Consent to Participate in Research

Study Title: Study of the Use of the Passy Muir Swallowing Self Trainer by Persons with Dysphagia

Identification of Investigators

You are being asked to participate in a research study conducted by Dr. Christy Ludlow and Dr. Erin Kamarunas from James Madison University, Department of Communication Sciences and Disorders. You will likely be seen at the JMU-Sentara RMH Medical Center (SRMH) Voice and Swallowing Services office at SRMH during this study. The JMU-SRMH Voice and Swallowing Services is a collaborative project that includes both JMU and SRMH. Dr. Ludlow is an inventor on the devices that will be tested as part of this research and could possibly benefit financially if the device becomes marketable.

Dr. Ludlow receives her salary from James Madison University; The Passy Muir, Inc., reimburses James Madison University for a portion of her salary that is equivalent to the time she spends on research using funds received from the National Institutes of Health as part of a small business innovative research grant. Dr. Kamarunas is paid by a grant to James Madison University from Passy Muir Inc.

Purpose of the Study

The purpose of this study is to learn whether or not using noninvasive vibratory stimuli (like a cell phone) on the neck will benefit swallowing retraining in persons with dysphagia as well as to gather feedback from participants about device use. The findings of the study will contribute to our overall understanding of swallowing rehabilitation and could help people with swallowing disorders in the future.

Background

Safe swallowing requires the ability to protect your airway control when you swallow food or liquid. A chronic swallowing disorder (dysphagia) can be life threatening, as it can place patients at risk for liquids and/or solids entering the trachea when swallowing. Repeated aspiration of substances into the lungs can result in pneumonia. We want to see if using vibratory stimuli during self-training will help people who have oropharyngeal swallowing disorders.

Study Population

Up to 20 persons who have oropharyngeal swallowing dysfunction.

Inclusion Criteria

You may be eligible for this research study if:

- You are 13 years old or older
- You are in stable medical condition
- You have a swallowing disorder based on your medical records and a modified barium swallow study, which we will perform. The modified barium swallow will be paid for by the research to assess your current swallowing status. We can provide you with the results of this testing if you request it.

- You will need to take a short pen and pencil test to assess your memory and cognitive skills to participate in the study. You must score 23/30 or higher, indicating normal cognition. We can provide you with the results of this testing if you request it.
- We will be asking you some questions about your ability to eat food and swallow liquids. This questionnaire will assess whether you are at risk of having food enter your airway during swallowing. We can provide you with the results of this testing if you request it.
- You must be willing to travel to SRMH in Harrisonburg, VA, at least 2 times to complete all training sessions and outcomes measures.

Exclusion Criteria

Exclusionary criteria by participant report:

- History of epilepsy
- Ongoing psychiatric problems for which you receive medicine and are under the care of a psychiatrist
- Speech or language problems affecting your communication and reading comprehension
- Dementia, agitation, or a decreased level of alertness limiting your ability to understand the consent process and ability to follow directions
- A previous diagnosis of an esophageal disorders interfering with the ingestion of food and/or liquid
- A previous diagnosis of a disease of the brain or nerves.

fNIRS exclusionary criteria:

- Highly-pigmented (dark) skin color, which interferes with the measurement of light transmission through the scalp
- Volunteers with the broken skin in the area that the fNIRS probes will be placed on the scalp

Additional exclusionary criteria are required for some participants who will be receiving a brain scan using MRI as part of this study:

- Pregnancy
- Cardiac problems
    - history of cardiac rhythm condition (including heart murmur or cardiac arrhythmia)
    - cardiac pacemaker in place
- Presence of metal in the body (prostheses, electrodes, shrapnel, aneurism clips, other medical hardware)
- Presence of certain tattoos with ferromagnetic metal or permanent makeup
- Subjects who were metal workers as a previous occupation will also be excluded due to the possibility of unknown/undetected metal in their body
- Claustrophobia
- Previous surgery that used surgical staples
- Artificial joints
- Any metal in your body such as prostheses, other implants, shrapnel, or aneurism clips; certain tattoos have metal in them as well.

