NIHR Nottingham Biomedical Research Centre

NHS National Institute for Health Research

Outcome Measures in Tinnitus – Electrical Stimulation (COMIT-ES)

IRAS Project ID: 297045

We invite you to take part in an online survey to help improve research on electrical stimulation tinnitus

- You can take part if you are over 18, speak English and you have relevant professional experience relating to tinnitus
- You will complete a survey about the important aspects (e.g., loudness, intrusiveness) to assess when deciding whether a tinnitus treatment is working.
- You will be asked to think about your views and the views of other experts in tinnitus, including researchers and healthcare workers.
- The survey involves two rounds of questions, which will each take about up to 60 minutes. You will be invited to take part in both, with a gap of several weeks in between, over a period of 6 months.
- You can do this over the internet in your home
- This study will help to improve treatment research in the future.

Why are these surveys important?

This research will produce a list of aspects of tinnitus that people agree should be measured. Future research that uses this list will allow us to:

- ✓ compare results across studies testing the same types of treatment.
- ✓ identify the best treatments available
- ✓ improve research on tinnitus treatment

For more information or to take part

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A participant receiving tDCS, a form of electrical stimulation

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Part A

1 Why are we doing this study?

Tinnitus is the perception of sound, usually a ringing, buzzing or hissing, without an external sound source. Tinnitus is common, affecting around 10-15% of people. There is no cure for tinnitus, but management techniques exist and other treatments are being studied. One of these is electrical stimulation. In this study, electrical stimulation is defined as treatment that aims to improve tinnitus or its symptoms by direct or indirect electrical stimulation of the brain. Researchers do not yet agree on what benefits and harms (known as outcomes) should always be assessed when deciding whether using electrical stimulation is an effective treatment approach for tinnitus. Different outcomes are measured in different studies. This makes it difficult to compare results, slowing progress in finding which electrical stimulation techniques may be effective for tinnitus. We are seeking to change this by developing a fixed list of aspects of tinnitus, known as a 'Core Outcome Set' (see "What is a Core Outcome Set and why is it important to improving tinnitus treatments?" in **Part B** that should be measured every time when assessing electrical stimulation treatments for tinnitus. We will work closely with people who have tinnitus and those with a professional interest. We will find agreement on what outcomes are most important to measure when assessing how effective these treatments are.

This study is part of a PhD being undertaken by Bas Labree.

2 Why am I being asked to take part?

You are being invited to take part because you have professional experience relating to tinnitus.

You can take part in the study if:

- You are aged 18 or over
- You are able to read and understand English.
- You have EITHER:
  - a clinical qualification, currently employed by a public or private institution that provides a tinnitus service to patients, experience of assessing, diagnosing or managing chronic subjective tinnitus in adults, have a working knowledge and/or clinical experience of electrical stimulation treatments for tinnitus

OR

  - an academic qualification, currently employed by a research organisation, current or 'recent past' experience with studies that focus on questions of clinical efficacy (benefit) of a tinnitus intervention in humans, with specific focus on interventions involving electrical stimulation, evidence of 'recent past' experience in clinical research will be defined as having been a co-author on a relevant peer-reviewed journal publication in the past 3 years

OR

  - currently employed by a company that develops, manufactures or sells product(s) that involve electrical stimulation that may be trialled for effectiveness in alleviating tinnitus

OR

  - currently employed by an organisation that has funded tinnitus research projects addressing electrical stimulation-based interventions in the last 3 years.

3 What will I need to do if I take part?

You will be asked to complete an online survey made up of two questionnaire rounds, about what is important when deciding whether electrical stimulation for tinnitus works. You will be asked to answer general questions about what you feel is important for this type of treatment, based on your own personal experience. The survey will not ask you about how well these treatments work or worked. The survey is not about assessing existing treatments. At the end, an optional online group meeting will be held to discuss the outcomes.

What does completing the survey involve?

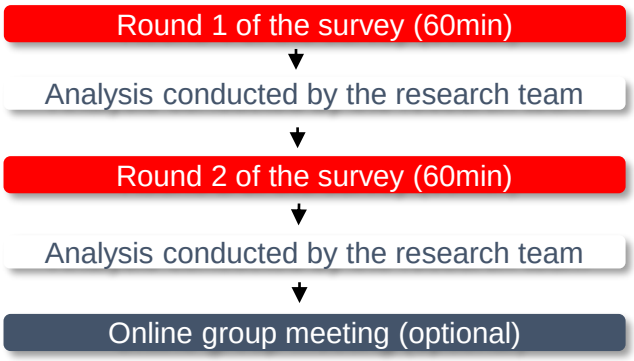
The survey will ask you what you think are the most important aspects of tinnitus to measure when deciding if an electrical stimulation treatment is working. Each survey involves two rounds of questions which will each take about 60 minutes to complete. You will be able to take breaks. Each round of questions will be sent separately, over a period of 6 months. After you have received the link for each round, you will have up to 3 weeks to complete the questions.

