COVER PAGE

Official Study Title:
An Evaluation of Neurobiological Similarities of Tinnitus and Posttraumatic Stress Disorder

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Title of Study: An Evaluation of Neurobiological Similarities of Tinnitus and Posttraumatic Stress Disorder

Consent to be part of a Research Study
To be conducted at
University of Texas Health Science Center at San Antonio,
Wilford Hall Ambulatory Surgical Center

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is John Moring, Ph.D., Department of Psychiatry and Behavioral Sciences at the University of Texas Health Science Center at San Antonio.

On-Site Investigator at WHASC
The On-Site Investigator is the person who supervises the research at Wilford Hall Ambulatory Surgical Center (WHASC) ensuring that the research team has access to what they need to conduct the study at WHASC as well as ensuring that your care meets all the military and hospital standards. The On-Site Investigator at WHASC for this study is Quintin Hecht, AuD, CCC-A, CPS/A, Hearing Center of Excellence, Wilford Hall Ambulatory Surgical Center, Lackland AFB, TX.

Funding
This study is being funded by the National Institute of Mental Health, National Institutes of Health.

Purpose of this study – "Why is this study being done?"

You are asked to participate in this research study of determining the overlap of symptoms between posttraumatic stress disorder (PTSD) and tinnitus-related distress (ringing or buzzing in one or both ears). We will evaluate the overlap of symptoms by conducting assessments for psychological problems and tinnitus, as well as evaluate your brain activity while undergoing a functional magnetic resonance imaging session (MRI). MRIs use strong magnets and radio waves to non-invasively acquire images of organs and tissues.

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Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are a veteran or an active duty service member and have posttraumatic stress disorder and/or bothersome or intrusive tinnitus, or are a healthy volunteer. This study will enroll approximately 160 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 2-3 outpatient visits over one to four weeks with the researchers or study staff.

Assessments – After you sign this consent, the following two procedures can take place in any order.

You will be asked to speak with a study staff member where she or he will ask you about stressful or traumatic experiences. You will also be asked to fill out additional questionnaires about exposure to traumatic events, PTSD symptoms, mental and physical health problems, such as depression and substance use, head injuries, and tinnitus. All or part of this assessment may take place at the STRONG STAR Offices at 7550 IH 10 West, San Antonio, TX 78229. There may be circumstances when you can complete the assessments electronically and/or over the telephone or video conferencing. Participants who do not have internet access will need to complete assessments in person. This assessment will take approximately 2 hours.

You will also be asked to complete an audiometric (hearing) assessment which will take approximately 60 minutes and will include using insert earphones for hearing loss, pure tone air- and bone-conduction thresholds, speech reception thresholds, and word recognition testing, speech recognition, dichotic digits (hearing test to right and left ear), middle ear functioning (acoustic immitance), cochlear functioning, and tinnitus loudness, pitch, and other characteristics. The audiometric assessment will take place in person at the Hearing Center of Excellence at Wilford Hall Ambulatory Surgical Center on Lackland Air Force Base.

The results of these procedures will be reviewed to determine whether it is appropriate for you to continue in the study and receive an MRI scan. If it would not be appropriate for you to continue in the study, the researcher will discuss the reasons with you and provide referrals for services outside of this study if appropriate for you.

If you are eligible to continue in the study, you may be asked to repeat the audiometric assessment at the Research Imaging Institute at the University of Texas Health Science Center at San Antonio before completing the MRI.

If you participated in another STRONG STAR study, we may be able to use the assessments you already completed.

You have my permission to use assessments collected as part of another STRONG STAR study as baseline data for my participation in this study.

Circle one: N/A YES NO _____ _____
Initials Date

Assignment to Study Groups – When it is determined that you are eligible for the study, you will be assigned to one of four groups, based on results of your tests: Tinnitus and PTSD Group; PTSD Only Group; Tinnitus Only Group; or the Healthy Control Group.

