The Passy Muir Swallowing Self Training Device to Enhance Recovery Post Stroke
Consent to Participate in Research

Identification of Investigators

You are being asked to participate in a research study conducted by Dr. Christy Ludlow (Primary Investigator) from James Madison University, Department of Communication Sciences and Disorders. You will likely be seen at the JMU-RMH Voice and Swallowing Services office at RMH during this study. The JMU-RMH Voice and Swallowing Services is a collaborative project that includes both JMU and RMH. 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.

Purpose of the Study

The purpose of this study is to learn whether or not using noninvasive and non-painful vibratory stimuli (like a cell phone) on the neck will change peoples' swallowing. The findings of the study will contribute to our overall understanding of swallowing and could help people with swallowing disorders in the future, but the study does not provide a new treatment for you.

Background

Safe swallowing requires the ability to control when you swallow and to protect your airway. A chronic swallowing disorder (dysphagia) can be life threatening, as it can place patients at risk for aspiration of liquids and/or solids into the trachea. Repeated aspiration of substances into the lungs can result in pneumonia. We want to see whether certain types of vibratory stimuli might be used to help people to swallow who have had a stroke and have a swallowing disorder.

Study Population

Up to 50 persons who have had at least one stroke and have a swallowing disorder.

Inclusion Criteria

You may be eligible for this research study if:

- You are 20 years old or older
- You are in stable medical condition
- You have had at least one stroke
- You have a swallowing disorder based on the review of an examination of your swallowing using videofluoroscopy. If you have not had such an examination of your swallowing in the last year and have previously had a swallowing disorder after a stroke we can arrange for you to have another videofluoroscopy that 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. 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.

Exclusion Criteria

Exclusionary criteria by participant report:

- History of past brain injury, epilepsy, or neurological disorders (excluding stroke)

- Previous neck injury
- Psychiatric problems
- Speech problems
- Dementia, agitation, or a decreased level of alertness
- Diagnosis of progressive neurodegenerative disorders, such as dementia, Parkinson's Disease, multiple sclerosis, peripheral neuropathy, and amyotrophic lateral sclerosis

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 participate in one or more studies (described below as Experiments, 1,2, 3 and 4) that we are conducting on different types of devices that we are assessing for future use with patients who have swallowing disorders.

To measure the effects of each vibrator, we will attach a small vibrator to the outside of your throat with a band to hold it in place. We will turn on a vibrator for different time periods such as 3 to 10 seconds, and then turn it off for between 15 to -40 seconds for up to 32 times. This may occur for up to 20 minutes at a time with short 2 minute rest period between testing different vibrators. Thus, the total time for one condition may be just over 10 minutes. These sessions will test the following.

Experiment 1: to identify an optimal speed of vibration

4 Vibrator Frequencies between 30 and 150 vibrations per second (30, 70, 110, and 150) and some combined vibrators will be tested in one session. This will require one hour and may be divided between different testing times if it takes more than 1 hour of testing time.

Experiment 2: to determine optimal pulsing rate

We will compare a pulsed vibrator and a continuous vibrator using one of the vibrators from Experiment 1. This should require less than 30 minutes of testing at a time.

Experiment 3: to determine vibratory pressure settings and relationship with neck fat

We will use a small balloon placed between the neck band and your neck to determine the effect of different pressure settings between the neckband and the neck which might increase the effect of the vibration using one of the vibrators we used in Experiment 1. We will also measure the thickness of the skin overlying your neck with a caliper that has 2 arms. This should require less than 30 minutes of testing at a time.

Experiment 4: To determine optimal automatic cycling rate:

We will compare different times of vibratory stimulation to see which duration is needed for you to initiate swallowing: between 3, 5, 7 and 9 seconds. Each trial will be approximately 10 minutes, requiring about 1 hour of testing time.

These experiments may be run on different days with you returning each day for three or more different visits.

For each experiment, 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. In some experiments you may have a tube placed on your tongue to record when you swallow.

You will feel shaking to the throat when a vibrator is turned on, but this will not be painful or uncomfortable. There will be periods when the vibrator is on and when it is off. Your saliva maybe suctioned if necessary. The suctioning would be done by a licensed speech pathologist.

We will also ask you to say the vowel “eee” for about 10 seconds, two times with a vibrator turned on and two times without it turned on. This will tell us whether or not the vibration is reaching your voice box.

Time Required

Participation in this study will require approximately 3 hours total from consenting to and participating in the experiments. Some of the experiments may be combined, but we expect that to complete the entire groups of studies approximately 3-5 one hour visits will be required, but more can be scheduled as needed.

Risks, Inconveniences and Discomforts

We will be measuring the frequency that you swallow your saliva during some of these studies. If you have difficulty swallowing you may find it difficult to swallow your saliva we may ask you to clear your throat and bring the saliva to your mouth so that we can suction it for you. We will test for increased saliva every 10 -12 minutes during the study. If you normally have difficulty swallowing your saliva, please let us know and we will give you some advice on how to manage this.