Survey round 1:

You will be asked to rate the importance of each aspect of tinnitus in deciding whether a treatment is effective. To do this you will use a simple 1-9 scoring system. You will be given the chance to add any aspects of tinnitus that you feel we have missed from the list.

Survey round 2:

We will remind you of the previous scores you gave and show you a summary of others' scores. Based on this information, you will have the chance to change or keep your score the same. No one else will be able to see your individual score or know who you are.



Group Meeting (optional):

There will be a group meeting to discuss and agree on the list of the most important aspects to measure, based on the survey results. Approximately 20 people with tinnitus and professionals working in the field of tinnitus and / or electrical stimulation will be invited to take part. The meeting will take approximately 7 hours, including regular breaks. The meeting will be held online to comply with the COVID-19 restrictions. The meeting will be audio-recorded and transcribed by the study management team. The recordings will be destroyed and the transcriptions will be stored as per local policies. There will be limited places so please register your interest in attending the meeting with the research team. If you do decide to take part and a place is available, then you will be sent the details of the meeting and will be asked to sign a consent form. Any quotes will be anonymised.

4 What do I need to do now?

If you would like to take part, read through the rest of this information. It is up to you to decide whether or not to take part. You will have the option to stop taking part at any time however, any data collected to that point will still be used. If you do decide to take part, contact the study team to register your interest and to ask any questions. We will check to see if you are eligible and decide which survey you will complete, based on your treatment experience. We will send you an online link to access the first round of questions for the relevant survey. You will consent to take part by agreeing to the statements shown at the start of the online survey.

Part B

5 What is a Core Outcome Set and why is it important to improving tinnitus treatments?

What is an outcome?

An ‘outcome’ refers to a single aspect experienced by people with tinnitus. To test how well treatments work, we measure one or more of these outcomes. For example, we might measure how loud or distressing someone finds their tinnitus.

What is a Core Outcome Set?

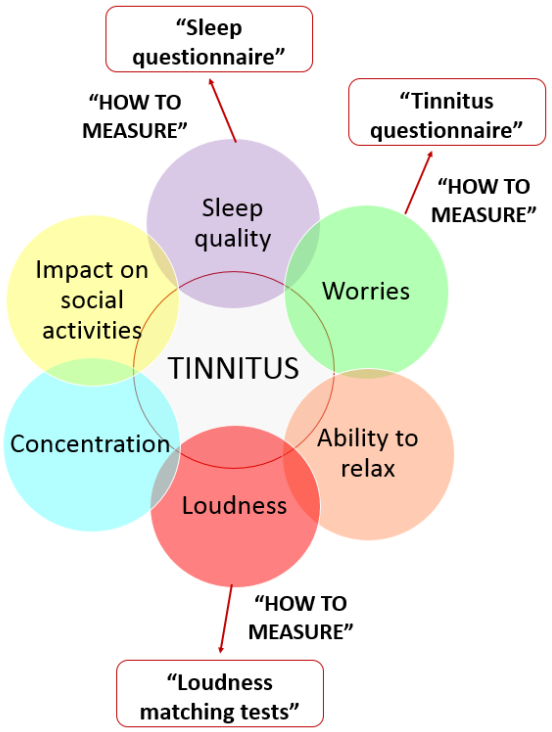
A ‘Core Outcome Set’ refers to a list of outcomes and outcome instruments (tests) that should be used, measured and reported in clinical research.

Why is a Core Outcome Set for electrical stimulation for tinnitus important?

Studies testing similar tinnitus treatments often measure different outcomes. If one measured loudness whilst another measured awareness we cannot compare results. It would be like trying to compare ‘apples and oranges’.

Researchers may also choose what they publish and may not include outcome results that were disappointing. This does not give a complete picture of the effect of a treatment.

If studies reported results for a set number of outcomes, data could be compared and combined correctly. This would help us to make sense of the evidence and see which, if any, forms of electrical stimulation are effective for tinnitus.



How is a Core Outcome Set defined?

