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Myopia Prevention and Control Record for Children and Adolescents

Note: This record form is intended for school- or clinic-based myopia prevention and control programs. It should be completed jointly by the child/adolescent and their parent/guardian, and verified by the examiner.

Participant ID :	Sex:	Examiner code: _____
School:	Grade/Class:	Assessment date: ____ / ____ / ____
Record source: ☐ School screening ☐ Clinic visit ☐ Follow-up ☐ Other ____		

Section A. Baseline Information

Section	Item	Response	Notes
Presenting reason	Chief complaint	_____	
Presenting reason	Onset of reduced vision	Since ____ / ____ (month/year) ☐ Unknown	
Presenting reason	Visual problem	☐ Distance blur ☐ Near blur ☐ Blackboard blur ☐ Other _____	
Presenting reason	Associated symptoms	☐ Squinting ☐ Head tilt ☐ Eye rubbing ☐ Frequent blinking ☐ Headache ☐ Eye strain ☐ None	
Ocular history	Refractive correction history	☐ None ☐ Yes: ☐ Spectacles ☐ Soft contact lens ☐ RGP/Orthokeratology ☐ Other _____	
Ocular history	Previous prescription	R: DS ____ DC ____ AX ____ L: DS ____ DC ____ AX ____	
Ocular history	Wear pattern / needs	Wear: ☐ None ☐ Occasionally ☐ In class/for distance ☐ All day New glasses needs: _____ Other needs: _____	Current glasses: ☐ Clear ☐ Not clear ☐ Uncomfortable ☐ Unknown

Section	Item	Response	Notes
Medical history	Birth history	Preterm birth: ☐ No ☐ Yes Birth weight: ____ g Delivery: ☐ Vaginal ☐ Caesarean Maternal illness during pregnancy: ☐ No ☐ Yes (_____)	
Medical history	Allergy history	☐ None ☐ Allergic rhinitis ☐ Dust mites ☐ Pollen ☐ Food/protein ☐ Alcohol ☐ Other _____	
Medical history	Other conditions/medications	_____	
General health	Anthropometrics	Height: ____ m Weight: ____ kg	
General health	Lifestyle (myopia-related)	Behaviours: ☐ Squinting ☐ Head tilt ☐ Eye rubbing ☐ Side glance Sleep position: ☐ Supine ☐ Prone ☐ Lateral Sleep: ____ h/day Outdoor time: ____ h/day Study: ____ h/day Screen time: ____ h/day	

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Section B. Ocular Examinations and Follow-up Measurements

Recording rule: If an examination was not performed at this visit, please mark “Not assessed”. If printouts are available, they may be attached in the “Attachment area”.

Objective tests	Autorefraction / Keratometry K readings: R: ____ / ____ @ ____° L: ____ / ____ @ ____° Corneal topography: R: ____ / ____ @ ____° Horizontal e-value: ____ L: ____ / ____ @ ____° Horizontal e-value: ____	Attachment area (autorefraction/topography report)
Intraocular pressure	R: ____ mmHg L: ____ mmHg Time: ____:____	Attachment area
Non-cycloplegic refraction	Small-pupil refraction (without cycloplegia) R: DS ____ DC ____ AX ____ VA: ____ L: DS ____ DC ____ AX ____ VA: ____ Notes (e.g., strabismus/ocular alignment): _____	Notes
Slit-lamp / fundus	Slit-lamp summary (H/F/P/C/O/Ad): Ocular alignment: ☐ Normal ☐ Other ____ Eyelid: ☐ Normal ☐ Abnormal (specify ____) Trichiasis: ☐ No ☐ Yes Conjunctiva: ☐ Normal ☐ Hyperaemia ☐ Papillae ☐ Follicles Cornea: ☐ Clear ☐ Other ____ Lens: ☐ Clear ☐ Other ____ Fundus: Optic disc: ☐ Normal ☐ Other ____ Foveal reflex: ☐ Normal ☐ Other ____ Retina: ☐ Normal ☐ Other ____	Other findings (if any)
Cycloplegic refraction	Post-cycloplegia refraction R: DS ____ DC ____ AX ____ VA: ____ L: DS ____ DC ____ AX ____ VA: ____ Cycloplegic agent: _____ Doses: ____ Time of last drop: ____:____	Notes
Spectacle prescription	Prescription (preferably based on cycloplegic refraction; add subjective refraction if needed) R: DS ____ DC ____ AX ____ PD: ____ L: DS ____ DC ____ AX ____ PD: ____ Lens recommendation: ☐ Single vision ☐ Myopia-control lens (e.g., DIMS) ☐ OK lens assessment ☐ Other ____ Follow-up plan: review in ____ months; key outcomes: axial length (AL), spherical equivalent (SE), uncorrected visual acuity (UCVA)	Notes

Examiner signature: _____ Verified by: _____ Date: ____ / ____ / ____

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Myopia Prevention and Control Record (Intervention Delivery and Adherence)

Recording rule: Professional interventions are recorded weekly. Overall delivery and adherence are summarised monthly. If an item was not delivered or not assessed in the stated period, please mark “Not delivered/Not assessed”.

