BMJ Open Ophthalmology

Effectiveness of bright light therapy and combination with myopic defocus for controlling myopic eye growth in schoolchildren: study protocol for a randomised controlled trial (phase 1)

Ying Hon ,[1] Rachel Ka Man Chun ,[1,2] Billy Kin Kwok Cheung,[1,2] Desmond Man Kit Lam,[1] Andy Chi Wai Kong,[1] Lai Ming Ho,[3] Wai-Ching Lam,[4] Thomas C Lam,[1,2] Carly SY Lam ,[1,2] JinXiao Lian,[1,2] Ian G Morgan ,[5] Chi Ho To,[1,2] Christopher Kai Shun Leung,[4] Dennis Yan-Yin Tse [1,2]

To cite: Hon Y, Chun RKM, Cheung BKK, *et al*. Effectiveness of bright light therapy and combination with myopic defocus for controlling myopic eye growth in schoolchildren: study protocol for a randomised controlled trial (phase 1). *BMJ Open Ophthalmology* 2025;**10**:e002044. doi:10.1136/bmjophth-2024-002044

Received 7 November 2024
Accepted 1 May 2025

For numbered affiliations see end of article.

Correspondence to
Dr Dennis Yan-Yin Tse; dennis.tse@polyu.edu.hk and

Dr Rachel Ka Man Chun; rachel.chun@polyu.edu.hk

ABSTRACT

Introduction Myopia and its complications can lead to irreversible visual impairment and even blindness, making this a worldwide public health concern for the 21st century. While treatments to slow myopia progression exist, their average efficacy is moderate. Bright light exposure, either in controlled animal models or naturally under sunlight for children, has demonstrated a protective effect against myopia development. This study hypothesises that bright light therapy (BLT), delivered via a home-based device mimicking sunlight, could slow myopia progression in schoolchildren.

Methods and analysis We propose a 2-year, double-masked, randomised controlled trial to investigate the effectiveness of BLT and its combination with myopia control treatment in schoolchildren. Chinese schoolchildren aged 7–12 years will be recruited and randomly assigned to one of three arms in phase 1. Subjects will be instructed to perform a minimum of 45 mins of near tasks daily under either BLT (10 000 lux white Light Emitting Diode (LED) light) or placebo light therapy (500 lux white LED light). The control subjects will receive single-vision spectacles and placebo light therapy; the single treatment subjects will receive single-vision spectacles and BLT; and the combination treatment subjects will receive defocus-incorporated multiple segments spectacles and BLT. The primary and secondary outcome measures are changes in cycloplegic objective refraction and axial length over a 2-year period.

Treatment dosage is indirectly measured using a monitoring sensor attached beneath the BLT lamp rather than a wearable light metre. Variations in dosage monitoring may influence the observed treatment efficacy.

Ethics and dissemination The study has been approved by the Institutional Review Boards of The Hong Kong Polytechnic University (HSEARS 20180829002–05) and The University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW 20–362). The study results will be disseminated in scientific conferences and peer-reviewed indexed journals.

Trial registration number ClinicalTrials.gov identifier: NCT04923841

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Myopia is a global public health concern due to its potential to cause irreversible visual impairment. Bright light exposure, either in controlled animal models or in children exposed to sunlight, has shown protective effects against myopia development.

WHAT THIS STUDY ADDS

⇒ This is the first randomised controlled trial to investigate the effectiveness of bright light therapy (BLT) for inhibiting the progression of myopia.

⇒ The trial also examines whether combination treatment using BLT and myopic defocus spectacle lenses is more effective than BLT alone.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ If proven effective, BLT could offer a novel, non-invasive and manageable at-home myopia control option for schoolchildren.

INTRODUCTION

Myopia is a common ocular disorder worldwide, which significantly impacts children in developed countries of East and Southeast Asia, including China, South Korea, Japan and Singapore.[1] In these regions, more than 80% of students graduating from secondary schools are myopic, of whom 10%–20% are highly myopic.[2 3] Although myopia can be visually corrected with spectacles or contact lenses, the elongated eyeball due to myopic progression is irreversible, leading to thinning of the retina and choroid.[4 5] Consequently, this increases the risk of developing sight-threatening complications including glaucoma, retinal detachment and myopic macular degeneration.[6 7] Since 2018, the Chinese government has implemented

measures, including academic reforms and increased outdoor time at the school level, to address the public health issue of myopia.[8]

Proactive treatments to control myopia progression have been investigated extensively over the past few decades.[9] Currently, clinically approved myopia control treatments include myopic defocus and diffusion optics[10] spectacles, soft multifocal contact lenses, overnight orthokeratology and low concentration atropine. However, the average efficacy of these treatments is 50%–60% when considered individually.[11] To enhance treatment effectiveness, combination therapies[12 13] and emerging approaches, such as low-intensity red light therapy[14] and violet light-emitting spectacles,[15] are being explored. However, caution should be exercised due to safety concerns.[16] The development of a new, more effective treatment option, preferably non-invasive, is still warranted.

