

The University of Auckland

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## CONSENT FORM

**This form will be held for a period of 6 years**

**Project title:** 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

### Declaration by participant:

I have read the Participant Information Sheet and have understood the nature of the research and why I have been selected. I have had the opportunity to ask questions of the investigators and have had them answered to my satisfaction.

- I agree to take part in this research.
- I understand that I am free to withdraw my participation at any time without giving reason, and to withdraw any data traceable to me up to 3 months after completion of the final questionnaire.
- I am 18 and over, and living in New Zealand.
- I can read and type in English.
- I have a smartphone which can be used to install the Tinnibot “app” (Android or iPhone) which I have no difficulties to use.
- I have internet and email access, and the ability to use these.

- I have been bothered with tinnitus for over 3 months.
- I have been examined by an ear, nose and throat (ENT) specialist and an audiologist to rule out any medical causes for tinnitus.
- My tinnitus is not a consequence of a medical disorder and is not currently under investigation.
- I am not reporting pulsatile, objective or unilateral tinnitus which have not been investigated medically.
- I am not reporting any major medical or psychiatric conditions.
- I am not undergoing any tinnitus therapy concurrently.
- I understand that I will have an appointment at the start of the study that will take approximately 90 min. and that will be conducted at Grafton campus at the Faculty of Science, University of Auckland.
- I am committed to complete the 8 weeks tinnitus programme.
- I understand that 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.
- I am agreeing to participate in either group and to be randomised to one of these groups.
- I understand if I am part of group 2, the counselling sessions will be delivered by Dr. Cara Wong who is contracted for the study through a “contract of service”. The sessions will be scheduled every fortnight (4 sessions of 30 min).
- I will make myself available for 2 months after finishing the study to complete a follow-up questionnaire.
- I have been given a copy of the Participant Information Sheet and Consent Form to keep.
- I understand that if I was injured as a result of this study, I would be eligible to apply for compensation from ACC just as I would be if I were injured in an accident at work or at home. This does not mean that my claim will automatically be accepted. I will have to lodge a claim with ACC, which may take some time to assess. If my claim is accepted, I will receive funding to assist in my recovery. If I have private health or life insurance, I may wish to check with my insurer that taking part in this study won’t affect my cover.
- I understand that participation in this study is confidential and that no material that could identify me will be used in any reports or publications relating to this study.
- I understand that I am free to withdraw participation at any time without providing a reason and to withdraw any data traceable to me, and that if I do withdraw, my future health care will not be affected.

- I understand that non-identifiable information will be kept for 6 years, after which they will be destroyed, and that non-identifiable collective data will be kept indefinitely. I understand this involves storage via a password protected data analysis computer, located in a secure University of Auckland building 507 area accessible only by approved, proximity key-card access. I understand the data management plan requires annual review of key-card access and personnel.
- I have had time to consider whether I wish to take part, and I know whom to contact if I have any questions or concerns regarding this study.
- I wish to receive non-cash payments in the form of:

shopping vouchers or  petrol vouchers

- I **wish / do not wish** to receive the summary of findings, which can be emailed to  
*(Please circle choice)*

me to this email address: \_\_\_\_\_

I, ..... hereby consent to take  
*(Please print full name)*  
part in this study.

**Signature:**.....

Date: .....

**Email:**.....

**Phone number:** .....

**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: .....

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