Section C. Monthly Intervention Delivery Summary (1146 Program)

Component	Delivered this month	Key details (tick/complete as applicable)	Notes / deviations
Structured health education	☐ Yes ☐ No	Mode: ☐ Online recorded session ☐ In-person lecture ☐ Printed material Session No.(s): _____ Target: ☐ Student ☐ Parent/Guardian ☐ Teacher	
Behavioral habit correction	☐ Yes ☐ No	Reading distance ≥ 33 cm guidance: ☐ Yes ☐ No Screen time < 2 h/day guidance: ☐ Yes ☐ No Supervision: ☐ Parent ☐ Teacher ☐ Both	
Environmental optimization	☐ Yes ☐ No	Desk illuminance checked (≥ 300 lx): ☐ Yes ☐ No Measured value (lx): _____ Glare-free / uniform brightness: ☐ Yes ☐ No	
Nutritional intervention	☐ Yes ☐ No	Parent consent: ☐ Yes ☐ No Guidance delivered: ☐ Yes ☐ No Advised items: ☐ Daily breakfast ☐ Water $\geq 1,000$ ml/day ☐ Low sugar ☐ Low fat	
Enhanced physical activity	☐ Yes ☐ No	Outdoor activity target ≥ 2 h/day reinforced: ☐ Yes ☐ No	
Professional interventions (overall)	☐ Yes ☐ No	Included: ☐ RLRL ☐ Visual function training ☐ Auricular acupoint pressing	

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Section D. Weekly Adherence Record (Professional Interventions)

Define one recording period as one calendar week.

Week (Date range)	RLRL planned (sessions)	RLRL complete d (sessions)	RLRL adherenc e (%)	Vision training planned (sessions)	Vision training complete d (sessions)	Vision training adherenc e (%)	Auricula r pressing planned (weekly)	Auricula r pressing complete d (weekly)	Daily self- pressing (☐ Often ☐ Sometime s ☐ Rarely)
Week ____ (____/____ _ to ____/____)	—	—	—	—	—	—	1	—	☐ Often ☐ Sometime s ☐ Rarely
Week ____ (____/____ _ to ____/____)	—	—	—	—	—	—	1	—	☐ Often ☐ Sometime s ☐ Rarely
Week ____ (____/____ _ to ____/____)	—	—	—	—	—	—	1	—	☐ Often ☐ Sometime s ☐ Rarely
Week ____ (____/____ _ to ____/____)	—	—	—	—	—	—	1	—	☐ Often ☐ Sometime s ☐ Rarely

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Section E. Monthly Overall Adherence Summary

Item	Planned (month)	Completed (month)	Adherence (%)	Category
RLRL	—	—	—	☐ Good ($\geq 80\%$) ☐ Moderate (50–79%) ☐ Poor ($< 50\%$)
Visual function training	—	—	—	☐ Good ☐ Moderate ☐ Poor
Auricular acupoint pressing (weekly)	—	—	—	☐ Good ☐ Moderate ☐ Poor
Overall compliance (professional interventions)	—	—	—	☐ Good ☐ Moderate ☐ Poor

Section F. Main Reason(s) for Non-adherence (if applicable)

Reason(s) (tick all that apply): ☐ Time constraints ☐ Absence ☐ Discomfort ☐ Device access ☐ Insufficient supervision ☐
Other: _____

Notes: _____

Self-Assessment Checklist for Home Visual Environment, Behaviours, and Habits

In recent years, the number of children and adolescents with myopia has increased and has shown a year-by-year upward trend. Preventing myopia and slowing its progression are no longer concerns of individual families only. They are public health issues. Risk factors for myopia mainly include heredity and the visual environment. This checklist is designed for home self-screening. It aims to assess a child's risk of developing myopia and, for children with myopia, the potential risk of faster refractive progression. Please answer according to the child's real situation.

I. Hereditary Factors

1. Does anyone in the family have myopia?

A. Yes (2 points)

B. No (0 points)

2. Who in the family has myopia? (Answer this only if you chose A in Question 1; multiple choices are allowed.)

A. Paternal grandfather (1 point)

B. Paternal grandmother (1 point)

C. Maternal grandfather (1 point)

D. Maternal grandmother (1 point)

E. Father (2 points)

F. Mother (2 points)

3. Does anyone in the family have high myopia? (Additional question; answer this only if you chose A in Question 1.)

A. Yes (2 points)

B. No (0 points)

4. Who in the family has high myopia? (Additional question; answer this only if you chose A in Question 3; multiple choices are allowed.)

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- A. Paternal grandfather (1 point)
- B. Paternal grandmother (1 point)
- C. Maternal grandfather (1 point)
- D. Maternal grandmother (1 point)
- E. Father (2 points)
- F. Mother (2 points)

II. Environmental Factors: Visual Behaviors, Dietary Habits, and Home Visual Environment

A. Visual behavior and habit assessment

- 5. Daily time spent on near work at home (including reading, homework, and playing with toys)
 - A. Less than 1 hour (1 point)
 - B. 1 to 2 hours (3 points)
 - C. More than 2 hours (5 points)
- 6. After how long of near work can the child rest for 10 to 15 minutes?
 - A. 30 to 40 minutes (1 point)
 - B. 1 to 2 hours (3 points)
 - C. More than 2 hours (5 points)
- 7. What does the child usually like to do at home? (Multiple choices are allowed.)
 - A. Reading (1 point)
 - B. Building/assembly toys (2 points)
 - C. Remote-control toys (0 points)
 - D. Handcrafts (1 point)
 - E. Playing musical instruments or drawing/painting (1 point)
 - F. Watching TV (1 point)
 - G. Using a mobile phone or computer (2 points)

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8. Does the child often take part in outdoor activities? What is the daily outdoor time?

