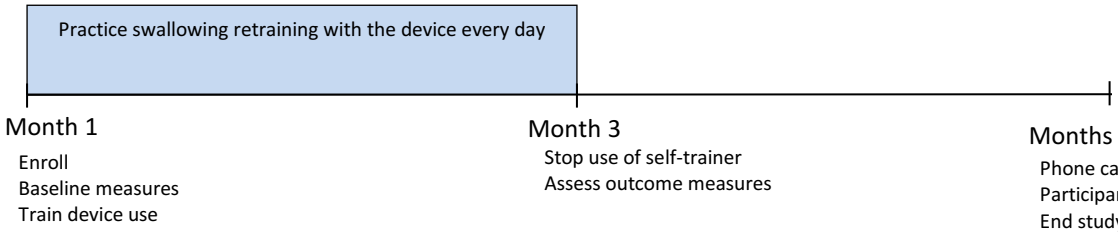
The participant will also engage in 30-60 minutes of active swallowing practice every day by switching the device to manual mode and manually pushing the button to turn on the vibration while swallowing, and releasing the button to turn off the vibration. The participant will complete a total of 60 practice swallows a day by doing 30 trials of practice 2 times a day. Participants will be given a small 5 cc syringe or ¼ teaspoon for administering 1-2 cc of water (equivalent to a saliva swallow) to moisten their mouths during each of their practice swallows.

Participant and Caregiver Instruction

Each participant and their caregivers will be trained in the following: 1) Self-Trainer placement; 2) Self-Trainer charging and use; 3) Self-Trainer cleaning; and 4) Aspiration precautions. Participants and caregivers will learn to locate the thyroid notch (Adam's apple) and place the motor contacts so that they are on either side of the thyroid notch (Figure 1). Each participant's device attachment cuff will be marked to illustrate where the Velcro should be secured to assure appropriate tightness for a neck pressure that is comfortable but effective for inducing swallowing during vibration. The participant and caregiver will also learn to verify correct placement by phonating while the vibration is on to determine if they can hear the sound of the vibration in their voice to indicate correct placement.

The participant and caregiver will learn the differences between automatic and manual modes and how to change the device to operate in each mode. Verbal, written, and/or video instructions will instruct the participant and caregiver to secure the Self-Trainer to the outside of the participant's neck (as described above) every morning after breakfast with the device set in automatic mode. The participant will wear the Self-Trainer set to automatic mode during waking hours with the exception of mealtimes, swallowing practice and during vigorous exercise when it may be cumbersome to use. The participant will learn to correctly sequence active swallowing practice with the Self-Trainer, which involves the following steps: 1) pushing the button to turn on the device vibration, 2) initiate swallowing within a 1/3 of a second while the vibrator is "on", and 3) releasing the button when the swallow is completed. Participants will be given written, pictorial, and/or video instructions on how to use the device and how to verify correct placement of the device. Instruction and training will be provided on how to daily clean and charge the device. Participants will learn to follow a daily regimen for preventing aspiration of secretions and for preventing aspiration pneumonia including good oral hygiene, monitoring for wet vocal quality, taking their body temperature, and only using the Self-Trainer in an upright position (see Human Subjects Protection).

Figure 3. Time course



Dependent variables:

Data on participant training: Each participant and their caregiver will be asked to demonstrate device setting up and use after each training session. When the participant and caregiver are able to demonstrate appropriate use based

on a checklist completed by the examiner, their training will be completed. The number of training sessions required and total training time before accurate use is demonstrated will be recorded for each participant. The participants will also be asked a series of multiple choice questions about the usefulness of training sessions and training materials.

Outcome measures for documenting swallowing and dietary changes will be taken at baseline and at end of the 3 month self-training period. Outcome measures for all participants will include the following: 1) Training and maintenance data; 2) Participant feedback questionnaire; 3) Participant fidelity data; 4) Modified Barium Swallow administered and scored with the Modified Barium Swallow Impairment Profile Protocol (Martin-Harris et al., 2008) and the 5) Dysphagia Outcome and Severity Scale (O'Neil et al., 1999) with the rater blinded to participant ID and condition; 6) the Dysphagia Handicap Index (DHI) (Silbergleit et al., 2012); and 7) percent change in hemoglobin oxygenation in the somatosensory and motor regions associated with swallowing and measured with functional near-infrared spectroscopy (fNIRS) as an indirect measure of brain activation changes.

