AMERICAN ACADEMY OF OPHTHALMOLOGY®

Behavioral Intervention with Eye-Use Monitoring to Delay Myopia Onset and Progression in Children

A Cluster Randomized Trial

Yuanyuan Hu, MD, PhD,[1,5] Mingkun Yu, MD, PhD,[2] Xiaotong Han, MD, PhD,[3] Nathan Congdon, MD, MPH,[3,4] Ziyun Wu, MS,[5,6] Jianping Liu, MD, PhD,[7] Zhaolan Liu, PhD,[7] Huanhuan Huo, MS,[5] Jike Song, MD, PhD,[1,2] Mingguang He, MD, PhD,[3,8] Hongsheng Bi, MD, PhD[1,2,5]

Purpose: To assess the efficacy of a behavioral intervention using Eye-Use Monitoring technology to delay the onset and progression of myopia in children.

Design: A prospective, cluster-randomized, parallel-groups, examiner-masked, clinical trial (Chinese Clinical Trial Registry, ChiCTR2100052101).

Participants: A total of 413 children from grades 2 to 4 in Shandong, China, from October 2021 to December 2023 were randomized by class into 3 groups: reminder and feedback (6 classes, 156 children), reminder-only (5 classes, 147 children), and control (3 classes, 110 children). Children with prior myopia control interventions, significant eye conditions, or a history of eye diseases were excluded.

Methods: The reminder-only group received simultaneous vibration alerts for prolonged near work, close proximity, head tilt, or inadequate lighting. The reminder and feedback group received these alerts plus behavioral feedback, including praise, rewards, and weekly reports. The control group received no intervention. The intervention lasted 49 weeks, followed by a 49-week observation period without intervention.

Main Outcome Measures: The primary outcome was the mean change in cycloplegic spherical equivalent (SE) at 49 weeks. Secondary outcomes included changes in axial length (AL), myopia incidence, rates of rapid myopic shift, participant compliance, and eye-use behaviors.

Results: At 49 weeks, changes in SE and AL were least in the reminder and feedback group (SE: 0.52 ± 0.35 diopters [D] vs. 0.59 ± 0.43 D vs. 0.73 ± 0.48 D, AL: 0.30 ± 0.14 mm vs. 0.33 ± 0.16 mm vs. 0.40 ± 0.20 mm, in reminder and feedback group, reminder only group, and control group, respectively, both $P < 0.001$). Myopia incidence was lowest in the reminder and feedback group (13.3% vs. 21.6% vs. 27.8%, in reminder and feedback group, reminder only group, and control group, respectively, $P < 0.05$). However, differences diminished by the 98-week follow-up.

Conclusions: This study demonstrated that the combination of Eye-Use Monitoring reminders and feedback on eye-use behaviors can effectively delay the onset and progression of myopia in children. However, sustained intervention may be necessary to maintain long-term benefits.

Financial Disclosure(s): Proprietary or commercial disclosure may be found after the references.

Supplemental material available at www.aaojournal.org.

Myopia is recognized as a major global public health challenge, with its prevalence and societal impact escalating alarmingly. As of 2020, myopia affected approximately 30% of the global population, and projections indicate this number will increase to 50% by 2050.[1–3] The economic and health care burdens stemming from myopia are substantial, with the global costs involving health care expenditures and lost productivity amounting to billions of dollars annually.[4] These underscore the critical need for continued research and interventions to curb the further worsening of the global myopia epidemic.

Although both genetics and environment play a role,[5] the increase in myopia prevalence in recent decades appears too rapid to be explained only by genetic factors and is more likely due to environmental changes. Factors such as increased schooling and decreased time outdoors have been strongly linked to greater myopia development in children.[6] However, the evidence connecting specific

behavior-related risk factors, such as the duration and proximity of near work, to myopia remains weak and inconsistent.[6–9] Studies by French et al,[10] Lin et al,[11] and Guo et al[12] reported that near-work time was an independent risk factor for myopia onset and progression. Pärssinen and Lyyra[13] also reported that more time spent on reading and other close work and reading distance were associated with faster myopic progression. A generally consistent association between near work and myopia has been shown in a recent meta-analysis.[14] However, Saw et al[15,16] indicated that near-work time, books read per week, and the eye-to-book distance while reading or writing were not risk factors for myopia progression. Likewise, Jones-Jordan et al[17] found that near-work time had little meaningful effect on the rate of myopia progression. A significant hurdle of the inconsistencies in evidence has been the reliance on self-report to assess lifestyle factors, including near work activities, which are susceptible to recall bias and inaccuracies. To address these challenges, simultaneous objective methods to measure these lifestyle factors have been developed, including devices such as RangeLife[18] and Clouclip,[19] offering new avenues to accurately assess their impact on myopia.

