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STUDY INFORMATION:

Study Title: Vestibular Rehabilitation utilizing Virtual Environments to Train Sensory Integration for Postural Control in a Functional Context

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to see if a new virtual reality (VR) study device is better than regular treatment for people with vestibular problems (disease of the inner ear). Current treatments include, for example, balance and walking exercises but do not always relate to real life situations. With the new VR study device you can train your balance in virtual environments that look like real life, and the therapist can make the exercises easier or harder

If you choose to participate, you will be asked to do 2 balance assessment sessions (each up to 90 minutes long); 8 sessions of vestibular therapy (each 30 minutes long) and another assessment session (up to 90 minutes long). Depending on the group you are placed into your sessions may include traditional exercises or virtual reality exercises. In both cases you will also perform exercises at home. There will be no cost associated with participation. You will receive compensation in the form of a gift card for the first 2 assessment sessions and the last assessment session if you complete the program.

The main risks to you if you choose to participate are dizziness and instability. These risks are no more than normal risks involved in vestibular rehabilitation.

You may also benefit from participation in this research with a decrease in dizziness and improved balance.

Instead of participating in this research, you may continue with traditional vestibular therapy.

If you are interested in learning more about this study, please continue to read below.

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PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you have dizziness and imbalance related to a vestibular (inner ear) problem.

Funds for conducting this research are provided by REACT NIH.

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.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 12 to 16 weeks.

The number of people expected to take part in this research study at New York Eye and Ear Infirmary of Mount Sinai is 28.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

- *Assessment of Balance will take place at the New York University, Department of Physical Therapy Human Performance Lab. This lab is located at the same building as the Ear Institute (3rd floor). The sessions will take place at the Ear Institute (380 2nd Ave, 9th floor).*
- *For the assessments you will do the following:*
  - *Complete several questionnaires about your demographics, dizziness, balance confidence, and anxiety. You can choose to skip questions or an entire questionnaire. All of your responses will be de-identified and we will only write your random ID number at the top of the questionnaire (not your name)*
  - *Complete tests of walking and balance*
  - *Stand on a force platform while wearing a virtual reality headset, observing different scenes and listening to sounds. While you're doing that we will record your movements under your feet and your head movements. We are not recording a video of you.*
  - *These procedures will take place regardless of which group you will be in.*

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- *You can choose to stop the assessment at any time. We will monitor your symptoms and take rest breaks as needed.*
- *The assessment will take up to 30 minutes. We will repeat the assessment within 1-2 weeks before you start the regimen.*

- *After the assessment you will be placed into one of two* study *groups.*
  The study group you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what experimental study group you get. You will have an equal chance of being given each experimental study device.

  - Training with the study device *will continue for 8 sessions, each 30 minutes long.*

    - *If you are assigned into the virtual reality group, you will perform balance exercises while wearing a virtual reality headset. You will see and hear different environments and your exercises will be guided by a physical therapist.*
    - *If you are assigned into the traditional rehabilitation group, you will perform balance exercises in the clinic guided by a physical therapist. This is the standard clinical care for vestibular rehabilitation.*
  - *Both groups will perform a home exercise program.*

Clinically Relevant Research Results

Clinically relevant research results, including individual research results, will be disclosed to subjects, at the conclusion of the study, and upon subject's request.

USE OF YOUR DATA AND/OR SPECIMENS:

In the future, your identifiable information may be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

The researchers would like to ask your permission to keep the data collected from you during this study to use them in future research studies. Please tell us how we may use this material in future research studies. Your data, with or without identifiers, may be used for commercial profit and you will not share in this profit.
(1) Will you allow the researchers to store your information and/or specimens to use in future research studies? Please initial next to your choice below.

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Yes_____ No_____ If no, please stop here. If yes, please continue to the next question.