Procedures:

A. Telephone screening done by speech pathologists in the Laboratory of Neural Bases of Communication and Swallowing
    a. Telephone screening script (Appendix A); if persons are not excluded at this point, they will be invited to continue enrollment with the informed consent process.
    b. Participants will be mailed records request to sign and mail to their hospital to obtain medical records for enrollment diagnostic verification. Diagnoses will be confirmed by medical records review before enrollment into the study.
    c. Participants will also be mailed the informed consent form for information purposes prior to the consenting visit

B. Informed Consent (Appendix B) and Research Screeners: Consenting appointment can take place at James Madison University's Laboratory of Neural Bases of Communication and Swallowing or SRMH Voice and Swallowing Service in the Outpatient Center. As all consent and release forms contain participant information (name), these will be stored separately from the de-identified case report forms in a locked cabinet at the James Madison University Neural Bases of Communication and Swallowing Lab. This lab remains locked at all times and allows only authorized keycard entry. Participants who are under 18 will be asked to sign an assent form, which describes the research procedures in grade appropriate language, and their parent/guardian will be asked to sign a parent consent form to allow their child to participate in the research.
    a. A medical history form will be used to gather background information on the participant's medical history (Appendix C)
    b. Eligible participants will read or be read the risks and benefits with the investigators before signing the consent form. Each participant will be provided with a copy of his or her signed informed consent form.
    c. After signing consent forms, participants will be asked to sign release forms
        i. Release form: Participants have access to the summarized group data from this research (Appendix D)
        ii. Release form: Researchers may use their data for educational purposes (Appendix E)
        iii. Release form: Permission for Future Contact Release Form, Neural Bases of Communication and Swallowing Laboratory (Appendix F)
        iv. Release form: Permission for Future Contact Release Form, Communication Sciences and Disorders Department (Appendix G)
    d. Folstein Mini-Mental State Examination (MMSE) will be administered as a screening examination (Appendix H)
    e. Dysphagia Outcome and Severity Scale (DOSS) (O'Neil et al., 1999) will be administered as a screening examination and allows the speech pathologist to assign a 1 to 7 numerical score to the safest food and liquid consistency that the participant can take orally, ranging from no food restrictions to no oral

intake. As a screening test, the DOSS will be completed by the speech pathologist per discussion with the participant about their current oral intake (Appendix J). This rating scale form will be identified only by ID number with no personal health information. Each participant must obtain a score of 5 or lower, indicating a restricted diet secondary to oropharyngeal dysphagia, to participate in the protocol.

f. Consented subjects will fill out the Edinburgh Handedness Inventory (Appendix O), a 10 question survey, to determine hand dominance.

g. Self-Trainer Motor Selection: If the participant has participated in the protocol "The Passy Muir Swallowing Self-Training Device to Enhance Recovery Post Stroke" (IRB 13-0010) then the optimal motor settings for the participant from this study will be used. However, if the participant has not participated in the previous study, then optimal motor settings will need to be identified for that patient. Motors at frequencies ranging from 30-150 Hz and other hybrid motors combining two frequencies (using 2-6 kPa neck pressure) will apply 8 seconds of stimulation followed by 15 seconds of rest for a total of 28 stimulation trials for a total of 10.7 minutes per motor frequency. Using the same vibration time specifications, neck pressure, vibration mode, and vibration duration may also be tested so that optimal motor parameters can be selected for each participant. Online recordings of bi-axial accelerometry of laryngeal motion and inductive plethysmography of respiration will identify laryngeal movement and respiratory apnea to confirm swallows. The rate of swallowing during the 10.7 minute condition will be computed for each motor condition and compared to baseline to identify the optimal motor to use with the patient for daily swallowing self-training during device use. All testing done for motor selection will be video recorded for later analysis. Each digital video file will be saved using the participant's study ID only and will be stored on an encrypted drive for 5 years after publication, after which it will be destroyed.

    i. Online digitizing with AD instruments Powerlab and Chart software will record accelerometry on the neck measuring laryngeal movement onset and offset and inductive plethysmography noninvasive recordings of chest wall and abdominal respiratory movement to identify swallows and the apneic period. These recordings will be identified only by ID number and stored as Chart files for analysis on encrypted computers or the secure server in the laboratory at JMU accessible by VPN from laptops in the Voice and Swallowing Service. Analyses will be conducted on workstations in the Laboratory of Neural Bases of Communication and Swallowing at JMU and only identified by ID code with no personal health information (PHI).