In addition, enhancing health education based on class and raising parental awareness are crucial strategies for myopia prevention in children, especially for behavior-related risk intervention.[20,21] However, although interventions targeting eye-use behaviors—such as near work duration, distance, posture, and lighting—are believed to be beneficial, the current evidence largely stems from observational studies, which are often subject to confounding variables and cannot establish causality. These limitations make it difficult to determine whether the observed effects are truly due to the interventions or other unrelated factors. Therefore, a randomized controlled trial is essential to rigorously evaluate these interventions under controlled conditions, eliminating biases and providing high-quality evidence on their effectiveness. Our study was designed to fill this gap by implementing and objectively assessing a behavioral intervention, with feedback from teachers and parents, to determine its true impact on delaying the onset and progression of myopia in children.

Methods

This study was an open-label, cluster-randomized, controlled trial conducted in the Huantai County, Zibo City, Shandong Province, China. Shandong Province, located in eastern China, is home to approximately 90 million people. Zibo City, centrally located in Shandong, includes Huantai County, where this study was conducted. The primary education system in Huantai spans from grade 1 to grade 5, catering to children typically aged 6 to 12 years. Given the potential challenges in intervention compliance among younger children and the preoccupation of fifth graders with their final year entrance examinations, our study specifically targeted children in grade 2 to 4. Before recruiting schools for the study, we engaged with the local educational authorities, the Huantai Education Bureau, to solicit their support and approval. After the consultation, the Huantai Education Bureau issued a letter to school principals, advocating for their participation in this research project.

One primary school in Huantai County was selected based on a list provided by local education bureaus, and all children from grade 2 to 4 in this school were included in our study. The period of recruitment was from October 18, 2021, to October 20, 2021. We further excluded children with (1) a history of myopia-control interventions, including orthokeratology lenses, low-concentration atropine eyedrops, and defocus spectacles; (2) amblyopia in either eye; (3) anisometropia $\geq$ 1.50 diopters (D); (4) astigmatism $\geq$ 2.50 D in either eye; (5) a history of severe eye diseases, for example, congenital cataract or fundus diseases; and (6) participation in another clinical trial within the last 3 months.

The study protocol was approved by the Medical Ethics Committee of the Affiliated Eye Hospital of Shandong University of Traditional Chinese Medicine on October 13, 2021 (HEC-HY-2021002KY). The trial was registered in the Chinese Clinical Trial Registry (ChiCTR2100052101) and followed the Consolidated Standards of Reporting Trials reporting guidelines. The study was conducted in compliance with the tenets of the Declaration of Helsinki. For all children for grade 2 to 4 in this study, parents or legal guardians signed informed consent before randomization, and verbal assent was collected from children themselves.

Randomization

The children were randomly assigned to 3 groups: the Eye-Use Monitor vibration plus eye-use behavior feedback group (reminder and feedback), Eye-Use Monitor vibration-only group (reminder only), and blank control group by the stratified cluster random sampling method (stratified by grade, cluster by class). Based on the class, a simple random sampling method was used to randomly assign classes in each grade by an independent statistician. SAS statistical software (version 9.4) was used to the stratified blocked randomization for 3 grades. In this school, grades 2 and 3 each had 5 classes, and grade 4 had 4 classes. For grades 2 and 3, 2 classes were assigned to reminder and feedback group, 2 to reminder only group, and 1 to pure control group. In grade 4, because of fewer classes, 2 classes were assigned to the reminder and feedback group, 1 to the reminder only group, and 1 to the control group.

Interventions

Before the trial commenced, all children, parents, and teachers in the 3 groups received health education on myopia prevention and control, proper eye-use behaviors, and how to use the Eye-Use Monitor (Jinan Tongxing Intelligent Technology Co., Ltd., China Compulsory Certification: 2021230805000936; Consulting and Certification: MICEZ-2003-0230-LVD, MICEZ-2003-0230-EMC, MICEZ-2003-0229-ROHS, Fig 1). The Eye-Use Monitor uses artificial intelligence–based computer vision recognition to quantify and record children's eye-use behaviors every 5 seconds. It can automatically identify whether a child is engaged in near work (10–60 cm, including reading, writing, playing the piano, playing chess, using cell phones and computers) or non-near work ($>$ 60 cm). The device records the average duration (minutes), time frame, working distance (centimeters), light intensity (lux), and head tilting angle (°) during near work activities. The detailed instruction of the working principles, measurement standards, accuracy, and stability of data collection is shown in the Supplementary material (available at www.aaojournal.org). In all 3 groups, participants were asked to wear the device during specific measuring weeks (weeks 5, 9, 25, 49, and 98) to assess their eye-use behaviors.

