3WAVeS: Three-Axis Wearable Adaptive Vestibular Stimulator

NCT06106256

July 30, 2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **July 30, 2024**
Not to be used after: **July 29, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: 3WAVeS: Three-Axis Wearable Adaptive Vestibular Stimulator

IRB#: 23-002124

Principal Investigator: Gaurav N. Pradhan, PhD and Colleagues

Key Study Information

This section provides a brief summary of the study. The U.S. Department of Defense is funding the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.

It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to improve current Galvanic Vestibular Stimulation (GVS) technology and to reduce motion sickness. You have been asked to take part in this research because you are 21-55 years old, are generally healthy and have no history of balance disorder, severe motion sensitivity, migraines or eye movement disorders.
What's Involved	Study participation involves the completion of two sessions of testing on two different days. Each visit will be approximately one hour long.
Key Information	You will participate in galvanic vestibular stimulation (GVS) which applies low electrical currents to the vestibular system, to induce the realistic sensation of motion (i.e. the g-forces that occur during flight). The vestibular system is a sensory system that is responsible for providing our brain with information about motion and head position.

	GVS uses small sticky pads that are placed around your forehead, behind both ears and back of your neck. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads. During your visits, you may be asked to interact with a Virtual Reality headset and performing a flight simulation task. There is the possibility that you may experience symptoms of motion sickness such as fatigue, headache, nausea and dizziness from using these devices during the session. As a precaution, the study team will provide breaks and please feel free to request additional breaks when needed.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Gaurav N. Pradhan, PhD **Phone:** (480) 301-7730 **Study Team Contact:** Michael Cevette, PhD Jan Stepanek, MD **Phone:** (480) 301-7020 **Institution Name and Address:** Mayo College of Medicine Aerospace Medicine and Vestibular Research Laboratory 13400 E. Shea Blvd. Scottsdale, AZ, 85259
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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 Web site will include a summary of the results. You can search this Web site at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you meet the criteria of this study as follows:

- Age range – 21 to 55 years
- Healthy condition, no history of vestibular disorder, migraine, or significant balance disorder; no history of severe motion sensitivity; not pregnant. No known significant eye movement disorder.

The plan is to have about 40 people take part in the study at Mayo Clinic.

Why is this research study being done?

Galvanic Vestibular Stimulation (GVS) is a well-known method of stimulating the vestibular system into detecting sensations of motion. The purpose of this study is to improve current GVS technology to ease the motion sickness often associated with VR simulation.

Information you should know

Who is Funding the Study?
The U.S. Department of Defense is funding the study and will pay Mayo Clinic to cover the costs related to running the study.

Information Regarding Conflict of Interest:

- This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.
- Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the financial interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this financial interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.

- Additional information is available to any interested study participant regarding the details of this financial interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at (507) 284-0075.
- One or more of the investigators associated with this project and Mayo Clinic have a financial interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

How long will you be in this research study?

There are two study visits each for 1 hour on separate days. Both visits are independent. The duration between two visits will be at least 3 months apart.

You may be contacted to participate either for both visits, or just for the second visit.
If you participate in any one visit (first or second), your visit will be for 1 hour.
If you participate in both visits, your total visit time will be for 2 hours.

We will ask you to make study visits (1 hour/visit) to Mayo Clinic to complete the testing.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

- Galvanic Vestibular Stimulation (GVS)
- Flight simulations in virtual reality (VR)
- Balance force plate system
- Questionnaires

Prior to completing study procedures women of childbearing potential will complete a urine pregnancy test. A negative test is required for study participation.

During the GVS stimulation task, you will be asked to stand on the firm surface/plate. You will be presented moving vertical and/or horizontal bars of alternating black and white either on the projector screen in front of you or in VR headset.

During the flight simulations in VR, you will be asked to do a flying task, a visuomotor task, and a situational awareness task. Before you do these tasks in VR, you will be trained on how to conduct the flight simulations on a computer screen (without VR).

During this study, we will ask you to fill out questionnaires about your general health and well-being, demographics, subjective experiences, motion sickness, and simulator immersion. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will take up to 10 minutes to complete.

You will come to the Aerospace Medicine & Vestibular Research Laboratory and your Visit 1 will take approximately 1 hour. At this visit we will:

- Review and sign the consent form
- GVS Stimulation
- Initial VR flight simulation
- Questionnaires: Pensacola motion sickness questionnaire and Presence Questionnaire

Your Visit 2 will take place at least 3 months after your Visit 1. Visit 2 will take approximately 1 hour. At this visit we will:

- Review and sign the consent form (if you have not participated in the first visit)
- VR flight simulation 1
- VR flight simulation 2
- Questionnaires: Pensacola motion sickness questionnaire and Presence Questionnaire

What are the possible risks or discomforts from being in this research study?

Throughout this study you will be asked to allow the research team to collect information about your subjective experiences and motion perception from flight simulations in virtual reality. You will participate in galvanic vestibular stimulation (GVS) which applies low electrical currents to the vestibular system, to induce the realistic sensation of motion (i.e., the g-forces that occur during flight). GVS uses small sticky pads that are placed around your forehead, behind both ears and back of your neck. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads.

During your visits, you may be asked to interact with a virtual reality headset, joystick and thruster, computer, and/or projector screen. There is the possibility that you may experience symptoms of motion sickness such as fatigue, headache, nausea and dizziness from using these devices during the session. As a precaution, the study team will provide breaks and please feel free to request additional breaks when needed.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

You won't benefit from taking part in this research study. It is for the benefit of research.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather data for research purposes. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Flight simulations in virtual reality (VR)
- Galvanic Vestibular Stimulation (GVS)
- Balance force plate system
- Study related questionnaires
- Urine Pregnancy test (if needed)

There are no other tests and procedures that you and/or your health plan will need to pay.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You may be contacted to participate either for both visits, or just for the second visit.
If you participate in any one visit (first or second), you will receive $150.

If you participate in both visits, you will receive $300; $150 after completion of the first visit, and the remaining $150 after completion of the second visit.

In other words, you will receive $150 for each study visit completed, for a total of up to $300.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. All information collected while on the study will be kept in strict medical confidence. You will only be identified by code, not by name. Information will be saved on password protected computers. Representatives of the U.S. Department of Defense will have access to research records as part of their responsibilities for human subjects' protection oversight of the study.

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During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other healthcare providers involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- U.S. Department of Defense may have access to protected health information collected for the study.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building, PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

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Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature