Non-pharmaceutical Motion Sickness Mitigation

NCT04859868

August 24, 2022

MAYO CLINIC

Name and Clinic Number

Approval Date: **August 24, 2022**
Not to be used after: **August 23, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Non-pharmaceutical motion sickness mitigation

IRB#: 20-005763

Principal Investigator: Gaurav N. Pradhan and Colleagues

Key Study Information

This section provides a brief summary of 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 validate the effects of Galvanic Vestibular Stimulation (GVS) to reduce motion sickness and understand the effect on human performance. You have been asked to take part in this research because you meet the criteria of this study as follows: • Age range – 21 to 55 years • Healthy condition, no history of vestibular disorder, migraine, traumatic brain injury, significant balance disorder or recent middle ear infection; no history of severe motion sensitivity; not pregnant.

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What's Involved	You will attend four visits of the experiment on four separate days. Each visit will be an hour and a half long. In the first visit, you will perform batteries of tests that involve balance, cognition, and determine motion perception at different current levels using a rotating chair. In the next three visits, we will test the GVS to mitigate motion sickness in the rotating chair by either turning stimulation ON from beginning, or middle or by not turning ON (the order will be randomized).
Key Information	Throughout this study, you will be asked to allow the research team to collect information about your subjective experiences and motion perception from the rotation of the chair. There is the possibility you may become uncomfortable during the study due to chair rotation. 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 joystick and rotating chair. 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

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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, traumatic brain injury, significant balance disorder or recent middle ear infection; no history of severe motion sensitivity; not pregnant

Why is this research study being done?

The purpose of this research is to validate the effects of Galvanic Vestibular Stimulation (GVS) to mitigate motion sickness and understand the effect on human performance. GVS is a process of applying low electrical currents to the vestibular system and is used to induce the realistic sensation of motion (i.e. the g-forces that occur during flight) as well as null out motion perception.

Information you should know

Who is Funding the Study?

The National Aeronautics and Space Administration (NASA) is funding the study. NASA will pay the institution to cover 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?

We will ask you to make four study visits on four separate days with at least two days apart. Each visit will be an hour and a half long.

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:

- Physiological measurements such as electrogastrogram (EGG), eye-tracking, and end-tidal carbon dioxide ($ETCO_2$).
- Flight simulations in virtual reality (VR)
- Galvanic Vestibular Stimulation (GVS)
- Gyrostim – a multi-axis rotating chair
- Cognitive Test
- Balance Performance Test
- Questionnaires

Only women will perform urine pregnancy test and will continue to participate in the study only after the results are negative.

You will come to the Aerospace Medicine & Vestibular Research Laboratory and each visit will take up to an hour and a half long. There will be at least two days between each visit.

First Visit:
On your first visit you will complete a balance performance test, cognitive test that involves eye-tracking, and flight simulation in VR. Then you will be sitting in the Gyrostim chair. You will be completely secured in the chair with adjustable 5-point harness system, lap belt, and ankle restraints.

You will begin with GyroStim training with slow, predictable motion profiles. This will allow you an opportunity to become acquainted with the sensations and activities involved during the experiment without experiencing motion discomfort or sensory overload.

After your training on the Gyrostim chair, we will record your motion perception by rotating you in the chair along the yaw (vertical) axis with the simultaneous application of GVS. There will be up to five trials of yaw motion at different current amplitudes. Each trial will be only for one minute. And you will get a break for up to two minutes after every trial where the chair will be at the regular sitting position.

During the motion in the chair, we will hand you a joystick to record your motion perception. You will operate the joystick in the same direction as you feel the motion.

During this study, we will ask you to fill out questionnaires about your general health and well-being, demographics, subjective experiences, and motion sickness. 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 5 minutes to complete.

Next three visits:
You will be sitting in the Gyrostim chair for most of the experiments in these visits. You will participate in an electrogastrogram (EGG) test, which uses small sticky pads that are placed on your stomach to measure the activity of your stomach muscles throughout the experiment. We will follow the same procedure in the chair as the first visit.

In all three visits, there will be ten trials of chair rotation. Each trial will be 3 minutes long. In each trial you will be cued to perform head movements every 10 seconds, alternating between pitch forward (chin resting on the chest) and pitch backward (head upright). During one trial of 3 minutes, you will perform nine forward/backward movements. There will be a short pause following each set of 9 forward/backward movements (3 min) to review symptoms, although motion sickness symptoms will be obtained throughout the test protocol using verbal reports.

In these three visits, the only difference will be the application of GVS. GVS will be ON for all ten trials, or GVS will be ON after the fourth trial, or GVS will not be ON at all.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

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 cognitive performance, subjective experiences, and physiological responses from sensors to flight simulations in virtual reality. There is the possibility one of the sensors may become uncomfortable during the study. In this case, tell a study representative.

Throughout this study, you will be asked to allow the research team to collect information about your subjective experiences and motion perception from the rotation of the chair. There is the possibility that you may experience symptoms of motion sickness such as fatigue, headache, nausea and dizziness during the study due to chair rotation. If this happens, please tell a study representative.

You will participate in an electrogastrogram (EGG) test which uses small sticky pads that are placed on your stomach to measure the activity of your stomach muscles. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads. The hair in the abdominal region may need to be shaved prior to the placement of the sticky pads.

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, computer, and/or projector screen. There is the possibility that you may become tired 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:

- Physiological measurements, electrogastrogram (EGG), eye-tracking, and end-tidal carbon dioxide ($ETCO_2$).
- Flight simulations in virtual reality (VR)
- Galvanic Vestibular Stimulation (GVS)
- Gyrostim chair testing
- Urine pregnancy test
- Oculo-Cognitive Addition Test (OCAT)
- Balance Performance Test
- Timed up and go Test

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 will receive $300 for completing the entire study. If you start the study but stop before finishing the study - you will receive prorated remuneration.

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?

Urine samples collected for the pregnancy test required to meet the eligibility criteria of this study will be discarded after the results are confirmed.

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information 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. The Mayo Clinic will de-identify all data with IRB approved procedures such as assigning research numbers, storing research materials in locked cabinets, and password-protecting data stored on a computer. Only the study team will have access to the ledger with your research number, which is kept on a password-protected computer separate from any of the data collection or processing systems. The team will follow data security protocols to ensure that only study personnel come into contact with individual and aggregate data. If the results of the research are made public, information that identifies you will not be used.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

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.
- Researchers involved in this study at other institutions.
- 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.

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
201 Building 4-60
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