Before study initiation, we invited representatives from parents, teachers, psychologists, ophthalmologists, optometrists, and behaviorists to participate in a group meeting to determine the most

Figure 1. Function module diagram and photo demonstration of the Eye-Use Monitor.

appropriate intervention methods tailored to the school's and students' routines. As a result, children in the 2 intervention groups were instructed to wear the Eye-Use Monitor when doing near-work activities on 2 weekdays (a minimum of 2 hours during school and at least 1 hour after school, anytime from 1 PM to 8 PM) each week. After each day of use, data were automatically uploaded to a cloud server. The Eye-Use Monitor will automatically output an eye-use behavior score based on a built-in algorithm, ranging from 0 to 10, with higher scores indicating better eye-use behavior. Scores ≥ 8 were considered as excellent (Supplementary material, available at www.aaojournal.org). The device will also record and output the number of vibration reminders and the average duration of near work (total near work time/number of near work sessions) for each child.

Children in the reminder only group received simultaneous Eye-Use Monitor vibration reminders if engaging in near work for ≥ 20 minutes, near work for ≥ 15 seconds with the distance < 33 cm, head tilt of ≥ 10o, or ambient light intensity below 300 lux, whereas children in the reminder and feedback group also received feedback on their eye-use behaviors from their teacher, school, and parents. Twice a week, teachers praised children with excellent eye-use behavior scores. Each instance of praise was recorded, and children could exchange their accumulated praises for prizes such as stationery and backpacks. The school awarded certificates and prizes to classes with outstanding eye-use behaviors at weeks 9, 25, and 49. Parents received weekly reports on their child's eye-use behavior along with suggestions for improvement. The control group received no intervention. The interventions were conducted from October 2021 to November 2022 (49 weeks), with an additional follow-up period from December 2022 to December 2023 (from the 49th to 98th week) to gather postintervention data. The integration of elementary and junior high education in the school involved in our study allowed for a feasible second-year follow-up for students who were in grade 4.

The study intervention and all study examinations were offered free of charge. For children who were assigned to the control group, they could receive the study intervention free of charge upon the study's completion. Weekly visits were conducted to collect any adverse effect from children, teachers, and parents throughout the study.

Measurements

Examinations were conducted at baseline, as well as at the 25-, 49-, and 98-week follow-ups, including uncorrected and corrected distance (ETDRS chart, Good-Lite Co.) and near visual acuity assessment (Good-Lite Co.), slit-lamp examination, fundus examination, intraocular pressure measurement (Topcon CT80; Topcon Corp.), noncycloplegic and cycloplegic auto-refraction (Nidek ARK-1, Co., Ltd.), and ocular biometry (IOL-Master 500, Carl Zeiss Meditec AG). Examinations were performed by optometrists or ophthalmologists at school who were blind to random allocation. For refractive error measurements, if the difference between the maximum and minimum values of the spherical or cylinder power was larger than 0.25 D, the test would be repeated until the difference was 0.25 D or less. The average of 3 tests was taken as the final result. Cycloplegia was performed using a 1% cyclopentolate hydrochloride solution (Alcon), administered 3 times 5 minutes apart. Evaluation of pupil diameter and pupillary light reflex was performed by an experienced ophthalmologists after 30 minutes. Cycloplegia was considered successful if the pupil became unresponsive to light and was ≥ 6 mm in diameter. If not, an additional drop was administered and auto-refraction was performed after another 10 minutes. A questionnaire was filled out by parents to collect data on parental myopia and outdoor time of their children at baseline.

Compliance

Compliance was rated on a scale of 1 (good compliance) to 0 (poor compliance). A child was considered to have poor compliance if any of the following conditions occurred: (1) failure to adhere to the required duration and time frame for wearing the Eye-Use Monitor; (2) higher frequency of vibration reminders during the study period than the baseline week; (3) worse eye-use behaviors during the current week compared with the previous week; (4) losing the equipment ≥ 3 times. During the first 25 weeks, compliance was assessed weekly, from week 26 to week 48, compliance was evaluated monthly, and 1 final compliance assessment was conducted at the 49-week follow-up.

Definitions and Outcomes

Spherical equivalent (SE) was defined as the sum of the spherical power plus half of the cylindrical power. Only right eye data were analyzed. Myopia was defined as cycloplegic SE less than or equal to −0.50 D, premyopia was defined as −0.50 D < SE ≤ 0.75 D. Hyperopia was defined as SE > 0.75 D. A fast myopic shift was defined as a myopic shift in SE ≥ 0.50 D over 49 weeks or ≥ 1.00 D over 98 weeks.

The primary outcome was mean change in SE at 49 weeks, which was the absolute value of the difference from baseline to 49 weeks. Secondary outcomes included mean change in axial length (AL), percentage of children with newly developed myopia of right eye, fast myopic shift of right eye, participant compliance, and improvements in eye-use behaviors during the follow-up. Mean changes of these parameters at 98 weeks were also the secondary outcomes.

