

Sensory Precision in Tinnitus  
Strand A: Acute Tinnitus  
Chief Investigator: Dr William Sedley

# Patient Volunteer Information Sheet (Form 2Ai)

Version 1 – Updated 18/09/2017

## Overview

Tinnitus is a common phenomenon, in which people hear continuous sounds in the absence of an external source producing those sounds. Most people experience tinnitus for short periods of time throughout their life, for instance after exposure to loud noise, and some people experience long-term tinnitus. Presently, it is not known what proportion of people who develop new onset tinnitus go on to have long-term tinnitus, and in what proportion it resolves spontaneously. It is very rare for tinnitus to represent any serious disorder of the brain or ear. There are no widely effective treatments for tinnitus to reduce its loudness or eliminate it, but the majority of people with long-term tinnitus lead a normal life, which is not reduced in quality on account of the tinnitus. A minority of people with long-term tinnitus experience distress as a result of it. In these cases, the majority of such individuals naturally adapt to their tinnitus, and experience progressively less distress over time.

The purpose of the study is to learn more about the natural history of new onset tinnitus; that is, what proportion of people who have developed tinnitus within recent weeks will have tinnitus long-term. Additionally, we aim to identify markers that might be used to identify who is more or less likely to have persistent tinnitus long term. In future, we hope that this knowledge will be useful in treating tinnitus, but the current study does not involve a tinnitus treatment.

## Frequently asked questions:

If I take part in the study, do I still need to seek medical attention for my tinnitus?

Although the study involves a number of clinical assessments, and the provision of information and advice about tinnitus, it is not a complete substitute for seeking a formal medical opinion where one would usually be sought. If your tinnitus has occurred alongside a sudden reduction in (or loss of) hearing then it is advisable to see an Ear Nose and Throat (ENT) doctor as soon as possible in case there is a specific cause that can be addressed. Where tinnitus occurs without sudden hearing loss, it is still advisable to see your doctor, who may refer you on to an ENT doctor or audiologist.

What is the purpose of the study?

The purpose of the study is to learn more about acute (recent onset) tinnitus, including its associated changes in the brain that may cause it, what proportion of cases turn into long-term tinnitus, and whether we can predict, by using hearing tests or brain recordings, which cases will persist long term. This knowledge may help us to understand how tinnitus develops, and potentially open the door to changing the way we investigate and treat new cases of acute tinnitus.

What does taking part involve?

The study involves one or two visits (at your discretion) to the study centre in Newcastle University Medical School. Additionally, the study team will contact you at 3, 6 and 12 months after the first visit to enquire about your tinnitus and any related symptoms. While the second visit is optional (i.e. if you decide not to come for it, we can still use your results in the study), the responses at 3, 6 and 12 months are necessary for us to use your results in the study. You would be free to leave the study at any time, and not provide any further responses, but it would just mean we would not be able to use your results. The visit(s) will involve 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 tinnitus and its effect on you, plus questionnaires about general mood and wellbeing.
- A hearing test (pure tone audiogram).
- An Uncomfortable Loudness Level (ULL) test. In this, you are played a series of sounds, starting very quiet, and building up gradually. You indicate when they begin to become uncomfortable, and they do not get any louder than this.
- An examination of your ears, and possibly a general neurological examination, including testing nerves in your face, plus strength, feeling, reflexes and coordination in your arms and legs. This does not require removal of anything but outer clothes.
- A computerised task to establish what your tinnitus sounds like. This involves hearing sounds played from a computer, and either rating how much they sound like your tinnitus, or tuning their pitch and other properties until they best match your tinnitus.
- Further computerised tasks in which sounds are played to you, and you have to perform a task such as saying whether a particular sound was higher or lower pitched than expected.
- An electroencephalography (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 30-60 minutes to set up, and then runs for around 60-90 minutes. During some of this time you will just need to sit, relaxed, and at other times you will be played sounds through headphones. For some of these periods you may need to perform tasks on a computer related to the sounds, and for other periods just watch a silent film.

## 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. Although we provide information about tinnitus, which can be helpful and provide some reassurance, we are not testing any sort of treatment, and taking part in the study will not alter the natural course of your tinnitus. 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 £7.50 per whole or part hour.

## What about the second visit?

The second visit is entirely optional. The research team will contact you some time after your first visit (within a few months) to ask if you would like to repeat some of the experiments. The second visit is very similar to the first, but involves a bit less in the way of questionnaires. Otherwise it is equivalent.

## What about the follow-up responses at 3, 6 and 12 months?

One of the major aims of this study is to learn more about the natural course of acute tinnitus over time, and also to see whether any factors present early on predict which way this course will go. To help establish this, the research team will need to contact you for brief responses at 3, 6 and 12 months from the onset of your tinnitus. Contact can be made by e-mail, phone or post (depending on your preference), and requires only brief responses to indicate whether your tinnitus is still present and, if so, how problematic it is.

## Where does the study take place?

The study takes place in the Institute of Neuroscience in Newcastle University Medical School, which is on Framlington Place, Newcastle upon Tyne, NE2 4HH. The meeting point is the Institute of Neuroscience Reception, which is just inside the Medical School Main Entrance down the corridor on the left.

## 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:**

- The presence of tinnitus (persistent sound heard in one or both ears that is not coming from an external sound source or actual sounds being generated inside your body such as turbulent blood flow), which has persisted for at least 3 days, and began within the last 3 weeks. You do not need to be aware of the tinnitus all the time, but it must be persistent in the sense that is can always hear it if you listen out for it, and there is not enough other sound around to mask it.
- 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 2 hours at a time.

### **Exclusion criteria:**

- 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, preferably also completing a copy of form 3i – Patient Pre-Screening Form.

### 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.

### What kind of physical examination is involved, and do I have to be examined?

Taking part in the study is not a substitute for seeking a medical opinion (e.g. from your GP, an audiologist or Ear Nose and Throat specialist). However, we acknowledge that some people taking part in the study will not yet have seen a doctor about their tinnitus. Therefore, the doctor carrying out the study will perform some basic assessments, including looking in your ears, testing your hearing, and possibly examining the nerves in your face and limbs. This does not require the removal of clothing other than outer layers, shoes and socks.

### Who is funding and running the study?

The study is funded by the Academy of Medical Sciences, and sponsored by Newcastle University. The Chief Investigator is Dr William Sedley, Academic Clinical Lecturer in Neurology.

### 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](mailto:william.sedley@newcastle.ac.uk)
- Raise the issue with the Institute of Neuroscience:  
[ion@ncl.ac.uk](mailto:ion@ncl.ac.uk)  
0191 208 6648
- 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 do take part?

If you would like more information, or to take part, then please contact:

Dr William Sedley  
[william.sedley@newcastle.ac.uk](mailto:william.sedley@newcastle.ac.uk)  
0191 222 3445