PARTICIPANT INFORMATION SHEET

Project: New spectacle lens design for myopia control: ocular effects

Research Team:

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To: Parent/Guardian of Participant

We invite your child to participate in our study investigating the short-term effects of wearing new spectacle lenses designed to reduce the progression of myopia (short-sight) in children. This study will examine possible short-lasting changes in the back of the eye during 1 hour of lens wear. The changes we are investigating relate to the thickness of the ocular choroid (the vascular bed supplying the photoreceptors of the retina), which we will measure without touching the eye using standard clinical equipment (Optical Coherence Tomography – OCT). Thickening of the choroid would suggest that the new lenses are likely to be effective in slowing myopia progression with long-term wear. This study is being conducted on behalf of Essilor, a lens design and manufacturing company, who are funding the project. All measures will be made by University Research Optometrist Safal Khanal.

Your child is eligible to participate if they

● Are 8 to 13 years of age
● Have aided (or unaided) visual acuity of 6/6 (20/20) or better
● Have glasses prescription of -1.00D to -4.00D spherical equivalent

They are not eligible to participate if they have

● A difference in prescription between the two eyes greater than 1.00D.
● Amblyopia, or any ocular pathology or previous history of ocular surgery or myopia control

Participation

Participation in this study is entirely voluntary (your choice) and you may withdraw from the study at any time without giving a reason. You may also withdraw any data collected as part of the study from the time of participation up to one month after data collection. Participation or non-participation in the study will bear no penalties or loss of benefits with regard to the services provided to you or your child by the University of Auckland Optometry Clinic. Your results will remain confidential to the named researchers.

If you both agree to participate, you and your child will be asked to attend two visits to the University of Auckland Optometry Clinic in Grafton, within a period of about 2 weeks. Each visit will take up to 2 hours. No drops will be used and nothing will touch your child’s eyes. At each visit your child will initially view a video for 20 minutes at a distance of 6 metres while wearing their own spectacles. Then, your child will be asked to look into two instruments. One instrument, the ocular biometer, will measure the size of each eye, while the other will make a detailed scan (Optical Coherence Tomography OCT scan) of the back of each eye. Your child will then view the video for a further 60 minutes wearing their own spectacles, but with the addition of a test lens in front
of one eye. OCT scans of both eyes will be made at 30 and 60 minutes. After the OCT scan at 60 minutes, ocular biometry will again be performed. Your child will then view the video for a further 20 minutes with their own spectacles only, after which final OCT and Biometry measures will be made. The procedure will be repeated at the same time of day on the second visit, with a different test lens.

**Is there any cost to participate?**
Taking part in the study will not cost you anything, apart from a certain amount of time.

**Benefits**
There are no individual benefits to research participants as a result of taking part in this study, but you will be compensated for your time.

**Compensation**
You will be offered a voucher for a pair of new spectacle lenses as an appreciation of your time and you may accept or decline it or seek recompense in an equivalent or culturally appropriate manner. You may use the voucher at any optometry practice which prescribes Essilor lenses. Your child will also be offered a small gift in appreciation of their taking part in the study. This will occur whether or not you withdraw from the study.

**Risks**
In the unlikely event of any adverse effects, the researchers, who are fully qualified optometrists, will be available to deal with them following standard protocols in the University Optometry Clinic.

**Incidental findings:** While we will not be conducting a full eye examination during the course of this research, we may identify abnormalities or issues with your child’s eyes. In the unlikely event that a condition which is assessed to be a clinical abnormality is detected, you will be informed of this and will be advised to make an appointment for your child to have a comprehensive eye examination. You should be aware that once you have been informed that a clinical abnormality has been detected through examination, this could affect your ability to obtain insurance whether or not you take the matter further. If you do not wish to know about this type of finding, please do not participate.

**Data storage/retention/destruction/future use**
All data collected as part of this study will be stored securely; paper records will be stored in locked filing cabinets and electronic data will be stored in password protected computers, accessible only by the named investigators and backed up and stored on the University of Auckland server. All data, including signed Consent Forms, will be stored for a minimum of 6 years and then destroyed using appropriate confidential document destruction services. Data obtained from this study will only be made available to Essilor and used in scientific publications and/or presentations by the researchers, once it has been de-identified (i.e. once all information of a personal nature e.g. name, date of birth etc. has been removed), to ensure that you and your child’s anonymity is maintained.

**Consent to Participate**
We will ask you to sign a consent form (attached) to confirm your agreement for your child to participate. You are also entitled to receive a summary of the study findings written in non-academic language. If you wish to receive a summary on completion of the study (May 2019), please indicate this on the consent form and provide a valid email address where the results can be sent. We will also ask your child to sign an assent form to indicate their willingness to take part in the study.

**Accident Compensation**
In the unlikely event of a physical injury as a result of 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 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 principal investigator, Dr John Phillips.

Thank you for giving us your time to consider your participation and helping with this research project. If you have any further questions about this project, please do not hesitate to contact us.

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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 25/10/2018 for (3) years, Reference Number 022140**