Appendix B – Participant Information Sheet

THE FACULTY OF SCIENCE

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PARTICIPANT INFORMATION SHEET

To: Individuals interested in their child participating in a study trialling a novel testing method, towards investigating a reliable and clinically feasible way of determining speech discrimination ability in infants with hearing loss. The method will involve an optimised evoked potential approach (the optimised Mismatch Response or MMR).

Project title: A reliable and feasible method for providing objective assessment of auditory discrimination; the optimised mismatch negativity (MMN) response

Principle Investigator: Professor Suzanne Purdy (Head of School, Psychology)
Co-Investigator: Dr Kim Wise (Audiologist; Research Fellow)
Co-Investigator: Dr Michael Maslin (Audiologist; Research Fellow)

Researcher introduction

The research project is under the supervision of Professor Suzanne Purdy (Head of School, Psychology), with logistical input and guidance from Co-Investigator Dr Michael Maslin, an Audiologist and Research Fellow.
The test results will be collected by:
(North Island) Co-Investigator Dr Kim Wise, an Audiologist Research Fellow working with the Speech Science Group, The University of Auckland
-or-
(South Island) Co-investigator Dr Mike Maslin, an Audiologist Research Fellow working with the Department of Speech and Hearing, The University of Canterbury.

Funding for this study is supplied by a research grant awarded by the William Demant Foundation.

Project description and invitation

Cortical auditory evoked potentials (CAEPs) are measurements of brain responses produced by the hearing pathways in the brain. They indicate whether sounds signals used to generate the responses are audible and reaching the higher, central hearing pathways. When the test

sounds are composed of human speech sounds, CAEP measurements can determine if speech sounds are *detected*.

A Mismatch Negativity response (MMN), is a type of CAEP generated when a series of similar sound signals are presented repetitively but, occasionally feature the rare presence of a different sound signal. The auditory system's ability to perceive and distinguish the presence of the rare sounds is reflected by the presence of the MMN. When the MMN is generated by signals composed of human speech sounds, it can be a potentially useful tool for testing speech *discrimination* ability. However, the MMN technique has previously been time-consuming and not a clinically feasible method to assess speech discrimination capabilities in infants.

For infants younger than 9 months with hearing loss requiring hearing aids, there is a lack of objective, clinical techniques that also index speech discrimination with amplification. Presently, an infant must mature to approximately 6 to 9 months of age before they can be expected to dependably engage in tests seeking a behavioural response (e.g., a head-turn towards an audible sound). Currently, behavioural tests are recommended practice for gaining reliable data about speech detection and discrimination ability via amplification, for these age groups.

Per international research, a promising solution to excessive MMN test timing is the "optimized" MMN method. Rather than the typical presentation of occasional, rare sound stimuli sequentially (time-consuming), the optimised MMN decreases test time by presenting multiple, mismatched stimuli in an interleaved fashion. However, there is a need to extend current research from normally-hearing adults to infants. This requires exploration of the optimised MMN approach, with a view to compare the procedure's clinical utility between normally-hearing infants, and infants with hearing loss affecting both ears.

Participants who are being selected for this study will be 3 to 12 months of age, have typical head/brain health (i.e., no neurological issues), no current ear infections, or issues with ear wax. Participants will be either infants in the required age range who have normal hearing, or infants with hearing loss affecting both ears. Having your infant participate in the study is voluntary.

Project Procedures

Interested participants will be requested to complete a consent form before a brief interview covering your child's audiological (hearing) history.

The data collection session for which your child (accompanied by the whānau, parent(s)/caregiver(s)) would need to be present for, will occur over **one, one-and-a-half hour session** for the study. Optional comfort breaks will be available after the audiological assessment and preceding the data collection. Additional breaks can be supplied.

Audiological Assessment:

This involves:

1. Brief developmental history

2. Brief otological (ear and hearing) history
3. Otoscopic examination (visual examination of the ear canal using a hand-held ear light)
4. Tympanometry (middle ear health check)

The screening procedure will be carried out according to New Zealand Audiological Society (NZAS) Best Practice Guidelines (2016).

Infants should be fed beforehand. Additional feeding could be considered during the break between the audiological assessment and set-up of evoked potential recordings, as it is ideal to finish the test once the recording set-up is complete. It is unlikely your child will need a break once the recordings start as they should be relaxed and held/seated comfortably on the parent's/caregiver's lap. However, comfort breaks can be scheduled as necessary.

Infants should not have their hair conditioner applied to their hair near the scalp the night before or morning of the appointment for optimal scalp contact for the recordings. Also, your child should not be exposed to loud noise 24 hours prior to testing as that may cause temporary changes in hearing ability.

