UNIVERSITY of BRADFORD

ID No.:

PARTICIPANT INFORMATION SHEET

A STUDY OF CONTACT LENSES TO PREVENT SHORT-SIGHTEDNESS

Your child is being invited to take part in a research project. Before you decide whether or not they should take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish.

Thank you for taking the time to read this document.

1. What is the purpose of this research project?
This research project aims to test if wearing overnight corneal contact lenses (commonly known as orthokeratology contact lenses) can prevent or delay the development of short-sightedness in children.

2. Why has my child been invited to take part?
Your child is being invited to take part because they have good vision and do not currently have short-sightedness, but they have a spectacle prescription and another risk factor such as family history which suggests they are at risk of developing short-sightedness within the nearby future.

3. Does my child have to take part?
No, your child's participation in this research project is entirely voluntary and it is up to you and your child to decide whether or not to take part. If you decide to take part, we will discuss the research project with you and ask you to sign a consent form. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights or affect the eye care you and your child receive.

You are free to withdraw your consent to participate in the research project at any time, without giving a reason, even after signing the consent form.

4. What will taking part involve?
The aim of the study is to find out if wearing overnight contact lenses, can prevent the development of short-sightedness (also known as 'myopia'). These lenses have been shown in several clinical trials to reduce the progression of short-sightedness in affected children. Our study is different from other studies because the children taking part will not already be short-sighted.

Short-sightedness is a very common condition that causes distance vision to be blurry. It is usually corrected by wearing glasses or contact lenses, and typically develops in childhood. Once short-sightedness develops it is extremely rare for it to go away, which means most

people with short-sightedness need to wear glasses or contact lenses for the rest of their life. Being short-sighted can have significant implications in the future, due to the associated increased risk of several sight-threatening diseases in adulthood.

In the first appointment, your child will have a variety of eye measurements taken, which will also include eye drops. This is to check that they are eligible for the study. To be able to take part in this study, they will need to be between the ages of 7-12 years old, and demonstrate that they fit the 'at risk' prescription once eye drops have been used. If your child meets this criteria, they will be enrolled into the study.

Children taking part in this study will be go into one of two separate groups, with the decision of which group the child goes in being made by chance (like tossing a coin). One of these groups will be asked to continue as they are no with no changes, (which is the current guideline for managing children with a risk of becoming short-sighted). The children in the other group will be asked to wear overnight contact lenses. It is important for you and your child to understand that you will not be able to choose which group your child will be allocated to.

The cost for all appointments, contact lenses, solutions and necessary items needed will be covered by us.

The study will last for approximately 18 months (1½ years). We will ask your child to continue with the instructions described to them based on the group they have been put in by chance. Should your child be in the contact lens wearing group, we will organise appointments for giving you these contact lenses, teaching both you and your child how to take care of them, and how to put them in and take them out of eyes.

At the first visit, we will ask you to complete a questionnaire. This questionnaire asks about your own vision and any eye problems you may have had in the past. It also asks about the interests and hobbies of your child. After this, during the 18 months of the study, we will ask your child to attend visits to the University Eye Clinic again. These visits will be spaced approximately 6-months apart once your child has been put into their group. Each of these visits will last about 1 hour. During the visit, we will ask you and your child to complete a questionnaire to find out how they are getting on, the experiences they have had during the last months, and about their vision. We will also carry out checks for short-sightedness and a check of the eye health. These checks will be similar to those you and your child may have when visiting an optician.

At the first and last visits, we will use eye drops to relax their eye focussing muscles in order to.measure your child's optical prescription precisely (There are no eye drops for visits 2 and 3). The drops we will use are the same as those commonly used by an optician when examining children's vision, or when dilating people's eyes.

You and your child are welcome to ask questions about any of the eye checks that we are carrying out during the visits. If we discover anything of concern about your child's eye health, we will advise you on any action that needs to be taken. This will be done in consultation with one of the University researchers leading the study, who are all experienced, qualified optometrists.

5. Will I be paid for taking part?
No, there is no payment for taking part.

6. What are the possible benefits of taking part?
The contact lenses may prevent children who take part in the study from becoming short-sighted, however they may also not prevent the development and progression of short-sightedness. There may be no benefit to you or your child from taking part in this study. However, you and your child's contribution will help us understand if these contact lenses should be recommended to children prior to becoming short-sighted.

7. What are the possible risks of taking part?
We will ask your child to wear contact lenses for 18 months. Normally, your child would not need to wear contact lenses. Therefore, should you be fitted with contact lenses this may cause some inconvenience for you and your child.

Orthokeratology contact lenses are very safe, however as with all contact lens use, there is a small chance of getting an eye infection. This has been estimated to be approximately 1 in 1000 in children wearing ortho-K lenses. Other studies looking at these contact lenses in children have reported no infections or significant problems occurring with lens wear. To reduce the risk of infections, we will make sure that you are taught how to correctly use and take care of the contact lenses, as well as what warning signs to look for and what to do in case of any difficulty. The researchers will be contactable throughout the duration of the study to offer advice, and see you for appointments should you wish to contact us or have any concerns.

