INFORMED CONSENT (FGID)

STUDY TITLE: A pilot study of auricular microstimulation to determine if it improves vagal modulation

PRINICPAL INVESTIGATOR: Gisela Chelimsky, M.D.

NOTE: In this consent form, "you" always refers to the research participant.
About this consent form:

You are being invited to participate in a research study. It is important that you carefully think about whether being in this study is right for you and your situation.
This consent form is meant to help you in thinking about whether you want to be in this study. Please ask the study doctor or the study staff to explain any information in this consent document that is not clear to you.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled. Not participating in this study will not impact your clinical care.

Why are we asking you to be in this research study?

You are being asked to take part in this study because you are someone who has a functional gastrointestinal disorder (FGID). An FGID is a condition that can change how your body works even though your body parts and organs look normal.

Why are we doing this study and what do we hope to learn from it?

The reason we're doing this study is to learn more about how well transcutaneous electrical nerve stimulation (TENS) units can help the brain communicate with other areas of the body, like your heart, more clearly. TENS units work by using a small electrical current that stimulates your vagal nerve in your nervous system, which is a nerve that controls automatic things that happen in your body without you trying- like your heartbeat, breathing, and sneezing. TENS units use an ear clip to send this current through your body. TENS units should not hurt to use, but you will experience mild feelings of tingling, tapping, buzzing, and/or muscle twitching.

About 30 people will participate in this study.

What will you have to do?

If you take part in this study, you will be doing the following:

- You will be asked some questions and take a pregnancy test to make sure it is safe for you to complete the study.
- You will be asked to come in-person to the Pediatric Research Unit for two visits.
    - Week 0 (Baseline Visit): You will be asked to fill out a few questions that ask about how much some certain symptoms may or may not have been bothering you recently. Then, information about your heart rate will be collected using sticky electrodes that are placed on your chest and stomach for about an hour and 15 minutes. During this measurement, you will be asked to stand up and sit down at different time points. You will also be hooked up to the TENS unit for a portion of the measurement. You will be given instructions and a demonstration on how to use the TENS unit at home.
    - Weeks 0-4 (After baseline): At home, you will use the TENS unit for 2 hours daily. Each day, you will complete a diary that asks when you used the unit, for how long, where on your ears you placed the clips, and whether you are having any problems with the unit or ear discomfort.
        - If you are not able to return for the final study visit at the 4-week mark, you will be asked to continue using your TENS unit and filling out your daily diaries until you can attend the final study visit.
    - Week 4 (or when you are able to return) (Final Visit): You will be asked to fill out the same symptom survey as you did at the first visit. Then, information about your heart rate will be collected using sticky electrodes that are placed on your chest and stomach for 30 minutes. Then, information about your heart rate will be collected again while you are hooked up to the TENS unit for about an hour and 15 minutes. You will be asked to stand and sit at the same times as you did in the first visit, and will be hooked up to the TENS unit for a portion of the measurement. You will also be asked to return your TENS unit at this visit.

Study Calendar

Type of Visit	Week 0 (in-person)	Weeks 0-4 after baseline (at home)	Week 4 (or when you can return) (in-person)

Study Procedures	Heart rate data collection Giving you a TENS unit, instructions, and a demonstration on how to use it at home Symptom questions	Using the TENS unit for 2 hours a day Daily diary	Heart rate data collection Returning TENS unit Symptom questions

How long will the study take?

Your participation in this study will last about 4 weeks. You will use the TENS unit for 2 hours a day. The heart rate data collection at both in- person visits will take about 1.5 hours.

Can anything bad happen to you because of this study?

The TENS unit ear clip may become uncomfortable or annoying to wear. There is a risk that you could have irritation and/or scabbing on your ear from using the TENS machine if you have sensitive skin. We will work with you to avoid this by giving you instructions and a demonstration on how to use the device. You could possibly have a skin reaction from electrodes placed during heart monitoring if you are very sensitive, but these are made with materials that usually do not bother people's skin.

A researcher will check in with you twice over the phone or email while you are using your TENS unit at home to see how you are doing with it. If you are having ear irritation or scabbing in between phone calls, you can report this on your daily diary or contact the study staff via email or phone.

If you have extreme adverse reactions to anything during the study, or if you have a medical emergency, the research team will follow VCU's public safety emergency response process. This could include the following steps:

- Transporting you to the VCU emergency department

Participating in any research study involves the small risk of privacy loss, however this is extremely rare. Your information could be accessed by people who are not involved in the study. We have taken steps to minimize this risk.

- Your data will be stored on password-protected databases or in a locked cabinet that only approved study members can access.
- We will replace your name with a Study ID on your data forms.

Are there any good things that could happen to you while you or others take part in this study?

Using the TENS unit might help your vagal nerve send more clear signals to other parts of your body, like your heart. We do not know if this is the case, hence why we are conducting this study.

We hope to use the results of this study to help find a good treatment for people with FGID in the future.

Will it cost anything for me to be in this study?

No, this study is free for you to participate in.

Will you be paid for taking part in the study?

You, the participant, will receive a mailed check of $25 for completing the first in-person study visit and $75 for completing the second in-person visit.

Do you have to take part in this study? Can you quit the study any time you want to?

You do not have to be in this study, and if you are in it you can stop at any time.
Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal
- if you start on a medication that affects your vagal modulation or gastrointestinal system, which will be assessed by the study doctor on a case-by-case basis

- if the TENS unit makes you too uncomfortable or if you experience severe scabbing or irritation on your ears
- you are not agreeable or unable to use your TENS unit for 2 hours a day

How will my information be protected and shared?

Your information will be kept private on VCU computer systems. Overall study results may be shared with other researchers, but none of your personal information will be shared with them.

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases according to VCU's policies (i.e. for a minimum of 5-6 years). It is only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

If you take a pregnancy test and it is positive, you will be withdrawn from the study as we do not know the effects of TENS unit usage on fetuses. The study doctor or other clinical staff member will talk to you about the positive result.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

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

PROTECTED HEALTH INFORMATION

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires. This type of information is considered "Protected Health Information" and is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

- Medication Information

Who will use or share protected health information about me?

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Other Researchers Outside of VCU
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you

revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at:
Gisela Chelimsky

1000 E Broad Street
Box 80646
Richmond VA 23298

Who should I contact if I have questions about the study after I start?
Gisela Chelimsky, M.D.
Phone: 414-266-3690
Email: Gisela.Chelimsky@vcuhealth.org

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298
Phone: (804) 827-2157
https://research.vcu.edu/human-research/hrppirb/research-participants/

STATEMENT OF CONSENT

Writing my name on this form means that the form was read (by me/to me) and that I agree to be in the study. I know what will happen to me during this study. If I decide to quit the study, all I must do is tell one of the people who are doing the study. All my questions about this form have been answered.

_____ _____

Name of Participant Date

_____ _____

Signature of Participant Date

_____ _____

Name of Person Conducting Consent Discussion Date

_____ _____

Signature of Person Conducting Consent Discussion Date

_____ _____

Signature of Principal Investigator Date