C. Training session

a. The participants will be trained on appropriate device placement, appropriate device pressure, how to verify correct placement of the device, and how to use the device daily for swallowing therapy. Caregivers will be encouraged to attend to provide support and will be trained to "coach" the participant.

b. Self-Trainer guides will be given to the participant in the following forms:
    i. Written directions with pictures
    ii. Optional DVD instructional video

c. Once the participant and their caregiver can demonstrate correct use of the Passy Muir Self Trainer for Swallowing, they will be given the device to take home and use for 3 months. The investigators will provide phone support to the participant and caregivers every day for the first 3 days of participation and on a weekly basis after that. The participants and caregivers will be encouraged to call the investigators with questions as needed and the investigators will be available for one on one meetings as needed. All contacts will be documented.

D. Outcome measures

Outcome measures a-e will be completed at the SRMH Voice and Swallowing Services in the Treatment Center. Voice and Swallowing Service is a collaboration between SRMH Healthcare and James Madison University.

a. Training and maintenance data will be taken on each participant and will include how many training sessions were required to demonstrate competency for device use, the duration of each training session, caregiver involvement, documentation of questions or comments during maintenance phone calls, and how many times the participant contacted the research team and for what purposes.
b. Participant feedback will be gathered at the end of the 3 month self-training period. The participant will read or be read a series of multiple choice questions (Appendix K) regarding their opinion on the training they received, ease of device use, and design of the device. The participants will be instructed to answer truthfully and will be assured that their answers will not impact their treatment or enrollment in this or future research studies at JMU/SRMH.
c. Participant fidelity will be measured by 1) daily documentation by the participant or caregiver on device use and 2) downloading the count data from the device periodically throughout the study which provides data on how many times the device has vibrated in automatic mode and in manual mode.
d. Modified Barium Swallow study (MBS) will be completed in radiology and requires the participant to swallow small amounts of barium. This will be done by a licensed speech-language pathologist who has been trained to complete MBS. An MBS study will be completed at baseline and after the 3 month self-training period. During each exam the participant will swallow thin liquid, nectar thick liquid, honey thick liquid, puree, and solid texture (cracker/cookie). For the entire MBS protocol, see Appendix L. The participant will be given each consistency in gradually increasing amounts from 5 ml to approximately 15 ml (See Human Subjects Protection). If more than a trace amount of aspiration is observed on any trial, the remaining trials of that consistency will be discontinued from the study. Radiation exposure time for each study will be 5 minutes or less. All MBS studies will be recorded for later analysis. All recordings will be de-identified with a random ID number. Each MBS study will include a 19 mm metal sphere calibration marker be taped to the side of the neck for future displacement measures. Each video will be analyzed for:
    i. Modified Barium Swallow Impairment Profile score (MBSImP) (Martin-Harris et al., 2008) allows the speech pathologist to rate specific physiological movement during each swallow and assign an overall 0 to 55 numerical score representative of swallowing impairment in the oral, pharyngeal, and esophageal phase (Appendix L).
    ii. Dysphagia Outcome and Severity Scale (DOSS) (O'Neil et al., 1999) allows the speech pathologist to assign a 1 to 7 numerical score to the safest food and liquid consistency that the participant can take orally, ranging from no food restrictions to no oral intake. The DOSS will be completed by the speech pathologist while reviewing each MBS while participant ID and condition will be masked (Appendix J). This rating scale form will be identified only by ID number with no personal health information.
e. Dysphagia Handicap Index (DHI) (Silbergleit et al., 2012) survey requires the participant to rate their agreement with 25 statements pertaining to their swallowing (Appendix M). The DHI is designed to determine how the patient's swallowing affects their day to day quality of life on a physical, functional, and emotional level and possible scores range from 0-100. The DHI will be completed by the participant with help from the caregiver or speech pathologist as needed. The DHI will be completed at baseline, after the 3 month self-training period, and at 1 month post the self-training period. This survey will be identified only by ID number with no personal health information.
f. Magnetic Resonance Imaging: Some participants may be scheduled to receive an MRI scan at SSRMH as a part of the study. The MRI image can be used to identify the 3 dimensional locations of particular regions of the brain from the scalp position and can also provide information as to the anatomical location of brain tissue damage, for example, if the patient has had a stroke or brain injury. MRI scans will be conducted at SRMH on a 1.5 Tesla MRI, to allow fNIRS recording from corresponding anatomy.

