VA Portland Health Care System (VAPORHCS) Informed Consent Form

Subject Name: _____ Date: _____

Title of Study: A new therapeutic approach for somatosensory tinnitus

IRB Number: 4339

Principal Investigator: Sarah Theodoroff, PhD ICF Version Date: 15 October 2020

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?

1. About the research, call Dr. Sarah Theodoroff at 503-220-8262 x51948.
2. If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call Dr. Sarah Theodoroff at 503-220-8262 x51948.
3. To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VA Regional Counsel at (503) 412-4580.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. The purpose of this study is to learn more about different types of tinnitus (ringing in the ears) in Veterans. Study goals are to figure out how many Veterans have a kind of tinnitus ("somatosensory") that changes how it sounds in response to certain movements of the head and neck. Another goal is to develop a new treatment approach for that kind of tinnitus.

We are also asking you to allow your contact information (name, address, and telephone number) and all data (age, date of birth, last 4 numbers of your social security number, dates of study visits, and behavioral and questionnaire responses) to be stored ("banked") in a repository located at the VAPORHCS. The data repository is called "Sensory Perception, Physiology and Outcomes Data Repository" (IRB #4635). The purpose of having a data repository is so that data from this study can be used to answer future research questions related to audiology, physical therapy, neurology, psychology, and other health science fields. Your contact information may be released to other researchers who have IRB approval to use the data repository for the purpose of contacting you about future research opportunities. You will always have the right to decline participation in future research studies, as well as request not to be contacted again. By signing this form, you agree to allow your contact information and research data listed above to be stored in the data repository to be kept for future research purposes.

WHO IS PAYING FOR THIS STUDY?

The VA RR&D is the Sponsor of this study.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 30 people will participate in this research study at the VA Portland Health Care System.

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HOW LONG WILL I BE IN THIS STUDY?

If you agree to join and do not withdraw from the study before all procedures are complete, your participation in this study will last for approximately 1-2 months.

WHAT WILL HAPPEN DURING THIS STUDY?

Everything done in this study will be done for research purposes. Although many of the procedures are routine to clinical practice, they are being done here for research purposes only and will not be completed if you decide not to take part in the study.

Description of Study Procedures

Consent: A research team member will explain the informed consent form and then ask you some questions to make sure you understand everything about the study. After you sign the informed consent form, you will be given a copy of it for your records. Your eligibility for the study will be determined during the first visit. If you are

not qualified for the study during this initial in-person screening visit, you may be rescreened at a later date at the discretion of study staff.

Health History and Questionnaires: You will be asked to fill out forms with questions about yourself, your hearing, your tinnitus, and your overall health. You will also be asked to complete these questionnaires: Tinnitus Screener; Tinnitus Functional Index; and the Hospital Anxiety and Depression Scale. The questionnaires will take approximately 20 minutes to complete. Should you qualify to participate in this study, some of these questionnaires may be repeated at follow-up visits and an additional questionnaire, the Neck Disability Index (5 minutes) will be administered during visit 2 and visit 4.

Tinnitus Loudness Testing (optional): The audiologist will look in your ears with an ear light to check for wax or other substances or obvious conditions that could interfere with the tests to be conducted. Next an ear-tip attached to an earphone will be placed in your ears. You will be asked to listen to a tone and compare the volume of the tone to the volume of your tinnitus. This test will be done to find the volume of an external tone that matches the volume of your tinnitus. This test will take approximately 15 minutes to complete and is similar to tests that are normally used to evaluate tinnitus in an audiology clinic. This procedure may be repeated at follow-up visits.

Musculoskeletal Screening Exam: You will be asked to monitor how your tinnitus sounds during movements of your head, neck, and jaw. Part of this screening includes applying gentle pressure to areas of your face during range of motion tasks (15 minutes).

Physical Therapy: A subset of qualified participants will receive a physical therapy (PT) assessment using standard of care procedures including evaluation of any of the following: head, jaw, and/or cervical spine (i.e.,

neck). Based on this assessment, the physical therapist will develop an individualized physiotherapy plan including exercises to be performed by the Veteran at home. During the individualized physiotherapy session, the PT will educate the participant about the at home exercises, on topics such as range of motion, strength training, and functional mobility (1 hour).

The at home exercises are anticipated to take participants 15 minutes to complete and be performed twice a day.