A straightforward lifestyle intervention for myopia prevention that eyecare professionals often recommend is to spend more time outdoors. Evidence for the protective effect of time outdoors is abundant. Many epidemiological studies have reported that children who spend more time outdoors are less likely to become myopic.[17–20] A few prospective randomised controlled trials (RCTs) conducted in China and Taiwan have also confirmed a lower incidence rate of myopia and slower myopia progression with more outdoor time on school days.[21–23] In the most recent cluster randomised trial, the researchers reanalysed their data using a pooled sample and found that children who spent less time outdoors but were exposed to high light intensity (≥10 000 lux) also enjoyed a protective effect against myopia.[23] Although the underlying protective mechanism is not fully understood, higher light intensity outdoors may be an important contributing factor.[18] It is supported that dopamine is involved in the signal cascade for the visual control of eye growth.[24] Bright light increased inputs from both the photoreceptors and the intrinsically photosensitive retinal ganglion cells and thus increased dopamine synthesis and release. It has been demonstrated that retinal dopamine release is directly related to light intensity and that the protective effect of bright light against myopia could be abolished by dopamine D1/D2 antagonists in several species.[24] Animal studies have shown that bright light of 15 000–40 000 lux could completely suppress form-deprived myopic eye growth in chicks and primates.[25–27] Clinically, daily light exposure at high intensity has also been associated with less axial elongation in children.[28]

Epidemiological and experimental evidence strongly suggests that bright light exposure could be an important factor that regulates eye growth. With the acceleration of urbanisation, increased academic stress and unpredictable weather conditions, consistent and adequate exposure of children to bright light outdoors is not always feasible. We hypothesise that artificially applied bright light indoors could slow down myopia progression in schoolchildren. Bright light therapy (BLT) is well recognised for its effectiveness and non-invasiveness in alleviating depressive disorders[29 30] by stimulating dopamine release through the visual pathways,[31] a mechanism shared with the inhibition of myopia development. BLT is commercially available as a desktop device that can be used alone or in combination with medications as treatment in psychiatry.[30] BLT may uniquely contribute to controlling myopic eye growth because bright light and myopic defocus are thought to target separate neuronal pathways, which independently process brightness and directional blur in parallel at an early stage,[24] before they are integrated as a combined signal to modulate eye growth at later stage. A recent animal study indicated that bright light, in combination with myopic defocus, produced an additive effect in slowing eye growth.[32]

The study protocol describes our aim to investigate the effectiveness of BLT and its effectiveness in inhibiting myopia progression with combination treatment in schoolchildren using an RCT setting. The original protocol outlines a double-masked, three-arm main RCT (phase 1) and a single-masked, two-arm auxiliary RCT (phase 2) to minimise potential biases. This protocol paper aims to present the study design for phase 1.

MATERIALS AND METHODS

Study design and setting

This protocol describes a single-site, double-masked, RCT investigating the effectiveness of BLT and combination with optical treatment for myopia control compared with placebo light therapy alone. The study will span 2 years, beginning with phase 1. The study consists of three arms: placebo light therapy, BLT, and BLT combined with the use of defocus incorporated multiple segments (DIMS) spectacle lenses. The subjects will be randomly allocated into three arms at a 1:1:1 ratio. The study will be conducted at the Optometry Research Clinic of the Hong Kong Polytechnic University. This trial protocol is reported following Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Sample size calculation

The sample size was estimated based on the data of the control group from a previous myopia control study,[33] in which the mean change in refractive error of Hong Kong schoolchildren was 0.83±0.51D (mean±SD) over 2 years. As 0.25D is considered as a clinically significant change with reference to the control group, the computed effect size is 0.41. To achieve 85% power with a significance level of 0.05 (two tailed), 108 subjects are required to detect a group difference. Assuming an attrition rate of 20%, the total sample required is 390 subjects, with 130 subjects in each group.

Inclusion criteria

The study will enrol subjects aged between 7 and 12 years and of Hong Kong Chinese descent. Both eyes of the subjects should have a spherical equivalent refraction

(SER) between −0.75D and −5.00D. Anisometropia should not exceed 1.50D, and astigmatism should be equal to or less than 2.00D. Subjects should have best-corrected visual acuity of 0.04 logMAR or better in both eyes. Parents/guardians and subjects must understand and accept random group allocation and adhere to the masked study design. Subjects have to wear the prescribed spectacles full time and receive light therapy.

Exclusion criteria

An individual who meets any of the following criteria will be excluded from participation in this study: (1) suffering from any existing or past eye diseases or having undergone eye surgery for conditions, including but not limited to strabismus, amblyopia, oculomotor nerve palsies or corneal disease, intraocular disease or any other conditions that may have an impact on vision or visual development; (2) intake of long-term medication for at least 3 days per week or use medications or supplements known to affect eye growth; (3) any systemic diseases that may impact vision or vision development, including endocrine, cardiac and respiratory diseases, diabetes or Down syndrome; (4) previous or current treatment for myopia control, including but not limited to orthokeratology, progressive addition lenses, myopic defocus lenses or atropine; (5) allergies to cyclopentolate eye drops; (6) unable to cooperate or follow instruction during eye examination on judgement of the Investigator.

Randomisation and masking

In phase 1, subjects will be age stratified into two subgroups and randomised into three arms using simple randomisation at a 1:1:1 ratio. The randomisation list is generated using a random number generator in Excel spreadsheet. An unmasked investigator who is not involved in data collection will be responsible for the randomisation, allocation and delivery of group assignments. The investigators and study participants will be double-masked. Group assignment will be concealed because the treatment and placebo light therapy, as well as the spectacles, are identical in appearance. Both parents/guardians, subjects and investigators performing data collection will be masked to group allocation throughout the study.

Procedures

Subjects in this study will be recruited through mass emails sent to the staff of the Hong Kong Polytechnic University, advertising posters on social media (Facebook and Instagram) and referrals from parents/guardians who are already participating in the study. Parents/guardians and their children will be invited to the Optometry Research Clinic for an initial screening to confirm their eligibility. Informed consent and assent will be obtained from parents/guardians and children on fulfilment of inclusion criteria. Subjects will be randomly allocated to one of the three arms after baseline measurement. Delivery of spectacles and light therapy lamp according to group assignment will be arranged 2 weeks after the baseline visit. Training will be provided to subjects and parents/guardians on how to set up and use the light therapy lamp at home. A 1-month adaptation period will be given for the subjects after delivery of the lamps. A follow-up visit will be scheduled after this adaptation period, during which any adverse events will be recorded. Subject enrolment will be confirmed on completion of the follow-up visit, provided there is no intolerance to the study devices.

Data collection, which will be conducted every 6 months from the baseline visit to 24 months, will be intraocular pressure, accommodative function, pupil size, choroidal thickness, cycloplegic objective and subjective refraction, ocular biometry, peripheral refraction and ocular health. A schedule of the study is presented in table 1.

Interventions

Eligible participants will be randomised into three arms: (1) the control arm that receives placebo light therapy and single-vision spectacles; (2) the single treatment arm that receives BLT and single-vision spectacles; (3) the combination treatment arm that receives BLT and DIMS spectacles.

Bright light therapy

BLT applies when subjects are exposed to the light during near-work tasks, for example, reading, doing homework or using a computer. The BLT lamp is assembled as a desktop device (Model DL93011, Carex Health Brands). The light box consists of 192 LED bulbs that emit 4000 K natural white light, providing an intensity of 10 000 lux at 30–35 cm from the screen to the eye, mimicking sunlight (figure 1). A polycarbonate diffuser blocks UV light with a cut-off at around 400 nm. Subjects will be given instructions on the appropriate viewing distance and angle (figure 2), and the recommended time and duration of use of the light therapy lamp at home. They are instructed to use the lamp for 45–120 mins daily, which can be divided into several sessions throughout the day. The dosage is chosen because clinical trials with similar protocols (10 000 lux for 30–60 mins) have reported effective remission of depressive symptoms and good treatment tolerability.[30] Treatment can be skipped on days when subjects have undergone more than 2 hours of outdoor activities under sunlight. To avoid affecting normal circadian rhythm and impacting sleep quality, subjects are advised not to use the lamp 3 hours prior to bedtime.

Placebo light therapy

The placebo light therapy lamp to be used in this study is manufactured by the same company as a desktop device. The light box consists of 192 LED bulbs that emit 4000 K white light rated at 500 lux at 30–35 cm from the screen to the eye and comes with a UV filter. Subjects are given the same instructions on the use of the placebo lamp as the treatment lamp.

