Participant Information Sheet

Tinnitus Sound Support feature trial

Formal Study title:

Open trial of the Oticon Sound Support feature in hearing aids

Sponsor: Oticon (a Demant AS company) Denmark

Lead Researcher: ASSOC PROF GRANT D SEARCHFIELD

Study Site: THE UNIVERSITY OF AUCKLAND

Contact phone number: 09 373 7599 ext 86316

You are invited to take part in a study on HEARING AIDS FOR TINNITUS. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time. After 1st May 2022 we will be unable to withdraw deidentified data.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.
Voluntary Participation and Withdrawal From This Study

Participation in this study is voluntary, you are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage. After 1st May 2022 we will be unable to withdraw deidentified data.

What is the Purpose of the Study?

The primary goal for this study is to assess the clinical performance of the Tinnitus Sound Support feature of the Oticon "More" hearing aid. It will examine if the hearing aid achieves the intended purpose of providing temporary relief from tinnitus. The study will also assess if the hearing aids achieve the intended purpose of helping hearing. Four different listening programs combining sound amplification and tinnitus therapy sounds will be provided to try.

How is the Study Designed?

This is a trial of hearing aid settings designed to help tinnitus. The process to be followed is the standard fitting of hearing aids and therapy sounds that occurs everyday in clinics. You will be asked to complete questionnaires and have hearing tests. The hearing aids will be fitted. Different settings will be chosen in the hearing aids for you to try. At the end of the trial you can use the best settings.

Who Can Take Part in the Study?

Adults (persons over 18 years old) with hearing loss in both ears and tinnitus for more than 6 months. You can already be using hearing aids or you can be getting hearing aids for the first time.

What Will My Participation in the Study Involve?

Project Procedures
The study consists of three clinical visits, where visit 1 comprises of a tinnitus and hearing assessment and a hearing aid fitting (90 minutes). Following this, you will wear the devices for a three-month trial, in which a clinical follow-up visit (30 mins) is scheduled after three weeks, plus the option of an additional follow-up if needed. These one-or-two follow-ups are to adhere with normal clinical practice and to adjust the program order to suit your preference. Visit 3 is a follow-up and final visit.

Measurements:

**First session – hearing tests and fitting.**
Hearing tests will require you to listen to sounds through earphones and push a button when you hear the sound. You will be asked to repeat words played through the earphones. Sounds will be played over the headphones and you will be asked if they match your tinnitus.

You will be asked to complete questionnaires:
Tinnitus Sample Case History Questionnaire asks questions about your tinnitus and health.

Tinnitus Handicap Inventory helps identify tinnitus problems in their daily life and activities.

Tinnitus Functional Index questions the tinnitus impact on quality of life.

Client Oriented Scale of Improvement in Tinnitus is used in setting goals for hearing aid treatment.

Depression, Anxiety, and Depression Scales is a self-report instrument that measures the dimensions of depression, anxiety, and stress separately.

SSQ-12 a questionnaire about your hearing.

IOI-HA is a questionnaire about hearing aids.

Fitting. The hearing aids will be fit using a computer to set-up the aids. Hearing aid sound in the ear canal will be measured using a thin plastic probe tube microphone and an external speaker making sounds. The aids will be set with 4 listening programs you can select from. The programs differ in the amount of background noise they amplify and the sounds used as therapy for tinnitus.

Trial. You will then be able to try the hearing aids in the real-world and return for tuning and then trial of different sounds for tinnitus relief. At the end of the trial you will be asked questions and complete the questionnaires again.

**WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?**

There is a slight risk that discussing hearing loss and tinnitus may make you more aware of difficulties you have hearing. If this happened, the researcher is an audiologist who can help or organise for appropriate referral if wanted.

The hearing aids are tested using a soft, small, tube positioned in the ear canal, this can very occasionally result in brief mild discomfort and/or an involuntary need to cough. If discomfort should occur it would be very brief and has no long-term effects.

There are no guarantees the hearing aids will reduce your tinnitus.

In the event of an incidental finding (e.g. unexpected hearing tests), the researcher, can provide additional support and referrals as appropriate.

**WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?**

Participation in this study provides an opportunity to try a new hearing aid technology. At the end of the hearing aid trial you will be able to keep the hearing aids for free. Refreshments and filtered water will be available at appointments. If you withdraw from the study before completing the trial you may still chose to keep the hearing aids.

**WHAT ARE THE ALTERNATIVES TO TAKING PART?**
This study is in addition to your normal hearing healthcare. Your current hearing aids or alternative hearing aids may be more suitable for you.

**WILL ANY COSTS BE REIMBURSED?**

You will be able to keep the hearing aids. Any cost of repairs, maintenance or loss after the trial will be at the users own expense.

**WHAT IF SOMETHING GOES WRONG?**

As this research study is for the principal benefit of its commercial sponsor Oticon, if you are injured as a result of taking part in this study you won't be eligible for compensation from ACC.

However, Oticon has satisfied the Northern Health and Disability Ethics Committee that approved this study that it has up-to-date insurance for providing participants with compensation if they are injured as a result of taking part in this study.