- A. 2 hours or more (0 points)
- B. Less than 1 hour (2 points)
- C. Less than 0.5 hour (3 points)

9. How many hours of after-school tutoring does the child have per week?

- A. Less than 2 hours (1 point)
- B. 2 to 4 hours (3 points)
- C. More than 4 hours (5 points)

10. During study, can the child consistently use a compliant student desk and chair?

(Feet flat on the floor, knees bent at a right angle, and the desk is about a half-arm length away from the chin.)

- A. Often (1 point)
- B. Rarely (3 points)
- C. Never (5 points)

11. During study, can the child maintain correct reading and writing posture?

- A. Correct (1 point)
- B. Cannot maintain correct posture (3 points)
- C. Incorrect (5 points)

12. Which of the following problems occur when the child reads or studies? (Additional question; multiple choices are allowed.)

- A. Head down (1 point)
- B. Head tilted (1 point)
- C. Poor concentration (1 point)
- D. Leaning on the desk (1 point)
- E. Lying down (1 point)
- F. Prolonged time due to slow pace (1 point)

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B. Dietary habit assessment

13. Does the child have unhealthy eating habits such as picky eating or unbalanced food choices?

A. Often (3 points)

B. Rarely (2 points)

C. Never (0 points)

14. Does the child often eat sweets, snacks, cold foods, or fried foods?

A. Often (3 points)

B. Rarely (2 points)

C. Never (0 points)

C. Home visual environment assessment

15. Do parents pay attention to the child's eye use and vision-related issues?

A. Often (1 point)

B. Rarely (2 points)

C. Never (3 points)

16. Between ages 3 and 5, did the child receive pre-school training such as musical instruments, drawing, literacy, or calligraphy?

A. Never (0 points)

B. Rarely (2 points)

C. Often (3 points)

17. Does the child currently attend extracurricular interest classes such as musical instruments, drawing, LEGO, or chess?

A. Never (0 points)

B. Rarely (3 points)

C. Often (5 points)

18. Is the child's visual acuity checked every 3 to 6 months?

A. Often (0 points)

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B. Rarely (2 points)

C. Never (3 points)

19. Are the child's vision screening results normal?

A. Normal (0 points)

B. Abnormal (2 points)

C. Not sure / unknown (3 points)

20. At what age was abnormal vision first noticed? (Answer this only if the child has abnormal vision.)

A. Under 6 years (5 points)

B. 6 to 9 years (3 points)

C. 9 to 12 years (2 points)

D. Over 12 years (1 point)

21. Does the child already wear glasses for myopia?

A. Yes (2 points)

B. No (1 point)

22. Are the glasses comfortable and appropriate for the child?

A. Comfortable (1 point)

B. Uncomfortable (2 points)

C. Reading feels tiring; sometimes eye swelling, soreness, or headache (3 points)

23. Can the child undergo a standardized refraction examination once a year?

A. Often (0 points)

B. Rarely (2 points)

C. Never (3 points)

24. After wearing glasses, how much does the myopic power increase each year? (Additional question; answer this only if the child wears glasses.)

A. Less than 0.50 D per year (1 point)

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B. 0.50 to 1.00 D per year (3 points)

C. More than 1.00 D per year (5 points)

25. How long does the child watch TV each time at home?

A. Less than 1 hour (1 point)

B. 1 to 2 hours (2 points)

C. More than 2 hours (3 points)

26. When watching TV at night, is the room ceiling light turned on?

A. Often (1 point)

B. Rarely (2 points)

C. Never (3 points)

27. When watching TV, does the child sit directly in front of the TV and keep a distance of at least 3 meters?

A. Often (1 point)

B. Rarely (2 points)

C. Never (3 points)

28. How long does the child sleep per night?

A. 10 hours or more (0 points)

B. 8 to 9 hours (1 point)

C. Less than 8 hours (3 points)

29. How long does the child use electronic devices each time?

A. Less than 1 hour (1 point)

B. 1 to 2 hours (3 points)

C. More than 2 hours (5 points)

30. Is the desk lamp used for reading and writing at home a compliant eye-protection lamp that meets the national standard?

A. Yes / compliant (1 point)

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B. Not sure (2 points)

C. No / non-compliant (3 points)

III. Knowledge and Attitudes (No scoring)

31. Do you think an eye-protection desk lamp can be tested for compliance?

A. Yes

B. No

C. Not sure

32. Do you think myopia can be prevented and controlled?

A. Preventable and controllable

B. Preventable but not controllable

C. Controllable but not preventable

D. Neither preventable nor controllable

33. Which factors do you think contribute to myopia?

A. Watching TV

B. Using electronic devices

C. Incorrect reading and writing posture

D. Inappropriate desk and chair height match

E. Picky eating or unbalanced diet

F. Inadequate lighting

G. Heredity

H. Other: _____

34. What do you think should be done after myopia develops?

A. Get glasses

B. Correct/rehabilitate vision

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- C. Glasses should not be worn; they will worsen myopia
- D. No need to take measures; it will improve when the child grows up
- E. Seek examination in a professional eye-care institution and follow professional advice
- F. Stop watching TV
- G. Other: _____

Do you know the potential eye damage associated with high myopia?

IV. Interpretation of the Total Score

Excellent (below 40 points): Parents and the child are doing well. If these habits are maintained, the chance of developing myopia is low. Regular vision screening and keeping an optometric record are recommended.

Good (40 to 60 points): Most behaviors meet recommended eye-use practices. The chance of developing myopia is relatively low. Regular screening and keeping an optometric record are recommended.

Moderate (60 to 80 points): Some unhealthy eye-use habits are present. The chance of developing myopia is higher. Many children in this range develop myopia at a younger age. Regular screening and an optometric record are necessary. If myopia has already occurred, the average annual increase is often around 0.50 to 1.00 D.

Poor (above 80 points): Eye-use habits are typically poor. The risk of developing myopia is very high, or the child may already have myopia. The average annual increase is often around 1.00 to 2.00 D. The child may have a higher risk of high myopia and related fundus changes. Regular screening and an optometric record are necessary, and evidence-based measures should be taken to slow progression.

Notes

A higher score indicates a higher risk of developing myopia. For children who already have myopia, a higher score suggests a faster rate of progression and a higher risk of high myopia. A lower score suggests healthier habits. Families can further reduce risk by increasing outdoor time, establishing a refractive development record with regular eye examinations, maintaining correct reading and writing posture, improving the home visual environment and lifestyle, and ensuring balanced nutrition.

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Adverse Event (AE) Assessment Form for the “1146” Comprehensive Myopia Intervention

Study ID: _____ **Study arm:** ☐ Intervention ☐ Control

Assessment date: ____/____/____ **Recall period:** ☐ Past month ☐ Past 3 months ☐ Past 12 months

Information source: ☐ Student ☐ Parent/guardian ☐ Teacher ☐ Research staff

Severity: Mild (no impact on daily activities); Moderate (affects daily activities and/or requires management); Severe (requires medical care and/or discontinuation of the relevant intervention). **Causality:** Unrelated / Possibly related / Probably related.

[illegible]

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Worsened visual fatigue (sore/strained eyes)	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (training)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Transient blurred vision or diplopia after training	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (training)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Dizziness or nausea after training	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (training)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
C. Auricular acupressure (ear-point pressing)										
Local ear pain/tenderness	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (auricular acupressure)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Redness/itching/rash (tape or seed irritation)	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (auricular acupressure)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Skin breakdown/oozing/infection at the ear	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (auricular acupressure)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Dizziness or nausea after pressing	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (auricular acupressure)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
D. Outdoor activity and lifestyle										
Sun-related discomfort/sunburn	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (outdoor activity)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Heat-related symptoms (dizziness, fatigue, nausea)	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (outdoor activity)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Sports injury/fall/abrasion	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (outdoor activity)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
E. Nutrition guidance										
Gastrointestinal symptoms (abdominal pain, diarrhea, constipation)	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (nutrition guidance)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
F. Behavior/environment management										
Neck/shoulder discomfort related to posture changes	☐ No ☐ Yes	___/___/___	___/___/ /___/___/ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____	☐ No ☐ Pause ☐ Stop (behavior/enviro nment)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable

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Sleep disturbance (difficulty falling asleep/insufficient sleep)	☐ No ☐ Yes	____/____/____ ____	____/____ /_____ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____ ____	☐ No ☐ Pause ☐ Stop (behavior/enviro nment)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Emotional distress or resistance (irritability/negative mood)	☐ No ☐ Yes	____/____/____ ____	____/____ /_____ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____ ____	☐ No ☐ Pause ☐ Stop (behavior/enviro nment)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable
Other (not listed; please specify)										
Describe: _____	☐ No ☐ Yes	____/____/____ ____	____/____ /_____ ☐ Ongoing	☐ Mild ☐ Moderate ☐ Severe	☐ Occasional ☐ Recurrent ☐ Persistent	☐ No ☐ Yes	_____ ____	☐ No ☐ Pause ☐ Stop (related measure)	☐ Resolved ☐ Not resolved ☐ Unknown	☐ Unrelated ☐ Possible ☐ Probable

Ocular warning symptoms during the recall period (check any that apply):

☐ Sudden, persistent decrease in vision ☐ New onset or marked increase of flashes/floaters ☐ Visual field defect/curtain-like shadow ☐ Severe eye pain with red eye

If yes, please document medical care and management: _____

INFORMED CONSENT FORM FOR RESEARCH

PARTICIPANTS

Dear Participant,

You are invited to take part in a clinical study entitled “**Clinical Study on Comprehensive Interventions for Adolescent Myopia**”.

Before you decide whether to participate, please read this informed consent form carefully. You may ask the researchers any questions you may have. You may also consult your family members, friends, or others. If you decide to participate, you will be asked to sign this informed consent form.

Background

Myopia is one of the most common refractive errors worldwide. In recent years, its prevalence has continued to increase and the age of onset has become younger. According to refractive error severity, myopia can be classified as low, moderate, and high myopia. High myopia is usually defined as a spherical equivalent of ≤ -6.00 D or an axial length > 26 mm. The harm of high myopia is not limited to blurred vision. More importantly, it is often accompanied by pathological fundus changes, such as retinal detachment, myopic maculopathy, glaucoma, and cataract, which may lead to irreversible blindness in severe cases. These conditions have become important factors affecting eye health and quality of life in China.