Evoked Potential Recording:

Evoked potential recordings will take place in a specified room for the test recordings. The participant will be held/seated on the parent's/caregiver's lap, as the parent's/caregiver's sit in a comfortable reclining chair for the duration of the testing. Whānau, parent(s)/caregiver(s) will be verbally reminded of the evoked potential recording procedure. Safe surface sensors (electrodes) will be placed onto specified locations on the head. The sensor site will be prepared by rubbing the skin with a mildly exfoliating water-soluble gel used in routine clinical practice and a clean gauze. Visual and auditory contact will be maintained with the infant, and their whānau, parent(s)/caregiver(s) present, at all times. A research assistant will be present in testing suite throughout the procedure.

Four recording sensors will be placed on the infant participant's scalp: (1) on the high forehead in the midline plane (Fz); (2) at the intersection where the midline plane crosses the centre plane (Cz), as indicated by an imaginary line drawn from the front aspect of the left ear, across the top of the head to the front aspect of the right ear; and (3 & 4) on left and right mastoids (region behind the ears, approximately level with the ear lobes). A range of commonly-used speech stimuli such as [/m/, /g/, /t/, /s/] will be used to elicit the MMN. Stimuli will be presented via a sound field speaker (loudspeaker) at an intensity level of 70 dBA (deciBels). Infant participants who remain awake will have their attention distracted by toys held by a research assistant. However, the MMN has been shown to be reliably recorded in sleeping infants as well.

Post-recording:

The water-soluble gel will be removed with tissue at the end of the test. Re-usable scalp electrodes will be cleaned in warm water and disinfected before the next session. A summary of

the results will be available for the Whānau, parent(s)/caregiver(s) at their request and time is allocated for any questions about the test results or the research project.

Parent(s)/caregiver(s) will receive a **voucher worth $20** at the end of the session by way of reimbursement for transportation costs and as an offer of appreciation for participation.

All of the research procedures described above, **will take place at the following locations, depending on convenience and availability:**

(North Island)

1) **The University of Auckland**
   22-30 Park Avenue, Grafton
   Building 507,
   Lower-ground Clinical Centre
   Auckland 1023

2) **The Greenlane Clinical Hospital Audiology Centre, Auckland New Zealand**
   214 Green Lane West
   One Tree Hill, Epsom,
   Fourth Floor
   Auckland 1051

(South Island)

1) The University of Canterbury
   Geography Building, Level 1 Reception
   Arts Road Entrance

Anonymity and Confidentiality

Infant participant data collected for the study will be de-identified. In any report of the data, the identity of participants will not be revealed.

Data storage/retention/destruction/future use

During the project, data will be recorded using written documentation and in software.
Infant participants will be identified by a number allocated to them, 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. Only non-identifiable information required for analysis of the results will be retained and stored for 6 years before being destroyed. Nonidentifiable aggregated data will be securely kept indefinitely. The consent form will be kept secure and separate from the data by the Principal Investigator for 6 years, per current University research practise, before being destroyed.

Risks

The optimized MMN recordings are low-risk as they are already in research use involving adults, children and infants, in NZ and overseas. There may be mild discomfort with evoked potential recordings – the gel is mildly abrasive and hypoallergenic (water based); stick-on disposable electrodes may be slightly irritating on the skin during the testing but should subside quickly; sounds played will be of a conversational level and the total noise dosage accumulating over the test duration will be below the daily recommended noise dosage.

Incidental findings

If a previously undiagnosed hearing loss or ear anomaly is found, the infant participants' Parent(s)/caregiver(s) will be informed and offered referral as appropriate. The Principal Investigator and the Co-Investigators are experienced, clinical audiologists and may advise GP referral depending on the case. As this study requires normal-hearing participants, or infants with hearing loss affecting both ears, in the case of an incidental finding consistent with an unexpected ear anomaly such as an ear infection or similar, a participant candidate may be excluded.

Right to Withdraw from Participation

The parent(s)/caregiver(s) can withdraw their child from participation at any time without providing a reason and withdraw any data traceable to them, up-to 1 February 2022.

Compensation

In the unlikely event of a physical injury as a result of your child's participation in this study, you may be covered by ACC under the Accident Compensation Act 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors, such as whether you are an earner or nonearner. 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 is 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, 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 for your child or are considering, such as medical insurance, or life insurance.

Contact Details

Further questions regarding the research project may be directed to:

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For any queries regarding ethical concerns, you may contact:

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