University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: Sensory Training for Visual Motion Sickness

Formal Study Title: High-precision Immersive Robotic Environment for Sensorimotor Training

Lead Researcher: Dr. Kreg Gruben; 608-262-2711

Where Lead Researcher works: Department of Kinesiology,
University of Wisconsin-Madison (UW-Madison)

Invitation

We invite you to take part in a research study about how information from body sensations can be used to treat visual motion sickness. We are inviting you because you experience dizziness and/or imbalance that is triggered watching things move.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are the researchers doing this study?

We created new tests of orientation and balance, as well as a new treatment for visually-induced dizziness. The new tests are designed to measure how well a person can sense the direction of gravity without using vision. The new treatment is designed to improve one’s ability to sense the direction of gravity, again, without using vision. You can think of the direction of gravity as the direction that an object would fall if you let it drop from your hand.

IRB Approval Date: 1/5/2021
University of Wisconsin – Madison

This is a study of the new treatment and how well the new tests measure the effectiveness of the treatment. Our main goals for this study are to show that the new tests are accurate and measure what they are supposed to measure and to show whether the new treatment is effective at reducing dizziness and improving balance.

This study is being done at the UW-Madison. A total of 30 people will participate in this study.

Funding for this study is provided by the UW-Madison Institute for Clinical and Translational Research through a grant provided by the National Institutes of Health.

What will happen in this study?

If you decide to participate in this research study and you are eligible, the researchers will ask you to complete questionnaires about dizziness, balance, and life activities; clinical tests of standing balance and walking, as well as a training program for orientation and balance.

We will ask you to complete the questionnaires through a secure website or in-person. You will complete questionnaires prior to, during, and after completing the training program. You may skip any question on the questionnaires that you do not wish to answer. Some of these questionnaires are similar to each other, but each is used for a slightly different purpose or in different situations.

You will complete the following questionnaires:

- Visual Vertigo Analogue Scale, a measure of visually-induced dizziness
- Vision-related Dizziness Questionnaire, a measure of visually-induced dizziness
- Dizziness Handicap Inventory, a measure of the impact of dizziness on physical , emotional, and functional health
- Activities-specific Balance Confidence Scale, a measure of balance-related self-confidence
- Vestibular Activities and Participation Measure, a measure of the impact of inner-ear problems on daily activities and responsibilities
- Vestibular Rehabilitation Benefits Questionnaire, a measure of how much a person benefited from a treatment program for dizziness and imbalance

You will do these tests at the UW-Madison Neuromuscular Coordination Laboratory:

- Subjective Visual Vertical Test, a measure of the sense of vertical
- Rod and Frame Test, a measure of the influence of vision on orientation
- Rod and Disk Test, a measure of the influence of motion on orientation
- Multisensory Balance Test, a measure of the forces under your feet while standing on a stationary rigid surface. This test is experimental.

- Functional Gait Assessment, a measure of walking-related balance
- Walking Speed, a measure of how long it takes a person can walk a short distance.

The training program will be done at the Neuromuscular Coordination Laboratory. The researchers will give you specific instructions for how to find the research lab. Free parking is available.

You will visit the lab a total of 8 times. The testing sessions last 45-60 minutes. The training program involves 6 sessions that last approximately 60 minutes each.

The training program in this study is experimental. The training sessions will be conducted 6 times within 3 weeks. Two rounds of training will be done during each training session. Each round of training lasts 15 minutes. During the training, you will be asked to figure out if a line that is shown to you using virtual-reality goggles is vertical or tilted left or right of vertical. The training is done in complete darkness while you are supported with padded straps in a standing position in a device that allows the researchers to position your body in vertical or tilted left or right of vertical. You may ask to take breaks during the training. A break will also be required after approximately 15 minutes of training. During the breaks, the virtual reality goggles may be removed, and you may sit down. You will receive feedback about how you are doing. The training will become more challenging as you progress.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your health

How long will I be in this study?

You will be part of the study for about 5 weeks. This includes the time required to complete the training sessions, as well as questionnaires and testing done before and after training.

The researchers may take you out of the study, even if you want to continue, if

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study

- the study is stopped by the researchers

How is being in this study different from my regular health care?

