Study title: How good is the visually enhanced vestibulo-ocular reflex (VVOR) at distinguishing combined vestibular and cerebellar dysfunction from either individually

[How does the speed of head movement affect eye movements in people with and without a diagnosed balance disorder]

Locality:
Clinical Research Centre
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Ethics committee ref: AH1110

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You are invited to take part in a study investigating how eye movement recordings can be used to distinguish between different causes of imbalance. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive, or your relationship with any University of Auckland department or staff member. If you do want to take part now, but change your mind later, you can pull out of the study at any time during the course of the study.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.
If you agree to take part in this study, you will be asked to sign a Consent Form. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 5 pages long. Please make sure you have read and understood all the pages.

What is the purpose of the study?
Eye movement recordings can be helpful in diagnosing balance disorders. One useful clinical test involves recording the eyes while the head is turned from side to side. We would like to know how these recordings are affected by the speed of head movement, and whether turning the head at different speeds is helpful in distinguishing between balance disorders of the ear, the brain, or both. To investigate this, we need to study and compare the eye movements of people with and without a diagnosed balance disorder. The results from this study will help clinicians who diagnose and treat people with balance problems.

This study is not funded. The project is under the supervision of the principal investigator, Associate Professor Richard Roxburgh (Consultant Neurologist at Auckland Hospital) and co-investigator, Dr. Rachael Taylor (Research Fellow and Audiologist, Department of Physiology, University of Auckland). The data collection will be undertaken by Thomas Chang, a Bachelor of Medical Science (Honours) student from the University of Auckland, School of Medical and Health Sciences, and/or Dr Rachael Taylor, University of Auckland Research Fellow. If you have any questions relating to the study, or you decide you would like to participate, please contact Thomas Chang or Rachael Taylor.

What will my participation in the study involve?
You are invited to participate in this study because you have indicated that you have normal balance and no history of dizziness, or diagnosed neurological conditions. Your involvement in the study will help to determine how people with no underlying inner ear, or brain balance problems, respond to their heads being rotated at different speeds. This will help to inform the research performed on patients with underlying balance disorders.

The study involves a single 35-minute appointment at the Clinical Research Centre, University of Auckland, Grafton Campus. During the appointment we will conduct a screening neurological assessment and some tests that involve
recording your head and eye movements. The study will run for one year, ending on the 31st of October 2021.

Screening Assessment (10 minutes): A short medical history will be undertaken prior to any testing to ensure there are no contraindications to your involvement, and to assist with the interpretation of results. Once these screening questions have been asked, a series of screening tests will be performed. These include assessing your range of eye movements; your range of neck movement; as well as your balance and some movements.

Head and Eye Movement Recordings (25 minutes): This testing will require you to wear a pair of video recording goggles while you sit in a straight-backed chair, with arms. You will be asked to focus on a target that is either fixed to a wall or moves in time with your head. During the test, the examiner will hold your head in both their hands and move your head from side to side at different speeds while you look at the target. Your consent for this test will be asked again at the time of testing. Your eye movements will be recorded by a small camera in the goggles. The tests will occur in the following order:

- Test 1: small fast movements of your head while looking at a fixed target
- Test 2: slow symmetrical movements of your head while looking at a moving target
- Test 3: slow symmetrical movements of your head while looking at a fixed target

What are the possible benefits and risks of this study?

Risks: The method of head/eye movement recordings used in this study is non-invasive and is already an established clinical test. However, all medical procedures carry some potential risk. For this study, the main risks are the aggravation of an existing neck problem and temporary motion sensitivity due to head movement. Individuals who have been medically advised to restrict head movement are therefore excluded. If at any point during the study you experience discomfort or pain, the assessment will be stopped.

Benefits: This study provides the opportunity to assess your inner ear balance function, and brain balance function at no cost. You may receive a copy of these results if you request this. This study may also provide satisfaction to you through involvement in clinical research.

Who pays for the study?
Your participation will not cost you anything.
Participants will be offered a $20 petrol voucher as koha for taking part.

What if something goes wrong?
If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

What are my rights?
- Your participation is voluntary. You are free to decline to participate in this study, or to withdraw from the research at any time up until 31st October 2021, without giving a reason, and this decision won’t affect your relationship with any University of Auckland department or staff member.
- You have the right to access the information about you that is collected as a part of the study
- You may obtain a summary of results regarding the outcome of the study following the completing of the study
- Your participation and the information you provide will be kept confidential throughout the study. You will not be identified in any publications arising from this work
- You are encouraged to consult with your friends, whānau/family, hapū, iwi, or healthcare providers regarding your participation in this study

What happens after the study or if I change my mind?
You can choose to find out about any abnormalities that are identified during the course of the study, in which case you will be given a summary of your results and recommendations from the principal investigator, to pass on to your GP.

If you choose to, you can additionally consent to your age/gender and test data being added to our database of normal data which we use to judge future experiments by. No personal details that could potentially identify you, such as your name, will be reused outside of this study. The data obtained from the study will be stored for a period of up to 6 years in a secure online folder that will only be accessible via password authentication. Any written documents, including the consent form, will be stored in a locked drawer by the principal investigator. After the 6 years, the online files will be deleted, and the physical documents will be shredded.
Results of this study will be published in a thesis, held by the University of Auckland library from 2022. Findings will be presented in journal publications, and at conferences. Links to these publications will be sent to study participants, on request, via email.

Who do I contact for more information or if I have concerns?
If you have any questions, concerns, or complaints about the study at any stage, you can contact:

Thomas Chang  
Bachelor of Medical Science (Honours) Student  
Email: mcha536@aucklanduni.ac.nz

Associate Professor Dr. Richard Roxburgh  
Principal Investigator  
Email: richardr@adhb.govt.nz

Dr. Rachael Taylor  
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Miriam Rodrigues  
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Email: mrodrigues@adhb.govt.nz

Ashleigh Baker  
Senior Study Coordinator  
Email: ashleigh.baker@auckland.ac.nz  
Phone 09 923 8652
If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

Or for concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at

ahrec@auckland.ac.nz,
or at 373 7599 ext 83711,
or at Auckland Health Research Ethics Committee,
The University of Auckland,
Private Bag 92019
Auckland 1142

If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324. If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

Professor Ian Reid, A/Prof Roxburgh’s Academic Head, Department of Medicine, The University of Auckland, Private Bag 92019, Auckland 1142.

Approved by the Auckland Health Research Ethics Committee on 18 Feb 2020 for three years. Reference number AH1110.