
STUDY INFORMATION:

Study Title: Vestibular Caloric Stimulation and the Modulation of Pain in Fibromyalgia: A Randomized Controlled Study

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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 help people diagnosed with fibromyalgia: a disease of chronic widespread body pain. There are three medications currently approved by the Food and Drug Administration (FDA) for fibromyalgia, though there are still many people who live with an unacceptable burden of pain, fatigue and associated poor quality of life. There is a small amount of data to suggest that pouring water into ears of people with certain pain syndromes could help them feel better. We are conducting this study to formally evaluate this procedure in fibromyalgia: we'd like to see if it helps people with fibromyalgia to feel less pain and enjoy a better quality of life.

If you choose to participate you could expect to fill out some information about your pain and associated symptoms. You would then fill out a daily survey about your pain using your smart phone or computer. The daily survey is expected to take less than two minutes. You would then come to our clinic once for water treatment into your external ears. The procedure itself is simple and is described in more detail below. If you decide to participate in this study, you will need to pay for your transportation to and from the hospital. There are no blood tests or needles.

Depending on the temperature of the water, it could be uncomfortable for a brief period of time and may be associated with some dizziness and/or nausea. These effects, if they occur, are not indicative of danger and are brief, resolving quickly over seconds to minutes. Further, water may spill on your skin or clothes. We will take extra precautions to keep you dry.

You may benefit from participation in this research if the treatment helps your pain, fatigue and/or improves your quality of life. There are some interesting small studies done in patients with other kinds of pain who report improvement with this procedure though it remains to be seen if it will be effective in fibromyalgia (that's why we're doing this study).

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 have widespread pains consistent with fibromyalgia and, despite your current medications and treatment plan, still experience a significant amount of pain.

Funds for conducting this research are provided by Mount Sinai. We're not working with any financial sponsors or drug companies.

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 three weeks. Throughout this three week period you will come to our clinic only once. Your clinic appointment will involve a water treatment into both ears. Before and after your appointment, we're going to ask you to rate your pain daily on an online scale. 38-50 people are expected to take part in this research study at Mount Sinai.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, you will complete some information at the outset that helps us understand your level of pain and how it affects you. We will then welcome you to our clinic.. This encounter is expected to take approximately thirty minutes in total. It only takes about a minute to pour water in the ear canals: most of the time will be spent checking in, getting comfortable and resting after the procedure.

During your appointment, you will lay down comfortably and an investigator will look inside your ears to make sure they're clean. If there's an abundance of wax, it will be cleaned out. The investigator will then gently pour water into the each ear canal, one ear at a time, for about 30 seconds each (60 seconds total). The temperature of the water will vary between 4°C and 20°C. Half of the participants will be randomly assigned, like flipping a coin, to receive 4°C water and the second half will receive 20°C water. As noted above, you may get a bit wet though we'll take all precautions to minimize this. You may also experience discomfort in your ear, dizziness and/or nausea, all of which are expected to resolve in seconds to minutes. After the procedure you will rest until you feel ready to return home and will then complete a brief post procedure survey about your pain. We will be asking you to rate your pain each day on an online ten point scale: this is not anticipated to take more than two minutes of your time each day. If you'd like to participate, you will need to pay for your own transportation to and from the clinic. We ask that you abstain from driving yourself after this procedure. There are no blood tests or needles.

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USE OF YOUR DATA AND/OR SPECIMENS:

The private information and/or samples collected as part of this research will never be used or shared for future research, even if the identifiable information is removed.

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_____

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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: coming to clinic once for a thirty minute appointment to receive water treatment into both ears, arriving on time, completing a daily brief online pain scale which will take roughly 2 minutes per day for three weeks.

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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 or time that may be required for study visits.

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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 improvement in pain, fatigue and/or quality of life.

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REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Wet clothes
- Discomfort in the ear, dizziness, nausea (happens approximately fifty percent of the time, all reversible within seconds to minutes).
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).
- If you are or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks might be minor or might be major (death) for the pregnancy. You should not become pregnant or impregnate a woman while on this research study.

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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. Instead of being in this research study, your choices may include supportive care, trial of other oral medications or non-pharmacologic interventions. The important risks and possible benefits of these alternatives need to be discussed with your primary physician.

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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.

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.

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. You may opt out at any time (including before, in the middle of, and after a water treatment at our clinic). We immediately honor 100% of requests to terminate participation and support your right to make these decisions for yourself.

If you decide to withdraw from the research study, depending on the circumstance, we may still ask you to complete your pain scale for the following week to assist with the research. However, it is again your right to abstain from any further contributions.

If you withdraw participation from the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the study doctor can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

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. Data already been used will not be affected by your decision.

Withdrawal without your consent: The study doctor, the sponsor 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 has been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include more than 1 missed clinic appointment, inability to adhere to protocol, inability to complete the daily scales, a major adverse reaction.

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 212-241-1671.

If you experience an emergency during your participation in this research, contact 911.

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 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.

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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.

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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.

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

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, e-mail, date of birth, medical record number, full list of medication name, dosage and schedule.

The researchers will also get information from your medical record from Mt. Sinai including further information on medications in the past relating to your fibromyalgia that you may not remember. Researchers will search your name once in the beginning of the study in the New York State Health Commerce System which is a computerized database that stores information on each controlled substance prescribed in new york state.

During the study the researchers will gather information by:

- Surveys

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 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?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce will not disclose your protected health information, including the results of the research study tests and procedures, to any people or organizations: we anticipate sharing the final anonymous data with the scientific community, though no PHI will be shared with outside sources. The only exception is The United States Department of Health and Human Services and the Office of Human Research Protection, if information should be requested.

There is no Certificate of Confidentiality for this study. In all disclosures outside of Mount Sinai, you will not be identified by name, telephone, date of birth or any other direct personal identifier unless disclosure of the direct identifier is required by law. 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 law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may 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, when applicable, the monitors, auditors, the IRB, 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. OHRP and FDA 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 have access to your medical record and any study information that is part of that record. 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.

If subjects are not patients of the Mount Sinai Health System site engaging in this research, and the information being gathered remains solely in the research record, the need to give out a Notice of Privacy Practices is eliminated and the following sentence can be removed (when in doubt leave the following sentence in, and give out the Notice of Privacy Practices to those who have not received it during the course of clinical care): If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case,

the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also 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 at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

[Ensure that the signature page fits on one page and signature lines are not broken up]

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 [required if used for FDA documentation purposes]

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