**Title of study**

# Wearable Monitoring Systems for Swallowing Function and Disorders

**NCT #**

**NCT04243577**

**Latest Approval Date**

**10/18/2023**

## Informed Consent

# RESEARCH PARTICIPANT CONSENT FORM

*(For Visit/Session 1)*

## Development and Validation of a Wearable sEMG Monitoring System for Swallowing Function and Disorders

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**Key Information**

Please take time to review this information carefully. This is a research study. Your participation in this study is voluntary which means that you may choose not to participate at any time without penalty or loss of benefits to which you are otherwise entitled. You may ask questions to the researchers about the study whenever you would like. If you decide to take part in the study, you will be asked to sign this form, be sure you understand what you will do and any possible risks or benefits.

- Approximately 15 million individuals in the United States are diagnosed with eating and swallowing problems each year. These individuals experience problems like coughing during meals and things going down the wrong pipe when they swallow. As a result, they often experience serious health issues. We are developing a new wearable device (that goes under the chin) that will help people with swallowing disorders get better. This current study is testing the effectiveness of this new sensor/device compared to commercially available ones. The devices do not transmit any electricity to your skin. They only measure the activity of your muscles during swallowing.
- Participating in this research may require you to come to our laboratory twice. This consent form is for your first visit only. Your first visit will take approximately 150 minutes or 2.5 hours of your time. If you decide to or we ask you to come back for visit 2, you will be asked to review and sign the consent form for visit 2 as well.
- During this first visit, you will be asked to complete some questionnaires, you will complete a quick cognitive screen, and then you will be asked to swallow foods and liquids with the new and the commercial devices in place.

## What is the purpose of this study?

The purpose of this research study is to validate the use of two new wearable sensors that have the ability to measure muscle activity, remotely monitoring your swallowing. You are being asked to participate because you have been identified either as a healthy adult or a patient with swallowing disorders. We plan to enroll a total of approximately 100 healthy adults and 50 patients with swallowing disorders in this study.

## What will I do if I choose to be in this study?

As part of the study, you will undergo a comprehensive evaluation of your swallowing while you are wearing the sensor.

This study may require up to two visits to our laboratory and if you choose or we ask you to participate in both visits, the entire study will take up to a total of 5.5 hours. This consent form is for your first visit only. During your first visit, you will participate in the following procedures that will take approximately 150 minutes (or 2.5 hours):

**In-house screening:** During the in-house screening, the following procedures will be completed and will take approximately 30 minutes:

1. You will complete a short questionnaire about your quality of life related to any difficulties you may have with swallowing.
2. We will perform a quick cognitive screening test that will help us examine your thinking abilities.
3. We will perform a quick cranial nerve examination to check the function of your head and neck muscles.

If you pass the in-house screening, you will participate in the following procedures. If you do not pass the screening, you will not participate in any other study procedures, but your screening data will be used for later analysis.

**Session 1**:

1. First you will be asked to complete a case history form with the help of the investigators or return to us this form completed if you chose to receive this via mail or email during your phone screening. This form includes questions about your age, sex, general health, swallowing and eating difficulties you may be experiencing, and your experiences with technology-related activities of daily living (e.g., use of computer, cell phone).
2. Then, we will first clean your skin under your chin with an alcohol wipe and we will place three types of electromyography (EMG) sensors under your chin, a type that is commercially available and has multiple stickers and separate wires and two types that we developed that have a single patch and collective wires. We will put each pair of sensors one at a time and we will ask you to swallow water, pudding and a pretzel, then complete some swallowing maneuvers typical of swallowing exercises (like, “swallow hard”, “swallow longer”). These sensors will allow us to record your muscle activity when you swallow the foods and liquids we will give you. This procedure is non-invasive and does not transmit any electricity to the skin; it just measures the activity of your muscles when you swallow.

Lastly, you will complete two short questionnaires: a satisfaction questionnaire and a pain questionnaire and we will conduct a visual inspection of your skin immediately after each of the three tests is done and 5 minutes later as well.

This research study will be completed in Lyles-Porter Hall, room 1062 or 3197 (Swallowing Research Clinic or Lab rooms) at Purdue University. Free parking will be provided to you for the duration of the study. Parts of this study may be photographed or videorecorded for research purposes.

**How long will I be in the study?**

This entire study may require up to two visits. The first visit (this consent form is for visit 1 only) will take approximately 150 minutes (or 2.5 hours). Please tell the experimenter at any time if you would like a rest break during your session.

