Participant Information Sheet

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Passive sound training as a means of tinnitus management

Investigators
Associate Professor Grant Searchfield (Principal Investigator/Supervisor)
Dunja Vajsakovic (Researcher/PhD student)

The mechanisms of tinnitus (phantom sound) perception are still poorly understood and ways to most efficiently suppress tinnitus are being investigated. Dr. Grant Searchfield, Associate Professor in the Audiology Section and director of the University of Auckland Hearing and Tinnitus Clinic, and Dunja Vajsakovic, PhD candidate, are conducting an intervention study to investigate the effectiveness of a passive perceptual training paradigm as a means of tinnitus management.

You are invited to participate in our novel tinnitus sound training trial at the University of Auckland Hearing and Tinnitus Clinics, Grafton.

In this trial, we will attempt to create a copy of your tinnitus (your tinnitus avatar) using computer software to gain a better understanding of your tinnitus experience. A treatment sound will be created based on your tinnitus profile; this sound will be loaded onto your personal smartphone so that you can take it home with you. You will be asked to listen to this sound daily for a minimum of 30 minutes over a period of 30 days (this can be done while doing other tasks). It is anticipated that exposure to the treatment sound will result in the brain passively learning to alter tinnitus perception and thereby reducing tinnitus audibility and distress.

In addition to measuring changes in tinnitus characteristics, we will also measure changes in psychological well-being (measured with emotion questionnaires) between the start and end of the trial.

This study will use EEG (brain wave) measurements to measure underlying changes in brain networks relating to tinnitus loudness and distress change following administration of
passive perceptual training. Past studies have shown that several networks (involving both auditory and non-auditory regions) may contribute towards final tinnitus perception.

In order to be eligible for this study, you must:

- Be aged 18 years or older
- Be fluent in English
- Have chronic tinnitus (minimum 6 months duration)
- Have tinnitus which is sufficiently severe as determined (using a tinnitus impact of life score calculation)
- Have no more than a moderately-severe hearing loss and no middle ear issues
- Have a tonal tinnitus (i.e., one that sounds like a pure tone and is **NOT** hissing/crackling in nature)
- Have tinnitus which **DOES NOT**:  
  - Fluctuate (i.e., is constant)  
  - Consist of more than one tinnitus sound
- Have a smartphone (android/iPhone)

As a token of our appreciation for your time and effort in participating in this study, you will be provided with your very own set of bone conduction headphones which you can keep following the study.

If during the screening tests in the first session you are found to not meet the inclusion criteria and proceed further for the study (e.g., too severe a hearing loss, tinnitus is not severe enough) you will still be given the opportunity to ask any questions regarding your tinnitus and provided general informational counselling.

Please find below an outline of the study.

**Prior to the appointment: Questionnaires (15 minutes)**

Before the initial appointment, you will be asked to fill in the following questionnaires measuring tinnitus history and impact on life (Tinnitus Case History Questionnaire, Tinnitus Functional Index, Tinnitus Severity Numeric Scale) and psychological impact (Positive and Negative Affect Schedule). The questionnaires will take approximately 15 minutes to complete. You will receive access to these questionnaires through a link that will be emailed to you. The link will take you to a website that will allow you to complete and submit the questionnaires at a time that is convenient for you.

If you meet the eligibility criteria for the study, you will be invited to the following appointment. The appointment consists of **one session lasting approximately 2.5-3h** and is split up into several parts as outlined below:

**Part one (approximately 60 minutes total): Hearing and tinnitus screening/assessment, baseline EEG measurements**

In this part of the appointment, we will discuss your tinnitus and conduct a full diagnostic hearing test:
A. Initial interview (10 minutes)
At the initial appointment, you will take part in an interview with the investigator where you will be asked to discuss your tinnitus. This will be an opportunity for us to assess your tinnitus, gain a better understanding of your experience, and offer appropriate counselling.

B. Pure Tone Audiometry (10 minutes):
You will be played a variety of sounds through a pair of headphones. These sounds will be short beeps at different pitches and volumes. You will be asked to respond by pressing a button when you hear a beep.

C. Generation of Tinnitus Avatar (15-25 Minutes):
Psychoacoustical measurement (how the tinnitus sounds) will be taken using tinnitus testing software for tinnitus pitch, loudness, maskability and location in space. The measurements will be used to generate a sound file which is an avatar of your tinnitus, and you will make fine adjustments until the sound best matches your tinnitus.

You will be asked to rate the pleasantness of the sounds you listened to and asked a few questions regarding whether you believe the sounds should be used in longer-term tinnitus interventions.