New Zealand ethical standards require compensation for injury to be at least ACC equivalent. Compensation should be appropriate to the nature, severity and persistence of your injury and should be no less than would be awarded for similar injuries by New Zealand’s ACC scheme.

The sponsors voluntarily commit to providing compensation:

- On their own they are not legally enforceable and may not provide ACC equivalent compensation.
- There are limitations on when compensation is available, for example compensation may be available for more serious, enduring injuries, and not for temporary pain or discomfort or less serious or curable complaints.
- Unlike ACC, the guidelines do not provide compensation on a no-fault basis:
  - The Sponsor may not accept the compensation claim if:
    - Your injury was caused by the investigators, or;
    - There was a deviation from the proposed research plan, or;
    - Your injury was caused solely by you.

An initial decision whether to compensate you would be made by the sponsor and/or its insurers.

If they decide not to compensate you, you may be able to act through the Courts for compensation, but it could be expensive and lengthy, and you might require legal representation. You would need to be able to show that your injury was caused by participation in the trial.

Please ask questions if you are unsure about what the compensation provisions mean for you.

**WHAT WILL HAPPEN TO MY INFORMATION?**

During this study the research staff will record information about you and your study participation. This includes the results of any study assessments.

**Identifiable Information**

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The Investigator and designated study staff, to fulfil protocol requirements, will have
access to this information. For the purposes outline only the following groups may access this information: study monitor(s) (for eligibility confirmation and source data verification purposes) the Health and Disability Ethics Committee (for legal and regulatory purposes) and Health, regulatory, or government agencies (for legal and regulatory purposes will have access to your identifiable information).

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researcher and any study information sent to the sponsor. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

This research includes basic information such as age range, and sex. It is possible that this research could one day help people in the same groups as you.

Security and Storage of Your Information.

During the project, data will be recorded using written documentation and in software. Participants will be identified by a number allocated to them, which will appear on these records. A separate record of participants’ names and their allocated number will be kept secure during the project and will be destroyed immediately after project completion, along with all other personal information which may identify individuals. Only non-identifiable information required for analysis of the results will be retained and stored for 6 years before being destroyed. Non-identifiable aggregated data will be securely kept indefinitely. The consent form will be kept secure and separate from the data by the Principle Investigator for 6 years before being destroyed.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over.

If you have any questions about the collection and use of information about you, you should ask Dr Grant Searchfield.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time until 1st May 2022, by informing your study researcher.
If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

Ownership Rights.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to Oticon. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Participants can withdraw participation any time until 1st May 2022 without providing a reason and withdraw any data traceable to them up until the study data acquisition is completed.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants will be provided with a plain English summary of study results, if requested, once a final report to the Sponsor has been completed. The summary will be available from Dr Searchfield. The study will be registered on the Australian and New Zealand Clinical Trials Registry (http://www.anzctr.org.au.)

WHO IS FUNDING THE STUDY?

Funding for this study has been obtained from Oticon (a hearing aid company).

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The HDEC Northern B committee has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Grant Searchfield  Assoc Prof/Director Hearing and Tinnitus Clinic
Section of Audiology
School of Population Health
Faculty of Medical and Health Sciences,
University of Auckland
Email: g.searchfield@auckland.ac.nz
Ph: (09) 373 7599 ext. 86316
If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Maori health support please contact:

*Alehandrea Manual, Maori Research Coordination Eisdell Moore Centre*

Email: alehandrea.manuel@auckland.ac.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz
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<tr>
<th>Please tick to indicate you consent to the following</th>
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<tr>
<td>I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.</td>
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<td>I have been given sufficient time to consider whether or not to participate in this study.</td>
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<td>I have had the opportunity to use a legal representative, whanau/family support or a friend to help me ask questions and</td>
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<tr>
<td>understand the study.</td>
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<td>I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and</td>
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<td>information sheet.</td>
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<td>I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any</td>
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<td>time without this affecting my medical care.</td>
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<td>I consent to the research staff collecting and processing my information, including information about my health.</td>
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<td>If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw</td>
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<td>may continue to be processed.</td>
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<td>I consent to my GP or current provider being informed about my participation in the study and of any significant</td>
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<td>abnormal results obtained during the study.</td>
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<td>I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant</td>
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<td>regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of</td>
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<td>checking the accuracy of the information recorded for the study.</td>
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<td>I understand that my participation in this study is confidential and</td>
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that no material, which could identify me personally, will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study. Yes ☐

I understand that if I wish I can keep the trialled hearing aids at no cost. Yes ☐

I know any cost of repairs, maintenance or loss after the trial will be at my discretion and own expense. Yes ☐

I know who to contact if I have any questions about the study in general. Yes ☐

I understand my responsibilities as a study participant. Yes ☐

I wish to receive a summary of the results from the study. Yes ☐ No ☐

**Declaration by participant:**

I hereby consent to take part in this study.

**Participant's name:**

Signature: Date:

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

**Researcher's name:**

Signature: Date: