Light therapy as a novel treatment for myopia

Parent Information Sheet

Your child has been invited to participate in a research study. Before you decide whether or not you would like your child to take part, it is important for you to understand why the research is being conducted and what is involved. Please take time to read the following information carefully and discuss it with others if you wish. The research team is available to go through the information leaflet with you or to answer any questions you may have. Their contact details can be found at the end of this leaflet.

Introduction

Myopia, also known as short-sightedness, is a common vision problem which results in blurred distance vision. This usually occurs because the eye grows too long. It can be corrected with normal glasses or contact lenses; however, myopia often progresses (worsens) over time, particularly throughout childhood until late teenage years. This is a concern as myopia can be associated with eye complications in later life.

The number of children with myopia (short-sightedness) has more than doubled in the UK over the past decade. Myopia management treatments which may reduce the rate of progression (worsening of myopia) include specialised contact lenses and spectacles. However, some children get a better effect on their myopia progression than others. Furthermore, treatments are costly (approx. £300-500 per year) and are privately paid for by parents until myopia stabilises in late teenager years.

Less time spent outdoors helps prevent myopia from occurring, most likely due to exposure to bright sunlight which helps regulate the body clock. In the UK, climate varies considerably throughout the year and by region. These climatic challenges are likely to influence how often a child can spend outdoors on a daily basis. In particular, more northern parts of the UK, including Scotland, experiences a wetter climate and there are significantly fewer daylight hours in the winter months. This makes spending more time outdoors difficult and increases the risk of UK children, particularly in Scotland, becoming myopic.

Currently, the total financial cost to the parent for specialised myopia management contact lenses and spectacles is significant and there is no guarantee that treatment will be effective. Light therapy may provide a more affordable, non-invasive alternative to these expensive treatments. In particular, it may provide an alternative treatment for myopia management in countries where climate limits the time spent outdoors. This study aims to investigate the potential benefits of morning light therapy in reducing myopia progression in children living in Scotland.

The study will involve two groups of participants- one group will receive a Seasonal Affective Disorder (SAD) lamp (https://www.lumie.com/products/vitamin-l) to use and the other group (called a control group) will continue to wear their normal spectacles. The rate that myopia changes in each group will be monitored over a period of 6 months and the results will be compared.

The study is funded by the Carnegie Research Trust and is being conducted by Eleanor Leech, a GOC registered optometrist, at Glasgow Caledonian University (GCU) and will be supervised by Dr Stephanie Kearney, Dr Mhairi Day and Dr Sven Jonuscheit.

Why is this study important?
Myopia that continues to worsen can be associated with substantial costs, such as increased spending on glasses and more regular eye examinations. Additionally, there is the inconvenience of having poorer vision when not wearing glasses or contact lenses, and the burden of having to wear spectacles for certain sports or activities. People with myopia are also at greater risk developing sight threatening eye conditions in adulthood, such as glaucoma, retinal detachment or myopic macular degeneration. The risk of an individual developing these complications becomes greater as their level of myopia increases but there is no 'safe' amount of myopia.

Myopia management treatments aim to slow myopia progression and reduce the likelihood of an individual developing a higher level of myopia. It is thought that by doing this, the risk of developing complications in later life is also reduced. An additional advantage of being able to reduce the severity of an individual's myopia is that they may experience a better quality of life. As treatments are required until late teenage years, the accrued financial cost to the parent is significant and can amount to thousands of pounds.

The project will explore the use of light therapy to try and slow down myopia progression (worsening). The results of this study will contribute to community eyecare guidance and teaching at GCU.

Does my child have to take part?
No. You and your child can decide whether you would like to take part. Your child can stop taking part in the study at any time, without giving a reason. Withdrawing from the study will not affect your child's eye care or legal rights.

Is my child suitable for the study?
If you decide that you would like your child to take part in the study, we will conduct an examination of your child's eyes, similar to the eye test normally received from their regular optician, to check that they are suitable for the study. This normally lasts around 1.5 hours. We will also ask a few questions about your child's general health, allergies and current or previous eye conditions. This is because we need to ensure that there aren't any general or eye health conditions which could affect your child's eyesight and the results of the study. We also need to check that your child hasn't received any treatments for myopia in the past (other than normal glasses and contact lenses).

What will happen if my child takes part?
If you and your child decide that you would like to take part in the study, we will ask you to sign a form (called an informed consent form) to say that you have agreed for your child to participate. Your child will also be asked to sign a form (called an informed assent form) to say they are happy to be part of the study. At this time, you will be given a copy of this information sheet and a copy of the forms you and your child have signed.