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. If your temperature is elevated from your normal levels by more than 2 degrees for 3 days straight 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.

We will contact you within 2 days after each test session to see if you are doing well. Please return our calls so that we can assure ourselves of your wellbeing.

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.

Movement transducer device and Respitrace and video recording

These are non-invasive and carry no known risks. The movement transducer device will be attached to the neck with tape which could cause brief skin irritation after removal. The Respitrace bands will be wrapped around your rib cage and abdomen during the experiment but should not cause any discomfort. A small tube will sit on the front part of your tongue and will be held in place with tape at the chin/side of mouth. This tape could cause brief skin irritation after removal. A video recorder will record each session for later analysis and data verification. All records, including video recordings, will be kept for 2 years on an encrypted computer and the secure server and then destroyed.

Benefits

There are no direct benefits to you from participating in this research. This is not a treatment study and 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.

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. 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 compensated $20.00 for every visit to the JMU/RMH Voice and Swallow Service for experimental research sessions while participating in this research study. For those patients without transportation to allow them to travel to the Rockingham Memorial Hospital we can offer to reimburse your transportation costs.

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. 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.

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:

Laboratory of Neural Bases of Communication and Swallowing, Dr. Christy Ludlow
Communication Sciences and Disorders
James Madison University
Lab phone: (540) 568 - 5059
Office Telephone: (540) 568-3876
ludlowcx@jmu.edu

Questions about Your Rights as a Research Subject

Dr. David Cockley
Chair, Institutional Review Board
James Madison University
(540) 568-2834
cocklede@jmu.edu

Dr. Stewart Pollock
Chair, Institutional Review Board
RMH Healthcare
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

Release for Participant to Obtain Research Information

I wish to receive my personal results from this study. I give permission for the investigators of the Voice and Swallowing Service to release to me my personal data for my personal records.

I wish to obtain my data electronically via email.

☐ My email address is _____

☐ I wish to obtain my data via US mail.

My permanent address is _____

_____

_____
Name (Printed) Date

_____
Name (Signed) Date

I **do not** wish to receive my personal results from this study. I **do not** give permission for the investigators of the Voice and Swallowing Service to release me my personal data for my personal records.

_____
Name (Printed) Date

_____
Name (Signed) Date

Protocol # 13-0010 Approved: 7/2/2013
From: 8/1/2013 through: 7/31/2014
James Madison University
Institutional Review Board
CT

Release of Data for Educational Purposes

I give permission for the investigators of the Voice and Swallowing Service to use my individual data for educational purposes at James Madison University and professional conferences (Your data will NOT reveal any personally identifying information). Examples of such usages would include: graphs of your brain responses to different types of stimulation where you are only identified by a participant number or charts of your responses only identifying you by a participant number.

_____

Name (Printed) Date

_____

Name (Signed) Date

I **do not** give permission for the investigators of the Voice and Swallowing Service to use my individual data for educational purposes at James Madison University and professional conferences

_____

Name (Printed) Date

_____

Name (Signed) Date

Permission for Future Contact Release Form

I, _____, have been informed and understand that _____ in the Voice and Swallowing Service and James Madison University is conducting a research study for the advancement of the field of speech-language pathology.

Please choose from the following:

☐ I give _____ (investigators) permission for future contact. I wish to receive a copy of the research manuscript that will be submitted for publication.

☐ I give_____ (investigators) permission for future contact that may include thank you letters and advertisements for future studies. You may contact me via (Check any that apply):

☐ Email address: _____

☐ Mail to home address: _____

_____

☐ Telephone number: _____

_____
Name (Printed) Date

_____
Name (Signed) Date

☐ I **do not** give _____ (investigators) permission for future contact. I **do not** wish to receive thank you letters, advertisements for future studies, or a copy of the research manuscript that will be submitted for publication.

_____
Name (Printed) Date

_____
Name (Signed) Date

Medical History

ID number: _____

Ethnicity (circle one): Hispanic or Latino Not Hispanic or Latino

Race (circle one): American Indian/Alaska Native Asian White

Black or African American Native Hawaiian or other Pacific Islander

Emergency Contact:_____Relationship:_____Phone:_____

Do you have any history of:

Voice disorders (including laryngitis, loss of voice)? YES NO
If YES please list:_____
Did you receive medical attention? ___ What was done? _____

Communication disorders? (Ex: Childhood speech or language problems) YES NO
if YES please list:_____

Brain Injury? (Ex: Car accident, sports injury) YES NO
If YES please list:_____
How many? _____Were you hospitalized?_____

Diseases/disorders? (Ex: Parkinson's Disease, Lyme Disease, Multiple Sclerosis, Tumor, etc.) YES NO
If YES please list:_____

Stroke or Transient Ischemic Attacks (mild stroke)**?** YES NO
If YES please list:_____

Heart disease or heart attacks? YES NO
If YES please list:_____

Do you currently have:

Any diseases or disorders? YES NO
If YES please list:_____
Allergies? YES NO
If YES please list:_____

Any additional relevant medical information? _____