This study also involves an MRI. If you have any metal, implants or other foreign bodies in your body, you cannot take part in this study. Foreign bodies which may interact with the magnetic field of the MRI can have risk for persons with foreign bodies implanted in their body. Cardiac pacemakers and cochlear implants may cease to function and can be permanently damaged by the MRI. Surgical clips on aneurysms and intestines may be moved by the magnetic field. Ferrous metal filings in the eye (e.g., in machinists) can be moved by the magnetic field. Foreign body risk is minimized by including only volunteers with no known foreign bodies and no exposure to circumstances which might predispose to foreign bodies (e.g., metal machine workers). We will ask you about any metal objects that may be in your body in order to ensure your safety. The MRI scan will take between 60 and 75 minutes.

Recordings: All evaluations will be audio-recorded to make sure that the study staff are correctly following the study procedures. These recordings may be reviewed by research experts who are part of the research team via encrypted email. By signing this consent, you are giving your permission for recordings.

Please note that your participation in this study may involve remote and/or virtual research interactions with our research staff. Remote evaluations will be audio recorded by an independent device (separate from the conferencing platform, i.e. Zoom or phone). Therefore, privacy and confidentiality is not guaranteed due to the nature of the research environment.

Long-Term Study Data Storage and Future Use of Your Information

The researchers will be asking your permission to store your questionnaire answers and audio-recordings with your personal identifying information after this study is completed in the STRONG STAR Repository. The Repository is designed to be used for other research investigating the causes, consequences, and treatment of PTSD and related conditions. Your consent to allow us to store your information, or request not keep your information, will be given in a separate consent document. Your participation in the current study does not depend on your decision to participate or not in the Repository. Please note however that if you decide not to participate in the Repository, the researchers intend to keep and use the information collected as part of this study, but your personal identifiers (such as name, SSN, and contact information) will be permanently destroyed so that it can never be linked to you again.

Future Use of Your Information Collected as Part of Your Participation

Identifiers may be removed and the de-identified information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Ending Participation Early - Could your participation end early?

There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

Risks – "What are the risks of participation in the research?"

Risks from the research

There are risks to taking part in this research study. One risk is that you may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, the study staff don't know all the side effects that may happen. Be sure to tell your study staff immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Online Conferencing
Due to the use of online conferencing systems, your privacy and confidentiality is not guaranteed.

Rare, but Not Serious
In 100 people, less than 5 may have:
Confinement claustrophobia (fear of tight spaces). During the MRI scan, you will be asked to remain perfectly still. The MRI can cause individuals to feel claustrophobic (fear of tight spaces). However, the incidence of claustrophobia with the MRI is low (approximately 1 per 150 persons). If you experience any discomfort or anxiety while undergoing the MRI, please notify the technician so that we can stop the scan. If you feel that you cannot complete the MRI scans, you will be excluded from the research.

Emotional distress due to tinnitus or more attention toward tinnitus sensation may occur for participants with tinnitus; however, since tinnitus is a chronic and stable condition, it is unlikely that a change will occur because of the assessment procedures.

Temporary distress during the MRI scan may occur for individuals who are sensitive to noise. If you experience distress due to the noise of the MRI scan, please notify the technician so that we can stop the scan. If you feel that you cannot complete the MRI scans, you will be excluded from the research.

Likely, but not Serious
The assessment of PTSD and trauma-related events may produce some discomfort or emotional distress and can even produce a temporary increase in PTSD symptoms. This is likely to happen during the evaluations when you are asked to describe the effect your trauma has had on you. Your evaluator will closely monitor your well-being throughout the study.

If you feel any distress at any time during the study, please inform study staff. If you become distressed after your participation, or in-between appointments, please contact your primary care physician or therapist. You can also be seen in any Emergency Room after hours.

Results of Assessments and Evaluations
The testing that you will undergo may indicate PTSD symptoms, anxiety, depression, alcohol use, or risk of hurting yourself or others that warrants treatment. Occasionally, previously unsuspected lesions or hearing changes that are not causing you any symptoms may be found as a result of the research testing. In these instances, a member of the Research Team will contact you, explain the test findings and, if appropriate, encourage you to see your primary care provider. The research testing is not being done to diagnose health problems, and so you will need to see your primary care provider to see if any action should be taken. The research team can help facilitate communication with your primary care provider and provide local resources. For active duty personnel, your military command will NOT be notified, and the results of your research testing will NOT be placed in your medical record. However, if any of the study testing indicates that you may be at risk for hurting yourself or others, the Researcher Team will want to immediately work with you to get help.

