# Real-world Registry Study of Red Light Treatment on Myopia Control: a Focus on Non-responders to Conventional Treatments

Version: 1.0

Date: 03/07/2024

**Principal Investigators:**

Prof Mingguang He

**Statement of Compliance**

This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the Note for Guidance on Good Clinical Practice (ISO 14155:2020; MDR 2017/745).

# INFORMATION SHEET

## Real-world Registry Study of Red Light Treatment on Myopia Control: a Focus on Non-responders to Conventional Treatments

You are invited to participate in the above project conducted by Prof Mingguang He, who is a staff member of the Department of Optometry in The Hong Kong Polytechnic University. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (or its Delegate) (Reference Number: HSEARS 20240113001).

Before committing to this study, as the legal guardian, please review this document to understand its purposes, your child's role, and the possible benefits and risks involved. We encourage you to discuss this with your close ones and address any queries to our research team on behalf of your child.

## Background and Purpose of this Study

*1.1 Background*

Myopia, commonly known as near-sightedness, is a prevalent eye condition where distant objects appear blurry. It is especially prevalent in school-aged children in the Asia-Pacific region, where it affects nearly 80% of East Asian children, and is a growing cause of visual impairment globally. Traditional treatments like atropine eyedrops and Orthokeratology have been effective in mitigating the progression of myopia, but some patients do not respond to these methods. Recently, Repeated Low-Level Red Light (RLRL) therapy has shown promising results in myopia control, particularly in children with higher degrees of myopia. Randomized controlled trials have indicated an over 80% control in refraction progression compared to single vision spectacles. The Eyerising Myopia Management System, an approved product in your country, delivers RLRL therapy. This study focuses on understanding the effectiveness of RLRL, delivered via the Eyerising System, in children who have not responded to conventional treatments. By targeting this specific group, we aim to explore RLRL's potential as an alternative treatment and contribute to developing personalized strategies for effective myopia management. If you have insufficient control of progression under myopia treatments for at least six months and are currently receiving or plan to start RLRL therapy, you are invited to participate in our real-world registry study, share your clinical data anonymously with our researchers and thus contribute to this important research.

*1.2 Purpose*

• To collect and analyze real-world data on the proportion of full myopia control (defined as axial length (AL) elongation of less than 0.1mm per year or SER progression of less than 0.25 diopter per year in the eye with least control) among children who do not respond to conventional treatments and are receiving or intend to receive RLRL therapy.
• To collect and analyze real-world safety data from myopia non-responders who are receiving or intend to receive RLRL therapy.

## Inclusion and Exclusion Criteria

*2.1 Inclusion criteria for data collection*

Patient data meeting the following inclusion criteria will be collected:

- Age: 8 to 16 years at the time of data collection, aligning with the approved usage guidelines of the RLRL device.
- Diagnosed with myopia and have been under conventional myopia treatments (include Orthokeratology, defocus incorporated multiple segments spectacles or equivalent, and 0.01% atropine or 0.05% atropine eyedrops) for at least six months. Eligible patient data must demonstrate insufficient control of myopia progression, defined as an axial elongation of 0.3 mm or more, or SER progression of 0.5 diopter or greater per year.
- Best corrected visual acuity (BCVA): 20/20 or greater.
- Data from patients who have utilized or are utilizing red light therapy as part of their myopia management strategy.

*2.2 Exclusion criteria*

Data will be excluded from the analysis if it pertains to patients with any of the following conditions:

- Ophthalmic diseases other than refractive errors, including but not limited to strabismus and binocular vision abnormalities in either eye.
- Presence of systemic diseases (e.g., endocrine, cardiac diseases) and developmental abnormalities.
- Concurrent use of atropine eye drops and RLRL therapy.

## Study procedures

*3.1 Study design*

This observational, real-world, web-based registry study will collect treatment data from multiple clinics of children aged 8-16 years old who have insufficient control of progression under myopia treatments for at least six months, and are receiving or intend to receive RLRL therapy. Insufficient control is defined as meeting either of the following criteria: AL elongation of less than 0.3mm per year or SER progression of 0.5 diopter (D) or greater per year. These subjects will then be defined as non-responders to conventional treatments for myopia, and offered RLRL therapy.