Research Procedures

Should you decide to participate in this research study, you will be asked to sign this consent form once all your questions have been answered to your satisfaction. If you decide to participate in this study, you will be asked to use a vibratory stimulus device for swallowing treatment every day for 3 months. The device has a strap that wraps around the neck to hold it in place at the front of the neck and it vibrates against your voice box.

To measure the effects of the vibratory device on swallowing, you will be asked to wear the device during waking hours every day for 3 months. You will be trained to use the vibratory device in the follow 2 ways:

1. **Automatic mode:** In automatic mode, the device is programed to vibrate for up to 15 seconds every 3-5 minutes. In the morning you will switch the device to automatic mode and wear it as it continues to vibrate for small amounts of time periodically throughout the day. This encourages and reminds you to swallow your saliva and increases the frequency of swallowing throughout the day. You will take the device off when you sleep, lay down, eat, and exercise (strenuous exercise, like running).

2. **Manual mode:** In manual mode, the device will only vibrate when you push the button and will last as long as you hold down the button. Twice a day you will switch the device to manual mode and perform practice swallows with the aid of the vibratory device. To complete these practice swallows you will push the button, swallow, and release the button. This is repeated 30 times and is done twice each day during the 3 months. When completing the practice swallows, you will feel your mouth is very dry from swallowing frequently, making swallowing difficult. When this occurs, you can moisten your mouth with water from a small syringe or ¼ teaspoon we will provide.

You will feel shaking to the throat when a vibrator is turned on, but this will not be painful or uncomfortable. If you are currently receiving swallowing treatment from your speech language pathologist, you are encouraged to continue treatment as you normally would. Any care you are now receiving can be continued while you are participating in this study.

Testing

During the 3 months of experimental treatment you will be using a device with the vibration frequency that is optimal for promoting swallowing. If the optimal vibration frequency for you has not been previously determined, then a session will be scheduled to determine the optimal frequency. Frequencies between 30 and 150 vibrations per second and some combination frequencies will be tested. This will require approximately 1.5 hours and may be divided between different testing times if you become fatigued. During this testing we will attach a small non-invasive sensor to the outside of your neck with tape (about the size of a pea) to record when you swallow. We will also wrap bands around your rib cage and abdomen to measure your

breathing and will video record this session to assist in later analyses. All recordings taken during this testing will be identified only by your study ID number and will be stored in a locked cabinet in the James Madison University Neural Bases of Communication and Swallowing Laboratory.

During your participation in this study, we will ask you travel at least 2 times to the Voice and Swallowing Services at the SRMH Outpatient Center. We will ask you to come at the beginning of your participation for training and baseline measures and at the end of the 3 month self-training period for reassessment. During your visits we will ask you to participate in the following items, all of which will be at no cost to yourself:

- Research Screening including a medical history screener, cognitive screening, handedness inventory, and two swallowing screening examinations.
- The Dysphagia Handicap Index questionnaire: This survey has 25 statements about how your swallowing problem has affected your quality of life. You will read or be read the statements and will answer that each statement is true for you "never", "sometimes", or "always". Completing the questionnaire will take approximately 10 minutes.
- Device use information: We will ask you to keep a daily record of your swallowing self-training such as how many hours you wore the device in automatic mode and how many active swallows you did for practice each day. We will also periodically download information from your self-trainer regarding how many times it has vibrated in automatic and manual modes.
- Participant survey: You will read or be read a series of multiple choice questions regarding your opinion on the device training you received the ease of device use, and the design of the device. This will take approximately 10 minutes.
- Modified Barium Swallow study: This is an X-ray video that will help us determine the function of your swallow. You will swallow food of different consistencies such as liquids, applesauce, and crackers/cookies that have barium in them. You should let us know if you are allergic to any medications or foods before we start this examination. This evaluation is well tolerated without discomfort. Each exam will be recorded for later analysis, but will be deidentified. We can provide you with the results of this testing if you request it. This exam will take approximately 10 minutes.
- Magnetic Resonance Imaging (MRI): After signing the informed consent, you may be asked to obtain a free MRI scan at SRMH, which we will schedule for you.
    - If you are a female, with child bearing potential we will need to be assured that you are not pregnant before undergoing a MRI scan. To determine if you have child bearing potential you will be asked the date of your last menses. To be considered post-menopausal you will need to be over 1 year past your last menses. If you have child bearing potential, you will be provided with a pregnancy testing kit (free of charge) and required to take the test the morning of the scheduled MRI scan and to report the test result to the research staff at JMU by phone or in person before going to the SRMH for

scanning. If you have not reported a negative pregnancy test before a scan, the scan will be cancelled by the JMU staff by contacting the SRMH prior to the scan. Results of the pregnancy test are confidential and discussed only with the participant.

