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Participant Information Form for Parents/Caregivers

Title of research:

Graph theory analysis of functional connectivity: links with Auditory Processing Disorder

This project is being carried out by Prof. Suzanne C. Purdy, Dr. Abin K. Mathew, Mr. Ashkan Alvand, Prof. Ian J. Kirk and Dr. Reece P. Robert (School of Psychology, The University of Auckland).

Thank you for taking an interest in this research!

Your child is invited to take part in this research being conducted by staff and students within the School of Psychology. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Key information

This research will investigate the link between your child's hearing abilities and brain processing to better understand Auditory Processing Disorder (APD) experienced by young school-aged children. The study may involve two separate sessions (2 hours in total) during which simple hearing tests and MRI brain scans will be acquired while your child is awake and at rest. (See below for further information). You can decide not to have your child participate in this study. Even if you decide to join the research now, your child is free to leave at any time if you change your mind.

In total, participants (including parents) will be offered \$30 (per-session) in vouchers to help with the travel cost. A copy of your child's results and MRI brain scan will be provided upon request.

There is a possibility that the MRI may reveal an abnormality that is already in your child's head or brain, such as a cyst or tumour. In this case, this is the policy of the University of Auckland to inform you about this.

This project may not offer any direct benefit to your child now but will help us better understand the neural processing associated with listening difficulties and better inform the diagnosis and treatment of APD in the future.

What is the purpose of the study?

APD is a hearing disorder in which the ears receive sound normally, but the auditory networks within the brain do not integrate this information accurately. This can affect understanding, especially in challenging listening situations such as in the presence of other distracting sounds, or when listening to complex information or instructions. It can affect 5% of school-aged children and 76% of middle-aged & elderly adults. They can hear but have trouble understanding what they hear. APD is an under-recognised hearing disorder that is an underlying cause of learning and behavioural concerns in thousands of New Zealand children. APD is not detected by basic hearing tests, and consequently, many children with undiagnosed APD are struggling both in school and with general communication.

How well an individual can understand speech depends not only on the sound being audible but also on the relationship between auditory brain networks and the representation of sound from the ear to the brain. Auditory processing difficulties results from an impaired neural function that cannot be explained by basic hearing tests. The present project aims to use magnetic resonance imaging (MRI) method to better understand how the brain of children and adults changes with age and how these changes affect the auditory processing of sounds.

Who may participate in this study?

Taking part in this study is completely **voluntary**. Your child does not have to participate if he or she doesn't want to. Your child may also leave the research at any time. If your child leaves the research before it is finished, there will still be compensation for his/her time.

Children aged 9-13 years with normal hearing and age-appropriate and language and cognition may participate in this study. Participants must be able to tolerate small, enclosed spaces without anxiety and should not have any metals or implanted devices within their body, e.g., Aneurysm clips, pacemakers, artificial limbs.

In addition, according to magnetic resonance imaging (MRI) safety protocols, participants will be excluded from any studies if they have any history of an implant of pacemakers or pacemaker wires, open-heart surgery, artificial heart valve, brain aneurysm surgery, middle ear implant, hearing aid, braces or extensive dental work, cataract surgery or lens implant, implanted

mechanical or electrical device, or artificial limb or joint. Participants will be excluded if they are claustrophobic, have uncontrollable shaking, or cannot lie still for half an hour.

It is extremely important that you tell us about any and all surgeries your child has had so that we might know if there is a chance that any metal would be inside your child. A strong magnetic field could disturb a metal fragment in your child's body or interfere with an implanted device, such as a pacemaker, causing your child harm.

What is expected from you, and from your child?

This study may involve two sessions lasting for about 1.5 hours each session. All behavioural testing will take place in session 1 and MRI testing in session 2.

Session 1 (behavioural tests)

Dr. Abin Kuruvilla Mathew and Ashkan Alvand will conduct the behavioural auditory processing tests at The University of Auckland, School of Psychology. Testing will be approximately 45 minutes for each participant.

Hearing tests (about one hour including a 15-minute break)

Your child will be asked to participate in an assessment that requires them to listen to some segments of sounds via headphones placed on their ears to detect presented tones. We will ask your child to place a small plug in their ear canal to measure the status of their middle ear. We assure you there will be no harm to your child's ear in this assessment. We will ask them to sit comfortably during this process. In the next phase of this assessment, we will ask your child to repeat sentences or discriminate non-speech stimuli (e.g., a high pitch vs. low pitched tone) with noise in the background presented via speakers/ headphones. At a different stage of the test, we will ask your child to either pay attention to both ears or one ear at a time.

Session 2 (MRI scan session)

While at CAMRI, your child will be screened for MRI precautions and have a sequence of MRI scans performed.

