Treatments of Mal de Debarquement Syndrome (MdDS) by Habituation of Velocity Storage
PI: Sergei Yakushin, Ph.D.
NCT04213079
Document Date: 8-24-2021

**Form Version Date:8/22/2021**

**STUDY INFORMATION:**

**Study Title:** Treatments of Mal de Debarquement Syndrome (MdDS) by habituation of Velocity Storage

**Principal Investigator (Head Researcher):** Sergei Yakushin, PhD

**Physical Address:** [redacted]

**Mailing Address:** One Gustave L Levy Place Box 1135, NY, NY 10029

**Phone:** 212-241-9349

**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.

Mal de Debarquement Syndrome (MdDS) is an under-recognized balance disorder, which in most cases occurs after exposure to prolonged passive motion (for example, a cruise). MdDS is manifested by constant rocking and/or swaying and by the gravitational pull of the body. It is accompanied by high sensitivity to light, noise, crowds, and cognitive dysfunctions (thinking difficulty), including short-term memory loss. In addition to motion-triggered MdDS, similar symptoms also occur without a clear trigger, identified as spontaneous MdDS. Recently, we developed an effective treatment method for MdDS based on the training of the vestibulo-ocular reflex (VOR), the reflex that reorients the eye movement to a position when the head is in motion. The VOR is the body's system of using the inner ear and vision to walk and stand against gravity. In this project, 60 MdDS patients with no history of inner ear problems and no severe neurological problems will be randomly assigned (like flipping a coin) into two groups. Group 1 will be treated with the habituation (reduction of velocity storage) protocol only. Habituation (the process of change) reduces the response time of eye movement due to rotation, and Group 2 will be treated with the VOR readaptation (re-training) protocol only. Patients will be followed up for up to 6 months by phone call. This study may potentially offer additional treatment options for MdDS and increase the current understanding of recurrent MdDS.

The purpose of this research study is to compare the effectiveness of two different ways to treat MdDS.

If you choose to participate, you will be asked to:

- Five consecutive (in a row) visits about 1.5-2.5 hours each.
- Follow-up questionnaires for symptoms will be obtained at 2 weeks, 1 month, 3 months, and 6 months after the treatment by phone. If it is more convenient for you, follow-up could be done in person or by email whichever you choose.

- Readaptation of vestibulo-ocular reflex or habituation of vestibulo-ocular reflex. Both protocols could induce small nausea or head pressure (headache). In both treatments, a patient sees full-field visual surrounding move, which may cause discomfort.
- Standard clinical Vestibular Nystagmography (VNG) test should be obtained locally prior to treatment. Alternatively it could be done on a first day of treatment. If this test is abnormal, you may be excluded from the study. A clinical VNG test is designed to determine abnormality of the inner ear. During the test, the patient sits in a rotating chair inside of circular chamber one yard in diameter. The test includes brief chair rotations in darkness, following with your eyes a visual target that moves in different directions. Test also includes colorization of the inner ear. During this test, patient is lying on a tilt table in supine (on his/her back) with the head elevated. Each ear is irrigated with air for 1 min, and the eye movement is recorded in darkness for another 1 min. The right and left ears are irrigated (with air) sequentially (one after the other) at temperatures 48°C and 18°C.
- There are no costs associated with participation
- The questionnaire will be obtained before and after treatment and on follow-ups.
- There is no compensation for participation in this study.
- You are asked not to share the results of your treatment on public media until the entire study is completed.
- After treatment is completed, you will not be able to receive the alternative treatment until your last phone call assessment at 6 months.

The main risks to you if you choose to participate are mild nausea or head pressure (headache sensation). Also, that treatment could potentially (5-30 min) increase your MdDS symptoms.

Instead of participating in this research, you may decide to be treated clinically. Feel free to discuss this with your doctor.

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

**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 are in age range 18-78
- You stay within 1 hour from Human Balance Center

- You report the following symptoms: sensation of oscillatory vertigo (rocking, swaying, bobbing, walking on a trampoline, gravitational pull) symptoms started after prolong transportation or suddenly; symptoms temporarily stop during passive transportation such as a car ride; Symptoms are present when laying down, sitting, and standing

Funds for conducting this research are provided by National Institute of Health/ National Institute of Deaf and Other Communication Disorders (NIH/NIDCD)

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 six months. The first five days are the screening followed by treatment days (1.5-2.5 hours per day). You also will be asked to complete follow-up questionnaires at 2 weeks, 1 month, 3 months, and 6 months after the treatment by telephone. You can do these in person if this is easier. These phone sessions are approximately 15 minutes.

The number of people expected to take part in this research study at Human Balance Laboratory at Neurology Department of Icahn School of Medicine at Mount Sinai is 60 people to achieve a total of 52 patients who complete the entire study. The overall enrollment goal is to compare the effectiveness of two methods in MdDS treatment.