China has a high prevalence of myopia among children and adolescents, with a year-by-year increasing trend. Epidemiological surveys suggest that uncorrected myopia not only impairs visual function but may also affect learning efficiency, mental well-being, and future employment opportunities, thereby influencing overall development. The lifelong visual impairment caused by high myopia is especially prominent, and the prevention and control burden continues to grow.

In response, since 2018, the Ministry of Education and the National Health Commission, together with other ministries, have issued a series of policy documents, elevating myopia prevention and control in children and adolescents to a national strategy. Establishing refractive development records is an important component of this strategy. The **Public Health Comprehensive Intervention Technical Guidelines for Myopia Prevention and Control in Children and Adolescents** further state that the onset and progression of myopia are influenced by multiple factors, including genetic susceptibility, environmental and behavioral habits, ocular growth patterns, and sociocultural factors. Therefore, prevention and control should involve multi-factor coordination and adopt an integrated approach of “**prevention–monitoring–intervention–correction**”, with a focus on three levels of prevention:

1. **Primary prevention:** Emphasize environmental and behavioral interventions, such as increasing outdoor activities and reducing excessive near work. Based on mechanisms such as “Increasing outdoor time may help reduce the risk of myopia

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onset and progression.” scientific eye health education and risk behavior interventions should be implemented.

2. **Secondary prevention:** Strengthen vision screening and health monitoring, establish refractive development records, and achieve early detection, early warning, and early diagnosis to avoid missing the optimal intervention window.
3. **Tertiary prevention:** Provide appropriate correction and control of progression for children who have developed myopia, including proper spectacle wear, pharmacological treatment, and/or traditional Chinese medicine interventions. For individuals with early onset, rapid progression, or high myopia, comprehensive measures should be implemented under medical guidance.

Under this policy and technical context, some regions in China have explored locally tailored comprehensive prevention and control models. For example, Xilin South Road Primary School in Hohhot has implemented the “**1146**” myopia prevention and control model through epidemiological investigation and intervention practice. The model includes **one scientific lecture, one professional refractive development record system, four key prevention and control stages, and six layers of professional interventions**, forming a closed-loop management process from health education to screening, and from monitoring to intervention. Early application has shown promising effects. It helps parents understand the importance of prevention and control and arrange appropriate eye-use habits for children, and it provides replicable experience for public health services.

However, nationwide systematic research on myopia prevention and control in children and adolescents remains limited, especially empirical studies centered on standardized model-based pathways. Both domestic and international fields still lack a scientific and operational prevention and control technical system. Based on screening and intervention experience from 2018 to 2020 and the exploratory results of the “1146” model, this project will conduct ongoing systematic research in representative regions. The study will help verify and optimize intervention effectiveness and will provide evidence to support policy-making and the dissemination of appropriate technologies for myopia prevention and control.

In summary, this study has important scientific and practical value. It responds to national strategic needs for myopia prevention and control, and it supports the optimization and promotion of the “1146” model in real-world settings, thereby contributing to the health and sustainable development of children and adolescents.

What is the purpose of this clinical study?

This study will investigate myopia among children and adolescents at Xilin South Road Primary School in Hohhot, Inner Mongolia, and will apply comprehensive myopia prevention and control interventions to evaluate the effectiveness of a comprehensive intervention program. Specifically, the objectives are:

1. To conduct an epidemiological survey of myopia among children and adolescents at Xilin South Road Primary School in Hohhot;

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2. To provide targeted comprehensive myopia prevention and control interventions for students at this school;
3. To evaluate the scientific validity, suitability, and effectiveness of the targeted prevention and control model, and to further apply it to myopia prevention and control among children and adolescents in the Hohhot region.

Study Methods

3.1 Participants and Grouping

Participants will be students aged 6–11 years from Xilin South Road Primary School in Hohhot. This is a **prospective, non-randomized, cluster-controlled** study. Participants will be **allocated by class (cluster)** to the intervention group or the control group according to the school-based implementation plan.

- **Intervention group:** Participants will receive targeted comprehensive prevention and control interventions guided by the “1146” model. Myopic children will also receive routine refractive correction (spectacles).
- **Control group:** Only myopic children will wear spectacles; no additional intervention measures will be implemented.

3.2 Intervention Measures

The “1146” comprehensive myopia prevention and control model includes:

- **One scientific lecture:** Health education for parents, students, and teachers;
- **One professional refractive record system:** Establish electronic records and monitor refractive development in real time;
- **Four key stages:** prevention education, management of pseudo-myopia and confirmation of true myopia, correction of true myopia, and prevention of complications;
- **Six layers of prevention and control design:** data assurance, behavior and habits, environment optimization, management of pseudo-myopia and confirmation of true myopia, delayed spectacle wear when appropriate, and control of refractive error and axial length.

Professional intervention components include:

1. **Repeated low-level red-light therapy (RLRL):** A 650 nm low-level red-light device (Eyerising) will be used. Each session lasts **3 minutes, twice daily, 5 days per week**.
2. **Visual function training:** Including monocular lens reading training and single-/binocular double-sided mirror training, **20 minutes per day**, every other day.
3. **Auricular acupressure therapy:** Procedures and education follow the *Guideline of Traditional Chinese Medicine for the Prevention and Control of Myopia in Children and Adolescents*. Performed **once per week** by stimulating specific auricular acupoints (Liver, Kidney, Heart, Spleen, Eye, Mu 1, Mu 2). Each point is pressed until a sensation of soreness, numbness, distension, or pain occurs. Participants will be instructed to press these points daily at **9:00 AM** and **9:00 PM**.