    Female participants who are pregnant cannot undergo a research MRI scan. Although there have not been any reports of injury to a fetus from MRI, we want to prevent any unforeseen difficulties when these scans are being performed for research purposes and are not needed for patient care. Female

participants who have child bearing potential will need to undergo pregnancy testing prior to MRI scanning. To decide whether a female participant has child bearing potential, we will also ask each female participant the date of their last menses in order to determine whether they are post-menopausal. Any female participant who is over 1 year since her last menses will be considered post-menopausal (unless they are breastfeeding) and not have child bearing potential and will not require a pregnancy test. All female participants who have child bearing potential (i.e. are not post-menopausal) will be given a pregnancy test kit by the JMU research team (free of charge) and will be asked to take the pregnancy test the morning before going to the SRMH for their MRI scan. They must report to the research staff at JMU that the test was negative before going for their MRI scan. If participants have not reported a negative pregnancy test before a scan, the scan will be cancelled by the JMU staff by contacting the SRMH. Results of the pregnancy test will be confidential and discussed privately with the participant alone, even if the participant is a minor. Participation in the MRI will not be essential for participating in the study.

g. Functional Near-Infrared Spectroscopy (fNIRS) will be conducted on those participants willing and able to travel to James Madison University Neural Bases of Communication and Swallowing Laboratory for testing prior to device use and after 3 months of device use. Therefore, fNIRS data may not be taken on every participant. fNIRS will be used to measure the hemodynamic response in the brain while the participant is asked to actively swallow, recording cortical activation changes in the primary motor cortex and somatosensory cortex bilaterally during swallowing in comparison with rest. Participation in the fNIRS will not be essential for participating in the study.
    i. This is a noninvasive technology using optodes to emit laser lights, similar to pulse oximetry in concept and practice. Light detectors are placed 3 centimeters from the emitters to absorb any reflected light from the emitter. These emitters and detectors are placed on the scalp after parting the hair to reduce inference from pigment in hair. The only risk to participants and the investigative team is if the emitters are turned on and a laser light could be shined in someone's eyes, similar to laser pointers. Therefore, the emitters will only be turned on after they are placed and attached to a participants scalp. The lasers will be turned off prior to moving or replacing the emitters on the scalp. Six emitters and ten detectors will be attached to the scalp over 6 locations with Coban material, a self-adhesive stretching material similar to an Ace bandage, which will be wrapped over the optodes and detectors to keep them in place. Bobby pins and clips will be used to part the hair when appropriate, a non-invasive procedure. No hair will be cut and any color markings made on the scalp for the Brainsight identified coordinates will wash off in the shower with shampoo.
    ii. fNIRS data files will be deidentified and saved for later analysis. fNIRS sessions will be video recorded and saved for future analysis. Each digital video file will be saved using the participant's study ID only and will be stored on an encrypted drive for 5 years after publication, after which it will be destroyed.

E. Participants will return to the SRMH Voice and Swallowing Service at the end of the 3 month self-training period to document outcome measures as outlined in section C. If the participant has also opted to participate in fNIRS, they will also return to the James Madison University Neural Bases of Communication and Swallowing Laboratory at 3 months.

F. Follow up and Discharge:
    a. During months 4-6 the investigators will contact the participant by phone or Skype one time each month to follow up on their progress and answer any questions. At the end of month 6, the participant will be mailed the Dysphagia Handicap Index survey (Appendix M) to complete and return by mail and a statement of discharge from the study (Appendix N). The participant will be encouraged to contact the investigators if they should have questions or concerns in the future.