MRI involves lying on a table, which then moves into a hollow machine (the magnet). The actual MRI examination of your child's body will take only 25 minutes, and your child will be asked to remain as still as possible during the entire period. Small hand and foot movements are allowed in between scans (your child will know they are being scanned because he or she will hear loud knocking noises), but it is essential that your child's head remains in the same position during the entire time he or she is in the scanner. Your child will hear knocking noises and will be able to talk with the operator or researcher through an intercom at various points during the scanning session. Your child will also be able to trigger an audible alarm at any time. Your child will be given

instructions prior to entering the scanner. In the first and third phases of the scan, your child will watch to his/her choice of animation for 5 and 10 minutes, respectively, while we image his/her brain anatomy and structural pathways. In the second phase, the MRI scanner will take images of the brain activity while your child has their eyes opened and remains awake. During this phase, he or she will be looking at a cross on the screen, which presents for them from the screen. This process will last for about 7 and a half minutes.

Note

If your child usually drinks caffeine (e.g., coffee, tea, energy drinks), we will ask you that your child does not drink an excessive amount on the day of the scanning session. This is important because excessive caffeine can affect their measures of heart rate and blood flow in the brain. We will call, text, or email you the day before your child's scan to remind you about this important instruction.

About MRI

MRI is routinely used for clinical purposes and has no known harmful effects on the human body. For an MRI scan, your child will lie in a short tunnel inside a scanner machine that produces a strong magnetic field. This scanner is used to take images of the brain anatomy and to detect increased blood flow to active areas of the brain.

What risks will I face by taking part in the study? What happens if abnormalities are detected?

Only those directly involved in this study will have access to the research records. All records will be maintained in a locked cabinet in a room with limited access and/or in an electronic password-protected file

Behavioural tests

If we find hearing problems that were not expected, we will refer your child back to their usual audiologist with a copy of the results or to the University Audiology Clinic or another clinic of your choosing.

MRI scanning

There are no known side effects or risks associated with MRI scanning. All methods are painless and involve no radiation exposure, needles, or injections. However, MRI is unsafe for people who have magnetic metal implants in their bodies (e.g., pacemaker, hearing aid, screws/plates from an operation, etc.). At the MRI Centre, you will be asked to fill out a safety checklist to make sure that this is not the case for you. People who are prone to claustrophobia can find lying in the narrow tunnel of the MRI scanner difficult; therefore, we do not recommend that they participate. Very rarely, people can find the scanner makes them feel warm or can feel a tickling or twitching sensation. These sensations are harmless. Your child will be able to talk to us throughout the study, and your child will be able to let us know right away if he or she wants to stop the study and get out of the scanner. It is always your right to request that scanning be

discontinued and that you be removed from the scanner. Your child will also be given the opportunity to experience what the MRI scanner is like via the use of a simulator or "mock scanner" which is a similar size and allows your child to see what it is like to be in the hole in the machine and hear the MRI scanner noises. The MRI scanner makes loud, vibrating noises. Your child will wear foam earplugs to reduce the loud noises made by the scanner and prevent any hearing damage.

More information about the risks and benefits of MRI can be found at the link below: https://www.fda.gov/radiation-emitting-products/mri-magnetic-resonance-imaging/benefits-and-risks

The MRI scan conducted in this study is for research and is not a medical examination; therefore, images are not routinely reviewed by a radiologist. It is possible (although unlikely) that we may incidentally find an abnormality in your brain that is clinically significant. In this event, it is CAMRI policy that you must be informed. You should be aware that such knowledge would have consequences for you. For instance, it could affect your ability to obtain insurance (whether or not you take the matter further), or your ability to work in certain professions. If you would not want to know, you should not participate in this study.

What Benefits can you get from this research?

The results of the study will contribute to our understanding of perceptual learning in children with auditory processing difficulties. You and your child will be reimbursed with a \$30 in vouchers. Children who have not had their hearing tested previously may benefit from learning more about their hearing. You will also be offered an anatomical image of your child's brain.

Will our taking part in this study be kept confidential?

All participants will be given a unique number when they join the study. This will be used by us, instead of their name, on all of their measurements. If the information you provide is reported or published, this will be done in a way that does not identify you as its source. You can be assured that the questionnaires will only be accessed by the researcher, and in any publication, the results will be reported in aggregate, and participants will be unable to be identified.

What will happen to the results of the research study?

The results of the study will be used to help us design future studies. It is also normal practice for the results of these studies to be published in the literature. If you are interested, then we will send you a summary of the results (please tick the box to request a summary on your consent form).

Whom can I contact about this study?

We would greatly appreciate it if you allow your child to participate in our research. If you have any Questions, please feel free to contact us. **Email** is the most reliable way to contact us.

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For any queries regarding ethical concerns, you may contact:

issues you may contact the Chair, the University of Auckland Human Participants Ethics Committee, at the University of Auckland, Research Office, Private Bag 92019, Auckland 1142. Telephone 09373-7599.EXT.83711.

Email: <u>ro-ethics@auckland.ac.nz</u>

Approved by the University of Auckland Human Participants Ethics Committee on 18/10/2019 for period of 6 years. Reference Number: 023546