Evaluation of clinical acceptance of novel myopia management spectacle lenses in anisometropic children

Parent/ Guardian Information Sheet

Invitation

We would like to invite your child to take part in a research study.

Before you decide if you would like them to participate, please take the time to read the following information carefully and if you wish, discuss it with others such as your family, friends, or colleagues.

Please ask a member of the research team, whose contact details can be found at the end of this information sheet, if there is anything that is not clear or if you would like more information before you make your decision.

What is the purpose of the study?

Myopia, also called short-sightedness, is a common refractive eye disorder. Later in life it can lead to eye diseases. Currently, there are spectacle lenses available to correct and manage myopia and its progression.

In this study we are going to evaluate the speed of adaptation with myopia management spectacle lenses in children.

Why has your child been invited?

Your child is being invited to take part in this study because they are myopic (short-sighted) in one eye (and near Plano in the other eye) with good vision and healthy eyes and are aged 6-12 years old.

Your child **should not** participate in this study if any of the following apply to them:

- They have binocular vision problems such as amblyopia (a 'lazy' eye) or strabismus (a squint or turn in one eye)
- They have any current eye diseases which might affect their vision or visual function
- They have had any previous eye surgery
- They have any systemic conditions which might have an influence on vision or visual function (e.g. diabetes, etc)
- They are under any medical treatment or medication which may have an influence on vision or visual function
- They are/ have received any myopia management treatment (e.g. myopia control lenses, atropine, etc)

- Our investigators will also include participants based on the spectacle prescription they measure in each eye

What will happen to my child if they take part?

Before your child takes part in the study, the investigators will explain the details of this study to you and your child. You will be invited to sign the consent form and your child will need to sign the assent form. They will ask you some questions about your child's eye condition and eye history. They will take some eye and vision measurements to see if your child is eligible to take part. These are called the 'screening tests'. If the results of the screening tests tell us that your child is eligible for the study, your child will be enrolled into the study.

The study consists of up to 5 visits over one year. We will provide your child with a new pair of glasses. Your child will wear the spectacles full time for the year. We will take a series of measurements and most of these measurements will use the same instruments that your child is familiar with from regular optometrist examinations.

1st Visit: Screening and baseline measures

At this visit we will ask you and your child about their eye health and spectacle wear history. We will measure how well they see letters on a chart (visual acuity) with glasses in place. We will assess the eye coordination (any squint) and the eye health of your child. We will use eye drops to make your child's pupils larger and to relax the eye's focusing muscles. These eyedrops are used as a standard part of children's eye examinations. Once these drops are in, we can measure your child's prescription and the eye length. To do this all your child has to do is put their chin on a chin rest and look at a target whilst these measurements are taken. We will ask your child to look at the letter chart again so that we can finalise their prescription needed for the study spectacles lenses.

2nd Visit: Spectacles collection

You and your child will attend our clinic to collect the spectacles. We will check the fit and comfort of the new glasses. We will measure visual acuity with high and low contrast letters with the new spectacles on. No eyedrops will be used in this visit.

Your child is required to wear these glasses as they would normally wear any spectacles. They should wear the spectacles and engage in their usual everyday activities. A diary will be given to you for recording your child's daily wearing time. If your child has any problems in the interim with these glasses, please contact the study investigator and we will arrange an unscheduled visit if needed.

3rd, 4th and 5th Visit: Repeat of baseline measures

At 3-, 6- and 12 months after wearing the glasses full time, you and your child will be invited to come to our clinic again. We will measure the visual acuity with high and low contrast letters. We will also measure your child's prescription and the eye length using the eye drops. In addition, we will give your child a questionnaire to fill in to see how they felt about

the glasses. We will also give you a questionnaire to ask about your child's wearing schedule and comfort.

These study visits do not replace your child's regular periodic eye examinations. You should continue to attend these as advised by your optometrist.

Does your child have to take part?

No. It is up to you and your child to decide whether they wish to take part. Whether they participate (or not) will have no bearing on their progress at school. You are free to withdraw at any time by notifying a member of the research team. You will not need to attend any remaining visits, however any data collected from the first visit will be used for the purposes of the study. If you are a staff member or a student at Aston University, you and your child's decision to participate (or not) will not influence your employment or degree in any way.

Will my child taking part in this study be kept confidential?

Yes. A code will be attached to all your child's data to maintain anonymity during analysis. You and your child's personal data (name and contact details) will only be used to contact you for arranging study visits. The study funder, SightGlass Vision, will also have access to the anonymous data set, but will not have any access to any personal data (e.g. name and contact details).