**DESCRIPTION OF WHAT'S INVOLVED:**

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

- You will be consented over the phone after receiving a copy of the consent form to perform a screening for you to be eligible for the study.
- Once determined you are eligible, you will come to your appointment time located at 1428 Madison Avenue, 1st floor, rooms 04/08, where you will sign the consent form and a copy will be provided.
- On the first day VNG test will be performed. During this test, you will sit in a small chair in a small chamber (like a closet) in darkness, wearing a helmet with a video camera looking into your right eye. The chair will be rotated in darkness for 1-2 minutes, and eye positional data in response to rotation will be collected over 15-20 min in total.
- Calorization of both ears will be performed unless you provide a recent (since the onset of your MdDS) report from another clinic. During this test, the patient is lying on a tilt table supine (on his/her back) with head elevated. Each ear is irrigated (continuous flow) with air for 1 min and the eye

motion is recorded in darkness for another 1 min. Right and left ears will be irrigated sequentially at temperatures 48°C (warm) and 18°C (cool).

- Postural data with the eye open and closed while standing on a stationary board will be collected for approximal 1 min in each condition.
- You will complete questionnaires about your MdDS on the first and last days of your treatment and on the phone call follow-ups. These questionnaires ask about your treatment and symptoms.
- Depending on your assignment to one of 2 groups: Group 1 will watch stripes, and the chair will be moved while you watch them for about 1 hour a day in 20 min increments. Group 2 will watch stripes going to the left or to the right while the operator standing behind you moves your head side-to-side or up-down for several minutes for about 1 hour total time.

- The study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what experimental study treatment you get. You will have a 50:50 chance of being assigned to a particular treatment group

**USE OF YOUR DATA AND/OR SPECIMENS:**

Future Research - Your identifiable information will be removed from the private information and/or data 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.

Since data obtained in this study are unique and may benefit other patients suffering from MdDS, 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.

**(1)** Will you allow the researchers to store your information and/or data to use in future research studies? Please initial your choice.

Yes _____ No_____

**(2)** The researchers can keep your information and/or data stored in one of two different ways: one way will store your information and/or data 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 stored with out a link to my identity.

**(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 data 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 data 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 data 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 data outside the fields of medicine and biological sciences? Please initial your choice:

Yes _____ No____

If the future research in a different area can be done without having to know that the information and/or data came from you personally, that will be done.
**(a)** If the future research in a different area requires that it is known specifically who the information and/or data 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 data is needed and what will be done with it. Your permission will be asked to use your information and/or data 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 data may still be used. The Institutional Review Board (IRB) will be asked for permission to use the information and/or data linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the information and/or data will not be more than a minimal risk to you or your privacy. The Institutional Review Board (IRB) is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

**(6)** Do you give permission to have portions of the data 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 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, the federal government maintains some, and some are maintained by private companies. For example, the National Institutes of Health (a federal government agency) 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: To participate in initial assessment session and in at least 4 treatment sessions, to complete phone call questionnaires at 2 weeks, 1 month, 3 months, and 6 months after the treatment. Do not discuss results of your treatment on public media until the entire study is completed.

## COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. You will not be reimbursed for your travel, accommodation in New York or time that may be required for study visits.

## 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 that your MdDS symptoms will be significantly lessened or cure. Furthermore, depending on the group that you are assigned you could have a potential improvement in your MdDS symptoms.

- Treatment could temporary increase MdDS symptoms.
- Treatment can trigger migraine which could last up to a week.
- Treatment could induce some motion sickness symptoms.
- 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 age 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 age or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

## REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Treatment could temporarily increase your MdDS symptoms
- Treatment could cause some motion sickness symptoms, but many individuals report that these are mild stop after a few days.
- Treatment could trigger a migraine which could last up to week, but this is rare, and most individuals report on a mild headache.
- 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 age, 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 age, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

**OTHER POSSIBLE OPTIONS TO CONSIDER:**

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Alternatively, you could choose to be treated outside of this study by a neurologist who has expertise in such treatment of MdDS with medications they may recommend.

After a six-month follow-up is completed, you have an option to come back and receive the same or alternative treatment free of charge.

**IN CASE OF INJURY DURING THIS RESEARCH STUDY:**

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

**ENDING PARTICIPATION IN THE RESEARCH STUDY:**

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.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your 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. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Withdrawal without your consent: The principal investigator or the institution 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 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 the phone number (212) 241-9349.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at the telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this 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:**

As you take part in this research project, it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, country and state of residence, age sex, telephone numbers e-mail address.

The researchers will also get information about your medical conditions. This information comes from the Patient's intake form.

During the study, the researchers will gather information by:

- completing the tests, procedures, questionnaires, and interviews explained in the description section of this consent.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study, as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events but would not include any information that would let others know who you are unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?
In almost all disclosures outside of Mount Sinai, you will not be identified by name, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA), will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information? Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will not be able to access your treatment records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your treatment record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

**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 were freely given by the subject.

| Signature of Witness | Printed Name of Witness | Date | Time |
|---|---|---|---|