Aniseikonia: A potential barrier to neural plasticity

PARTICIPANT INFORMATION SHEET FOR ADULTS OVER THE AGE OF 16

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To the Participant,
You are invited to participate in the above named research project. Please take your time to read this document and feel free to discuss your decision with whanau, family or significant other support people. Taking part is completely voluntary (your choice) and if you decide you do not wish to take part, it will have no effect on your optometric care at the University of Auckland where this is relevant. The study is being conducted at the School of Optometry and Vision Science, University of Auckland, New Zealand.

What is the study about?
We are investigating how visual information is combined and processed in a condition called aniseikonia which results in asymmetrical retinal image sizes due to a difference in refractive error between the eyes. Aniseikonia is common in another visual disorder called amblyopia which is also known as “lazy eye”. We will be investigating how prevalent aniseikonia is in different types of amblyopia and the best techniques for measuring it.

Eligibility
You are eligible to participate in this study if you have amblyopia in one eye with a fully corrected visual acuity of 6/12 or less. There should be no other explanation for the loss of vision in this eye. Vision in your non-amblyopic eye should be normal. You are not eligible to participate if you have poor vision (less than 6/12 fully corrected) in both eyes or if the cause of your visual loss is not solely due to amblyopia. You will not be eligible to participate in this study if there is a less than 1 LogMAR lines difference between your eyes (one line of letters on an eye chart) when you are wearing your visual correction (glasses or contact lenses). If you have amblyopia and you have not recently had an optometric examination, you will be asked to undergo an optometric examination at the School of Optometry and Vision Science, University of Auckland (at no cost to you) to ensure that you are eligible for the study. If any previously unknown problems with your eyes are found during this examination you will be referred to the University of Auckland Optometry Clinic or your preferred eye-care provider for further assessment. If you are unwilling to be informed of any previously unknown problems with your eyes then you will not be eligible to participate.
Control Participants: You will also be eligible to participate as a control participant if you have fully corrected visual acuity in each eye of at least 6/6 with no associated ocular pathology or neurological conditions. If you have not recently had an optometric examination, you will be asked to undergo an optometric examination at the School of Optometry and Vision Science, University of Auckland (at no cost to you) to ensure that you are eligible for the study. If any previously unknown problems with your eyes are found during this examination you will be referred to the University of Auckland Optometry Clinic or your preferred eye-care provider for further assessment. If you are unwilling to be informed of any previously unknown problems with your eyes then you will not be eligible to participate.

What does the study involve?
The study will involve 2 1.5 hour visits (total of 3 hours’ time commitment) to the Optometry Clinic, School of Optometry and Vision Science, University of Auckland. During these visits psychophysical measurements of visual function and aniseikonia will be completed. These involve viewing a computer screen or eye chart at various distances and making judgements regarding line position or reading letters. Standard clinical measurements of depth perception, ocular alignment, eye movements and inter-ocular suppression will also be completed. Measurements of eye size will also be taken which involves a short ocular biometry measurement and optical coherence tomography (OCT) scan (both non-contact). The OCT scan will also be checked for structural abnormalities (incidental findings will be referred as specified above). If refractive correction is required whilst completing any of the above procedures, this will be provided in the form of spectacles (trial frame) or contact lenses for the duration of the study visits.

Risks and Benefits
During vision assessment there may be a mild degree of eye strain. If this occurs we recommend taking short (1-2 minute) breaks. There are no definite long-term benefits of your participation in this study.

Participation
Your participation is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part this will not affect the standard of care you receive at the optometry clinic. If you do agree to take part, you are free to withdraw from the study at any time, without having to give a reason. Again, this will in no way affect the standard of care that you will receive at the optometry clinic. In addition, if you are a student at the University of Auckland, withdrawal from the study will have no impact whatsoever on your academic assessment or teaching. Participation will not cost you anything other than your time. You will be offered reimbursement for your travel expenses.

General Information
Your agreement to participate in this project will be obtained in writing on a Consent Form. Your eligibility will be based on information regarding your vision. This information may be obtained from an optometric examination. If you undergo an optometric examination, your agreement to participate in the project will include your permission for the investigators to obtain only the information from the results of this examination that will allow your eligibility to be assessed. You may have a friend, family or whanau support to help you understand the risks and/or benefits of this study and any other explanation you may require.

This research is funded by the Health Research Council. A summary of the results of the study can be made available on request when the study if complete. There is an option on the consent form where you can indicate whether you would like to receive this summary.

Confidentiality
No material that could personally identify you will be used in any reports on this study. The information and data collected from you will be stored securely, in locked cabinets and on secure computer networks. Only the investigators will have access to this information, and your data will be made anonymous by assigning a unique code to it.

Compensation
In the unlikely event of a physical injury as a result of your 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 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 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 or are considering, such as medical insurance, life insurance and superannuation.

Summary of Your Rights
- Your participation is entirely voluntary. If you choose not to take part you will still receive the usual treatment/care.
- You may withdraw from the project at any time without providing a reason. This will not affect your continuing or future health care.
- You may have your data withdrawn from the study within three months of data collection.
- You will be asked to sign a Consent Form.
- Your identity will be kept strictly confidential, and no identification of you or your data will be made at any time during collection of the data or in subsequent publication of the research findings.
- Discomfort and incapacity has not been reported from any of the procedures that will be used in this project, however, if the procedures cause you concern, you may withdraw from the project.
- Maori participants are encouraged to consult with your whanau, hapu or iwi regarding participation in this project.

Who should I contact if I have further questions?
If you have any questions about the study, or would like to participate in this study, please contact the project supervisor:

**Project Supervisor:**
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For any concerns regarding ethical 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 09 373-7599 ext. 83711. Email: ro-ethics@auckland.ac.nz

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON 4 OCTOBER 2017 FOR THREE YEARS, REFERENCE NUMBER 019927