

Participant Information Sheet

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PARTICIPANT INFORMATION SHEET FOR PARTICIPANTS

Internet-based cognitive behavioural therapy in tinnitus sufferers: does the mode of delivery correlate with therapy effectiveness?

Principle Investigator: Dr Michael Maslin (Research Fellow, Speech Science)

Co-investigators: Dr Fabrice Bardy, Prof Suzanne Purdy

Tinnitus is the perception of sound in the absence of corresponding external stimuli. There is no cure for tinnitus but research has shown that cognitive behavioural therapy (CBT) is effective in managing the clinical sequelae.

What is the purpose of the study?

We are inviting people who are experiencing tinnitus to participate in this research where you will receive internet-based cognitive behavioural therapy (iCBT) through an engaging virtual coach which delivers iCBT through an app installed on your mobile phone. The virtual coach called “Tinnibot” will help you better manage your tinnitus and its effects using a chat conversation interface.

This study is an intervention study where the aim is to understand the benefit of human support through video conferencing in addition to the virtual coach “Tinnibot”.

What is involved in iCBT for tinnitus program in the study?

Features of the iCBT program delivered by “Tinnibot” to help you with your tinnitus are highlighted below:

i) Empowerment through self-management

The overall aim of iCBT is to promote self-efficacy by increasing the confidence individuals have to manage their own tinnitus. The content promotes an understanding and acceptance of tinnitus and empowerment to better manage tinnitus. This includes identifying unhelpful thoughts and behaviours, improving problem-solving skills and planning how to address possible setbacks in the future. It will also include mindfulness and meditation exercises.

ii) Tailoring

A tailored intervention is one that is adapted to the characteristics of the individual. As tinnitus can affect different people in different ways, a tailored intervention is helpful. One way that iCBT is tailored is by allowing individuals to select modules applicable to them. Modules addressing sleep, concentration, sound sensitivity and communication problems are thus optional. Tailoring is also included in the level of engagement with the materials.

iii) Accommodating different learning styles

By having the material delivered by a virtual coach, different learning styles can be accommodated. This ensures the content is accessible to a range of needs by presenting materials in visual or auditory form.

What will my participation involve?

If you decide to participate, you will be asked to complete 8 weeks of the iCBT program using an app installed on your mobile phone. Before the start of the program you will be invited to complete an online eligibility questionnaire.

If you met the eligibility criteria, we will book an appointment to explain the study to you and to complete an audiological assessment and a series of questionnaires (see table 1). We will conduct the session in a dedicated testing room located in the Speech Science Group Research Rooms, School of Psychology, Faculty of Science, University of Auckland Grafton campus:

Grafton, Park West
Lower Ground (LG), Building 507
85 Park Road
Auckland Central, 1023

The audiological assessment will involve:

1. Otosopic examination (visual examination of the ear canal using a hand-held ear light)
2. Audiometry (a diagnostic hearing test)

During the 8 weeks program, you will interact with the virtual coach for 5 to 15 minutes per session. The virtual coach will also send you notifications to start interacting with you. You will have the possibility to turn off the notifications sent by the app.

There will be two groups of participants. The first group will only be completing the iCBT program with the virtual coach. The second group will receive human-delivered counselling through video call on top of the iCBT program delivered via the virtual coach. The counselling sessions will be scheduled every fortnight (4 sessions of 30 min). The counselling will be delivered by Dr. Cara Wong who is contracted for the study through a 'contract of service'. You will be randomly assigned to one of the two groups.

At the end of the 8 weeks program as well as 2 months after the end of the program, we will ask you to complete another series of questionnaires to monitor the efficacy of the program.

What are the criteria to be part of the study?

The eligibility criteria to participate are as follow:

1. Age 18 and over, and living in New Zealand.
2. Can read and type in English.
3. Have a smartphone which can be used to install the Tinnibot "app" (Android or Iphone).
4. No difficulties to use a mobile phone (e.g., significant fine motor control or visual problems).
5. Have internet and email access, and the ability to use these.