3.3 Primary Endpoints

To evaluate the effectiveness of the “1146” comprehensive model for myopia prevention and control in children and adolescents.

Primary outcome measures include:

- Change in **axial length (AL)**;
- Change in **uncorrected visual acuity (UCVA)**;
- Change in **spherical equivalent refraction (SE)**.

3.4 Secondary Endpoints

Secondary outcomes include:

- Incidence and new-onset rate of myopia;
- Conversion rate between pseudo-myopia and true myopia;
- Adherence and safety under different prevention and control measures;
- Improvements in eye-use behaviors, environmental factors, nutrition, and mental health;
- Parents’ awareness and cooperation regarding prevention and control measures.

3.5 Significance of Endpoints

- **Primary endpoints (AL, SE, UCVA):** Core objective indicators reflecting the onset and progression of myopia, used to evaluate the effectiveness of interventions in controlling myopia progression.
- **Secondary endpoints:** Complementary indicators reflecting the effects of comprehensive interventions across the full prevention and control chain, including prevention of new onset, functional improvement, lifestyle optimization, and safety/feasibility.

Study Procedures

This is a prospective controlled study. First, baseline screening will be performed in a primary school in Hohhot, including measurements of axial length (AL), refraction (SE), corrected visual acuity, uncorrected visual acuity, corneal curvature, and related health behavior questionnaires. At baseline, eligible participants whose parent/legal guardian provides written consent will be allocated by class (cluster) to the intervention group or the control group. The allocation is non-randomized.

- The intervention group will receive comprehensive interventions based on the “1146” model, including health education, establishment of refractive records, environmental and behavioral interventions, nutrition guidance, outdoor activity interventions, and professional visual function training. Myopic children will wear spectacles as routine refractive correction.
- The control group will have spectacle correction for myopic children only, and no additional intervention measures will be implemented.

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During the study period, follow-up visits will be conducted every **3 months** to repeat vision, refraction, and axial length measurements, and to record lifestyle and adherence. The intervention program may be adjusted dynamically and individually. For students requiring additional intervention, visual function training or auricular acupressure may be added.

At the end of the study, data before and after intervention and between groups will be compared to evaluate the effectiveness of comprehensive interventions in controlling the onset and progression of myopia and to explore a scalable targeted prevention and control model.

How does the study end?

If you complete all follow-up visits, the study will last **12 months**. After the study ends, the “1146” comprehensive interventions will no longer be provided.

The study will end after the last participant completes all follow-ups and data collection. Your participation time may last about **1 year**.

You may withdraw from the study at any time. The study doctor may also ask you to withdraw for your health and benefit. Before withdrawal, the study doctor may arrange relevant examinations to ensure safe withdrawal.

The study doctor, study sponsor, regulatory authorities, and the ethics committee may terminate the study.

Potential Benefits

Your health condition may improve by participating in this study, but we cannot guarantee that you will benefit.

You will receive closer follow-up during the study.

Risks and Inconveniences

Any research may involve known or unknown risks. Some risks are mild and temporary, while others may be serious and permanent. Whether risks occur, which risks occur, and their severity vary among individuals. The study doctor will take preventive measures and monitor your condition closely. If you feel unwell, please inform the study doctor immediately so that necessary treatment can be provided in time.

This study is conducted within a school setting for myopia screening and comprehensive interventions. Overall risk is low, but the following situations may occur:

- 1. Discomfort during examinations:** Some students may experience temporary eye fatigue, photophobia, or discomfort during examinations such as visual acuity, refraction, and axial length measurement.

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2. **Discomfort during interventions:** During red-light exposure, visual function training, or auricular acupressure, a small number of students may experience mild ocular discomfort or short-term attention fatigue.
3. **Psychological stress:** Some students or parents may feel anxious after learning about the child's myopia status.

These risks are mild and controllable. With professional guidance, timely rest, and psychological support, they can be effectively relieved and are not expected to cause serious or long-term harm.

Possible inconveniences: Students need to participate in periodic screening and follow-up, which may take some break time or study time. Parents need to cooperate by completing questionnaires and attending education sessions, which will require additional time. At the first visit, you will need to complete questionnaires, which may take an additional **about 30 minutes**. Please consider these inconveniences carefully before deciding whether to participate.

New Information During the Study

If the researchers obtain new important information related to the study during the study, we will inform you in a timely manner, and you will decide whether to continue participating.

Study-Related Costs

You do not need to pay any study-related costs. This includes intervention measures (e.g., red-light therapy, visual function training, auricular acupressure) and study-related examinations (UCVA, corrected visual acuity, refraction, axial length, corneal curvature, accommodative facility, and ocular health assessments). Lifestyle and eye-use behavior questionnaires will also be conducted according to the study protocol. All examinations and follow-ups will be arranged by the research team and provided free of charge.

Research-Related Injury

If you experience any discomfort during the study, please contact the study doctor promptly. The study doctor will guide your subsequent diagnosis and treatment. If your health is harmed due to participation, Inner Mongolia Center for Disease Control and Prevention (Inner Mongolia CDC). will be responsible for providing medical expenses and compensation.

If you experience any discomfort during the study, please contact the study doctor promptly. Insurance has been purchased for this study. If your health is harmed due to

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participation, the insurance company will be responsible for medical expenses and compensation.