Risks whether you participate in this research or not

Individuals with PTSD may have suicidal thoughts or to attempt suicide. This is a risk to you whether you are being treated for PTSD or not. Therefore, the risk of suicide is not any higher in the study than it would be if you were not in this study. The study assessments will likely require you to talk about some things that might be painful or uncomfortable for you, which could cause increased emotional distress and the possibility of increased suicide risk, which can result in death. In the event you are thinking about hurting yourself, please tell a member of the study team. We will develop a plan with a licensed therapist that will include specific steps for you to follow when in crisis. If we believe you are at high risk for hurting yourself, we might also contact your medical provider to maintain your safety.

For more information about risks, ask one of the researchers or study staff. We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

You may not receive any personal benefits from being in this study.

It is hoped that information gained from this study will improve treatment for service members and veterans with tinnitus and PTSD. Results may help researchers identify specific areas of the brain to be targeted using innovative technological procedures, such as transcranial magnetic stimulation.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you.

Treatments for PTSD that are available include the following:

- Various forms of psychotherapy (talk therapy) including CPT for PTSD.
- Various forms of psychotherapy (talk therapy) including Acceptance and Commitment Therapy for tinnitus.
- Drug treatments for PTSD.
- There may be other research studies involving experimental treatments that could be helpful in treating PTSD and/or tinnitus.

Treatments for tinnitus are available include the following:

- Acceptance and Commitment Therapy
- Progressive Tinnitus Management
- Tinnitus Retraining Therapy
- Cognitive Behavioral Therapy for Tinnitus

Not participating in this study is an option.

Payments – Will there be any payments for participation?

Participants will be compensated $50 for completing the study MRI scan.

The researchers will provide you with a MasterCard®. Compensation will be automatically credited after completion of the MRI scan. Your name, address and date of birth will be shared with a third-party solely for the purposes of compensation processing. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential. Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt and you may not receive a check.

In addition to the compensation on the card, you may also elect to receive study-related messages (text and/or email). These messages will contain information confirming that money has been loaded onto your card. You may also receive reminder messages with information about your next appointment with researchers or study staff.

Please indicate your willingness to receive study-related messages:

- □ **Yes,** I would like to participate (please select the best method(s) for communication)
  - Cell Phone (text messages)
  - Email
- □ **No,** I choose not to participate

Costs – Will taking part in this study cost anything?

You will be required to pay for your own transportation to and from the sites whenever you are scheduled to attend a visit there. The MRI and other assessments will be provided at no cost to you.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The

information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Diagnosis and health history
- Information from clinical interviews and assessment measures
- Results from the audiometric assessments

We will get this information by interviewing you to ask about your medical and psychiatric history and asking you to complete questionnaires about symptoms you may be experiencing.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The sponsor of the study, the National Institute for Mental Health, National Institutes of Health, and the entities that they use to monitor, administer, or conduct the research
- Members of the local research team at University of Texas Health Science Center at San Antonio (UTHSCSA), and Wilford Hall Ambulatory Surgical Center, and affiliated STRONG STAR investigators
- The Institutional Review Board and the Compliance Office UTHSCSA, and other groups that oversee how research studies are carried out as allowed by law
- The Research offices at UTHSCSA and University of Illinois Urbana-Champaign
- The University of Illinois Urbana-Champaign Institutional Review Board (IRB)
- The STRONG STAR Data Core, developer of the electronic consent form
- State and federal government representatives when required by law

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records and any recordings sent to reviewers. Recordings will be kept on a secure server hosted by the University of Texas Health Science Center at San Antonio. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Dr. John Moring
University of Texas Health Science Center at San Antonio
Department of Psychiatry – Mail Code 7747, 7550 IH 10 West, Suite 1325
San Antonio, TX 78229-5820.

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact John Moring, PhD, who can be reached at (210) 562-6716 in San Antonio, TX during normal work hours. If Dr. Moring is not available or if you need assistance after business hours, you always have the option to be seen in an emergency room.

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

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Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time AM PM

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time AM PM

☐Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: _____

The specific means by which the subject communicated agreement to participate was:

_____