(2) The researchers can keep your information and/or specimens stored in one of two different ways: one way will store your information and/or specimens in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will store your information and/or specimens anonymously (no one will know who the information is from). It will not be stored both ways, so you must choose one of these two options. Please note that if you choose to have your information and/or specimens stored anonymously, you will not be able to change your mind to ask for your information and/or specimens to be destroyed at a future date. How would you like your information and/or specimens stored? Please initial **ONE** choice:

I would like my information and/or specimens stored with a link to my identity_____
I would like my information and/or specimens stored anonymously _____

(3) Do you give the researchers permission to **contact you** in the future to collect additional information about you, discuss how your information and/or specimens might be used, or to discuss possible participation in another research project? Please initial your choice:

Yes_____ No_____

(4) Do you give the researchers permission to keep the information and/or specimens indefinitely and use them for future studies that are **directly related** to the purpose of the current study? Please initial your choice:

Yes_____ No_____

(5) Do you give the researchers permission to keep the information and/or specimens indefinitely and use them for future studies that are **not related** to the purpose of the current study (for example, a different area of research)? Please initial your choice:

Yes_____ No_____

(5.1) From time to time researchers outside of medicine and related sciences would like to use this information. This might be in the field of anthropology, human origins, mapping human migration patterns etc. Do you give permission to use your information and/or specimens outside the fields of medicine and biological sciences? Please initial your choice:

Yes_____ No_____

(a) If the future research in a different area can be done without having to know that the information and/or specimens came from you personally, that will be done.
(b) If the future research in a different area requires that it is known specifically who the information

and/or specimens came from, then one of the following will be done:
(i) If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your identifiable information or specimen is needed and what will be done with it. Your permission will be asked to use your information and/or specimens in that research project.
(ii) If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical, for example, because you have moved, your identifiable data and specimens may still be used.

(6) Do you give permission to have portions of the specimens and/or information given **to other researchers,** including those at Mount Sinai, other academic institutions and for profit companies, for use in research within the limits you have chosen above? Please initial your choice:

Yes_____ No_____

(7) Do you give permission to have portions of the specimens and/or data **deposited in large public repositories, (explained below)** for use in research with the limits you may have chosen above? Please initial your choice:

Yes_____ No_____

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai or another institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

- attending all sessions and performing a home exercise program.

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COSTS:

You will have no costs associated with this study.

PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you $20 per assessment session in the form of a gift card (at the end of each session) if you participate in 2 assessment sessions prior to using the study device and 1 session after the study device . You will not be reimbursed for transportation.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be a decrease in dizziness and imbalance.

ALTERNATIVES:

You do not have to participate in this research study to receive treatment for your condition.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Physical risks: during the assessment and the study sessions you might get dizzy or experience other symptoms. We will take rest breaks as needed. You can choose to stop the experiment at any time.
- Psychological risks: if you feel uncomfortable answering any of the questionnaires question you can choose not answering.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

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- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database

Instead of being in this research study, your choices may include: participating in traditional vestibular rehabilitation without being involved in a research study.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

No other compensation will be offered by the Sponsor, Mount Saini Health System, or the Biomedical Research Alliance of New York.

You are not waiving any legal right to seek additional compensation through the courts by signing this form.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

Your participation in this study is voluntary. You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. There will be no adverse consequences to you because of withdrawing from the research.

If you decide you don't want your samples and/or data to be used for research anymore, you can contact the researcher and ask to have your samples and/or data removed from future use. If any samples or data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. Any samples and/or data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your samples and/or data will take place. If your samples have already been deposited in an external repository, the study team will request that your samples be removed.

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Withdrawal without your consent: The study doctor, the sponsor, the institution, the FDA, or other regulatory authorities may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number 646-438-7868
If you experience an emergency during your participation in this research, contact 911.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be

presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done,

and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

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.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

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The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as including research data in the medical record.

Notice Concerning HIV-Related Information

HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights or New York City Commission on Human Rights. These agencies are responsible for protecting your rights.

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ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of Witness	Printed Name of Witness	Date	Time