Informed consent

Study Title: The Rebound Effect on Repeated Low-Level Red Light Therapy for Myopia: A Randomized Controlled Clinical Trial

Version Number: V1.0, Date: 2026-1-28

Version Number of Informed Consent Form: V1.0, Date: 2026-1-28

Research Institution: The First Affiliated Hospital of Anhui Medical University

Principal Investigator (Responsible Physician): Feng Lixia

Your child will be invited to participate in a clinical trial. This information sheet provides some information to help you and your child decide whether to participate in this clinical trial. Please read this carefully; if you have any questions, please contact the principal investigator overseeing this study.

Participants have voluntarily agreed to participate in this study. This study has been approved by the Ethics Review Committee of the research institution.

Research Objective: Myopia is a globally recognized public health issue, with its incidence and severity increasing annually, particularly among children and adolescents. Projections indicate that by 2050, the global prevalence of myopia will reach 49.8%, including a high myopia prevalence of 9.8%. As myopia prevalence rises, the risk of myopia-related complications—such as cataracts, glaucoma, myopic macular degeneration, and retinal detachment—also increases significantly; failure to control these conditions can lead to severe visual impairment and substantial societal burdens. Therefore, preventing and slowing the progression of myopia has become a critical strategy in myopia control efforts.

Repeated low-level red light (RLRL) therapy is an emerging treatment modality for myopia control. In a 12-month multicenter randomized clinical trial, the RLRL group demonstrated a 69.4% reduction in axial length elongation and a 76.6% decrease in myopic refractive progression compared to the single-vision spectacle (SVS) group. Additionally, RLRL exhibited superior therapeutic efficacy in patients with high myopia, achieving an axial length reduction of over 0.05

mm in 53.3%−59% of cases. Comparative studies with atropine-controlled myopia showed that after 12 months of treatment, RLRL significantly outperformed 0.01% atropine in controlling axial length. Among myopic patients undergoing orthokeratology correction but still exhibiting poor axial length control, combined RLRL therapy markedly suppressed axial growth. To further investigate the long-term efficacy of RLRL and rebound effects post-treatment discontinuation, as well as strategies to mitigate these rebound effects, this study focused on participants receiving continuous RLRL therapy for one year, examining axial length (AL) and spherical equivalent refraction (SER) rebound effects in those who discontinued or gradually reduced RLRL treatment compared to those who continued therapy.

Research Process:

purpose of research ：

Investigate the rebound effect of myopia progression after discontinuing RLRL continuous treatment, and explore strategies to mitigate this effect by comparing changes in AL and SER between participants who interrupted treatment and those who gradually reduced treatment intensity.

research design ：

This study was a three-arm, randomized controlled, prospective trial conducted at the Department of Ophthalmology, The First Affiliated Hospital of Anhui Medical University, enrolling pediatric participants who had received RLRL treatment for 1 consecutive year. Participants were randomly assigned to one of three groups: the RLRL continued treatment group (RLRL-C), the RLRL interrupted treatment group (RLRL-I), and the RLRL step-down treatment group (RLRL-T). The protocol for the RLRL step-down treatment regimen was as follows:

1. First month: twice daily, for 5 days per week.
2. Second month: Once daily, for 5 days per week.
3. Third month: Once daily for 3 days per week.

Data including AL, SER, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), and choroidal thickness (CnT, optional) were collected from subjects at baseline and at months 6 and 12. Additionally, adverse events were assessed using questionnaires at baseline and during follow-up.

Inclusion and exclusion criteria for participants:

Inclusion Criteria:

①Children and adolescents aged 8 to 16 years

② The patient has received continuous RLRL treatment for 1 year (± 1 month) without interruption.

③Diagnosed with myopia (ciliary muscle paralysis SER ≥ -0.50 D), astigmatism ≤ 2.50 D, anisometropia ≤ 1.50 D, and bilateral best corrected visual acuity (BCVA) ≥ 20/20 on Snellen test before receiving RLRL treatment.

④The consent of the guardian and the consent of the participant.

Exclusion Criteria:

①Any history of ophthalmic surgery or ocular diseases (e.g., glaucoma, retinal disorders).

②Systemic diseases that may affect vision or eye health (e.g., diabetes).

③After discontinuing RLRL treatment, other myopia control interventions other than monocular glasses should be employed (including atropine, orthokeratology lenses, defocused/DOT lenses, etc.).

Risks and Discomforts:

（1） The intervention employed in this study utilized the Elxing Myopia and Amblyopia Comprehensive Treatment Device, a product certified as a Class II medical device with a valid manufacturer's license for medical device production. The device is commercially available and widely used in major hospitals. It operates on the principle of low-intensity single-wavelength red

light, employing diodes to generate visible red light at a wavelength of 650 ± 10 nm with an energy delivered to the eye of 0.29 mW. Certified by the National Center for Radiation Safety Quality Supervision and Inspection of Optoelectronic Products, its radiation category falls under Class I. According to China's GB 7247.1-2012 standard "Safety of Laser Products − Part 1: Equipment Classification and Requirements," its radiation is deemed safe for ocular use during application. No known adverse effects on ocular structure or function have been reported; however, a minority of users may experience transient symptoms such as glare, photophobia, or post-image scotoma. These symptoms typically resolve spontaneously after resting with the eyes closed for several minutes.

