PARTICIPANT INFORMATION SHEET
For adult participants ≥16 years old

Project title: Adaptation to optical treatment in adults and older children with amblyopia

Research team:
We are a group of clinical researchers at the School of Optometry and Vision Science, University of Auckland (UOA). We are interested in investigating how wearing glasses might help improve vision in people with amblyopia.

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Why are we asking for your help?
We are studying a vision condition called “anisometropic amblyopia“, which affects about 1-3% of people. This is where a young child has a large focusing difference between eyes (anisometropia), which impacts how visual processing in their brain develops, leading to reduced vision (amblyopia or “lazy eye“) in one eye and poor 3D vision. Most children with amblyopia are treated with prescription glasses to balance the two eyes, followed by patching or atropine eye drops. However, some people may have missed out on treatments as a child, or they may have stopped wearing glasses, which means that their vision stays poor long-term.

Previous studies at UOA and overseas have found that about 25% of teenagers and adults experience improvements in vision after 4-16 weeks of wearing new prescription lenses. However, for some people it can be hard to get used to wearing glasses, which will prevent their vision from getting better. In this pilot study, we want to look specifically at the process of adapting to glasses in older children and adults, and understand why some people may stop wearing glasses after childhood. The information we gain will be used to design larger scale clinical trials and to inform clinical guidelines, to help people with anisometropic amblyopia achieve the best and most comfortable vision possible.

This document provides information to help you decide whether this project is something you would like to be a part of. Please take your time to read this document and to decide whether you wish to take part, and feel free to discuss your decision with whānau, family, or other support people.

How do you know if you will be eligible?
We need adults (16-40 years) and children (12-15 years) with anisometropic amblyopia. To be eligible, you need to:

- Have a history of amblyopia (“lazy eye”, or unequal vision from before 7 years old)
- Have a large difference in focusing error/prescription between eyes.
- Have a difference in vision between your two eyes of at least 2 lines on a standard chart, even when wearing prescription glasses or contact lenses.
- Have no other eye diseases or conditions that affect your vision, apart from amblyopia.
- Not currently doing any active amblyopia treatments such as patching, atropine, binocular treatments.
- Not currently wearing glasses or contact lenses of your full prescription.
- Be willing to try wearing glasses for up to 6 months.
If you are unsure whether you meet these criteria, we can check for you at the first assessment or by asking your eyecare provider.

What does the study involve?
This study involves wearing prescription glasses and attending 7 visits at the Grafton Campus of the University of Auckland across a 6-month period. You will first be invited to attend a Comprehensive Eye Exam (CEE) at the UOA Optometry Clinic, in which you will have your vision, refractive error, and eye health assessed. Dilating eye drops may be needed to fully check your prescription and eye health. The CEE takes about 1.5 hours. The results of this examination will confirm your eligibility and provide the prescription for new glasses. If you have had an eye examination in the last 12 months, then we will ask for your permission to obtain a copy of the records of that examination, from which we will assess your eligibility. In this case, you will need to attend a short assessment (<1 hour) to confirm your eligibility and to select glasses frames.

At the same time, we will invite you to participate in an online questionnaire, which you can complete at home. The questionnaire will ask about your past experiences with eyecare and amblyopia (including glasses and any other treatments you have received). This questionnaire is expected to take 15-30 minutes to complete. If you wish, you can have your whānau help you to answer some sections of the questionnaire (for example, we will ask about amblyopia treatments that you may have received when very young, and it may be helpful to ask older family members for information).

The new glasses prescribed in this study will be made based on standard guidelines for amblyopia treatment in children. The lenses are designed to balance the focusing of your eyes and enable the two eyes to work together. After the new glasses are ready, you will be invited to attend a Baseline assessment which will take about 1 hour, during which we will measure your vision in the new glasses using standard clinical tests and some computer-based tests (1-5 minutes each). You can take breaks between tests as needed. After this Baseline assessment, you will be asked to wear your prescription glasses every day, for as much of the day as possible while you’re awake, until the last study visit at 24 weeks (~6 months).

The glasses you receive will have a small monitoring device (the SpecsOn monitor) attached to the frame. The SpecsOn monitor contains non-contact sensors that measure the temperature difference between the inside of the glasses frame and the outside, to detect whether glasses are being worn. The device does not record anything else. The device does not have any transmitting parts and does not require you to maintain or charge it. We ask only that you do not attempt to remove or damage the device. We remove the device every 12 weeks to download the data and change the batteries. The SpecsOn device has been custom-built by the researchers at the School of Optometry and Vision Science and the Auckland Bioengineering Institute to ensure it meets all safety regulation guidelines.

Between 1-2 weeks from Baseline, one of the study researchers will contact you by phone or email (your preference), to check whether you are able to wear your glasses. This phone call will not be recorded. If you are having significant adaptation problems, we may suggest that you return for a check to see if adjusting the glasses or changing the lenses may help.

