Macquarie University Hearing
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Participant Information and Consent Form

HREC Project Number:	11262
Title:	Hearing Impairment in Adults: A Longitudinal Outcomes Study
Short title:	HALOS
Principal Investigator (PI):	Professor Bamini Gopinath

1. Introduction

You are invited to participate in the Hearing Impairment in Adults: A Longitudinal Outcomes Study. You are invited to take part in this study because you meet the following eligibility criteria: 1) aged 40+ years; 2) wears a hearing device in at least one ear; 3) sufficient English language competency to complete the online survey; and 4) able to give informed consent.

This Participant Information and Consent Form (PICF) tells you about the research project. It explains what taking part in this study will involve. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Our research team are happy to go through this information with you and answer any questions you may have. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research?

The purpose of the study is to investigate adults with hearing loss who have undergone interventions or treatment for their hearing loss and:

- Evaluate the impacts of treating hearing loss on health, relationships, education, and work/employment outcomes.
- Examine differences in long-term outcomes within and between groups of hearing aid and cochlear implant users.
- Determine the impact from the timing of hearing aid/cochlear implant intervention and the effectiveness of earlier intervention on outcomes
- Evaluate the cost-effectiveness of early intervention/ rehabilitation for hearing loss.

3. What does participation in this research involve?

If you have expressed an interest in participating in the study, your eligibility will be screened by a research team member via a telephone interview. If you meet the criteria listed above, you will be asked to sign an online consent form. The consent form will also give you the option to sign an 'authorisation to release information' form that will permit the study team to collect retrospective data from your hearing service provider around your hearing thresholds, and type of hearing device that you use. Upon signing the consent form you will be emailed a link to complete the survey. Please advise the researcher if you prefer a paper version of the consent form and survey. These will be posted to you along with a reply-paid envelope.

The survey will include questions about your demographics e.g. age, sex, education level; medical history; hearing loss; quality of life; cognitive function; employment; unmet needs; and relationships. The survey will take up to 60 minutes to complete, and you will have 2 weeks to complete it. We will also ask you to complete a separate brief cognitive assessment in your web browser, which will take approximately 15 minutes. This will involve some short thinking tasks.

You are also invited to complete an interview to discuss your opinions about the current hearing services in Australia. It should take approximately 20-30 minutes and will take place over the phone. If you agree, you will be contacted by the research team to organise a time to conduct the interview at your convenience. With your permission, the interview will be audio recorded, however there will not be an opportunity for you to review or edit your responses. Participation in the interview is optional and you may choose to only complete the survey as described previously.

With your permission, we will also invite you to complete the survey again at time points in the future e.g. 2 years, 4 years. You will be contacted via the details you have provided and be invited to participate again.

There are no costs associated with participating in this research project. On completion of the survey, you will be reimbursed a $30 Coles-Myer gift card for your time.

4. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Macquarie University.

5. What are the possible benefits of taking part?

There are no direct benefits of taking part in the survey. However, your participation will help to better understand the impacts of hearing interventions (hearing aids and/or cochlear implants) and evaluate how these interventions compare against each other. These data can help to improve the delivery of hearing health services in the future.

6. What are the possible risks and disadvantages of taking part?

We don't expect this survey to cause any harm or discomfort, however, if you experience feelings of distress as a result of participation in this study, you can let the research team know and they will provide you with assistance. We have also provided a list of support services at the end of this document that you can contact in the unlikely event that you feel distressed as a result of participating in this study.

You may experience some minor tiredness completing the surveys. We encourage you to take breaks as needed, and you will have two weeks to complete the survey.

7. What if I withdraw from this research project?

If you do consent to participate, you are still free to withdraw at any time and without giving a reason. If you do decide to withdraw from the study then please inform the research team as soon as possible, and they will facilitate your withdrawal. If you do

withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decided to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results.