Timeline for subset of Veterans who qualify and participate in physical therapy
Visit 2 occurs approximately 1-3 weeks after Visit 1
Visit 3 occurs approximately 1 week after Visit 2
Visit 4 occurs approximately 1 week after Visit 3

SCHEDULE OF VISITS
Durations of appointments will occur over a 1 to 2-month period:

	Visit 1	Visit 2	Visit 3	Visit 4
Informed Consent	X			
Tinnitus Screener, Tinnitus History, Health History	X			
Tinnitus Functional Index	X			X
Hospital Anxiety and Depression Scale	X			X
Tinnitus Loudness Testing (optional)	X			X
Musculoskeletal Screening Exam	X	X		X
Neck Disability Index		X		X
Physical Therapy		X	X	X
Exit Interview				X
Total time	1.5-2 hours	1-1.5 hours	0.5-1 hour	1.5-2 hours

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WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

There are only minimal known or expected risks associated with this study.

1. Discomfort at being left alone in a sound booth to perform the testing.

2. Physical discomfort and/or annoyance when listening to some of the sounds.

3. Remote risk of hearing damage if the testing equipment were to malfunction and emit a loud sound. Although this has never happened to our knowledge, it is a potential risk.

4. For some people, completing questionnaires and discussing topics that may arise during study-related procedures may cause emotional distress. Some of the questions may seem very personal or embarrassing. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor.

5. The testing may cause your tinnitus to seem louder than it was prior to testing. To minimize this risk, you will be asked to report any discomfort during testing, which would result in testing being terminated immediately.

6. The musculoskeletal screening exam will be performed by a trained clinician. It is possible that the screening procedures could aggravate your tinnitus, underlying dizziness, headache, ear discomfort, or neck symptoms. To minimize these risks, you will be told to let the clinician know immediate if symptoms appear or worsen in any way during the screening exam.

7. For Veterans who receive individualized physiotherapy, you will be working one-on-one with the physical therapist who will provide both exercises and manual treatments (i.e., physiotherapy) to correct any deficits that are identified using standard of care clinical procedures. After a treatment session, there is a minimal risk that you may experience an increase in tinnitus, discomfort associated with the cervical spine, jaw, or back. To minimize any discomfort occurring, you will be educated on: 1) proper form of the exercises and expectations; 2) how to prevent worsening of symptoms; and 3) what to do if symptoms worsen.

8. Being in this study may result in a loss of privacy. Information that identifies you will be used in this study. A breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft or carry other risks affecting your ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history, status in the community, or could result in embarrassment. However, the research team will make every effort to protect your private health information and guard against any loss of privacy.

WILL I BENEFIT BY PARTICIPATING?

You may or may not personally benefit from being in this study. You may benefit by learning about your tinnitus. In some cases, people who are bothered by their tinnitus are helped simply by receiving information and having their questions answered. If you do not personally benefit from being in this study, by serving as a research participant you may contribute new information that may benefit patients in the future.

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DO I HAVE TO PARTICIPATE IN THIS STUDY?

No. You may choose not to be in this study. There are other forms of tinnitus therapy available. These methods include Cognitive-Behavioral Therapy, Progressive Tinnitus Management, and Tinnitus Retraining Therapy (along with many others). No one method of treatment for tinnitus has been proven to be better than any other. Health care providers who might be able to help you include otolaryngologists (ear, nose and throat physicians), psychologists, psychiatrists, and audiologists.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

Identifiers related to you (i.e. information that can identify you) that will be used in this research study include: your name, last four digits of your Social Security number, birth date, phone number, and address. These identifiers may be used to obtain information about you from VA records.

Mandatory reporting of suspected child or elder abuse. Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

Possibility of Disclosure and Notice of Privacy Practices.
The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at: http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3048).

WILL I BE ABLE TO SEE MY RESEARCH DATA?

During this research study, you will not be able to see the research data collected about you. After the study is complete and the study results are determined or published, you may request your health information.

WILL I BE TOLD ABOUT THE STUDY RESULTS?

We will not contact you with results of this study after it is completed. This study will not be funded after testing is completed. After the study is complete and the study results are determined or published, you are welcome to contact us to find out about the results of the study.

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WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

None of the participants will pay for any of the following because they are only for research study purposes: Questionnaires, tinnitus evaluation, and for a subset of participants, physical therapy.