Table 1 Schedule of enrolment, interventions and assessments

Timepoint	Baseline	1M	6M	12M	18M	24M
ENROLMENT						
Allocation	√					
INTERVENTIONS						
Control group:						
SV lenses & placebo light therapy		√	√	√	√	√
Single treatment:						
SV lenses & BLT		√	√	√	√	√
Combination treatment:						
DIMS lenses & BLT		√	√	√	√	√
ASSESSMENTS						
Primary outcomes:						
Cycloplegic objective refraction	√		√	√	√	√
Secondary outcomes:						
Axial length	√		√	√	√	√
Other outcomes:						
Intraocular pressure	√		√	√	√	√
Accommodative function						
Pupil size						
Peripheral refraction						
Safety outcomes:						
Treatment compliance		√	√	√	√	√
Visual performance						
Adverse events						

BLT, bright light therapy; DIMS, defocus incorporated multiple segments; M, month; SV, single-vision.

DIMS spectacle lens

The DIMS spectacle lens is a custom-made polycarbonate lens that comprises a central optical zone for clear central vision and a peripheral focal zone of multiple segments giving myopic defocus of +3.50D. Driven by the evidence that peripheral myopic defocus inhibits eye growth, the DIMS spectacle lenses have been clinically proven to slow myopia progression by 59% in myopic schoolchildren.[34] Subjects in combination treatment will be given DIMS spectacle lenses prescribed with cycloplegic subjective refraction for full-time wear. An update in prescription is indicated if an increase or decrease of myopia by 0.50D or more or habitual visual acuity equal or worse than 0.20 log MAR is found at any follow-up visit.

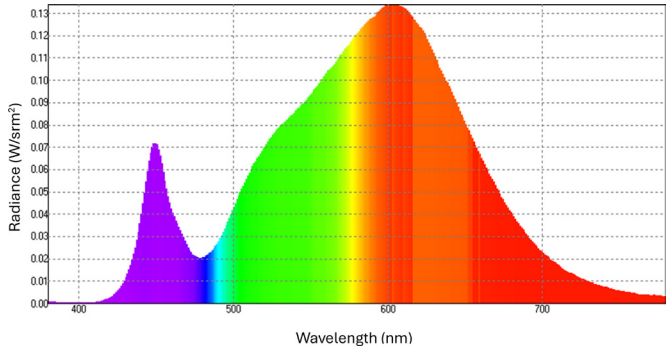

Figure 1 Spectral radiance of the light source from bright light therapy rated at 10 000 lux, measured using a spectroradiometer (Model S-R3 Topcon Technohouse Co., Japan).

Single-vision spectacle lens

The single-vision spectacles prescribed with cycloplegic subjective refraction will be given to subjects in both the control and single treatment arms. The lenses are made of plastic with a refractive index of 1.6. The instructions for use and the criteria for prescription change are the same as for DIMS spectacles.

Outcomes and measurements

The primary and secondary outcome measures are changes in cycloplegic autorefraction in SER and axial length (AL) at 6-month intervals over 2 years from baseline, respectively. Cycloplegia is performed after applying one drop of topical anaesthetic (Alcaine 0.5%) in each eye, followed by one drop of cyclopentolate (Cyclogyl 1%). The full cycloplegic effect can

Figure 2 Household setting of a subject performing a near-work task under bright light therapy.

be confirmed when the amplitude of accommodation is reduced to 2D or less 30 mins after dilation. Otherwise, another drop of cyclopentolate will be instilled. The main outcome measures, including cycloplegic refraction and AL, will be obtained objectively using an open-field autorefractor (Shin-Nippon NVision-K5001, Japan) and a partial coherence interferometer (ZEISS IOLMaster 500, Germany). Five consecutive readings will be taken and averaged for data analysis.

To monitor ocular and environmental changes throughout the study period, intraocular pressure, accommodative function, pupil size, choroidal thickness, peripheral refraction and questionnaires on treatment compliance, visual performance, adverse events and hours spent on various activities will also be collected at 6-month intervals.

Compliance

Compliance with spectacle wear will be monitored by conducting questionnaires at 6-month intervals. Compliance with light therapy will be monitored by two means: subjects or parents/guardians being instructed to record the day and duration of treatment using a mobile application; a cloud-enabled monitoring sensor is attached at the bottom of each light therapy lamp and functions to collect background lighting, working distance and time of usage for each subject. Compliance data will be analysed monthly, and subjects with poor compliance will be reinforced to follow the treatment modality via WhatsApp messages.

