PARTICIPANT INFORMATION SHEET

STUDY TITLE:
Hearing and cognitive outcomes using a cognitively focused hearing aid fitting strategy compared to current practice.

Investigators:
Associate Professor Grant Searchfield (The University of Auckland)
Professor Megan McAuliffe (Canterbury University)
Professor Ngaire Kerse (The University of Auckland)
Ms Ying Huang (The University of Auckland)
Dr Elana Curtis (The University of Auckland)
Dr Hinemoa Elder (Te Whare Wānanga o Awanuiārangi)
Christine Fok (The University of Auckland)
Eric Williams (Canterbury University)
Tin Aung Kyaw (The University of Auckland)

Researcher Introduction:
We wish to invite you to participate in research that will investigate the effect of hearing aids on hearing and cognition (thinking and understanding). This research is being undertaken by the University of Auckland and Canterbury University Audiology (Hearing) Clinics.

Project description and invitation
Volunteers over 65 years of age seeking hearing aids are invited to participate in this research project.

Untreated hearing loss speeds up age-related decline in our ability to process & understand information. Hearing aids can slow or halt this decline (hearing aids help thinking and processing information). Some
technology used in hearing aids may be more or less helpful as we age. This research will compare standard hearing aid fitting (that which is normally provided) to a hearing aid fitting modified according to results on tests of attention and memory. You will be able to select hearing aids with your audiologist as you normally would. The hearing aids in the study are the same as normally used. The way the hearing aids are “tuned” is different. The results will lead directly to better hearing services for older New Zealanders.

For half of the participants, hearing aid processing will react quickly to changes in level and types of sound, for the other half the hearing aid will use slower changes to adapt to the environment. There is some evidence that slower processing is more helpful as we age.

We will submit a report for publication at the end of this research. The outcomes will help improve hearing aid service delivery in NZ.

**Eligibility to participate**

If you are aged over 65 years old and are seeking hearing aids you are eligible to participate in the first part of the research. Half of those participating in part 1 will be eligible for part 2.

**Part 1. Testing of hearing and cognitive ability.**

Hearing tests and measures of cognition (thinking and understanding) will be undertaken. These tests are clinical tests, the hearing tests are a normal part of hearing aid fitting, and the cognitive tests are included for the research. The cognitive testing will take place as a separate appointment, requiring 1.5 to 2 hours of your time. In part 1 you will receive a $20 petrol voucher as thanks for participating and as a contribution to your travel costs.

Participants will be selected for part 2 on the basis of these tests.

**Normal hearing test appointment:**

**History and otoscopy (5 minutes):**

We will look in to your ear canal using a torch light (otoscope) to see if the ear canal is wax free and check the status of the ear canal and ear drum. The Audiologist will also ask you some standard questions about your hearing history and hearing needs.

**Pure Tone and speech Audiometry (30 minutes, part of normal appointment):**
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. You will be asked to repeat words played to you over headphones.

**Cognitive tests (1.5 - 2 hours in a separate appointment, for research only):**

A series of tests of thinking will be undertaken. The tests will be presented on an iPad (a tablet computer). Instructions will be provided on what is required to complete these tests, you will be asked to tap on the screen in response to sounds or pictures. Results will be automatically recorded. These tests will calculate your attention, vocabulary, memory abilities and hearing in noise. The cognitive tests will take between 60 to 90 minutes. Additionally, we will use questionnaires to collect some demographic information and to understand your hearing background. These include a demographics questionnaire, the Modified Abbreviated Profile of Hearing Aid Benefit (MAPHAB) and the Hearing Handicap Inventory (HHIE-S).

**Part 2. Effects of hearing aid settings on hearing and cognitive ability.**

**Project procedures**

You and your audiologist will select hearing aids based on your needs in the normal way. Eligible participants will be assigned to one of two groups: standard hearing aid settings or modified based on test results. The settings used in the hearing aid fitting will be slightly different. The audiologist will fit and tune the hearing aids to your needs to obtain the best results. You will not know which setting you receive until the end of the trial. At the end of the trial (after 12 months) you will be told the setting you received and you will have the option of trying the other setting.

