PARTICIPANT INFORMATION SHEET
For child participants 12-15 years old

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

Research team:
We are a group of 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 ("lazy eye").

<table>
<thead>
<tr>
<th>Phone</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>(09) 923 2955</td>
<td><a href="mailto:t.gao@auckland.ac.nz">t.gao@auckland.ac.nz</a></td>
</tr>
<tr>
<td>(09) 923 2405</td>
<td><a href="mailto:j.black@auckland.ac.nz">j.black@auckland.ac.nz</a></td>
</tr>
<tr>
<td>(09) 923 6484</td>
<td><a href="mailto:a.collins@auckland.ac.nz">a.collins@auckland.ac.nz</a></td>
</tr>
</tbody>
</table>

Why are we asking for your help?
You are invited to take part in this research study because you have a large focusing difference between your eyes, which has caused vision problems (amblyopia or “lazy eye”) since you were very young. In a previous research study, we found that in some children like you, wearing glasses with the right lenses can improve vision slowly over a few months. But some people found it hard to get used to wearing glasses in this previous study. We want to look at the process of getting used to new glasses, to see if we can make it easier for people with lazy eye to wear glasses.

This information sheet will tell you about the study, to help you decide whether this is something you would like to be a part of. Please take your time to read this and to decide whether you want to take part. You should discuss your decision with your mum/dad/family.

How do I know if I can take part this study?
We are looking for children (12-15 years) and adults (16-40 years) with a specific type of lazy eye caused by large focusing differences between eyes (anisometropic amblyopia). You may have had glasses and other treatments to help with your lazy eye when you were younger. You need to have a difference in vision between your eyes, even when wearing lenses. You must not be doing any active treatments for your lazy eye like wearing an eye patch or using atropine eye drops. You must not be wearing lenses of your full prescription at the moment, but you should be willing to try it.

If you are unsure whether you are suitable for this study, we can check for you through an eye test, or by asking your optometrist or eye doctor.

What do I need to do in this study?
This study involves wearing glasses every day, for as much of the day as possible for 6 months, as well as about 7 visits at the Grafton Campus spread over the 6 months.

If you agree to take part in this study, we will first need to check that you have the correct type of lazy eye, your eyes are healthy, and also check what prescription you need for glasses. This can be done through a full eye test at the UOA Eye Clinic, or by asking your optometrist/eye doctor. If you meet these study criteria then you can choose a glasses frame and we will have lenses made for you. These lenses will fully correct the difference between your two eyes.
While you are waiting for the eye test appointment or for us to check with your optometrist/eye doctor, we will ask you and your mum/dad/carer to fill in an online survey together. This can be done at home and takes 15-30 minutes. The survey will ask about what treatments you have previously done for your lazy eye, and your thoughts about wearing glasses.

After your new glasses are ready, you will be asked to come to the Grafton Campus to pick up the glasses and for a vision check. The vision check will take about 1 hour, and will include different types of vision tests – some are on letter charts or booklets with pictures, and some are on a computer. You can take breaks between the tests whenever you like.

After this visit, you will need to wear your new glasses every day, for as much of the day as possible while you’re awake (except for swimming, baths, and contact sports like rugby). The more you wear your glasses, the more likely it is that your vision will get better. You will need to wear the glasses until the last study visit (24 weeks after starting glasses, or about 6 months).

The new glasses will have a small device (the SpecsOn monitor) attached to the side to measure how much you are wearing the glasses. The device does not measure anything else, and does not need charging. We ask that you do not try to take the device off or do anything to it. The SpecsOn device will be changed after 12 weeks, and then at the last study visit (24 weeks) it will be removed and you can keep your glasses.

Between 1-2 weeks from Baseline, one of the study researchers will contact your mum/dad/carer, to ask whether you are able to wear your glasses. If you are having problems with your glasses, please tell your mum/dad/carer so that we can help fix those problems.

You will be asked to come back for vision checks at 6, 12, 18, and 24 weeks from when you first start wearing glasses. We ask that you attend as many visits as you can. At each visit we will repeat the same vision tests, to see if there is any change in your vision. Each vision check will take just under 1 hour.

At the last visit (24 weeks), after the vision tests, we will ask you and your mum/dad/carer to take part in an optional interview. In this interview, we will ask you to describe how you feel about wearing glasses and about taking part in this study. We will also ask your mum/dad/carer and any other family members who come to the interview to describe what they thought about your glasses and about this study. The interview will be recorded and then transcribed (written down). The recording will be deleted. You and your mum/dad/carer will get a copy of the transcription (written down copy) and can make changes to it, before we analyse it.

Benefits and risks
It is possible that your vision will get better from wearing glasses. Our previous study found that about 25% of children your age will improve, but the amount of improvement is different between people. Since this is a new area of research, we don’t know how much people can improve or how best to achieve it, which is why we are conducting this study.

When you first wear the new glasses, you may feel your 3D vision is strange or have mild eyestrain. Usually this is mild and will go away in a few days or 1-2 weeks. However, in some people, these problems are so bad that it stops them from wearing glasses, so they never get used to them. It is really important for us to know if you are having these problems so that we can try to fix them. We can learn from what you are experiencing to help other people with lazy eye. If you do get eyestrain or other problems, then please stop wearing the glasses for that day and ask your mum/dad/carer to call or email the study researchers as soon as possible.

The glasses from this study are made to your prescription and will not permanently hurt your eyes. You may have worn similar glasses when you were younger, when you first had treatment for your lazy eye.

It is possible that during the study we may find problems with your eyes that you and your mum/dad/carer didn’t know about. If this happens, you will be referred to the UOA Eye Clinic or to your own optometrist/eye doctor for the problem to be checked out.
Who pays for the study?
This study is supported by a research grant from the Faculty of Medical and Health Sciences. This research grant pays for eye exams, new prescription glasses, and the SpecsOn monitors. The grant also provides koha for coming to the vision checks (up to 6 visits). You will receive a $20 voucher after each vision check visit.

Please take care of your glasses and the SpecsOn monitor. If your glasses or the SpecsOn device are damaged or lost, we ask that you ask your mum/dad/carer to contact the study researchers as soon as possible. We will order new glasses or a new monitor for you, and will not charge you or your mum/dad/carer.

Rights of the participant(s)
You can choose to take part or not to take part in this study. If you choose to take part, you can change your mind and stop at any time, without needing to give a reason.

Confidentiality and anonymity:
We want to publish the results of this study to help other people with lazy eye, but we will not publish any personal details about you or your mum/dad/carer, so the people reading the results of this study will not know who you are. We may quote some of the things that you tell us in the online survey and the interview, but we will remove information that might reveal who you are (e.g. your name, or the name of your school).

What will happen after the study
After 24 weeks of wearing glasses, the SpecsOn monitor will be removed from the side of your glasses, and you can keep the glasses.

Your mum/dad/carer may ask us to write a report about your vision, based on what was measured during the study. This report will be sent to your mum/dad/carer directly, and also can be copied to your doctor, optometrist, and/or eye doctor (if you have one).

Contact Details
If you want to take part in this study, please first talk to your parents/carers/family. They can contact us for more information and to let us know you want to take part:

**Principle Investigator:**
Tina Gao
School of Optometry and Vision Science, UOA.
Ph: 09 923 2955
Email: t.gao@auckland.ac.nz

**Associate Head (Research):**
Sam Schwarzkopf
School of Optometry and Vision Science, UOA.
Ph: 09 923 9734
Email: s.schwarzkopf@auckland.ac.nz

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 4868920 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.*