How will my data be handled?

This study mainly involves examinations and assessments such as axial length (AL), refraction (SE), visual acuity (UCVA), corneal curvature (K1, K2), and behavioral questionnaires. No human tissue samples will be collected. All test data will be collected, organized, and entered by the research team to establish an electronic refractive development record. Data will be used only for scientific analysis in this study. Confidentiality will be strictly maintained, and personal privacy will not be disclosed. After the study, original data will be de-identified and archived appropriately, and the retention period will follow relevant research and ethics requirements. Unless approved by the ethics committee, data will not be used for other studies.

Confidentiality

This study may collect or process your personal and medical information, including but not limited to your name, sex, date of birth, address, telephone number, diagnosis and treatment, examinations and tests, and medical imaging.

Your personal information will be used only for the purposes described in the study protocol and this informed consent form.

Your medical information obtained in this study will be kept confidential. When study results are published in academic journals, no identifiable personal information will be disclosed.

The researchers will be responsible for storing and using all personal data collected in this study. Authorized representatives of the ethics committee, regulatory authorities, and study monitors may review study records for quality control and compliance. All information will be handled confidentially, and data will be de-identified for analysis and publication.

Funding Source and Potential Conflicts of Interest

This study is funded by the **Clinical Medical Research and New Clinical Technology Promotion Program of the Inner Mongolia Autonomous Region Physicians Association**.

The researchers have no conflicts of interest related to this study.

Voluntary Participation

Your participation is completely voluntary. You may choose not to participate or withdraw at any time during the study. Whether you participate or withdraw will not affect your relationship with medical staff, and it will not affect your daily study, life, or routine medical care.

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Notes for Participants

- This study follows the principle of voluntariness. You may choose not to participate or withdraw at any time, without affecting normal schooling or medical care.
- Please read and sign this informed consent form carefully before participation to fully understand the purpose and potential risks.
- Please complete scheduled follow-ups and examinations on time to ensure scientific validity of study results.
- Please provide information truthfully during the study. If any discomfort occurs, please inform the research staff in a timely manner.
- Your privacy and study data will be kept strictly confidential and used only for research purposes.

Contact Information

If you feel unwell or have any questions about this study, you may contact the researcher:

Title/Position: Principal Investigator

Name: Lina Yun

Telephone: 13704711369

Thank you for reading this document and considering participation in this study.

Signature Page

Participant Statement

I confirm the following:

1. I have read and understood the above information, and I have had sufficient time to consider whether to participate.
2. All of my questions have been answered to my satisfaction.
3. I voluntarily agree to participate in this study and to follow study procedures.
4. I understand that I may withdraw from the study at any time without providing any reason, and my treatment or rights will not be affected.
5. I have received a copy of the participant information sheet and the signed informed consent form for my own records.
6. I agree to the collection and use of my data as described in the participant information sheet and this informed consent form.
7. I allow the collection and use of my personal information in this study.
8. I understand that I may be contacted in the future to obtain my permission for this study or any related sub-studies.

By signing this document, I agree to participate in this study as described in the participant information sheet and this informed consent form.

Participant name (print): _____

Participant signature: _____

Date: ____ / ____ / ____

For participants without legal capacity (guardian signature required)

[Participant name (print): _____ ; Relationship between guardian and participant: _____]

Guardian name (print): _____

Guardian phone number: _____

Guardian signature: _____

Date: ____ / ____ / ____

For participants who cannot read or write (independent witness signature required)

Witness name (print): _____

Witness phone number: _____

Witness signature: _____

Date: ____ / ____ / ____

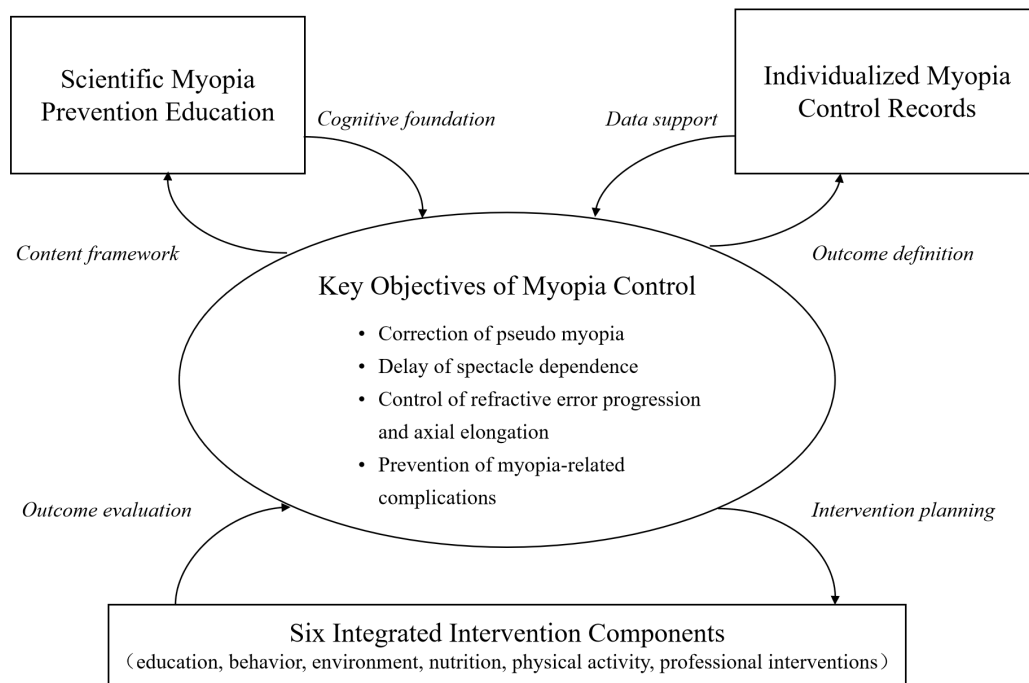
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Researcher/Authorized staff signature: _____