Potential Problems and Alternative Strategies: Anticipated problems include difficulties with recruiting an adequate sample of patients in the Harrisonburg area for testing in our clinic at SRMH. A website has been developed for promoting research on the swallowing Self-Trainer (swallowingselftrainer.com), which can be used by the public, speech pathologists or participants, to educate themselves on the uses of the Self-Trainer or to get contact information. Advertisements on Google and on the National Foundation of Swallowing Disorders are also in place to help with recruitment. In this manner, participants who are interested in swallowing research can self-refer. Also participants who have participated in a previous protocol involving the Self-Trainer and have stated that they give permission for future contact will be contacted for participation in this study. Participants can also be recruited from the SRMH/JMU Voice and Swallowing Service, the SRMH/JMU Swallowing Support Group, which meets bimonthly as well as other dysphagia services in the area, including other local support groups. Local speech-language pathologists will be informed of current research projects and will be able to inform their patients to contact us for more information.

Statistical Analysis: Questionnaire data will be categorized and coded. Quantitative data will be analyzed using Analysis of Variance (MANOVA) for repeated measures with a Bonferroni corrected alpha of 0.05.

Human Subjects Protection

A. Potential Risks

During this case series, the participants are asked to wear the swallowing Self-Trainer around their neck to provide vibratory stimulation to the nerves that influence swallowing. They will wear the device during waking hours and prior research has shown that the stimuli can increase the frequency of swallowing 2-3x their normal rate. Participants will be instructed to only take food or liquid consistencies by mouth for nutritional purposes as recommended by the SLP based on their modified barium swallow while the device is on for swallowing training. Rather, the participants will swallow their own saliva or an equivalent amount of water (1-2 ml) as a part of the self-training, as they do on a normal basis throughout the day. As the most persons use up their saliva after 3 swallows, participants will be given a small syringe or ¼ teaspoon for administering 1-2 ml of water, equivalent to a saliva swallow, to moisten their mouths while practicing.

For participants who take food orally these consistencies must be approved by the SLP as being safe to use with the device. If the participant is not safe for any intake, instructions will be given to remove the device from the participant's neck prior to food consumption they take for pleasure. As the Self-Trainer is known to increase the frequency of swallowing, the participants will be swallowing their secretions more frequently and therefore it is possible that each participant's risk of aspirating could change. For some participants, specifically those who do not swallow their secretions and instead periodically expectorate, the participant is now attempting to swallow the secretions instead of attempting to clear them form their oropharynx using regurgitation. Participants who do not feel secretions pooling in their throat may have a decreased risk of aspirating secretions while using the device as they are now prompted to swallow. As saliva swallows and the risks associated with saliva aspiration are an ongoing daily risk for these participants, this study provides only a minimal increase in risk. Efforts will be made to minimize any risk associated with participation in this study (see Protection against risks). If a participant expectorates their saliva as a part of reducing aspiration risk, they will be encouraged to continue with this practice as needed, but to try to swallow when they feel the urge to swallow as part of the self-training. The study will be conducted by a licensed speech language pathologist who will counsel each participant on minimizing secretion aspiration risk.

Participants will be encouraged to continue with their current swallowing treatment plan of care as determined by their speech language pathologist. We will take great care to make certain that all participants and their family and caregivers do not misinterpret the purpose of this research and fully understand that this study is experimental research with no guarantees of benefit. It will be made clear in the advertising material, informed consent and in any discussions with the participants and family members that treatment received is experimental research and there is no guarantee of improvements in swallowing function. The speech language pathologist conducting the research will provide participants and their

caregivers with referrals to patient services in their area for treatment of their swallowing disorder if appropriate.

During the Modified Barium Swallow study the participant will be exposed to small amounts of radiation. As we are testing a minimum of 2 and a maximum of 12 swallows for each test, it is expected that the amount of radiation the participant will be exposed to will be negligible.

MRI does not involve radiation and is safe when used on individuals who are appropriately screened for the procedure. The FDA has classified MRI as a class II risk. Individuals with any implanted metal objects in the brain or body are at risk of injury with MRI procedures due to the high magnetic force to which they are exposed. Therefore, individuals with one or more of the MRI exclusion criteria will be excluded from the study. The principal investigator will review each of the exclusion criteria with the participant. Acoustic noise is generated in the magnet when the gradient coils are energized and de-energized in the magnetic fields to create MRI images. Subjects will be required to wear earplugs during the scan, which will be placed by the investigators. No incident of hearing impairment has been reported before in clinical scanners. During the scan, the investigator will monitor the patient's comfort level. We consider that the procedures described above are safe and should not produce any undue discomfort for subjects. The main discomfort associated with the study is the need for the subject to remain quiet within the scanner for the duration of testing, about 20 minutes maximum.