- The MRI scanner is a metal cylinder surrounded by a strong magnetic field. During the MRI, you will be on a table that can slide in and out of the cylinder. While in the scanner, you will hear loud knocking noises and you must wear earplugs (which will be placed in your ears by trained professionals) to muffle the sound. You will be able to communicate with the MRI staff at all times during your scan. You may ask to be moved out of the machine at any time. The MRI does not involve radiation exposure because X-rays are not used.

- Functional Near Infrared Spectroscopy (optional): This is a non-invasive method of examining blood flow changes in the brain while you swallow. Laser lights and light detectors are used to measure blood flow changes in a way similar to pulse oximetry. Light emitters and detectors will be attached to your head with Coban wrap. Bobby pins and hair clips will be used to part your hair as needed. All fNIRS recordings will take place at James Madison University's Laboratory of Neural Bases of Communication and Swallowing and will take approximately 1 hour.

These measures with the exception of the screening examinations will be completed each time you come to the Voice and Swallowing Service. Participation in functional near infrared spectroscopy is an optional part of participation and requires travel to James Madison University. All are free of cost to you as a part of your participation. These appointments will be set up by the speech pathologist and will be done so in a manner that is as convenient to your schedule as possible. Also, as part of your participation, data will be downloaded from the vibratory device periodically to document device use. This will take less than 5 minutes and will be scheduled with you by the speech pathologist.

Time Required

Participation in this study will require approximately a total 7-12.5 hours spent at the Voice and Swallowing Service for consenting, defining optimal vibration frequency, and the two visits required to obtain outcome measures (defined in bullets above). Participation will also require 30-60 minutes daily spent in active swallowing practice using the device in manual mode. As the device is small and portable, this daily practice can take place anywhere that is convenient for you.

Risks, Inconveniences and Discomforts

As a part of this experimental research study, you are being asked to wear the vibratory device during waking hours every day for 3 months. The device fits around the neck with soft, cloth-like strips and is expected to be comfortable, but may lead to discomfort over time. If this should happen, you are to contact the speech pathologist in charge of this study immediately and describe the discomfort. Because of the vibratory nature of the stimulus on the neck, you may feel the urge

to swallow more often than usual. If you have increased incidence of coughing or choking while wearing the device, you are to contact the speech pathologist in charge of this study immediately.

Many people who have swallowing problems are at a higher risk of developing pneumonia because of their swallowing problems. For that reason, while you are participating in this study we want you to take your temperature at the same time of day each day and not directly after eating or drinking. If your temperature is elevated from your normal levels by more than 2 degrees for 3 days in a row you must call us so we can arrange for someone to see you in the next couple of days to see if you have a medical problem. You will also be instructed on keeping good oral hygiene, periodically test vocal quality for wet sounding voice, and to not use the device while lying down, vigorously exercising (like running), or ingesting any intake by mouth not approved by the SLP

We will contact you every week while you are actively participating in this experimental study to see if you are doing well and if you have any questions or concerns regarding your swallowing and device use. Please return our calls so that we can assure ourselves of your well-being. You are also encouraged to call or email the research staff if you have any questions.

*Vibrotactile Stimulation*

This is a non-invasive form of stimulation which carries no known risks. You will feel a vibration on your throat with the throat stimulator.

*Modified Barium Swallow Study*

This is an X-ray video that requires you be exposed to small amounts of radiation while you are tested. As we are testing a minimum of 2 and a maximum of 12 swallows each time, it is expected that the amount of radiation you will be exposed to will be negligible. Any charge incurred by this exam will be covered by the study.