Safety considerations

Previous RCTs have confirmed that DIMS spectacle wear did not cause any adverse effects on visual function in myopic children.[35] Side effects of BLT have been studied thoroughly on both psychiatric patients and healthy adults.[30 36] No ocular abnormalities were detected either short-term or long-term treatment with BLT.[37] Some common side effects, including headache, eye strain, blurred vision and nausea, have been reported but were mild and transient.[36 38] In general, BLT is considered a safe, well-tolerated and non-invasive treatment for a range of depressive disorders.[30] As this is the first study applying BLT to children, clinically qualified investigators will strictly monitor visual function, ocular health and visual and non-visual symptoms at the first month of follow-up and at every 6-month interval. Any adverse events such as reduction in visual acuity, visual disturbances, eye strain, eye infection or allergic response, photophobia, headache or nausea that may or may not be causally related to the study intervention need to be described, classified according to the severity, and recorded. Adequate medical care will be offered and provided to subjects for any clinically significant adverse events. Any related serious adverse events will be reported to the IRB of the Hong Kong Polytechnic University within 48 hours.

Data management plan

The source documents related to the study will include signed consent forms, printouts of ophthalmic investigations, and electronic case report forms (eCRFs). All paper documents will be stored in lockable cabinets. All study data will be recorded on standardised eCRFs and stored in an online database named Research Electronic Data Capture (REDCap),[39] in which the server is built and protected under a secured campus network. Access is only given to authorised study investigators with unique account IDs and passwords, and only specific forms can be viewed and modified according to their roles. Anonymised subject identifiers will be used for any data entry and documents uploaded to REDCap. An unmasked investigator must review and endorse each eCRF after all data have been entered.

Statistical analyses

Statistical analyses will be performed with the latest version of SPSS software (IBM, USA) after the 2-year data collection. Data from right eyes will be used for analyses. Demographic variables will be analysed using descriptive statistics and presented in tables.

Means and SD will be calculated for numerical variables, and frequencies and percentages for categorical variables. The normality of the data will be examined using Kolmogorov-Smirnov tests.

The one-way analysis of variance (ANOVA) and the χ^2 test will be used to compare the baseline characteristics. Changes in primary, secondary and other outcomes at different time points will be analysed using a mixed-effects model for repeated measures, which includes fixed effects for the treatment group, time, the interaction between group and time, and covariates such as age and baseline myopia. The interaction term will determine whether treatment effects differ across time points and whether combination treatment demonstrates a stronger effect than single treatment alone. If significant interaction is observed, pairwise comparisons between groups at each time point will be conducted with Bonferroni correction to adjust for multiple testing.

Myopia progression over 2 years will be calculated as the difference between SER and AL at baseline and the 2-year visit. The relative treatment effect in each arm will be determined by dividing the difference in myopia progression between the treatment group and the control group by myopia progression in the control group, then multiplying by 100%. Additionally, the absolute treatment effect[40] will be presented to facilitate comparison between studies. Multiple regression analysis will be employed to identify factors that may be associated with myopia control effectiveness.

Data analyses will follow an intention-to-treat approach. Missing values of outcome variables and covariates will be replaced using multiple imputation procedures with 10 sets of imputations assuming missing at random. Sensitivity analyses for the primary outcomes include: (1) complete case analysis and (2) per-protocol analysis. All analyses will be two-tailed with a significance level of 0.05.

DISCUSSION

To the best of our knowledge, this is the first RCT to evaluate the effectiveness of BLT in inhibiting myopia progression in schoolchildren. The study also aims to assess whether combination treatment using BLT and DIMS spectacles offers superior effectiveness compared with BLT alone. Previous school-based trials explored modifications to classroom lighting, including increasing illuminance levels,[41] implementing artificial natural lighting[42] and constructing an outdoor glass classroom.[43] These trials provided preliminary evidence that manipulating indoor light could reduce the incidence of myopia and slowed myopic and axial changes. However, these approaches involved higher maintenance costs and less controllable treatment dosages. If proven effective in controlling myopia, our current BLT could have positive implications for clinical practice and public health policies. BLT could be regarded as a novel, non-invasive and home-based treatment option for myopia control. Clinicians could incorporate BLT alongside existing myopia control strategies, such as myopic defocus spectacles and low concentration atropine, to enhance treatment efficacy. Health authorities could establish safety guidelines and quality control measures for the use of BLT in children. Public education campaigns could be organised to raise awareness about the importance of light exposure based on the findings of this study. In regions with high academic demands, limited outdoor light exposure or climate uncertainty, schools could integrate BLT into their classroom lighting to ensure adequate light exposure for schoolchildren.