At your child's first appointment, they will be randomly assigned to either a treatment group or a control group. The treatment group will be provided with a SAD lamp and the control group will continue to wear their normal spectacles. Your child will attend for an appointment every 6 months to monitor their vision and myopia progression. The study will last 6 months, so your child will receive a total of two appointments: the first appointment to take initial measurements, followed by one 6 monthly check-up after using the lamp over the winter months. During the study period, your child should continue to attend their regular eye examinations at their usual optometry practice.

The appointments will take place in the GCU Vision Centre and are likely to last approximately 1.5 hours. During each appointment, the following measurements and assessments will be performed:

- We will ask you and your child a few questions about their eye health, general health, medical history, family history of myopia and lifestyle. We will also ask some questions about your child's ethnicity and the age they started wearing glasses for myopia- this is important as both of these factors can influence how quickly your child's myopia progresses. We may issue you and your child a questionnaire to complete which will contain questions related to your child's vision with their glasses. You will also be issued a questionnaire to complete on your child's sleeping habits and on any issues with using the SAD lamp

- At the initial appointment, we will assess the health of your child's eyes to confirm that they are able to take part in the study. This is normally done using an instrument called a slit lamp biomicroscope, which uses a light and magnifying lens to allow the optometrist to view the eye in greater detail. For this assessment, your child is asked to place their chin on a chin rest and is asked to look in different directions whilst the research optometrist looks through a set of eyepieces to examine the eye.

- We will collect a sample of your child's saliva to measure melatonin (the sleep hormone). This involves asking your child to drool into a small tube. We will ask your child to rinse their mouth with water 10minutes prior to this and to avoid eating sugary or acidic foods just before the appointment. This test is quick and easy to do.

- We will take some measurements of your child's vision using a letter chart. Your child will be shown letters of various sizes and we will ask them to tell us the smallest letters they can see whilst they are wearing their glasses. A test of your child's binocular vision (how well the eyes work together) will be carried out by placing a cover over each eye whilst they look at an image or letter.

- The focussing ability of your child's eyes will be measured using a machine called an autorefractor. For this measurement, your child places their chin on a chin rest whilst wearing their glasses and they are asked to focus on a letter or image which will be placed at a short distance from them. The machine will take a few quick measurements of your child's ability to focus accurately on near objects.

- The size of the pupil (the black part of the eye) will be measured using a handheld autorefractor. Your child will be asked to look into the device for a few seconds whilst the measurement is taken.

- We will use an eye drop called Cyclopentolate in your child's eyes to allow a more accurate assessment of their level of myopia. The drops will make your child's pupil larger and relax the muscles inside the eye. These drops are routinely used by optometrists during children's eye examinations so your child may have received them before. The drops normally take around 30 minutes to take full effect. The effect of the drops is temporary. Your child's pupils may appear larger than normal for up to 24 hours after the drops have been put in. They may also notice some mild light sensitivity and blurred near vision whilst wearing their glasses, which can last up to 4 hours.

- After the drops have taken full effect, we will measure your child's level of myopia using the autorefractor. For this measurement, your child places their chin on a chin rest and they are asked to

focus on a distant object. Nothing comes into contact with your child's eye and they do not feel anything during the measurements.

- The length of your child's eye will be measured using a machine called an ocular biometer. Similar to the autorefractor, your child will be asked to place their chin on a chin rest and look at a light inside the machine. The machine will take a quick measurement of the eye. Nothing comes into contact with your child's eye and they do not feel anything during the measurements.

- Lastly, the thickness of a layer at the back of the eye (called the choroid) will be measured using a machine called an OCT. This machine uses light to scan the back of the eye and take an image. For this measurement, your child places their chin on a chin rest and they are asked to look at an image inside the machine. Your child will then see a bright light as the OCT takes a scan of the back of their eye. Nothing comes into contact with your child's eye and they do not feel anything during the measurements.

Apart from the eye drops, nothing will touch your child's eye during their appointment. All the measurements taken are simple, quick and painless and are routinely performed in the GCU Vision Centre.

Additionally, half way through the study, you will be asked to complete the questionnaires again. This will be done remotely via phone, email or online. Whichever is more convenient.

Will my child receive myopia management treatment if they take part?

If your child takes part in the study, they will be randomly assigned into either a treatment group or a control group. The treatment group will be provided with a SAD lamp (https://www.lumie.com/products/vitamin-l) . The control group will not receive any myopia management treatment but will continue to wear their normal spectacles. Using a control group in this type of study is important. By comparing the rates of myopia progression between the treatment and control groups, the researchers can determine the effectiveness of light therapy. .

