Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: October 2014

Protocol Title: Evaluation of auditory mirror-therapy for tinnitus

Principal Investigator: Clas Linnman

Site Principal Investigator:

Description of Subject Population: Adults with Tinnitus

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Why is this research study being done?

We are doing this research study to do a pilot evaluation of a new treatment approach to tinnitus, called auditory mirror therapy (AMT). Tinnitus is increasingly being recognized as a form of phantom experience, similar to the phantom limb pain that can be experienced after amputation.

Our brain constantly binds information obtained from vision, touch, body position and hearing to form a coherent experience of the world. In the case of phantomb limb pain, placing a mirror so that the good limb can be seen where the amputated limb used to be tricks the brain into re-interpreting the signals from the damaged nerves, and this illusion can help reshape, and reduce, the experience of pain. The idea in this project is to do a simmilar illusion to the ears, where sound is recorded with a microphone at the right and left ear, and then presened via headphones to the left and right ear respectively, in effect flipping the soundscape and thereby creating a form of hearing illusion.

We are asking you to take part in this study because you have tinnitus.
If you agree to participate, you will be fitted either with a pair of headphones that modulate sound and flip sound left and right, or with a pair of headphones that modulate sound. These two interventions are being compared to one another, and you have a 50% chance of being assigned to either the mirroring or the non-mirroring device.

We will enroll 80 subjects in this study.

This study is sponsored by the Harvard Catalyst

How long will I take part in this research study?

It will take you up to 8 weeks to complete this study. During this time, we will ask you to make two study visits to the Spaulding Rehab Hosptuial Charlestown. You will receive the headphones to use at home for three weeks, and a computer tablet to test your hearing and rate you tinnitus at home over three weeks. We will also call you or email you for follow up questioning six weeks after the last visit.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

Visit 1 (Screening and study Visit)

The visit will take about 1 hour.

During the visit, we will:

- Ask you to fill out questionnaires about your tinnitus. We will also ask you to answer questions about how you feel and how your tinnitus affects your life.
- After the questionnaires, we will conduct a brief hearing test and a matching procedure to determine how you experience your tinnitus. This will be done on a tablet, and we will instruct you how to use this tablet for at-home testing.
- We will then give you either a pair of headphones that mirror sound, or a pair of headphones that modulate sound. The goal of the study is to compare how either of these headphones may improve your tinnitus. The type of headphone you receive will be determined by a coin toss. We will fit you a pair of headphones, explain how they work, and ask you to wear them as you walk about in the lab.

- Once you have tried the headphones and are comfortable with how they work, we will lend you a pair to bring home and use for the next 21 days. We will ask you to keep a record of your daily use of the headphones.
- You will also receive a tablet to do at-home hearing tests and tinnitus matching. We will ask you to do seven hearing tests during the three weeks that you wear the headphones.

We suggest that you use the headphones for a maximum of 3 hours per day in a safe environment.

Visit 2
The second visit will take about 30 minutes. During this visit, we will ask you about your usage and experiences with using the headphones. We will ask you to rate your tinnitus and how tinnitus affects your life, and to do a final hearing test on the tablet. We will also ask you to return the headphones and tablet.

Follow up
We will contact you via phone and/or email about 6 weeks after you finish wearing the headphones to ask you to rate your tinnitus severity and how it affects your daily life.

Stopping the Study Early
We may decide to take you out of the study without your permission. This may happen because:

- Of technical problems
- Of unanticipated risks to you

If this happens, we will explain why you need to stop taking part in the study. If you decide to stop taking part in the study, you may do so for any reason.

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

What are the risks and possible discomforts from being in this research study?

Risk of device use

Previous trials on these headphones, and on other sound stimulation devices, such as music therapy, indicate a risk of worsening tinnitus symptoms in 0.5 to 8% of subjects. If you at any point experience a worsening of symptoms, we ask you to stop using the headphones immediately.

We anticipate a slight risk of vertigo, confusion and nausea associated with wearing the headphones. If at any point you experience symptoms or feel uncomfortable, we ask that you stop wearing the headphones immediately.

There may be other risks that are currently unknown.

A potential risk of using the headphones is a reduction in situational awareness. For example, while using the mirroring headphones, you would hear a car approaching from your left as if it were approaching from your right, and you may jump in the wrong direction to avoid the car. It is therefore paramount that you do not wear the headphones while in traffic or near traffic, while bicycling, operating a motor vehicle, or in other potentially unsafe environments.

Risk of Sharing Medical information
There is a small risk that your confidential medical information could be revealed or discovered by mistake. In addition, your samples and information will be coded and the key to the code will be kept in a separate, locked file. We won't share or publish any information that will identify you.

What are the possible benefits from being in this research study?

You should not expect to benefit from your participation in this study. We do not know how using the device will affect your tinnitus.

What other treatments or procedures are available for my condition?

You do not have to participate in this study to be treated for tinnitus.
Many people have also benefited from using hearing aids, tinnitus maskers, and devices resembling hearing aids that play a sound more pleasant than the internal noise produced by the tinnitus.
Many people with tinnitus also find relaxation techniques and cognitive behavioral therapy to be helpful in coping with tinnitus.
People with tinnitus should consult with their ENT or primary care provider about their treatment options.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You will receive $100 when you complete the study and return the headphones and tablet.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Clas Linnman, PhD, is the person in charge of this research study. You can call him at 857 284 2816 Monday to Friday, 9-5.

You may also contact research assistant, Brit Seipp, at 516 551 6256 or bseipp@partners.org

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products,

and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.

- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: September 13, 2022