The current study has a few limitations. Treatment dosage is not directly measured using a wearable light metre at the subject's eye level. Instead, we collect data on the illuminance of BLT, the subject's working distance and duration of usage through a monitoring sensor attached beneath the lamp. Thus, treatment dosage and compliance are indirectly monitored throughout the study period. Additionally, outdoor activities under sunlight are regarded as treatment in substitution of BLT. However, the duration of outdoor light exposure relies solely on self-reports from parents/guardians and subjects, making them susceptible to recall bias. Consequently, variations in dosage monitoring may influence the observed treatment efficacy. Despite these limitations, the study reflects the real-world feasibility of BLT in myopia management, where treatment adherence and environmental factors play significant roles.

Trial status

The recruitment process started in Q4 2021 and is expected to end in Q4 2024.

Author affiliations
[1]Centre for Myopia Research, School of Optometry, The Hong Kong Polytechnic University, Hong Kong, Hong Kong
[2]Centre for Eye and Vision Research Limited, Hong Kong, Hong Kong
[3]School of Public Health, The University of Hong Kong, Hong Kong, Hong Kong
[4]Department of Ophthalmology, The University of Hong Kong, Hong Kong, Hong Kong
[5]Research School of Biology, Australian National University, Canberra, Australian Capital Territory, Australia

Acknowledgements The authors acknowledge HOYA Lens Thailand Limited for providing a discounted price for DIMS spectacle lenses used in this trial. The authors acknowledge Ms Pauline Cheung, Ms Yvonne Li, Mr Jack Law, Ms Jenny Kwong, Dr Jason Lau, Ms Sandy Au, Mr Leo Lee, Dr Matin Ma for data collection, Ms Winky Wong, Ms Sze Wai Fong, Ms Cathy Cheung, Ms Yee Mui Kwok for liaison with parents, Mr Andy Kong and Mr Anson Lau for technical support with experimental tools and database management and Dr Maureen Boost for English editing.

Collaborators Not applicable.

Contributors Conceptualisation and design: DY-YT, RKMC, CSYL, CHT, LMH, W-CL, TCL, JXL, IGM, CKSL. Funding acquisition: DY-YT, CHT, CKSL, RKMC, LMH, W-CL, TCL, CSYL, JXL, IGM. Investigation: BKKC, DMKL, YH. Technical support: ACWK, DMKL. Project administration: YH, BKKC, RKMC. Analysis and interpretation:

DY-YT, RKMC, CHT, LMH, JXL, YH. Supervision: DY-YT, CKSL. Validation: YH, LMH. Visualisation: YH, RKMC, DY-YT. Writing—original draft: YH. Writing—review and editing: YH, DY-YT, RKMC, CSYL, CKSL.

Funding The study is supported by RGC Research Impact Fund (grant number R5032-18), UGC RMGS (grant number U-ZEZ1, U-ZEZ8) and the InnoHK initiative of the Innovation and Technology Commission of the Hong Kong Special Administrative Region Government. It is also supported by Grant number BD90,1-BBC0 and BDDR from The Hong Kong Polytechnic University. The funders had no role in study design, data collection and analysis, decision to publish or preparation of the manuscript.

Competing interests DY-YT, RKMC, CSYL and CHT received research funding from Hoya Corporation. CSYL and CHT received royalty payments from Hoya Corporation. DY-YT, CSYL and CHT hold patents on myopia treatment using spectacle lenses, contact lenses or pharmaceuticals.

Patient and public involvement Patients and the public are not involved in the design, or conduct, or reporting, or dissemination plans of this research. Written, informed consent and assent will be obtained from the parent/guardian and participants before the study commences. Once the study is published, parents/guardians and participants will receive the results through a newsletter.

Patient consent for publication Consent obtained from parent(s)/guardians.

Ethics approval The protocol has been reviewed and approved by the Institutional Review Board (IRB) of The Hong Kong Polytechnic University (HSEARS 20180829002–05) and the IRB of The University of Hong Kong/Hospital Authority Hong Kong West Cluster (UW 20–362). The study has also been registered with the international standard randomised controlled trial number National Clinical Trials number 04923841 (ClinicalTrials.gov). All procedures will be carried out according to the guideline for Good Clinical Practice. Study personnel including administrative staff and investigators will have attained a certificate of completion of the course on Good Clinical Practice. The results of this study will be disseminated in scientific conferences and peer-reviewed indexed journals in optometry and ophthalmology.

Provenance and peer review Not commissioned; externally peer-reviewed.

