

What is important to measure in tinnitus?

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

- You can take part if you are over 18 and have been experiencing tinnitus for 3 months or more, for which you have received or considered treatment.
- You will complete a survey about the important aspects (e.g. sleep quality) to consider when deciding if 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 3 rounds of questions, which will each take about up to 60 minutes. These rounds will be sent to you, one after the other, over a period of 5 months.
- You can do this over the internet in your home, or in our unit if you don't have a computer or iPad.
- This study will not test an existing treatment or develop a new treatment for tinnitus but it 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:

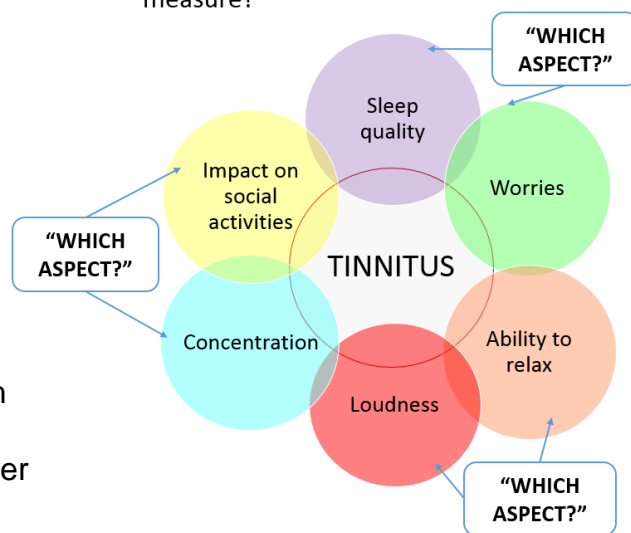
- ✓ compare results across studies testing the same types of treatment.
- ✓ identify the best treatments available
- ✓ improve research on tinnitus treatment

For more information or to take part



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Which aspects are important to measure?



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Part A

1 Why are we doing this study?

What is tinnitus?

Tinnitus is the medical name for perceiving noise in one ear, both ears or the head. This noise comes from inside the body and may be described as a ringing, beeping, roaring, whistling or buzzing sound.

One in 10 people in the UK have tinnitus. The impact of tinnitus differs from person to person, with some reporting sleep disturbance and others reporting concentration difficulties. The amount of problems experienced vary widely between individuals. About one in 200 people are severely affected by their tinnitus.

What is the problem we are trying to solve?

This study is not developing a new treatment, nor testing an existing treatment.

Tinnitus research continues to evolve. While good news, this presents challenges. Tinnitus research varies widely in what is measured, how it is measured and what is reported. This makes it difficult to understand what treatments work, how they work and who for.

We are seeking to change this by developing a fixed list of aspects of tinnitus, known as a “Core Outcome Set” that should be measured and reported in all future trials of tinnitus treatments.

We will work with people who have tinnitus, healthcare professionals and tinnitus researchers to agree on a list of which aspects (or ‘outcomes’) of tinnitus should be included in the Core Outcome Set.

2 Why am I being asked to take part?

We want you to have your say in what is measured in future tinnitus research. We would like up to 210 people with tinnitus to take part and 210 health professionals and researchers.

Can I take part?

You can complete our surveys if you:

- Are aged 18 or over,
- Have had tinnitus for 3 months or more.
- Are able to read, understand and complete questionnaires in English.
- You have received or considered trying treatment for your tinnitus.

Taking part is voluntary. You will not receive any payment for completing the survey.

Which treatments must I have received or considered trying?

They can be any of the types below:

- **Sound-based treatments**
Electronic devices to make sounds louder (hearing aids) or produce therapeutic sounds to mask or distract from tinnitus (e.g. wearable sound generators or the radio).
- **Psychology-based treatments**
‘Talking’ or ‘thinking-based’ treatments to deal with how tinnitus makes you feel or ways of managing it. For instance, Tinnitus Retraining Therapy, Cognitive Behavioural Therapy and Mindfulness.
- **Drug-based treatments**
Drugs aimed at improving effects of tinnitus. For instance, depression, anxiety, vertigo and cardiovascular medication. This does not include herbal remedies or dietary supplements.

You will be asked to answer general questions about what you feel is important for one or more these types of treatment, based on your own experiences. The survey will not ask you about whether you liked or disliked these treatments or how well they work or worked.