- There is no single standard treatment for dizziness and/or balance problems. As part of their regular health care, people might get medications, surgery, physical therapy, or no treatment at all. Everyone who takes part in this study will get the training program described in this consent form.
- This study is not part of your health care.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study. There are no risks associated with leaving the study. No matter what decision you make, and even if your decision changes, there will be no penalty to you. or any legal rights.

What if I am a UW Health Patient?

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. You will not lose medical care.

What if I am a UW-Madison student?

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect your class standing at the University of Wisconsin-Madison.

What if I am a UW-Madison or UW Health employee?

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect your employment at the University of Wisconsin-Madison, any organizations affiliated with UW-Madison, or UW Health.

Your authorization for the researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for the researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Dr. Kreg Gruben, at 1081 Gymnasium-Natatorium, 2000 Observatory Drive, Madison, WI, 53706-1121

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get care for your dizziness and/or imbalance. If you decide to not take part in the study, you have other choices. For example:

- you may choose to get the regular care described above for dizziness and/or imbalance
- you may choose to take part in a different study, if one is available

Will being in this study help me in any way?

<u>The training program used in this study is experimental.</u>

- If you have dizziness and/or imbalance, being in this study may reduce your dizziness and/or help you have better balance. The study treatment may work better than the alternatives described above, but we cannot promise this will happen. The study treatment might not work at all, or it might have side effects. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us learn more about how the brain and balance systems function.
- This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

Will I receive the results of research tests?

All of the tests that are part of this study are for research purposes only. Because of this, we will not tell you or your doctors the results of these research tests. If you have general questions, you may discuss them with the study team.

If you have additional questions or concerns about your health, contact your primary care provider. You (or your insurance company) will be responsible for costs related to any follow-up care.

What are the risks?

The most common risks associated with this study include fatigue, headaches, joint discomfort, and eye strain. Less common risks include temporary dizziness or feeling faint during testing or training and falls may occur during balance tests. We have developed procedures to minimize the chances of these things happening. For example, taking rest breaks may help manage symptoms. Also, a member of the research team will guard your safety during balance tests and you will be in a harness for balance tests and during training. We encourage you to let the researchers know if you experience any symptoms during testing and training. There is a risk that your information could become known to someone not involved in this study.

Will being in this study cost me anything?

- There will be no cost to you for any of the study activities or procedures. You will have to pay for basic expenses like any childcare, food, or transportation related to study activities.

Will I be paid or receive anything for being in this study?

- The study team will arrange for free parking at the Neuromuscular Coordination Laboratory.
- We will pay you up to $250 for participating in this study. Payment will be provided several weeks after the end of your participation in the study.
- Researchers may develop products from information you provide for this study. Some of these products may have commercial value. If the research team or others use your information to develop products of commercial value, you will not receive any profits from products created from your samples or information.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular health care provider.

- Call the Lead Researcher, Dr. Kreg Gruben, at 608-262-2711 to report your sickness or injury.

How will the researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to abuse or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- The National Institutes of Healthy
- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- Collaborating researchers outside UW-Madison, including Susan L. Whitney, PT, PhD, a research advisor at the University of Pittsburgh who is also overseeing this study
- A description of this research will be available on http://www.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.

Will information from this study go in my medical record?

- None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

What if I have questions?

If you have questions about this research, please contact the Study Coordinator, Dr. Colin Grove, at UWNCL_Lab@outlook.com or Dr. Kreg Gruben at 608-262-2711. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Why does the research team want to use email to contact me?

You do not have to provide your email address to participate in this study. We are requesting your email address so we can provide study-related instructions and information, visit information, and links to our secure database where you will complete study-related questionnaires. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone by phone, please contact Dr. Gruben or Dr. Grove at 608-262-2711. If you wish to contact the study team using email, please write to UWNCL_Lab@outlook.com.

Agreement to Participate in the Research Study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Printed Name of Research Participant

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Signature of Research Participant Date

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Email of Research Participant

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Phone Number of Research Participant

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Signature of Person Obtaining Consent and Authorization Date

****You will receive a copy of this form****