After the hearing aid fitting (a process that normally requires several appointments) you will use the hearing aids as you intend to. Routine follow-up appointments (30 minutes) will be made at 6 months and 12 months following the hearing aid fitting. For the research the hearing
questionnaires and tests of thinking and understanding, used in part 1, will be repeated (an extra 60 minutes).

Participants in the trial will not be charged for the cost of appointments. The cost of hearing aids will be the standard cost for the brand and model chosen. Participants will receive free hearing aid batteries for the duration of the trial (12 months). Normal hearing aid warranties and conditions will apply.

**Time required**

The normal hearing aid fitting process occurs over several appointments of 30-60 minutes with follow-up appointments of 30 minutes at 6 and 12 months after the fitting.

The research will require additional time of 1.5 – 2 hours (part 1) and 60 minutes at 6 and 12 months (part 2). The total time added to normal hearing aid fitting process, if selected for the whole trial, will be about 3.5 to 4 hours spread across three appointments for the study duration (12 months).

**Anonymity and confidentiality**

Access to completed consent forms and questionnaires will be restricted to the researchers. Participation in this study and all information collection from participants will remain confidential. During the research project, data collected from questionnaires/forms will be recorded using written and secure digital documentation and in statistical software for analysis. Each participant will be assigned an identifying number, which will appear on these records. No participant will be individually identified in published data relating to this research.

**Data storage/retention/destruction/future use**

A record of participants’ names and their allocated number will be kept securely during the project and will be deleted immediately after completion of the project. Data will be collected using the web-based REDCap system, stored on a secure password protected server. At the completion of the study, all electronic data will be digitally archived and accessible only to the principle investigators. Non-identifiable data used for statistical analysis will be retained for 6 years before being deleted. All questionnaires and consent forms will be stored in a secure filing cabinet by the principal investigator for 6 years before being destroyed.
Risks and incidental findings

Minor, relatively rare, adverse effects of hearing aids include irritation to the external ear canal from local allergic reactions from ear moulds. Hearing loss from hearing aids is extremely rare, output limiting in the hearing aids prevents damaging amplification of sound. Any minor adverse effects are managed as part of the normal hearing aid fitting process. If any participant’s hearing aid settings are modified by the audiologist following real-world trial in such a way that the settings do not match the specified settings, the participant’s data will be withdrawn from the study. Participants will still receive free consultations and batteries for the 12 month period of the trial. The study would be terminated early if there was unequivocal evidence of harm or superiority of one hearing aid setting over the other.

Right to withdraw from participation

Participation in this study is purely voluntary and participants may withdraw from the study at any time without providing a reason as well as withdraw any data provided up until October 2020.

Compensation

In the unlikely event that a physical injury occurs as a result of your participation in this study, you may be covered by ACC under the Accident Compensation Act 2001. Your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If your claim is accepted, there is still no guarantee of receiving any compensation. This would depend on factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses, and there may be no lump sum compensation payable. There is no cover for mental injury unless it occurs as a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, please contact your nearest ACC office or the investigator.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance, and superannuation.
Funding
Funding for this study was obtained from the Health Research Council (HRC) of NZ.

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 prior to October 2020. 
Your participation will take approximately 3.5 – 4 hours in addition to normal hearing aid fitting time, spread across 3 appointments. 
You may obtain results regarding the outcome of your hearing aid fitting from your audiologist upon completion of your trial. 
You may choose to trial the alternative setting of the hearing aids at the end of the trial.

Contact Details
If you have any questions about the study or would like to participate, please contact one of the following:

Auckland
Grant Searchfield (Section of Audiology, The University of Auckland): 
Phone: 09 3737599 ext. 86316; 
E-mail: g.searchfield@auckland.ac.nz

Christchurch
Megan McAuliffe (Communication Sciences, Canterbury University) 
Phone: 03 364 2987 ext. 7075; 
Email: megan.mcauliffe@canterbury.ac.nz

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: ro-ethics@auckland.ac.nz.

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 3/11/17 for (3) years, Reference Number 020188.