ISRCTN25433872 https://doi.org/10.1186/ISRCTN25433872

Daylight therapy as a novel treatment for myopia (short-sightedness)

Submission date
09/05/2024

Recruitment status
No longer recruiting

Registration date
13/05/2024

Overall study status
Completed

Last Edited
27/08/2024

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

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

Who can participate?
Healthy children with myopia (short-sightedness) up to -10D and who are aged 7-12 years.

What does the study involve?
Children will be randomly assigned to 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.
The study involves two visits to the Vision Centre at Glasgow Caledonian University over a 6-month period. At these visits, machines will be used to measure the length of the eye and how much myopia the child has and to take a photograph of the eye. Questionnaires will be used to collect information on lifestyle and genetic risk factors for the worsening of the myopia and on the tolerability of the lamp. Halfway through the study, the questionnaires on lifestyle risk factors and tolerability of the lamp will be completed.

What are the possible benefits and risks of participating?
Children assigned to the treatment group will receive a SAD lamp which may help slow down the progression of their myopia and reduce the risk of them developing a higher level of myopia in the future.
The possible risks associated with this study are minimal. As the study involves using cyclopentolate eye drops, participants 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.

Where is the study run from?
Glasgow Caledonian University (UK)

When is the study starting and how long is it expected to run for?
November 2022 to September 2024

Who is funding the study?
The Carnegie Trust for the Universities of Scotland (UK)

Who is the main contact?
Dr Stephanie Kearney, Stephanie.kearney@gcu.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Stephanie Kearney

ORCID ID
https://orcid.org/0000-0003-1531-3117

Contact details
Glasgow Caledonian University
Cowcaddens road
Glasgow
United Kingdom
G4 0BA

+44 (0)141 331 3978
stephanie.kearney@gcu.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RIG012527

Study information

Scientific Title
Broad spectrum light therapy as a novel treatment for myopia

Study objectives
Morning broad spectrum light therapy slows myopia progression in children

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/06/2023, Health and Life Sciences Ethics Committee (Cowcaddens road, Glasgow, G4 0BA, United Kingdom; +44 (0)141 331 8518; HLSEthicsLifeSciences@gcu.ac.uk), ref: HLS/LS/A22/074

Study design
Single-centre non-blinded randomized trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Myopia

Interventions
This is a prospective randomised controlled trial with a 1:1 allocation of intervention and control (light therapy vs no light therapy). There is no placebo group, rather, there will be a group of children not provided with the intervention and these children will be observed. Participants will be invited to attend the Vision Centre at Glasgow Caledonian University for two visits over a 6-month period.

The intervention group will receive one SAD lamp per child to use once daily in the morning for 30 minutes at 20 cm (https://www.lumie.com/products/vitamin-l) for 3 months.

The child and parent will attend the Vision Centre GCU both prior to and after the intervention period for a face-to-face appointment (Visit 1 and 3). Additionally, halfway through the intervention period, questionnaire data will again be collected. This will be completed remotely with guidance from the researcher with the parent and child either by phone or online (Visit 2).

Children will be randomly selected for light therapy using the method of minimisation (Altman D 2005). The control group will be matched by age, ethnicity, refraction and parental myopia to the intervention group. The control group will continue to wear their normal refractive correction (spectacles) and will be monitored.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase II

Drug/device/biological/vaccine name(s)
Seasonal affective disorder lamp: the 'Vitamin L' lamp (Lumie)

Primary outcome measure
Axial length measured using biometry at baseline and 6 months

Secondary outcome measures
1. Refractive error measured using cycloplegic autorefraction at baseline and 6 months
2. Salivary melatonin measured using a commercial ELISA kit at baseline and 6 months
3. Tolerability measured using participant questionnaire at baseline, 3 months and 6 months

Overall study start date
01/11/2022

Completion date
08/09/2024

Eligibility

Key inclusion criteria
1. Healthy children aged over 7 years and younger than 13 years
2. Minimum amount of -0.50 D spherical equivalent refraction (SER) of myopia
3. Best corrected distance visual acuity of at least 0.3 logMAR in each eye (healthy level of vision)

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Myopia level of -10D or greater in either eye
2. Astigmatism of 4D or greater in either eye
3. Presence of significant ocular comorbidities
4. Amblyopia in either eye
5. Allergy to cyclopentolate eye drops
6. Use of atropine eye drops in the previous year
7. Taking melatonin supplements
8. Travelled across more than one time zone in the past month

Date of first enrolment
08/08/2023

Date of final enrolment
08/08/2024

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre

Glasgow Caledonian University
City Campus
Glasgow
United Kingdom
G4 0BA

Sponsor information

Organisation
Glasgow Caledonian University

Sponsor details
Cowcaddens road
Glasgow
Scotland
United Kingdom
G4 0BA
+44 (0)1413318844
Sharron.Dolan@gcu.ac.uk

Sponsor type
University/education

Website
http://www.gcu.ac.uk/

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Charity

Funder Name
Carnegie Trust for the Universities of Scotland

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal, presentation of findings at national conference

Intention to publish date
08/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Stephanie Kearney (stephanie.kearney@gcu.ac.uk). Anonymised, non-identifiable data on ocular biometry, refraction, risk factors and tolerability will be shared. No identifiable information will be shared. Randomised IDs will be used for participant-level data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			10/05/2024	No	Yes
Protocol file	version 2.3		27/08/2024	No	No