It is important that your child does not receive any myopia management treatments either from the GCU Vision Centre or from their regular optometrist during the study. This is because the researchers need to measure the 'natural' myopia progression of the control group (changes to their myopia without any treatments) in order to determine the effectiveness of light therapy. Similarly, subjects in the treatment group should not undertake other myopia management treatments (e.g. myopia management contact lenses) in addition to their light therapy during the course of the study. This is to ensure that any observed changes in myopia progression are due to the light therapy being investigated and not due to any other factors.

Delaying treatment in the control group by 6 months is not expected to significantly affect a child's overall myopia progression as the treatment effects of myopia management over a 6-12month period period are generally small. Based on the results of previous studies, it is expected that the group receiving light therapy will have around 0.25D less myopia than the control group. 0.25D is the smallest clinically measurable change in myopia, and in typical optometric practice, a 0.25D difference would not warrant a change in spectacle prescription. Furthermore, it is common practice in the Myopia Management clinic at GCU to monitor children for up to one year to determine their rate of myopia progression before offering treatment.

What are the possible costs associated with the study?

There are no costs associated with the study other than traveling to the university for measurements.

What are the possible risks with taking part?
The possible risks associated with this study are minimal. As the study involves using Cyclopentolate eye drops, your child may experience some minor side effects such as blurred vision and light sensitivity. Cyclopentolate drops are used routinely in optometry practices and are considered safe to use in children.

Light therapy is considered safe to use for both adults and children. Mild side effects may include temporary eye strain. Please let the researcher know as soon as possible if your child has any side effects.

What are the possible benefits of taking part?
If your child is assigned to the treatment group, they will receive a SAD lamp which may help slow down the progression of your child's myopia and reduce the risk of them developing a higher level of myopia in the future.

What happens when the study stops?
Your child can continue to be seen at their regular optometry practice. The anonymised data collected in the study may be discussed at research conferences and published as a research paper. The results of the study can be made available to you via email.

What if there is a problem?
Every effort will be made to minimise the risks to you or your child during the study. If you have any questions or concerns about the study, you can contact the Research Team using the details noted at the end of this form. If you are still not happy then you can contact the GCU Complaints Team at complaints@gcu.ac.uk.

What will happen to the information given during the study?
Information will be collected about your child's name, age, gender and details of the measurements taken during their assessments at the Vision Centre. All personal data will be stored securely according to the Data Protection Act (2018) and General Data Protection Regulation (GDPR) legislation. Data will be anonymised at the time of collection and stored in encrypted/password protected files. Only anonymised data will be contained within the final report. Data destruction will occur according to GCU guidelines.

The data controller is Glasgow Caledonian University. Information is being processed on the basis of Article 6(1)(e) of the General Data Protection Regulation and to perform a task carried out in the public interest.

Enquiries specifically relating to data protection should be made to the University's Data Protection Officer (DPO). The DPO can be contacted by email: dataprotection@gcu.ac.uk. If you are unhappy with the response from the University, you have the right to lodge a complaint with the Information Commissioner's Office (ICO). The ICO can be contacted by email: casework@ico.org.uk.

GDPR also gives study participants the right to ask for their personal data to be erased. If you would like us to stop using your personal data, then you can contact dataprotection@gcu.ac.uk and ask for your personal data to be erased. However, it will only be possible to erase data that has not been anonymised and/or published. Further information about your rights can be found at:
https://www.gcu.ac.uk/dataprotection/rights/

Who is funding the study?
This study is funded by the Carnegie Trust

What will happen to the results of the study?
The study results will be available to a range of people including health professionals, researchers, and the public. It will not be possible to identify any individual participant from these reports or publications.

Who has reviewed the study?
All studies involving human participants carried out at Glasgow Caledonian University are reviewed by an ethics committee. The role of the ethics committee is the protect the safety, rights, wellbeing, and dignity of study participants. This study was reviewed by the School of Health and Life Sciences departmental committee and given ethical approval on 12.6.23 under the following approval code: HLS/LS/A22/074

What happens next?
If you are interested in participating and would like to know more then please contact Stephanie.kearney@Gcu.ac.uk

How do I make contact with the study team?

Researcher:
Eleanor Leech

Principal investigator:
Dr Stephanie Kearney
Stephanie.kearney@Gcu.ac.uk

Co-investigators:

Dr Mhairi Day
Dr Sven Jonuscheit

Point of contact outside of the research team:
Prof Niall Strang
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Thank you for taking the time to read this information.