B. Human Subjects Protection- Recruitment and Informed Consent

Participants will be recruited through community hospitals, rehabilitations, and home health services. We will recruit from area speech language therapy service centers by placing advertisements in the waiting areas and asking professionals including neurologists, otolaryngologists, and speech-language pathologists to place notices in their waiting and office areas. Notices will also be mailed to professional involved in rehabilitation in the Shenandoah Valley area asking them to place notices in their waiting and office areas. We will also be using email blasts, discussion board postings, and a website (swallowselftrainer.com) to increase awareness of the study among speech language pathologists and patients with swallowing disorders in the community. We will only ask professionals to place notices and make literature available on our study but not to refer patients directly to us so patients will not feel under any undue influence from their professional caregivers to participate. Our notices and literature will provide information that will allow participants to contact us directly and the website will allow patients to self-refer.

We have 3 rooms in the JMU-SRMH Voice and Swallowing Service to support multiple participants being tested simultaneously. Free parking is immediately available within 100 ft of the entrance to our testing grooms in the Treatment Center on the ground floor of SRMH. The burden to participants will be the daily use of the Self-Trainer for 3 months, the majority of which the device will be switched in "automatic" mode requiring no active engagement on the part of the participant. Active practice required of the participant consists of 60 swallows and will take from 30-60 minutes a day. Additional burden to the participant includes 3 or more visits to SRMH for testing measures, while periodic counts taken from the Self-Trainer can be completed with laptops and can be done in the participant's home, JMU or SRMH as is convenient. Weekly check ins can be done over the telephone, Skype, or as needed by the participant to answer questions and verify compliancy, although in person appointments can be made if needed.

Administration of informed consent: Participants will be telephone screened and if they meet the inclusion criteria, they will be mailed the consent form for information purposes to allow them to review it before coming to the Voice and Swallowing Service. The consent will inform participants that Dr. Ludlow has a financial interest in the research. Either Dr. Ludlow or Dr. Kamarunas, the speech language pathologist, will administer informed consent to the participant. During the consent process, either Dr. Ludlow or Dr. Kamarunas will review the study with the participant and any family members present to answer questions. The participant will then read or be read the consent and answer a few questions to demonstrate they have

understood. The consent will then be signed, witnessed, and a copy given to the participant. Participants who have sight or literacy problems will have the consent read to them and a series of questions will be asked of all participants to assure their comprehension of the study before completing the informed consent process. No proxy consent or assent will be accepted for this study.

C. Protection against risk

As listed above under Potential Risks, this application is expected to involve only minimal increased risk from the research procedures for participants with swallow disorders as only saliva swallows or 1-2 ml water swallows as needed (equivalent to a saliva swallow) will be used while the device is on. All participants will be producing saliva normally and will be exposed to the risk of saliva aspiration throughout the day in their normal living. This risk occurs even when they are receiving enteral feeding either through a PEG tube or nasogastric tube. With the increased frequency in swallowing associated with the Self-Trainer, there is a minimal increased risk for the participant because of their swallowing disorder.

To minimize the risk associated with saliva aspiration, the speech language pathologist conducting the research will train all participants and their caregivers on a daily regimen to follow for secretion aspiration prevention and an oral hygiene regime to reduce oral bacteria. Each participant and their caregivers will be trained to competency on the following aspiration monitoring methods:

1. Oral hygiene including cleaning the mouth, teeth (or dentures), tongue, etc. with toothpaste and mouthwash, as deemed appropriate, after meals or 3 times a day.
2. Voice quality testing to detect a wet, gurgly voice quality which would indicate increased fluid in or around the airway. If voice quality sounds “wet” they will be trained to voluntarily move secretions away from the airway by throat clearing/coughing to bring the secretions in the mouth and then spitting or swallowing the materials brought up.
3. Daily body temperature monitoring: The participant and their caregivers will be instructed to contact the research staff if they have a rise in body temperature over three days sequentially while participating in the study.
4. Participants and caregivers will be instructed to only use the Self-Trainer while sitting in an upright position, which may be helpful in preventing the aspiration of oral secretions. If the participant needs to lay down for any reason, the Self-Trainer should be switched off and/or removed from the participant’s neck. They will also be instructed not to use the self-trainer during vigorous exercise (like running) as this would be cumbersome and could result in damage to the device.
5. Participants will be instructed not to use the device with any oral intake they are unsafe for. The SLP will make recommendations as to what food consistencies the participant is safe for consuming while using the device. If they are unsafe on all consistencies, the recommendation will be not to wear the device while there is any food in their mouth.