**What are the possible risks or discomforts?**

(a) Minor skin irritation when the surface electromyography electrodes are removed (at the end of the testing) may occur in rare occasions. If this occurs, the investigators will provide you with an Aloe Vera ointment for your skin, which alleviates this symptom. This is very infrequent. If any severe adverse effects are observed, you will be referred to a physician.

(b) Questionnaires: In rare instances, you may be uncomfortable with answering the questions about your health and swallowing problems. Some questions on the screening tool can be frustrating. However, you do not have to answer a question if you do not want to, and you may withdraw from participation at any time. Also, because we are seeking to learn from you, there is no such thing as a "right" or a "wrong" perspective.

(d) Confidentiality: We will make every effort to keep your personal information confidential, as outlined in the Confidentiality section, below. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

(e) Pregnancy: If the participant is or becomes pregnant during this study, the procedure may involve risks to the embryo or fetus, which are currently unforeseeable. The effect of these sensors has not been evaluated in pregnancy. However, no adverse effects have been reported up to date.

(f) SARS-CoV-2: To ensure we minimize the risk of exposure to COVID-19, you will be screened (asked to answer related questions) upon your arrival, a distance of 6+ feet will be maintained between the experimenter and you to the extent possible during the testing, and the experimenters will be wearing a surgical mask and gloves. Further you will be

provided with and asked to wear a surgical mask for the majority of the experiment, if you wish. You may be asked to remove your mask for 1-2 min at a time when a task required involves the face or when you are asked to swallow.

**Are there any potential benefits?**

There are no direct benefits of participation to you. However, the benefits to society may be important. Specifically, the findings from this research will help us test the effectiveness of an innovative dysphagia therapy tool. If proven effective, it may improve quality of care for thousands of patients with swallowing disorders.

**Will I receive payment or other incentive?**

You will receive $25 for the screening and session 1. This money is used to compensate you for time spent during the testing session. If you only participate in the in-house screening, but do not qualify for the study, you will receive $10 for your participation. Your name and address will be provided to the business office of Purdue University for the purpose of facilitating payment for participating in this study.

**Are there costs to me for participation?**

There are no extra costs for you related to your participation in this study.

**Will information about me and my participation be kept confidential?**

Your name and assigned identification number will be maintained by the investigators. Confidentiality will be maintained during all data analyses. Reports of project findings will not identify you. All data will be kept in perpetuity on password-protected computers and servers in a locked room (I-EaT Laboratory: Director Dr. Malandraki) and may be used for comparison in future studies. Only individuals associated with this study will have access to these data.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

The project's research records may be reviewed by the **National Institute of Health** and by departments at Purdue University responsible for regulatory and research oversight.

**Certificate of Confidentiality**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information,

documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. For additional information about CoCs see http://grants.nih.gov/grants/policy/coc/faqs.htm

**What are my rights if I take part in this study?**

You do not have to participate in this research project. The decision to participate or not will not have any effect on your relationship to Purdue University. If you agree to participate, you can withdraw participation at any time without penalty. Please tell the experimenter if you wish to end your participation at any point in the study. If you wish to withdraw your records or data after you have completed your participation, please contact the primary investigator by phone, email, or writing.

**Use of Videotapes and Photographs for Teaching and/or Research**

Please insert your initials on the line below that indicates your preference regarding the use of your video and photographic files for the purpose of teaching and/or research presentations and publications:

_____ I VOLUNTARILY GIVE MY CONSENT or
_____ I DO NOT GIVE MY CONSENT

_____ _____
Initials Date

**Speech Language Hearing Sciences Research Registry**

I grant authorization to Purdue University personnel to contact me regarding participation in future research studies. It is understood that this authorization does not obligate me to participate in any research, and that I may withdraw my authorization at any time. I understand that my decision regarding whether to be contacted in the future will not impact my participation in the current study.

Yes _____ No _____

**Who can I contact if I have questions about the study?**

If you have any questions about this research project, you can contact Dr. Georgia Malandraki at (765) 496-0206.
If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:

Human Research Protection Program - Purdue University
Ernest C. Young Hall, Room 1010
155 S. Grant St.,
West Lafayette, IN 47907-2114

**Documentation of Informed Consent**

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to participate in the research project described above. I will receive a copy of this consent form after I sign it.

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|---|---|
| _____ | _____ |
| Participant's Signature | Date |
| _____ | |
| Participant's Name | _____ |
| _____ | |
| Researcher's Signature | Date |