You will be invited to return for follow-up vision checks at 6, 12, 18, and 24 weeks from Baseline. We ask that you attend as many visits as you can, so that we can get a complete picture of how your vision may change from wearing glasses. The same clinical and computer-based vision tests that were conducted at Baseline will be repeated at each visit. Each follow-up visit is expected to take about 1 hour, except for the last visit where after completing vision tests, you will be invited to participate in an optional interview about your experiences in the study.

The interview will be conducted in-person by one of the named study researchers, and will be audio-recorded. We will ask you to describe your experiences with wearing the study glasses, describe any problems you may have experienced, and to tell us about how you feel about prescription glasses as an amblyopia treatment. You are welcome to bring your whānau to support you, and they are welcome to share their perspectives. The audio recording will be transcribed verbatim by the interviewer afterwards, and then the recording will be permanently deleted. You will be sent a copy of the transcription to review and edit before it is used in any analyses.
Benefits and risks
It is possible that your vision will improve from wearing glasses. Our previous study suggests that about 25% of older children and adults will show measurable improvements in corrected vision (when wearing lenses), but the amount of improvement differs between people. Since this is a new area of research, we do not currently know what the maximum amount of improvement is or how best to achieve it, so we cannot guarantee that your vision will improve.

Some people may experience some visual discomfort or eyestrain when adapting to new glasses. Generally, this is mild and only occurs in the first few days or weeks, going away as you adapt. However, in some cases, visual discomfort can prevent people from wearing glasses. It is valuable for us to know about any adaptation problems, so that we can try to solve them and adjust future prescribing protocols to help others. If you are having significant difficulties adapting to the new glasses, we ask that you stop wearing the glasses temporarily and contact the researchers as soon as possible. We will offer strategies or adjustments to the glasses which may help. We do not expect any long-term harmful effects from this study, as glasses are routinely used in the treatment of anisometropic amblyopia and any side effects stop as soon as you take off the glasses.

It is possible that during the study we may find previously unknown problems with your eyes. If this occurs, you will be referred to the UOA Optometry Clinic or to your preferred eyecare provider for further assessment. If you are unwilling to be informed of this type of incidental finding then you should not participate in this study.

Who pays for the study?
This study is supported by the Faculty of Medical and Health Sciences Research Development Fund. This research grant pays for Comprehensive Eye Exams at the UOA Optometry Clinic, new prescription glasses, and the SpecsOn monitors. The grant also provides koha for participants who attend the Baseline and follow-up vision checks. You will receive a $20 voucher at the end of every visit attended. Participation will not cost you anything other than your time.

We ask that you take care of your glasses and the SpecsOn monitor to the best of your ability. If your glasses or the SpecsOn device are damaged or lost, we ask that you contact the study researchers as soon as possible so that we can order replacements. These will be provided at no charge to you. You will not be held liable for any damages to the glasses or the SpecsOn monitor.

Rights of the participant(s)
Your participation is voluntary. You have the right to withdraw from participation at any time, without any disadvantage, and without needing to give a reason. You also have the right to withdraw your data from the research up to 3 months after your most recent visit or the submission of the online questionnaire.

If you are a patient at the UOA Optometry Clinic, your participation or non-participation will not result in any disadvantage in the standard of clinical care you receive. If you are a student at the School of Optometry and Vision Science, your participation or non-participation will not impact your grades or your academic relationships with the School or with staff.

Confidentiality and anonymity:
No material that is personally identifiable will be used in any reports or publications resulting from this study. All participants will be assigned a unique code to protect confidentiality. A document linking the code with your name will be stored separately from the clinical data and can only be accessed by the researchers. All data will be collected, stored and analysed using this unique code. The linking document will be destroyed after 6 years. Only the named researchers involved in this study will have access to data collected, which will be saved in a research folder on the University of Auckland server and accessed via password protected computers.

This is a small pilot study where we intend to recruit and prescribe glasses for up to 15 participants. Due to the small number of participants and the optional recorded interview at the end of the study, we cannot fully guarantee confidentiality even with the above de-identification procedures. However, we will remove your personal details from the data and avoid reporting or publishing identifiable information to
the fullest extent possible. The study researchers who conduct and transcribe the in-person interview will sign a confidentiality agreement, and will not share what you say in your interview with anyone outside the study.

**What will happen after the study**
At the end of your study participation, the SpecsOn device will be removed from the frames of your glasses, and you can keep your glasses. You can also request a report of the clinical findings from the study, which will document your vision status and your glasses prescription. This report will be sent to you directly, and a copy can also be sent to a medical professional or eyecare provider of your choice.

The data collected in this study will help us to develop future projects to improve outcomes for children and adults with amblyopia. Therefore, we plan to keep the de-identified data indefinitely. Data will only be accessible to the named investigators.

If you would like a summary of the project findings, please indicate this on the consent form. This study is intended to conclude in late 2024. However, there is often quite a delay between when a study is completed and when data analyses are complete, so there may be some time between when you participate and when you receive the summary.

**Contact Details**
If you wish to participate in this study or have further questions, please contact:

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

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 x 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

*Approved by the Auckland Health Research Ethics Committee on 14 Dec 2022 for three years. Reference number 25011.*