Conventional treatments include Orthokeratology (Ortho-K), defocus incorporated multiple segments (DIMS) spectacles (or equivalent), and low-concentration atropine (0.01% atropine or 0.05% atropine eyedrops). For the purpose of data collection, we will include data from participants who have been undergoing Ortho-K or wearing DIMS spectacles and have added RLRL therapy to their current treatment regimen, as well as those who have chosen to discontinue their previous treatment in favor of RLRL therapy. Similarly, data from participants who were previously on low-concentration atropine eyedrops but have since switched to RLRL therapy will also be collected. This approach allows for a comprehensive analysis of real-world treatment patterns and their outcomes in the management of myopia.

We will gather information on the use of the RLRL device, which has already received regulatory approval. The data will include treatment patterns as per its approved indications for use, where subjects may have received treatment sessions twice daily, each lasting for 3 minutes with a

minimum interval of 4 hours between sessions. Our analysis will focus on the real-world outcomes, specifically evaluating the proportion of participants who have achieved effective myopia control (defined as AL elongation of less than 0.1mm per year or SER progression of less than 0.25 diopter per year) after 12 months of documented RLRL therapy use among the collected data from eligible subjects.

Our study is approved by the ethics committee at the Hong Kong Polytechnic University, ensuring high ethical standards across all participating clinics.

Your privacy is our top priority. We anonymize your data before adding it to our web-based registry, removing any personal details to protect your identity. The online platform is secure, with strong encryption and strict access controls to prevent data breaches.

Remember, the data we use is collected as part of your regular clinical care. Each clinic involved in the study will seek your informed consent to use your data for research purposes, ensuring you understand and agree to this use. We regularly review our data practices and consent processes, guided by the ethics committee, to uphold these high standards throughout the study.

*3.2 Study methodology*

Our study involves a detailed web-based registry system to track and evaluate the RLRL therapy's effectiveness for myopia. Clinical staff will carefully input your treatment information into this secure system, ensuring data accuracy and integrity. Our system is designed with privacy in mind, adhering to GDPR guidelines. This means your personal data is de-identified and securely processed, ensuring confidentiality. Data collected will include participant demographics, visit information, prior and current treatments, ocular measurements at each visit, treatment and follow-up compliance, self-reported side effects and any incidents of discontinuation. You can access our system using any internet-connected device. Your participation is vital in helping us collect valuable data to improve myopia treatment.

*3.3 Time required*

- RLRL Therapy: The participants will use the therapy device at home every day, adhering to their usual treatment routine under parental supervision. Typically, this involves two sessions daily, each lasting three minites, with a minimum interval of 4 hours. This routine is based on the device's approved indications and regulatory acceptance. The treatment pattern will be collected individually. The total study duration is 12 months.
- Attending Scheduled Visits: Participants are expected to visit the clinic at 1 month, 6 months and 12 months after their participation in this study. The exact timing of the visits may vary depending on the clinic's routine. Generally, each visit is estimated to take 2 to 4 hours.

*3.4 Data collected*

We collect following data at the baseline of the study and during follow-up visits:

At baseline:

- Demographics and visit information: Study ID, date of birth, sex, ethnicity, and date of visit.
- Previous Eye Treatments: Details about past treatments for each eye (type,duration, refraction and biometric data).
- Ongoing or upcoming RLRL treatment measures with start date.
- Ocular measurements: Axial length, subjective and optional cycloplegic refraction, best

corrected visual acuity (BCVA), and an optional OCT report.

During follow-up visits (1-month, 6-months, 12-months):

- Demographics and visit information: Study ID, date of birth, sex, ethnicity, and date of visit.
- Ocular measurements: Axial length, optional cycloplegic or non- cycloplegic refraction, best corrected visual acuity (BCVA), and an optional OCT report.
- Ongoing RLRL treatment measures and compliance.
- Self-reported side effect(s).
- Reason for discontinuation (if any).