Data availability statement No data are available. Since the manuscript is the study protocol without pilot or preliminary data, we would like to make deidentified research data publicly available when the study is completed and published.

ORCID iDs
Ying Hon http://orcid.org/0000-0003-0350-4020
Rachel Ka Man Chun http://orcid.org/0000-0001-6978-0963
Carly SY Lam http://orcid.org/0000-0002-6808-5018
Ian G Morgan http://orcid.org/0000-0002-4548-3574
Dennis Yan-Yin Tse http://orcid.org/0000-0001-7561-9121

REFERENCES

1 Morgan IG, French AN, Ashby RS, *et al*. The epidemics of myopia: Aetiology and prevention. *Prog Retin Eye Res* 2018;62:134–49.
2 Morgan IG, Ohno-Matsui K, Saw SM. Myopia. *Lancet* 2012;379:1739–48.
3 Dolgin E. The myopia boom. *Nature* 2015;519:276–8.
4 Nishida Y, Fujiwara T, Imamura Y, *et al*. Choroidal thickness and visual acuity in highly myopic eyes. *Retina* 2012;32:1229–36.
5 Wu P-C, Chen Y-J, Chen C-H, *et al*. Assessment of macular retinal thickness and volume in normal eyes and highly myopic eyes with third-generation optical coherence tomography. *Eye (Lond)* 2008;22:551–5.
6 Saw S-M, Gazzard G, Shih-Yen EC, *et al*. Myopia and associated pathological complications. *Ophthalmic Physiol Opt* 2005;25:381–91.
7 Mitchell P, Hourihan F, Sandbach J, *et al*. The relationship between glaucoma and myopia: the Blue Mountains Eye Study. *Ophthalmol* 1999;106:2010–5.
8 Ministry of Education of the People's Republic of China Blog. Ministry of education and eight other departments on issuing the implementation plan of comprehensive control of myopia in children and adolescents. 2018. Available: http://www.moe.gov.cn/srcsite/A17/moe_943/s3285/201808/t20180830_346672.html
9 Wildsoet CF, Chia A, Cho P, *et al*. IMI - Interventions Myopia Institute: Interventions for Controlling Myopia Onset and Progression Report. *Invest Ophthalmol Vis Sci* 2019;60:M106–31.
10 Laughton D, Hill JS, McParland M, *et al*. Control of myopia using diffusion optics spectacle lenses: 4-year results of a multicentre randomised controlled, efficacy and safety study (CYPRESS). *BMJ Open Ophthalmol* 2024;9:e001790.
11 Zhang G, Jiang J, Qu C. Myopia prevention and control in children: a systematic review and network meta-analysis. *Eye (Lond)* 2023;37:3461–9.
12 Tan Q, Ng AL, Cheng GP, *et al*. Combined 0.01% atropine with orthokeratology in childhood myopia control (AOK) study: A 2-year randomized clinical trial. *Cont Lens Anterior Eye* 2023;46:101723.
13 Nucci P, Lembo A, Schiavetti I, *et al*. A comparison of myopia control in European children and adolescents with defocus incorporated multiple segments (DIMS) spectacles, atropine, and combined DIMS/atropine. *PLoS One* 2023;18:e0281816.
14 Jiang Y, Zhu Z, Tan X, *et al*. Effect of Repeated Low-Level Red-Light Therapy for Myopia Control in Children: A Multicenter Randomized Controlled Trial. *Ophthalmol* 2022;129:509–19.
15 Mori K, Torii H, Hara Y, *et al*. Effect of Violet Light-Transmitting Eyeglasses on Axial Elongation in Myopic Children: A Randomized Controlled Trial. *J Clin Med* 2021;10:5462.
16 Liu H, Yang Y, Guo J, *et al*. Retinal Damage After Repeated Low-level Red-Light Laser Exposure. *JAMA Ophthalmol* 2023;141:693–5.
17 Guggenheim JA, Northstone K, McMahon G, *et al*. Time outdoors and physical activity as predictors of incident myopia in childhood: a prospective cohort study. *Invest Ophthalmol Vis Sci* 2012;53:2856–65.
18 Rose KA, Morgan IG, Ip J, *et al*. Outdoor activity reduces the prevalence of myopia in children. *Ophthalmol* 2008;115:1279–85.
19 Dirani M, Tong L, Gazzard G, *et al*. Outdoor activity and myopia in Singapore teenage children. *Br J Ophthalmol* 2009;93:997–1000.