(2) During the ciliary muscle paralysis examination (mydriasis) in the study, the use of compound tobutamidine eye drops (Medoril) may cause transient dysmetropia and photophobia in some children. These symptoms will completely resolve within 5−72 hours, during which parents are required to monitor closely and accompany the participants. If photophobia leads to mobility difficulties, researchers will provide light-blocking eyeglass clips to alleviate dysmetropia and photophobia in affected individuals. Less than 1% of participants may experience elevated intraocular pressure, headache, ocular pain, or vomiting (manifestations of acute angle-closure glaucoma). For those with photophobia or blurred near vision, light-blocking glasses will be provided, and additional near-vision lenses may be offered when necessary to facilitate reading. All subjects will undergo preliminary slit-lamp screening; patients with extremely narrow anterior chamber angles will not undergo mydriasis examination. Should any participant exhibit symptoms such as elevated intraocular pressure, headache, or ocular pain, on-site staff will promptly administer pharmacological treatment and arrange referral. In cases of research-related injuries, you and your family members may receive free medical care at our hospital through the participating physicians. Treatment costs are covered by Hong Kong Polytechnic University (Wuhan) Science and Technology Innovation Research Institute Co., Ltd., with compensation provided in accordance with applicable Chinese laws.

benefits: By analyzing the participants' demographic data, essential recommendations for myopia treatment can be provided, or valuable information for disease research can be obtained. Eligible participants will receive free treatment opportunities if meeting the criteria.

Cost: The annual treatment funding amounting to RMB 9,600 (in words: Nine Thousand Six Hundred Yuan) shall be provided by Hong Kong Polytechnic University (Wuhan) Institute of Science and Technology Innovation Co., Ltd.

Compensation: Apart from free access to the equipment, there is no monetary compensation for participating in this trial.

Privacy Issues: If a participant decides to participate in this study, all personal data collected during participation will be kept confidential. The principal investigator and other researchers will use the participant's medical information for research purposes. This information may include the participant's name, address, telephone number, medical history, and any details obtained during study visits. Participant records will be stored in locked filing cabinets accessible only to researchers. To ensure compliance with regulations, members of government authorities or the ethics review committee may access personal data at the research site when necessary. No personal information of participants will be disclosed upon publication of the study results.

If your child sustains injuries as a result of participating in this study, such as when harm occurs related to the clinical trial—the participant may receive free treatment, including treatment at our hospital or at other public medical institutions selected by you and your family; the treatment costs shall be covered by Anhui Aierxing Medical Technology Co., Ltd., and compensation/case settlement shall be conducted in accordance with relevant Chinese laws.

Your child may choose not to participate in this study or may notify the researchers at any time to withdraw from the study; the participant's data will not be included in the study results, and the participant's medical care and rights will not be affected as a result.

If the subject requires additional treatment, fails to comply with the study protocol, experiences study-related injury, or for any other reason, the principal investigator may terminate the subject's participation in this study.

You and your family members may access information related to this study and updates on its progress at any time. We will promptly notify you and your family members of any new safety-related information associated with the study. Should you have questions regarding the study, experience any discomfort or injury during participation, or have concerns about the rights and interests of study participants, please contact Professor Feng at 13075590585.

If you have any questions or concerns regarding your rights and well-being during participation in this study, please contact the Institutional Ethics Committee at telephone number 0551-62923004; contact person: Professor Chen.

Sign page for the Informed Consent Form

I have read this informed consent form.

I had the opportunity to ask questions, and all of them were answered.

I understand that participation in this study is voluntary.

I may choose not to participate in this study, or withdraw at any time upon notifying the researchers without facing discrimination or retaliation; my medical treatment and rights will not be affected as a result.

If additional treatment is required, if I fail to comply with the study protocol, if a study-related injury occurs, or for any other reason, the principal investigator may terminate my participation in this study.

I will receive a signed copy of the Informed Consent Form.

Subject Name: _____

Subject Signature: _____

Date: _____ Year _____ Month _____ Day

Name of the subject's legal guardian: _____

Sign of the subject's guardian: _____

Date: _____ Year _____ Month _____ Day

I have accurately informed the subject of this document, requesting that they carefully read this Informed Consent Form and provide a thorough response to any questions or queries raised therein.

Researcher's Name: _____

Researcher's Signature: _____

Date: _____ Year _____ Month _____ Day

(Note: If the subject is illiterate, a witness's signature is required; if the subject lacks legal capacity, a representative's signature is required.)