D. Adverse events

Participants will be monitored for the occurrence of adverse events throughout their enrollment in the clinical study. All adverse events occurring during the course of the clinical study, whether device-related or otherwise, will be recorded on the Adverse Event CRF. Records of adverse events (AE) will be evaluated by the medical officer, Dr. Kini, the Study Team and the JMU and SRMH IRBs for participants in the protocol. Serious adverse events (SAE) will be evaluated by Dr. Kini and reported to the IRBs at JMU and SRMH within 10 days of their occurrence. The study physician will assess and report on the relationship of the adverse event to the investigational device as well as the severity of the event, the outcome of the event, and whether or not the adverse event could have been anticipated. The IRBs will evaluate the reports of AEs/SAEs to determine if use of the device shows increased risk of aspiration pneumonia and other problems indicating that use of the device produces “more than minimal“ risk.

Data Analysis

Data integrity will be assured by using the LabTrack electronic notebook system in Dr. Ludlow's lab which is on a secure backup server. This system meets FDA standards for data monitoring. Case Report Forms (CRF) will be setup with templates requiring entry of all essential data elements on each participant such as inclusion/exclusion criteria, consent records and records of visits, telephone contacts, and correspondence tracking each participant's involvement in the research. The LabTrack system tracks all entries, the date and the identity and any data changes by user ID. All measures will be entered into data files on the Laboratory server by participant ID number. All videos associated with the study will be stored on encrypted drives for at least 5 years. The PI and speech pathologist will conduct monthly quality assurance reviews of the CRFs and data files.

The outcome measure data points will include training and maintenance data, participant feedback survey, fidelity data, MBSImP score, Dysphagia Outcome and Severity Scale score, Dysphagia Handicap Index score, and fNIRS data (optional) at baseline and at 3 months. Each of these data points will be entered into data files by participant number in LabTrack and Excel.

Paper case report forms will not contain any identifying information and will be stored in a locked cabinet at the James Madison University Neural Bases of Communication and Swallowing Laboratory, which requires authorized badge access. All deidentified data will also be recorded in the case report form on encrypted Laptops connected by VPN to the LabTrack system on a server in Dr. Ludlow's laboratory. Participants' status at the end of each test session will be recorded in the CRF in LabTrack.

Reporting Procedures

Result of this research study will be published in a professional peer reviewed journal intended for professionals who perform research in the field of dysphagia and/or work with individuals who have dysphagia. Participants will be given the opportunity to opt to have the research results in the form of the journal article sent to them by mail or email.

Experience of the Researcher (and advisor, *if student)*:

Dr. Ludlow has conducted clinical research for over 35 years.

Dr. Kamarunas successfully defended her dissertation in August of 2012. She is an author on two publications and has presented numerous times at national conferences.

Seng Mun Wong, is a doctoral student in Communication Sciences and Disorders at James Madison University. She has completed a Bachelor of Science degree in speech sciences from University College London in the UK. Her research experience includes 2 co-authored publications in her previous employment at the Singapore General Hospital.

Erin Staudt is a 1st year graduate student in the CSD department at JMU. Her involvement in this research project will include telephone and medical records screening, assisting in data collection, data analysis, and maintaining records.

Additional Attachments as applicable:

The following appendices are attached:

Appendix A - Telephone Screening
Appendix B - Consent to Participate
Appendix C - Medical History Form
Appendix D - Release for Participant to Obtain Research Information
Appendix E - Release of Data for Educational Purposes
Appendix F - Permission for Future Contact Release Form, Neural Bases of Communication and Swallowing Laboratory
Appendix G - Permission for Future Contact Release Form, Communication Sciences and Disorders Department
Appendix H - Folstein Mini-Mental State Examination (MMSE)
Appendix I - Penetration-Aspiration Scale

Appendix J- Dysphagia Outcome and Severity Scale
Appendix K- Participant Survey
Appendix L- MBSImP Protocol and Scoring (Martin-Harris et al., 2008)
Appendix M- Dysphagia Handicap Index
Appendix N- Discharge letter
Appendix O- Edinburgh Handedness Inventory

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