Veteran participants. A Veteran participant will not be required to pay for care and services (treatment) received as a subject in a VA research project. However, some Veterans are required to pay co-payments for medical care and services provided by VA ***that are not part of this study*** (e.g., normal hospital and prescription expenses that are not part of the research study, any treatment that is standard clinical treatment for your condition).

WILL I BE PAID FOR PARTICIPATING?

To compensate for time and travel to attend study visits, you will be paid $30 for each visit you attend. You will receive the payment at the end of each scheduled visit in the form of a payment voucher. The subset of Veterans who qualify for three sessions of physical therapy will be paid $30 for each of those additional visits. If you complete one visit you will receive $30. If you complete a total of four visits, you will receive a total of $120. Participants who do not show for appointments will not receive payment for missed visits/appointments. If you drop out of the study before completing all study visits, you will be paid only for the visits that you attended.

WHAT WILL HAPPEN IF I AM HURT?

Every reasonable effort to prevent any possible injury from this study will be taken. In the event the study results in any physical, mental or emotional injuries to you, the VA will provide necessary medical treatment (not just emergency care) at no cost to you. This does not apply to treatment for injuries that result from if you do not follow the study procedures. Additional compensation, beyond paying for treatment, has not been set aside. The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA Regional Counsel at (503) 412-4580. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

WHO SHOULD I CONTACT IF I AM INJURED DUE TO THE RESEARCH?

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact Dr. Sarah Theodoroff at 503-220-8262 x51948 or via the NCRAR front desk at 503-220-8262 x55568.

In the event of a life-threatening emergency, call 911 or go to the Emergency Department (ED).

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WHAT ARE MY RIGHTS?

You may ask questions about research or about your rights as a subject. Dr. Sarah Theodoroff at 503-220-8262 x51948 will answer any questions you may have about this research study. This study has been approved and is overseen by an Institutional Review Board ("IRB"), a committee that protects the rights and welfare of research subjects. If you have any questions regarding your rights as a research subject, you may contact the VA Portland Health Care System Research Office at (503) 273-5125, or VA Regional Counsel at (503) 412-4580.

Participation is voluntary. Your participation in this research study is voluntary. The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also voluntary. You may refuse to sign this consent form and the Health Insurance Portability and Accountability Act (HIPAA) authorization. However, in order to participate in this study, you must sign this consent form and the HIPAA authorization.

What if I decide not to participate? You do not have to join this or any other research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or if you drop out of the study at any time, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

CAN I DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?

You may withdraw from this study at any time. This will not affect your rights as a VHA patient or your eligibility for medical care and benefits for which you are otherwise eligible with this institution or with the VHA.

To withdraw, you must write to Dr. Sarah Theodoroff at VA Portland Health Care System, 3710 SW US Veterans Hospital Road, Mail Code: NCRAR (P5), Portland OR 97239, or ask a member of the research team to give you a form to withdraw your consent and HIPAA authorization. If you withdraw your consent and HIPAA authorization, you will not be able to continue to participate in the study. If you do withdraw, we will not look at your medical record for purposes of the research anymore and will not collect any more information about you. However, we will keep and use the data that we already collected before you withdrew your consent.

Can someone else stop me from being in the study?

Yes. Your participation may be stopped if the investigator decides that it is in your best interest. If you do not follow the study instructions, it may be determined that continued participation may be a waste of your time, effort, and money.

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WILL I BE TOLD IF THERE IS NEW INFORMATION THAT MIGHT CAUSE ME TO WANT TO QUIT THIS STUDY?

During this research project, new information may become available that may affect whether or not you want to remain in the study. If this new information becomes available, you will be notified. You may decide if you still wish to stay in this study.

Signature

Dr. Sarah Theodoroff or a member of the research team has explained the study to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I have been told I do not have to take part in this study and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are medical problems or questions, I have been told I can call Dr. Sarah Theodoroff at 503-220-8262 x51948 or via the NCRAR front desk at ext. 55568 from 8am to 5pm, Monday through Friday. If any medical problems occur in connection with this study, the VA will provide emergency care.

My signature below indicates that I have read, or had read to me, all of the above information about the study, and that my rights as a research subject have been explained to me. I authorize the use of my identifiable information as described in this form. I voluntarily consent to participate in this study. I have been told that I will receive a copy of this consent form.

_____
Printed Name of Subject

_____ _____ _____
Signature of Subject Date Time

_____
Printed Name of Person Obtaining Consent

_____ _____ _____
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