Sensory Precision in Tinnitus
Tinnitus Predictions & Attentive State
Chief Investigator: Dr William Sedley

# Volunteer without Tinnitus Information Sheet

Version 1 – Updated 14/12/2022

## Overview

Tinnitus is a common phenomenon, in which people hear continuous sounds in the absence of an external source producing those sounds. Presently we have an incomplete understanding of the mechanisms in the brain that lead to tinnitus, which is one of the major factors preventing the development of effective treatments to suppress or eliminate the tinnitus sound itself. Another major factor is the relatively lack of research investment in tinnitus by pharmaceutical companies, which is to a large extent due to the lack of an objective marker of (i.e. a 'biomarker') of tinnitus that can be used to predict and track the response to treatments.
This study aims both to reveal key brain mechanisms of tinnitus, and lead to the development of a biomarker of tinnitus that can be used in the development and testing of new tinnitus treatments. However, this study is not developing or testing a treatment in and of itself.
The basis of the study is automatic predictions made by the brain in the processing of sounds. The experiment itself involves using electroencephalography (EEG) to measure your brain activity while we play you various sounds, mainly short beeps. The study measures automatic responses by your brain, and whether they are affected by you attentive state (attention to the beeps, to an unrelated visual task, or a neutral condition where you watch a subtitled movie).
As a volunteer without tinnitus, your responses will be used as a comparison to participants with the condition, to see whether any differences can be seen between the groups.

# Frequently asked questions:

## What is the purpose of the study?

This study aims both to reveal key brain mechanisms of tinnitus, and lead to the development of a biomarker of tinnitus that can be used in the development and testing of new tinnitus treatments.
The basis of the study is automatic predictions made by the brain in the processing of sounds. Forming predictions is a fundamental part of how we perceive the world, and helps us focus on what is important and ignore what is irrelevant. A specific hypothesis of the study is that our brains use this kind of automatic prediction to suppress a noise signal originating at a low level in the hearing pathway, and that in tinnitus this mechanism is less effective (but not generally ineffective). By presenting specific sequences of sounds, and measuring electrical brain responses to these, we aim to detect and measure this prediction mechanism in the brain and see how it differs between people with and without tinnitus. We also hope that, irrespective of whether this hypothesis is correct, there will be a different pattern of brain responses in people with tinnitus, which will serve as a biomarker of tinnitus in future research studies developing and testing treatments.

## What does taking part involve?

The study involves one visit to the study centre in Newcastle University Medical School, which will include the following:

- Discussion of the study, and a decision whether or not to take part, plus the signing of a consent form.
- Completion of standard questionnaires about general mood and wellbeing.
- A hearing test (pure tone audiogram), if not done previously.
- A computerised task to establish a comfortable volume of a set of tones. This will be the loudness of the tones (beeps) to be used in the EEG experiment (see below).
- An EEG session. In this, a fabric cap is placed over your head, and a number of spots of gel placed in this (a similar consistency to hair gel, which will remain in your hair until washed out with water). This cap records the electrical signals your brain naturally generates. This takes around 30 minutes to set up, and then runs for around 60 minutes. The most important things you need to do during the EEG session are to stay awake, keep your eyes open, and keep your head, face, neck and body in a relaxed state.
- During the EEG recording, you will be asked to do 3 tasks in a randomised order:
    - A 10 minute visual task (x2), in which you will need to look at moving dots on the screen and decide whether they are moving randomly or in a specific direction;
    - A 10 minute auditory task (x2), in which you will need to listen out for gaps in the sequence of beeps and press a button when you can hear the gap;
    - A 10 minute period (x2) in which you can watch a subtitled movie of your choice.

## What would I gain by taking part in the study?

By taking part, you would be helping to better understand tinnitus in a way that might lead to improved treatments. Some volunteers find it an interesting experience to take part in this type of research. We also will reimburse any reasonable travel expenses incurred, on top of which volunteers receive a participation fee of £15.

## Where does the study take place?

The study takes place in the Auditory Cognition Laboratory in Newcastle University Medical School, which is on Framlington Place, Newcastle upon Tyne, NE2 4HH. The meeting point is the Medical School Main Reception, which is just inside the Medical School.

## Are there any risks to taking part?

The study is essentially safe. The sounds used are confined to safe levels, which are not uncomfortably loud, and cannot cause any damage to hearing. The EEG does not have any associated risks. The only substance applied to your skin is electrolyte gel (which looks, feels and washes out like ordinary hair gel), and allergic reactions to this are very rare. Very slight rubbing with a blunt plastic syringe is applied to various spots on your scalp, but it is rare for this to be uncomfortable or cause any minor skin abrasion.

## Am I eligible to take part?

You have been sent this information because it is likely that you are eligible to take part. The official inclusion and exclusion criteria are:

**Inclusion criteria:**
- No presence of tinnitus
- Age 18 or over
- The ability to make and communicate an informed choice about whether to take part in the study
- The ability to sit still and comfortably in a comfortable chair for around 1 hour at a time.

**Exclusion criteria:**
- The presence of tinnitus that is not due to any external source
- Tinnitus due to a physical sound source in the body, such as turbulent blood flow or muscle contractions in the middle ear.
- Meniere's disease
- Any abnormality of brain structure (e.g. stroke, tumour), or other neurological disorder (e.g. multiple sclerosis or epilepsy)
- The ongoing use of sedating medications, or certain other nerve-acting medications
- A current mental health condition of sufficient severity to prevent certain activities of everyday life.

If in any doubt about your eligibility, please contact a member of the research team.

## Do I have to take part?

No. You are under no obligation to take part. You may decline to take part with or without giving a reason.

## What information will I have to provide, and what will happen to it?

We obtain two types of information from you:
- **Personal information:** This is details such as name, age, sex, and contact details. This is stored securely and confidentially. In line with local policy, these data are held for 5 years after the end of the study. There is a chance that the study will be audited, in which case certain individuals from the regulatory authorities may need to look at these records.
- **Research data:** This is not identifiable to you as an individual, and contains the results of all the experiments you take part in. It also contains the responses you give to questionnaires. These data may be stored indefinitely, but you have the right to request that your data be deleted. This is possible up until the personal information for the study is deleted, after which point it may become impossible to identify which research data is yours.

## Who is funding and running the study?

The study is funded by the Wellcome Trust, and sponsored by Newcastle University. The Chief Investigator is Dr William Sedley, Academic Clinical Lecturer in Neurology.
The PhD student, Ekaterina Yukhnovich, is sponsored by Action on Hearing Loss/ Masonic Charitable Foundation.

## Who has reviewed the study?

The study had been reviewed internally by the research team, and externally by expert reviewers acting on behalf of the Academy of Medical Sciences.

## What if I change my mind?

Before agreeing to take part in the study, you will have the opportunity to discuss any questions you wish with the researcher, and make a decision at that time whether to participate. After this, you are free at any time to decide to stop taking part with immediate effect, with or without giving a reason.

## What if something goes wrong?

The study is essentially safe, but if you have a grievance with how you have been treated during the study, or feel you have suffered as a result of taking part then the following options are available:

- Raise this issue with the research team – Dr William Sedley:
  0191 222 3445
  william.sedley@newcastle.ac.uk
- Raise the issue in writing with the Newcastle University Central Executive Office:
  (Care of the) Head of Executive Office
  Newcastle University
  King's Gate
  Newcastle upon Tyne
  NE1 7RU

## How to take part?

If you would like more information, or to take part, then please contact:
Kate Yukhnovich
E.yukhnovich2@newcastle.ac.uk

Or

Dr William Sedley
william.sedley@newcastle.ac.uk
0191 222 3445