## Benefits and Risks

*4.1 Benefits*

By participating in this study, you help improve understanding of red light therapy for myopia control, particularly for those not responding to standard treatments. While this study does not offer direct medical interventions, your involvement helps gather valuable data and could benefit many children at risk of high myopia in the future.

*4.2 Risks and Discomforts*

The primary risk associated with participating in a registry study is the collection and storage of personal health information. Therefore, we have implemented a series of robust procedures to ensure the utmost privacy and security of participant data. Only minimal personal information, including date of birth, gender, name, and ethnicity, will be recorded. Furthermore, we have adopted stringent measures to safeguard the anonymity of participants. All data transmissions between users and the server will be encrypted, adding an extra layer of protection to the information exchanged. These measures are in place to mitigate the risks associated with data confidentiality and to provide participants with the assurance that their personal information will be handled with the highest level of care and security.

To this end, an independent data and security monitoring committee will also be established. The members of the data and security monitoring committee will regularly check the data collection, storage, and analysis process, and will be able to access the original data related to this clinical trial to determine the integrity, accuracy and consistency of the information recorded with the original data. Relevant information will be available to members of the data and security monitoring committee at all times. The data and security monitoring committee will also be able to review informed consent data.

## Confidentiality Issues

The project webpage will be designed to provide maximum data security and anonymity. The system will generate a unique identifier (a string of numbers and letters) specific to each participant. This will allow for complete tracking of outcomes, even if the participant is treated for different conditions by different doctors at different locations, as each string is unique in the database and linked directly to each User group's practice identifiers. As an additional measure to ensure that the right data are being entered for the right patient, basic demographic information of the participant’s initials, gender, ethnicity, and date of birth will be stored. No other personal information will be recorded. Anonymity of participants will also be closely guarded. Practitioner users will only be able to see their own data, as well as summary descriptive data from their country, against which they will be able to compare their outcomes. Participants are also free to

withdraw their data from the database at any time upon request, without needing to provide a reason.

All data transmissions between the user and the server will be encrypted using 128-bit encryption. The data will be stored and backed up on secure servers.

**Rights of the subject**

*6.1 Withdrawals*

You have the right to withdraw from this study at any time, without needing to give a reason. If you decide to withdraw, we will respect your choice regarding the use of your clinical data already in our registry. Should you choose to retract consent for data use, we will promptly remove your information from the system. This policy is in line with the study's observational nature, where we collect data from routine clinical practices, ensuring your autonomy and data integrity.

*6.2 Data access*

You retain the right to request access to any of the data you have provided for the project.

*6.3 Inquires*

If you have any questions, you may ask our helpers now or later, even after the study has started.

You may contact Dr Chen Yanxian (tel. no.: +85227666111/ email: yan-xian.chen@polyu.edu.hk) or Dr Zhao Ziwei (tel. no.: +85261548412 / email: zavia.zhao@connect.polyu.hk) of PolyU under the following situations:

- if you have any other questions in relation to the study; or
- if, under very rare conditions, your child becomes injured as a result of their participation in the study; or
- if you want to get access to/or change your child's personal data before (31/12/2025).

In the event that you have any complaints about the conduct of this research study, as a guardian, you may contact the Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.

Thank you for considering allowing your child to participate in this study.

Prof Mingguang He
Principal Investigator/Chief Investigator

## CONSENT TO PARTICIPATE IN RESEARCH

### Global Real-world Registry Study of Red Light Treatment on Myopia Control: a Focus on Non-responders to Conventional Treatments

I _____ hereby consent to participate in the captioned research conducted by Prof Mingguang He.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant _____

Signature of participant _____

Name of Parent or Guardian (if applicable) _____

Signature of Parent or Guardian (if applicable) _____

Name of researcher _____

Signature of researcher _____

Date _____