The data we collect will be stored in a secure document store (paper records) and electronically on a secure encrypted mobile device, password protected computer server and cloud storage device. All consent forms and hard copies of documentation will be scanned and stored to BOX cloud storage; paper copies will then be destroyed.

To ensure the quality of the research Aston University may need to access your child's data to check that the data has been recorded accurately e.g. for the purposes of audit. If this is required, your child's personal data will be treated as confidential by the individuals accessing your data.

What are the possible benefits of taking part?

You and your child will gain more understanding and knowledge of how to manage the progression of myopia. The data obtained will help us to determine how children with different levels of short-sightedness in each eye adapt to the myopia management spectacles lenses. The results will be shared and could be useful to short-sighted children, their parents, optometrists and other eye care professionals.

What are the possible risks and burdens of taking part?

The risks associated with all procedures and devices in this study are extremely low.

The side effects of eye drops that are used in this study are the same as those your child experiences during a routine eye exam. The eye drop is called 'cyclopentolate' (1.0%) which is used to dilate your child's pupils and relax the focusing muscles of the eye. This can help our study investigator to measure and examine your child's eye more efficiently. If one drop is insufficient, a second drop of cyclopentolate may be required. The cyclopentolate drops take up to 30 minutes to work. For most people, it takes around 3-4 hours for their focusing ability to return to normal. The pupils may stay dilated for up to 36-48 hours. So, your child's eye will be more sensitive to light and their vision will be slightly blurred. Sunglasses are advisable on a bright day and care should be taken until the effects of the drops have subsided. However, these eye drops are commonly used in optometric practices for children eye exam and it is rare for children to have any adverse effects.

Your child's response to the eyedrops will be monitored during the visit. The possible side effects are stinging, redness of the eyes and rarely a facial rash. The symptoms would be self-resolved. A leaflet produced by College of Optometrist will be provided that explains the use of cyclopentolate, potential side effects and what to do in an emergency.

The myopia management spectacles lenses used in this study are similar as those of commercially available spectacles lenses. Your child may observe blurriness in the periphery of their vision. They may feel a little strange to begin with, however it should not take long for your child to get used to them.

What will happen to the results of the study?

The results of this study may be published in scientific journals and/ or presented at conferences. If the results of the study are published, your child's identity will remain anonymous.

A summary of the results of the study will be available for participants when the study has been completed. Please indicate if you would like to receive a copy.

The anonymised results will be shared with the company providing funding for this study (SightGlass Vision. Inc).

Expenses and payments

As compensation for you and your child's time, travel and participation in the study: you will receive Love2shop physical gift vouchers of £50 per visit and then an extra £150 gift voucher as a thank you when you completed the study (totaling £400). The payment will be made at the end of the study. Your child will also be able to keep their spectacles at the end of the study.

Who is funding the research?

The study is funded by SightGlass Vision, Inc.

Who is organising this study and how is my data being used?

Aston University is organising this study and acting as data controller for the study. Research data will be used only for the purposes of the study or related uses identified in this Information Sheet or Appendix A.

Who has reviewed the study?

This study was given a favourable ethical opinion by the Aston University College of Health and Life Sciences Research Ethics Committee.

What if I have a concern about my participation in the study?

If you have any concerns about your child's participation in this study, please speak to the research team and they will do their best to answer your questions. Contact details can be found at the end of this information sheet.

If the research team are unable to address your concerns or you wish to make a complaint about how the study is being conducted you should contact the Aston University Research Integrity Office at research_governance@aston.ac.uk or via the University switchboard on +44 (0)121 204 3000.

Research Team

School of Optometry, College of Health & Life Sciences, Aston University

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Thank you for taking time to read this information sheet. If you have any questions regarding the study please don't hesitate to ask one of the research team.

Appendix A: Transparency statement

Aston University takes its obligations under data and privacy law seriously and complies with the Data Protection Act 2018 ("DPA") and the General Data Protection Regulation (EU) 2016/679 as retained in UK law by the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 ("the UK GDPR").
Aston University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study. Aston University will process your personal data in order to register you as a participant and to manage your participation in the study. It will process your personal data on the grounds that it is necessary for the performance of a task carried out in the public interest (GDPR Article 6(1)(e). Aston University may process special categories of data about you which includes details about your health. Aston University will process this data on the grounds that it is necessary for statistical or research purposes (GDPR Article 9(2)(j)). Aston University will keep identifiable information about you for 6 years after the study has finished.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.
You can find out more about how we use your information at https://www.aston.ac.uk/about/statutes-ordinances-regulations/publication-scheme/policies-regulations/data-protection or by contacting our Data Protection Officer at dp_officer@aston.ac.uk.
If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).