If you meet the eligibility criteria for the study, you will carry on with the following task:

Part two: Electroencephalography (EEG) recordings (60 minutes)

EEG is a non-invasive technique to measure the brain activity by electrodes placed on the head. Participants’ scalp under the electrode will be cleaned with alcohol swabs and a cap with inbuilt sockets for electrodes will be placed on the head and electrodes will be connected to those sockets. EEG is a painless technique for recording brain activity and will require washing head/hair after the testing.

In this part of the session, you will be asked to sit still while your brain activity is being measured. Three recordings will be taken while you:

1. Sit in silence in a dimly lit room and watch a grey cross presented in the center of a computer monitor screen for 10 minutes. During this time, we will observe your baseline (resting-state) EEG (brain waves).
2. Sit listening to your custom-made training sound. During this time, you will watch a grey cross presented in the center of a computer monitor screen for a further 10 minutes.
3. Once again sit in silence in a dimly lit room and watch a grey cross presented in the center of a computer monitor screen for a final 10 minute period.

The EEG will be recorded with participants sitting in a comfortable chair, in a sound treated room. Our research team will be happy to talk through the procedure (EEG) if you need further clarification, before consent is given.
Part three: Intervention (one month)

During the final part of this session, the training sound clip will be loaded onto your personal device (smartphone). The sound will be set at a comfortable and safe listening level as determined by both you and the investigator. You will be encouraged to listen to this for a minimum of 30 minutes per day over the following one-month period (you can do quiet activities while listening to the sounds, e.g., reading, gardening, etc.).

Part four: Follow-up (one month after your initial session)

One month following your initial appointment, you will once again be asked to complete the battery of questionnaires (a link will be sent to you via email giving you access to the questionnaires). The link will take you to a website that will allow you to complete and submit the questionnaires at a time that is convenient for you.

You will also receive some questions about your tinnitus and how you feel the perceptual training may or may not be influencing it, the situations in which you are using the sound clip, and any other incidental observations or fine fittings which need to made.

Part four will be completed remotely – you will not have to come in to the clinic.

We will submit a report for publication at the end of this research.

Risks and Benefits, Incidental Findings

There are no specific risks associated with taking part in the research. As a benefit, you can choose to receive a free detailed copy of your hearing/audiological testing results or take away the treatment sounds.

It is not anticipated, but in cases you may come to realise that tinnitus is of high concern or is impacting various aspects of your daily life. For any concerns, you can get in touch with the primary investigators both during and after the study in order to discuss concerns. All of the investigators are qualified audiologists with relevant tinnitus training, and can hence address your queries appropriately.

Consent, Participation and Withdrawal

Completing the consent form will indicate your consent to participate. Participation is entirely voluntary. You have the right to withdraw from the study at any stage without stating a reason and withdraw your data up to two months after the date of testing.

Summary of Findings

You can also request for a summary of study findings by entering in your details on the consent form. This information will be stored separately from the experimental data, in a
secure electronic folder on the primary investigator’s computer and destroyed after all research reports are sent out.

**Data Storage, Retention, Destruction**

The data obtained from this experiment will be stored to disc for a period of up to six years and will be used for publication in a scientific journal. The consent forms will be stored in a separate folder to study data. After six years, your data will be deleted from disc and your consent form and all related paperwork put through a shredder. No material that could personally identify you will be used in any reports in this study. The information and data collected from you will be stored securely, in locked cabinets and on secure computer networks. Only the investigators will have access to this information, and your data will be made confidential by assigning a unique code to it.

**Summary of Your Rights**

- Your participation is entirely voluntary.
- You may withdraw from the project at any time without stating a reason.
- You may have your data withdrawn from the study within **two months** of your participation.
- You may obtain results regarding the outcome of the project from the experimenters upon completion of the study.
- Your identity will be kept strictly confidential throughout the study. You will not be identified in any publications arising from the work.
- After six years, your data will be deleted from disc and your consent form and all related paperwork put through a shredder.
- You are encouraged to consult with your whanau/family, hapu or iwi regarding participation in this project.
- For some people discussing their tinnitus may be distressing. Support is available through the University of Auckland clinics.

Thank you for reading this Participant Information Sheet and considering our study.

**Contact Details**
If you have any questions, concerns, or complaints about the study at any stage, please contact:

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If you require Māori cultural and health support, talk to your whānau in the first instance. Alternatively, you may contact the Eisell Moore Centre, Māori Hearing Research Co-ordinator via email: Alehandrea.Manuel@auckland.ac.nz.

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 x 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

APPROVED BY THE AUCKLAND HEALTH RESEARCH ETHICS COMMITTEE on 16/09/2021 for three years. Reference Number AH22843