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

You will complete the online survey, made up of 3 questionnaire rounds, about what is important when deciding if sound-based, psychology-based or drug-based treatments work:

- We will ask you which of the types of tinnitus treatments you have received or considered trying. We will then ask you to complete a survey on the treatment type you have experience with.
- If you have received or considered more than one treatment type, you will have the option to complete a survey on more than one treatment type.
- We shall send you a link to the survey online for the treatment type(s) agreed.

What is involved in completing the survey:

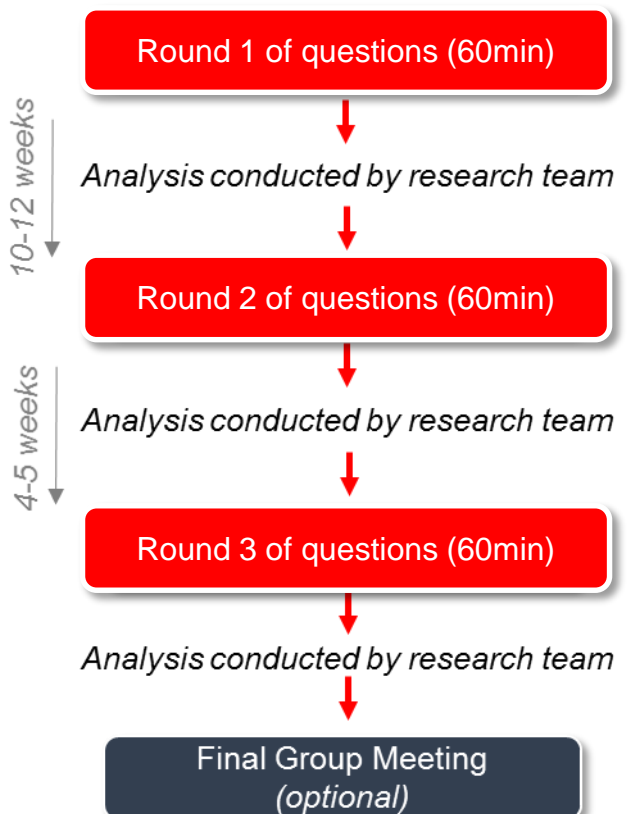
- The survey will ask you what you think are the most important aspects of tinnitus to measure when deciding if a treatment is working.
- Each survey involves 3 rounds of questions, which will each take about up to 60 minutes to complete. You will be able to take breaks.
- Each round of questions will be sent separately, one after another, over a period of 5 months.
- After you have received the link, you will have up to 3 weeks to complete each round of questions.
- **If** you wish to complete a survey on more than one treatment type, you will complete each one separately. This will take more time.

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.

For rounds 2 and 3:

- We will remind you of the previous scores you gave and show you a summary of others' scores. These scores will be grouped according to whether those taking part have tinnitus, treat tinnitus or research tinnitus.
- 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.



Part B

There will be a group meeting to discuss and agree on the list of important aspects to be included in the Core Outcome Set, based on the survey results.

This meeting will be held in the United Kingdom (expected June 2017). There will be limited places so please register your interest in attending the meeting with the research team. Travel expenses will be reimbursed for UK participants only.

Who will benefit from the research?

European Tinnitus researchers will adopt the final agreed list of aspects for measuring the effect of 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.

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.

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 important to improving tinnitus treatments?

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 pears'.

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 treatments and improve the way tinnitus is managed.

A Core Outcome Set for different tinnitus treatments

The three main types of tinnitus treatments, Sound-based treatments, Psychology-based treatments and Drug-based treatments, aim to improve different aspects of tinnitus. There may be some outcomes which are only meaningful to measure for particular types of treatment.

To address this, we aim to establish 'Core Outcome Sets' that are specific to each of these treatment types (e.g. a sound-based 'Core Outcome Set'). Treatments of the same type could then be easily compared.