6. Bothered with tinnitus for a minimum period of 3 months.
7. Have been examined by an ear, nose and throat (ENT) specialist and an audiologist to rule out any medical causes for tinnitus.
8. Tinnitus is not a consequence of a medical disorder and is not currently under investigation;
9. Committed to complete the initial appointment at the University of Auckland, the 8 weeks tinnitus programme and the online appointments.
10. Agreeing to participate in either group and to be randomised to one of these groups.
11. Not undergoing any tinnitus therapy concurrently.
12. Not reporting any major medical or psychiatric conditions.
13. Not reporting pulsatile, objective or unilateral tinnitus which have not been investigated medically.
14. Be available for 2 months after finishing the study to complete a follow-up questionnaire.

	Enrolment	Initial appointment: Program start	Tinnibot program (8 weeks)	Video-call: Group 2	Video-call: Program end	2 months after the end of the program
How long will it take?	10 minutes	60-90 minutes	15 min per session	4 x 30 min	60-90 minutes	45-60 minutes
Eligibility screening	✓ <input type="checkbox"/>					
Study explained, written consent obtained		✓ <input type="checkbox"/>				
Inclusion and exclusion criteria checked		✓ <input type="checkbox"/>				
Hearing Assessment		✓ <input type="checkbox"/>				
Online Questionnaires about your hearing, tinnitus, hyperacusis, insomnia, mindfulness, anxiety, cognitive failure, quality of life.		✓ <input type="checkbox"/>			✓ <input type="checkbox"/>	✓ <input type="checkbox"/>
Interaction with the virtual coach Tinnibot (from once a day to once every 3 days)			✓ <input type="checkbox"/>			
Counselling session with psychologist (only for Group 2)				✓ <input type="checkbox"/>		
Feedback on the smartphone application					✓ <input type="checkbox"/>	

Table 1: Schedule of the different activities during the study.

What are the possible benefits and risks of the study?

Several studies have indicated that iCBT program delivered online have the potential to reduce tinnitus distress significantly. The intervention has moreover shown to reduce clinically tinnitus-related difficulties such as insomnia, anxiety, depression, and increase quality of life. The “Tinnibot” app will be installed for free on your mobile phone at the start of the study and will remain available and free for you once the study is finished.

Who pays for the study?

This project is funded by Eisdell Moore Center Research Grant awarded to Dr Michael Maslin.

Anonymity and Confidentiality

Any information or personal details gathered in the course of the study are **confidential**, except as required by law. No individual will be identified in any publication of the results. Researchers will have access to the data. A summary of the results of the data can be made available to you on request through email. Your data may be used in future research on the same project.

Data storage/retention/destruction/future use

During the project, data will be recorded using written documentation and in software. Participants will be identified by a unique number, 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. Data related to the use of the third-party software "Tinnibot" being studied will be encrypted, de-identified and stored on secure AWS cloud servers in Sydney, Australia, under the control of the investigator. 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 10 years before being destroyed.

Results will be disseminated through academic literature and/or at conferences. Your personal information will not be used in any way that could possibly identify you during and following this research project.

What are my rights?

Your participation is voluntary, i.e., you decide whether or not wish to take part in this research study. You are free to decline to participate, or to withdraw from the research at any time, without giving reasons. You can also decide to withdraw any data traceable from the study up to 3 months after completion of the final questionnaire.

If any information about the study becomes available during the study, which could affect your decision to participate, you will be informed.

Compensation

You will be offered a non-cash payment in the form of a shopping vouchers or petrol vouchers with total value of \$160 at the end of the study.

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

Who do I contact for more information?

Questions regarding the research project may be directed to:

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Chair contact details: For any queries regarding ethical concerns you may contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone: 09 373 7599 Ext: 83711.

Email: humanethics@auckland.ac.nz

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE
ON 27th OF JULY FOR 3 YEARS, REFERENCE NUMBER **024482**