20 French AN, Ashby RS, Morgan IG, *et al*. Time outdoors and the prevention of myopia. *Exp Eye Res* 2013;114:58–68.
21 He M, Xiang F, Zeng Y, *et al*. Effect of Time Spent Outdoors at School on the Development of Myopia Among Children in China: A Randomized Clinical Trial. *JAMA* 2015;314:1142–8.
22 Jin J-X, Hua W-J, Jiang X, *et al*. Effect of outdoor activity on myopia onset and progression in school-aged children in northeast China: the Sujiatun Eye Care Study. *BMC Ophthalmol* 2015;15:73.
23 Wu P-C, Chen C-T, Lin K-K, *et al*. Myopia Prevention and Outdoor Light Intensity in a School-Based Cluster Randomized Trial. *Ophthalmol* 2018;125:1239–50.
24 Feldkaemper M, Schaeffel F. An updated view on the role of dopamine in myopia. *Exp Eye Res* 2013;114:106–19.
25 Ashby R, Ohlendorf A, Schaeffel F. The effect of ambient illuminance on the development of deprivation myopia in chicks. *Invest Ophthalmol Vis Sci* 2009;50:5348–54.
26 Cohen Y, Peleg E, Belkin M, *et al*. Ambient illuminance, retinal dopamine release and refractive development in chicks. *Exp Eye Res* 2012;103:33–40.
27 Karouta C, Ashby RS. Correlation between light levels and the development of deprivation myopia. *Invest Ophthalmol Vis Sci* 2014;56:299–309.
28 Read SA, Collins MJ, Vincent SJ. Light Exposure and Eye Growth in Childhood. *Invest Ophthalmol Vis Sci* 2015;56:6779–87.
29 Lam RW, Levitt AJ, Levitan RD, *et al*. Efficacy of Bright Light Treatment, Fluoxetine, and the Combination in Patients With Nonseasonal Major Depressive Disorder: A Randomized Clinical Trial. *JAMA Psychiatry* 2016;73:56–63.
30 Terman M, Terman JS. Light therapy for seasonal and nonseasonal depression: efficacy, protocol, safety, and side effects. *CNS Spectr* 2005;10:647–63.
31 Levitan RD. The chronobiology and neurobiology of winter seasonal affective disorder. *Dialogues Clin Neurosci* 2007;9:315–24.
32 Zheng H, Tse DY, Tang X, *et al*. The Interactions Between Bright Light and Competing Defocus During Emmetropization in Chicks. *Invest Ophthalmol Vis Sci* 2018;59:2932–43.
33 Lam CSY, Tang WC, Tse DY-Y, *et al*. Defocus Incorporated Soft Contact (DISC) lens slows myopia progression in Hong Kong Chinese schoolchildren: a 2-year randomised clinical trial. *Br J Ophthalmol* 2014;98:40–5.
34 Lam CSY, Tang WC, Tse DY-Y, *et al*. Defocus Incorporated Multiple Segments (DIMS) spectacle lenses slow myopia progression: a 2-year randomised clinical trial. *Br J Ophthalmol* 2020;104:363–8.
35 Lam CSY, Tang WC, Qi H, *et al*. Effect of Defocus Incorporated Multiple Segments Spectacle Lens Wear on Visual Function in Myopic Chinese Children. *Transl Vis Sci Technol* 2020;9:11.

36 Botanov Y, Ilardi SS. The acute side effects of bright light therapy: a placebo-controlled investigation. *PLoS One* 2013;8:e75893.
37 Gallin PF, Terman M, Remé CE, *et al*. Ophthalmologic examination of patients with seasonal affective disorder, before and after bright light therapy. *Am J Ophthalmol* 1995;119:202–10.
38 Kogan AO, Guilford PM. Side effects of short-term 10,000-lux light therapy. *Am J Psychiatry* 1998;155:293–4.
39 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
40 Brennan NA, Toubouti YM, Cheng X, *et al*. Efficacy in myopia control. *Prog Retin Eye Res* 2021;83:100923.
41 Hua W-J, Jin J-X, Wu X-Y, *et al*. Elevated light levels in schools have a protective effect on myopia. *Ophthalmic Physiol Opt* 2015;35:252–62.
42 Cai H-M, Li M-Y, Cao Y, *et al*. Effect of artificial natural light on the development of myopia among primary school-age children in China: a three-year longitudinal study. *Int J Ophthalmol* 2024;17:924–31.
43 Zhou Z, Chen T, Wang M, *et al*. Pilot study of a novel classroom designed to prevent myopia by increasing children's exposure to outdoor light. *PLoS One* 2017;12:e0181772.