Aniseikonia: A potential barrier to neural plasticity

PARTICIPANT INFORMATION SHEET FOR PARENTS

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To the Participant,

Your child is 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 for your child to take part, it will have no effect on their 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
Your child is eligible to participate in this study if they have amblyopia in one eye with a fully corrected visual acuity of 6/9 or less. There should be no other explanation for the loss of vision in this eye. Vision in your child’s non-amblyopic eye should be normal. Your child is not eligible to participate if they have poor vision (less than 6/12 fully corrected) in both eyes or if the cause of their visual loss is not solely due to amblyopia. Your child will not be eligible to participate in this study if there is a less than 1 LogMAR lines difference between their eyes (one line of letters on an eye chart) when they are wearing their visual correction (glasses or contact lenses). If your child has amblyopia and they have not recently had an optometric examination, you will be asked to bring them for an optometric examination at the School of Optometry and Vision Science, University of Auckland (at no cost to you) to ensure that they are eligible for the study. If any previously unknown problems with their eyes are found during this examination they 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 child’s eyes then you will not be eligible to participate.

What does the study involve?
The study will involve 2 x 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 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 your child takes short (1-2 minute) breaks. There are no definite long-term benefits of your participation in this study.

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

General Information
Your agreement for your child to participate in this project will be obtained in writing on a Consent Form. Their eligibility will be based on information regarding their vision. This information may be obtained from an optometric examination. If they 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 child’s 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 is 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 your child 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 child’s case will need to be assessed by ACC according to the
provisions of the Accident Compensation Act 2001. If your child’s claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors. 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 child’s participation is entirely voluntary. If you choose for them not to take part you will still receive the usual treatment/care.
- You may withdraw your child from the project at any time without providing a reason. This will not affect your continuing or future health care.
- You may have your child’s data withdrawn from the study within three months of data collection.
- You will be asked to sign a Consent Form.
- Your child’s identity will be kept strictly confidential, and no identification of you or your child’s 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 your child 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**