Also, at the first and last of the research visits, we will use eye drops to dilate the pupils of your child. The eye drops are called 1% tropicamide.

Eye drop	Purpose	Side-effects
1% tropicamide	Dilate pupil and relax focussing	Blurry close-up vision; Sensitivity to bright light

The eye drops sting mildly for a few seconds at first. The drops will make it difficult for your child to focus at things up close. The effects usually last a maximum of 6 hours, occasionally lasting for a little longer. Sunshine outdoors will also seem very bright for a few hours after having the eye drops. We recommend your child wears sunglasses if they wish to spent time outdoors during the first few hours after having the eye drops.Very rarely, children may have a bad reaction to eye drops such as an allergy. If this happens, it will make your child's eyes red and sore for several hours. We will recommend your child stops taking part in the study if we, or you, notice that they have a bad reaction to the eyedrops.

As part of the criteria for being part of the study, your child is at high risk of developing short-sightedness in the near future. If your child is progressing into short-sightedness at a high rate through the course of the study (determined by a set length of eye growth with a certain time frame or issues with distance vision) we will make you aware of this, withdraw you from the study, and provide options for myopia management, if wanted. This may include overnight contact lenses, as well as other spectacle and contact lens options.

After the trial has finished, your child will also be offered these optical myopia control options through the University Eye Clinic if appropriate.

8. Will my taking part in this research project be kept confidential?

All information collected about you and your child during the research project will be kept confidential and any personal information you provide will be managed in accordance with data protection and GDPR legislation.

9. What will happen to my Personal Data?

We will store the personal data relating to you and your child separately from the results of the study. This personal data will include your child's name and your name and contact details. We will use a code-label to link you and your child's personal information to the research data that is collected during the study. Written information such as Consent Forms and Questionnaires will be stored in a locked filing cabinet at the University, to which only the research team will have access. Research data will be transferred to a computer file, which will be stored securely on password protected devices, with only the research team given access.

Once the study has been completed, the research team will anonymise all the personal data it has collected from, or about, you and your child in connection with this research project, with the exception of your consent form and contact details. Your consent form and contact details will be retained for 15 years, in accordance with current regulations and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised information may be retained indefinitely and published in support of the research project.

We may share anonymised data from this study with other researchers in the UK and overseas who are carrying out similar research studies into short-sightedness, in order to compare the findings between the different studies. Your personal data, or information that would give any indication of who you are will not be shared.

If you and your child choose to withdraw from the study while it is ongoing then we will destroy any research data that has been collected about you and your child. However due to regulations on maintaining clinical records, all clinical data obtained will be retained for 15 years as advised by regulatory and advisory bodies. However, once the study has been completed and the research data have been anonymised, it will not be possible for us to remove data for individual participants.

10. What will happen to the results of the research project?

It is our intention to publish the results of this research project in academic journals and present findings at conferences. Participants will not be identified in any report, publication or presentation. As mentioned above, we may share anonymised data from this study with other researchers in the UK and overseas who are carrying out similar research studies into short-sightedness, in order to compare the findings between the different studies. Your personal data will not be shared.

Once the study has finished, we will be able to tell you the results and whether the use of overnight contact lenses in this study has demonstrated any prevention or delay in short-sightedness. We will inform all participants who are interested about the results of the study in a presentation at the end of the trial.

11. What if there is a problem?

If you wish to complain, or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this research, please contact Dr Neema Ghorbani Mojarrad (contact details below) who is leading the project. Alternatively, if you prefer to contact somebody who is not directly involved in the research or if your complaint is not managed to your satisfaction, please contact Dr Niall Mcloughlin (contact details below) who is the acting Head of School at the University of Bradford School of Optometry and Vision Sciences.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action.

12. Who is organising and funding this research project?

The research is organised by Dr Neema Ghorbani Mojarrad, Dr Annette Parkinson and Dr Matthew Cufflin from the School of Optometry & Vision Science at the University of Bradford. The research is funded by University of Bradford.

13. Who has reviewed this research project?

This research project has been reviewed and approved by the School of Optometry & Vision Science Research Ethics Committee.

14. Further information and contact details

Should you have any questions relating to this research project, you may contact us during normal working hours:

Sophie Coverdale
School of Optometry & Vision Science
University of Bradford
Phoenix South West Building, Bradford, BD7 1NX
Tel +441274 232179
Email. s.l.coverdale@bradford.ac.uk

Dr Neema Ghorbani Mojarrad
School of Optometry & Vision Science
University of Bradford
Phoenix South West Building, Bradford, BD7 1NX
Tel +441274 232179
Email. nghorban@bradford.ac.uk

Dr Annette Parkinson (Researcher)
School of Optometry & Vision Science

ID No.:

University of Bradford
Phoenix South West Building, Bradford, BD7 1NX
Tel +441274 235586
Email. a.parkinson@bradford.ac.uk

Dr Niall Mcloughlin (Head of School)
School of Optometry & Vision Science
University of Bradford
Phoenix South West Building, Bradford, BD7 1NX
Email. n.mcloughlin@bradford.ac.uk

Thank you for considering to take part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a signed consent form to keep for your records.