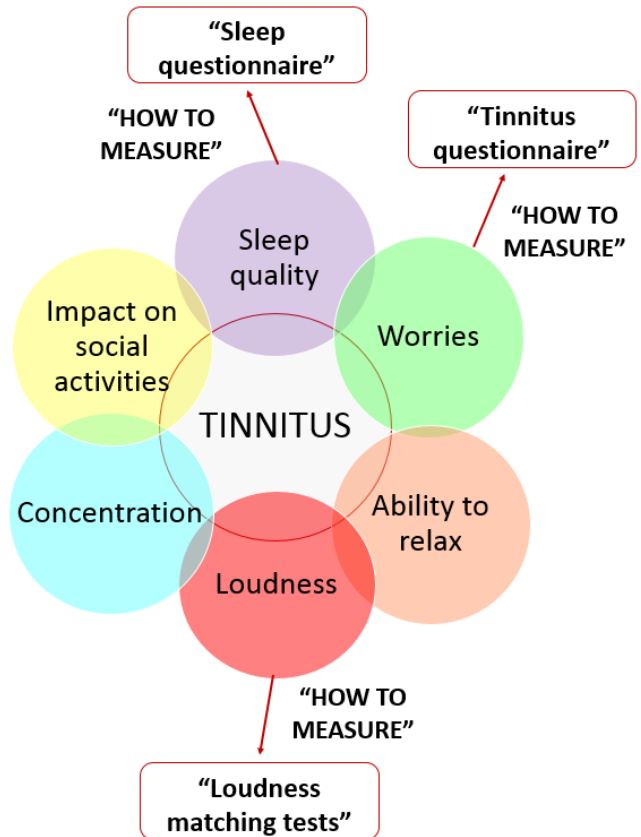
How is a Core Outcome Set defined?

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 a face-to-face 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:



Research Assistant: Harriet Smith

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Research Coordinator: Dr Kathryn Fackrell

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Chief Investigator: Professor Deb Hall

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Our team includes volunteer members of the public who have tinnitus. They ensure that what we do is relevant to the needs of people with tinnitus and that information is clear.

8 Will my results be kept confidential?

All information you provide will be securely stored at the NIHR Nottingham Biomedical Research Centre and the University of Liverpool.

- Any data that is stored electronically will be password protected.
- Data will be made anonymous using unique participant identity codes that will not include your name or address. Only members of the research team will have access to your personal data.
- Although all information will be kept confidential, if you disclose anything to us which we feel puts you or others at any risk, we may need to report this to the appropriate persons.
- Personal data (names and email addresses), will be kept for 2 years after the end of the study, other data will be stored for 7 years and then disposed of securely.

9 What will happen to the results?

If you make a request, we will provide you with a summary of the results at the end of the study. This may take a little while after you have completed the final round of the survey. We will need to wait for everyone to complete all 3 rounds of the survey and to prepare the summary.

The overall results of the study will be presented at national and international conferences.

We will also aim to publish the results in a scientific journal. A copy of this can be emailed to you or mailed to you in the post if requested.

Anonymous data from the study may be used to inform future studies or shared with other researchers.

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.

The project is being carried out as part of a wider EU-initiative called TINNET, which supports a network of tinnitus researchers across Europe to improve standards in tinnitus research <http://tinnet.tinnitusresearch.net/>.

Within the TINNET group, Professor Deb Hall leads the 'Core Outcome Measures in Tinnitus (COMiT)' research effort which this study forms a key part of.

Additional funding:

Patient and Public involvement in the study development

(T)

British Tinnitus Association

Specialist online survey software



11 Who has reviewed the study?

This study has been reviewed and given favourable opinion by:

- ✓ West Midlands-Solihull Research Ethics Committee.
- ✓ The Study Sponsor (University of Nottingham) and Nottingham University Hospitals NHS Trust Research and Development.
- ✓ The Research Steering Group.

Patient and Public Involvement

- ✓ Two members of the public with tinnitus (known as 'Public Research Partners') in our Research Steering Group have been involved in the creation of the research plan, participant information sheet and survey content.
- ✓ Members of the British Tinnitus Association Readers' Panel reviewed the list of outcomes to ensure that the definitions were clear and understandable.

Helping us to make sure that the research was relevant and understandable to all participants.

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: Professor Deb Hall,

- Email: Deborah.hall@nottingham.ac.uk
- Tel: + 44 (0) 115 8232600 (reception)

If you remain unhappy and wish to complain formally, you should then contact:

- *[Outside Wales and Velindre NHS Trust]* Patient Advice and Liaison Service (PALS). For details of your nearest PALS, telephone NHS 111
- *[Wales (not including Velindre NHS Trust)]* The NHS complaints procedure.

<http://www.hearing.nihr.ac.uk/research/tinnitus-online-survey-comitid-study>



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