8. What will happen to the information collected about me?

By signing the consent form, you consent to the research team collecting and using personal information about you for the research project.

Any information or personal details gathered in the course of the study are confidential, except as required by law. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

The research team has put a number of procedures in place to protect the confidentiality of participants. Your name or other personal details will not be associated with your data and the consent form that you sign will be kept separate from your data. All paper records will be stored in a locked filing cabinet, accessible only to the research team, and all electronic data will be stored on a password protected server. Any data collected about you in the questionnaires will be stored on a password protected server.

Data collected from the cognitive assessment will be stored overseas and accessed by the software provider Cogstate. Data collected from the telephone interview may also be stored overseas when being transcribed. We do not disclose your personal identifying details to any overseas recipients of the data.

Data collected may be shared in an anonymised form to allow reuse by the research team and other third parties for unspecified, ethically approved health and medical research studies in the future. These anonymised data will not allow any individuals to be identified or identifiable.

9. Who is organising and funding the research?

This study is being carried out by the following researchers: Professor Bamini Gopinath, Professor David McAlpine, Professor Catherine McMahon, Professor Kerry Sherman, Professor Jeffrey Braithwaite, Dr Yvonne Tran, Professor Greg Leigh, Professor Frances Rapport, Professor Viviana Wuthrich, Professor Janaki Amin,

Professor Rebecca Mitchell, Professor Patrick Garcia, A/Prof Jorg Buchholz, A/Prof Melanie Ferguson, A/Prof Kompal Sinha, and Dr Diana Tang.

This research is being funded by a Cochlear-Macquarie University Joint Research Fund and the Martin Lee Centre for Hearing Health Innovations.

10. Who has reviewed this study?

The ethical aspects of this research project have been approved by an Ethics Committee at Macquarie University.

11. Further information and who to contact

If you require further information, have any questions or would like to withdraw from the study or withdraw your data then please contact:

Research contact person

Name	Jessica Turner
Position	Study Coordinator
Telephone	(02) 9850 8750
Email	Jessica.turner@mq.edu.au

Complaints contact details

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact The HREC that approved this study:

Name	Macquarie University Human Research Ethics Committee
Telephone	(02) 9850 7854
Email	ethics@mq.edu.au

Support Services Contact Details

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

Lifeline	13 11 14 https://www.lifeline.org.au/
Beyond Blue	1300 22 46 36 https://www.beyondblue.org.au/

Thank you for taking part in this study. You should keep this participant information sheet as it contains important information and the research teams.

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Consent Form (Investigator's / Participant's Copy)

I, _____have read and understand the information above, and any questions I have asked have been answered to my satisfaction. I agree to participate in this research, knowing that I can withdraw from further participation in the research at any time without consequence. I have been given a copy of this form to keep.

Authorisation to Release Information

I authorise the release of my information from my hearing service provider around hearing thresholds and type of hearing device used.

□ No
□ Yes

Telephone Interview

I agree to participate in a telephone interview to discuss my opinions about the current hearing service in Australia and for this interview to be audio-recorded.

□ No
□ Yes

Future HALOS surveys

I agree to be contacted about completing the HALOS surveys again in the future.

□ No
□ Yes

Unspecified consent

HALOS seeks consent for the data to be used in any other projects in the future. I provide 'unspecified' consent for the use of my anonymised data in any future unspecified, ethically approved health and medical research studies.

□ No
□ Yes

I would like to receive a summary of the findings:

□ No

□ Yes, via post

Address: _____

□ Yes, via email

Email: _____

Participant's Name: (Block Letters)	
Participant's Signature:	
Date:	

The ethical aspects of this study have been approved by the Macquarie University Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics & Integrity (telephone (02) 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

Revocation of Consent Form

I wish to **WITHDRAW** my consent to participate in this research study and understand that such withdrawal **WILL NOT** affect my relationship with Macquarie University.

Participant's Name: (Block Letters)	
Participant's Signature:	
Date	