The ‘Core Outcome Set’ for each treatment type must be relevant to health professionals **and** to people with lived experience of tinnitus. We want to make sure that everyone is involved and agrees on the core outcomes.

Defining outcomes has two major parts:

Stage 1. Agreeing on **which** aspects of tinnitus are important to always measure when evaluating tinnitus treatments. These are called ‘outcome domains’.

Stage 2. Agreeing on **how** to measure the outcome domains by identifying which tests should be used, for example, a loudness matching test or a questionnaire. Such tests are called ‘outcome instruments’.

6 What are we doing to define a Core Outcome Set for tinnitus?

We are currently concerned with stage 1; identifying and agreeing **which** aspects of tinnitus to measure for the three main types of tinnitus treatment.

To do this, we are running these online surveys, referred to as “Delphi (consensus) surveys”. Individuals taking part will either have tinnitus (patients), treat tinnitus (healthcare professionals) or research tinnitus (researchers).

Following the survey, there will be an online group meeting to finalise the Core Outcome Set for each treatment. This will involve the research team and a number of participants who completed the surveys (taking part is optional). By doing this, we will ensure that all key parties’ views are taken into account.

Part C

7 Research Team

The research team are happy to answer any questions you have before you agree to take part or when you are taking part in the survey:

PhD student:

Bas Labree

bas.labree@nottingham.ac.uk

+ 44 (0) 115 8232600 (reception)

Chief Investigator:

Dr Magdalena Sereda

Magdalena.sereda@nottingham.ac.uk

+ 44 (0) 115 8232600 (reception)

8 Will my results be kept confidential?

We will need to use information from you for this research project. This information will include your name and email address. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you. You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by asking one of the research team.

Your data will be kept strictly confidential, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data).

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. Electronic data generated by the online questionnaires will be accessible and will be maintained by the COMET Initiative (http://www.comet-initiative.org/) which is located at the University of Liverpool. These may include but are not limited to, consent records, study records, and written feedback. Only two System Administrators from the University of Liverpool and staff identified on the delegation log shall have access to study documentation other than the regulatory requirements listed below. Data may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty. Where possible information about you which leaves the Nottingham Biomedical Research Centre will have your name removed and a unique code will be used so that you cannot be recognised from it. However sometimes we need to ensure that we can recognise you to link the research data with your records so in these instances we will need to know your name and email address.

Your contact information will be kept by the University of Nottingham for two years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data obtained from the online surveys and group meeting will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality. Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. Where possible information about you which leaves the Nottingham Biomedical Research Centre will have your name and address removed and a unique code will be used so that you cannot be recognised from it

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

9 What are the possible advantages or disadvantages of taking part?

What are the possible disadvantages/risks of taking part?

Based on previous experience of similar projects, we do not foresee any particular risks or disadvantages.

Expenses and payments

Participants will not be paid to participate in the study as they will be able to take part online and will not incur any travel expenses.

What are the possible disadvantages/risks of taking part?

We cannot promise the study will help you but the information we get from this study may help future tinnitus studies. Researchers working in the field of tinnitus will adopt the final agreed list of aspects for measuring the effect of electrical stimulation treatments in every clinical trial. In the long run, this will make it easier and quicker to find out which treatments work best and why.

Part D

10 Who is organising and funding the study?

This project is funded by the **NIHR Nottingham Biomedical Research Centre** and will be managed by researchers based at this centre. This study is funded by an NIHR Senior Investigator Award.

11 Who has reviewed the study?

This study has been reviewed and given favourable opinion by:

- ✓ This study has been reviewed and given favourable opinion by Yorkshire & The Humber - Sheffield Research Ethics Committee.
- ✓ The Study Sponsor (University of Nottingham) and Nottingham University Hospitals NHS Trust Research and Development.

Patient and Public Involvement

- ✓ Members of the public have reviewed study documents, including this participant information sheet.
- ✓ The survey content, including the definitions of the outcomes have been reviewed by members of the public.

12 Who do I speak to if problems arise?

Our staff always try to conduct research in a way that is caring and respectful.

If you do have any concerns about any aspect of the study, you should contact:

Chief Investigator: Dr Magdalena Sereda,

- magdalena.sereda@nottingham.ac.uk
- + 44 (0) 115 8232600 (reception)

If you remain unhappy and wish to complain formally, please contact Dr Derek Hoare, Head of Hearing Sciences:

- derek.hoare@nottingham.ac.uk
- + 44 (0) 115 8232600 (reception)

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