*Magnetic Resonance Imaging (MRI):*

You may be asked to undergo an MRI as a part of this study. People are at risk for injury from the MRI magnet if they have pacemakers or other implanted electrical devices, brain stimulators, dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, implanted delivery pump, or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible small metal fragments in the eye of which they may be unaware. You will be screened for these conditions prior to the study, and if you have any, you will not be able to participate in the study. If you have a question about any metal objects being present in your body, you should inform the physician. In addition, all magnetic objects (for example, watches, coins, jewelry, and credit cards) must be removed before entering the MRI scan room.

Women who are pregnant may not undergo a research MRI. Therefore, all women of childbearing potential will have a pregnancy test performed, which must be negative, before proceeding. Individuals with fear of confined spaces may become anxious during an MRI. The noise of the MRI machine may be too loud and affect your hearing. Therefore, trained professionals will place earplugs in your ears for this procedure. You will be asked to complete

an MRI screening form, and to sign a separate MRI consent for each MRI. There are no known long-term risks associated with MRI scans. 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.

When you register for the MRI at the SRMH they will ask you to sign a release for the radiologists to send the report to your primary care physician. If there are unexpected abnormal findings on the MRI you will be notified and the findings will be communicated with your primary care physician. Once you are notified that abnormal findings have been identified it will be your responsibility to follow-up with your primary care physician.

*fNIRS*

This is a non-invasive method of examining blood flow changes in the brain while you swallow using laser light and light detectors. During near infrared spectroscopy if we inadvertently turned on the lasers before they are placed on your scalp, there is a risk that the lights might shine in your eyes. We will prevent this from occurring by not turning on the lasers until they are securing placed on your scalp away from your eyes. These lasers are similar to a laser pointer and the risk is minimal. Also, crayon markers will be used on the scalp during probe placement of the fNIRS sensors. These marks will wash away and no hair will be removed. Additionally, the sensors can be slightly uncomfortable on the scalp as they are held in place with light pressure.

Benefits

There are no guaranteed benefits to you from participating in this research. Your swallowing may or may not improve as a result of participating in this research. You should continue any treatment or regimen that you are now following for management of your swallowing disorder. The results of this stimulation study will likely yield generalizable knowledge which might benefit others with dysphagia in the future and will help us design patient friendly devices and treatment regimens.

Confidentiality

Your participation in this study is entirely confidential. All personally identifiable data will be kept in a locked and secure location that can only be accessed by authorized investigators. The results of this project will be coded in such a way that your identity will not be attached to the final form of this study. Your identity will be disassociated from your data and you will be assigned a participant number. All deidentified data and videos will be stored on an encrypted drive and secure server. The researchers retain the right to use and publish non-identifiable data. The overall results of this research may be presented at professional conferences. You may sign a release form to obtain your results from this study and to allow use of your non-identifiable data for educational purposes here at JMU.

Compensation

You will be paid for your participation in this study at the rate of $20.00 per visit and $100.00 on completion of the study. For those patients without transportation to allow them to travel to the

SRMH we can offer to reimburse your travel mileage and/or arrange and cover hotel stay for your appointment days during your participation in this study. All testing completed as a part of this protocol is covered by the study and is done at no cost to yourself.

Participation & Withdrawal

Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time without it affecting your current treatment or access to care for your swallowing disorder. At that time you will be paid for any visits that you have made to the study but not the $100.00 for completion. The investigator can remove you from the study at any time if continuation is not in your best medical interest or if you are unable to follow the study requirements. Should you withdraw from this study for any reason, we will ask for you to return all equipment loaned to you by JMU/SRMH for the purposes of this study within 7 days.

After your three months of treatment, we will continue to contact you once a month for three months to see if you are doing well and if you have any questions or concerns regarding your swallowing.

Questions about the Study

If you have questions or concerns during the time of your participation in this study, or after its completion or you would like to receive a copy of the final aggregate results of this study, please contact:

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Questions about Your Rights as a Research Subject
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540-689-1000

Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I freely consent to participate. I have been given satisfactory answers to my questions. The investigator provided me with a copy of this form. I certify that I am at least 20 years of age.

_____
Name of Participant (Printed)

_____ _____
Name of Participant (Signed) Date

_____ _____
Name of Researcher (Signed) Date

_____ _____
Name of Witness (Signed) Date

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James Madison University
Institutional Review Board CT