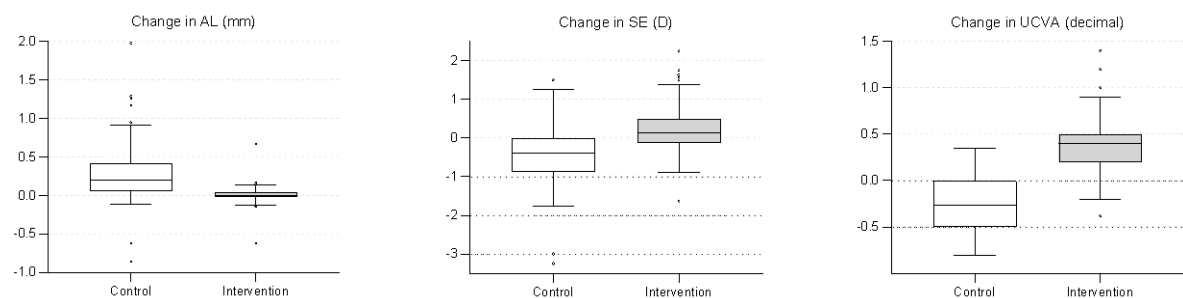
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Supplementary Figures

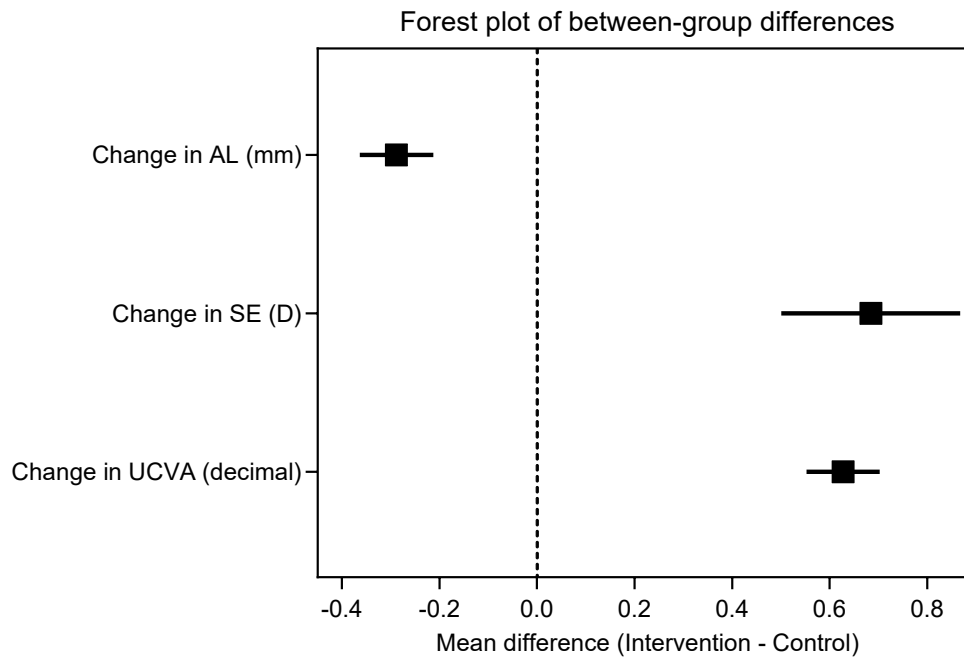
Supplementary Fig. S1. Conceptual framework of the “1146” comprehensive myopia prevention and control model.



Supplementary Fig. S2 Box plots of 12-month changes in AL, SE, and UCVA. Changes were calculated as 12-month follow-up minus baseline.



Supplementary Fig. S3 Forest plot of adjusted between-group differences in 12-month changes in AL, SE, and UCVA. Squares indicate adjusted mean differences, calculated as intervention minus control. Horizontal lines indicate 95% confidence intervals. Estimates were obtained from mixed-effects models adjusted for the baseline value of each outcome, age, and sex, with class included as a random effect.



AL: axial length, SE: spherical equivalent; UCVA: uncorrected visual acuity

Supplementary Table S1 Comparison of changes in UCVA categories between the 2 groups at 12 months.

Change in UCVA	Intervention (n = 100) n (%)	Control (n = 98) n (%)	χ^2 value	P value
Worsening by ≥ 2 lines	1 (1.00)	55 (56.12)		
Change within 1 line	46 (46.00)	42 (42.86)		
Improvement by ≥ 2 lines	53 (53.00)	1 (1.02)		
Overall	—	—	102.32	< 0.001

Note: Abbreviations: UCVA, uncorrected visual acuity.

Data are presented as number of participants (percentage within each group).

Changes in UCVA were defined as the difference in visual acuity lines between baseline and 12-month follow-up.

P values were calculated using the χ^2 test.