Sample Size

Based on the primary outcome, the sample size was calculated using PASS 21.0 (generalized estimating equation [GEE] tests for multiple means in a cluster-randomized design). The calculations were conducted with power set at 0.80 and alpha set at 0.05. The intracluster correlation coefficient for mean change in SE at 49 weeks was estimated to be 0.02 based on data from a previous study.[22] Considering not all students would participate in this study, the cluster size was set at 26. The study included 3 groups (k = 3) with a ratio of 3:5:6 according to the number of classes in each grade of the selected school. The mean (standard deviation) values for each group were 0.67 (0.41) D, 0.56 (0.37) D, and 0.44 (0.30) D, respectively. This required a total of 14 clusters, resulting in sample sizes of 156 for the reminder and feedback group, 130 for the reminder-only group, and 78 for the control group.

Statistical Analyses

We defined the full analysis set based on modified intention-to-treat principles, which included all randomized cases excluding minimally excluded cases. The analyses on the primary and secondary outcomes were performed based on the full analysis set. The per protocol data set, including only children who completed the 49-week intervention, was used for sensitivity analysis. Missing data were completed through multivariable multiple imputations by chained equations, and the full conditional specification method was used for iteration. In the descriptive analysis, the differences in cycloplegia SE changes, AL changes, and eye-use behaviors among the 3 groups were assessed with analysis of variance test if data were normally distributed or Kruskal−Wallis test if the data were not normally distributed. Data from right eyes were analyzed.

For the analyses of primary outcome, a GEE model was used to evaluate the effectiveness of the study intervention by comparing the between-group differences in the mean SE changes over the 49-week follow-up period. Unstructured correlation matrix and robust covariance matrix estimator was applied to account for the clustering effect in GEE. Adjustments were made for potential confounding factors, including baseline age, sex, SE, self-report outdoor time, head tilting angle, light intensity, working distance, average duration of eye use at close distance, and number of myopic parents, using cluster as a covariate within the model. Generalized estimating equation was used to assess the trends in SE changes among the 3 groups. Sensitivity analysis based on children with different baseline refractive status (myopia, premyopia, hyperopia) was performed.

For the analyses of secondary outcomes, GEE was used to analyze changes in AL, cumulative myopia incidence and percentage of participants with fast myopic shift over the 98-week follow-up. Statistical regression coefficients and 95% confidence intervals were reported. P values < 0.05 were considered statistically significant.

Results

Fourteen classes were randomized into 3 groups: 3 classes to the control group, 5 classes to the reminder-only group, and 6 classes to the reminder and feedback group (Fig 2). The intracluster correlation coefficient was 0.01 for the primary outcome. Of the 520 eligible children, 107 were excluded (45 did not meet the inclusion criteria and 62 declined participation); the remaining 413 children (79.4%, full analysis set) underwent the baseline examination. Thirty-three children (7.99%) did not complete the 49-week follow-up because of refusal of cycloplegic refraction (n = 24), refusal to use the device (n = 4), or school transfer (n = 5). Consequently, a total of 380 children (92.0%, 380/413, per protocol set) completed the 49-week follow-up, of whom 343 (343/413, 83.1%) completed the 98-week follow-up (Fig 2). Children who completed and who did not complete the 49-week follow-up had no significant difference in baseline characteristics (Table S1, available at www.aaojournal.org).

As shown in Table 2, there was no significant difference among children in the 3 study groups at baseline, except for age because of the absence of 1 class in the reminder only group in fourth grade. Although the age difference was statistically significant (P = 0.02), the absolute difference was relatively small. The mean age in the control, reminder only, and reminder and feedback groups was 8.10, 7.92, and 8.19 years, respectively. The results of GEE model remained consistent regardless of whether age was adjusted or not (Tables 3 and S4 [available at www.aaojournal.org]).

The primary outcome of changes in SE in the intervention groups was smaller than in the control group, with mean changes of 0.52 ± 0.35 D in the reminder and feedback group (mean difference [MD], −0.21, 95% CI, −0.31 to −0.12, compared with control group), 0.59 ± 0.43 D in the reminder only group (MD, −0.12, 95% CI, −0.22 to −0.02, compared with control group), and 0.73 ± 0.48 D in the control group at the 49-week follow-up (Table 3, Fig 3). The reminder and feedback group had the lowest mean myopic shift (P for trend < 0.001). Sensitivity analysis based on the per protocol set and subgroup analysis based on different baseline refractive status also yielded similar results (Table S5, available at www.aaojournal.org).

The mean increase in AL at the 49-week follow-up in the intervention groups were also smaller than in the control group (P < 0.001, P for trend < 0.001). The mean AL change was 0.30 ± 0.14 mm in the reminder and feedback group (MD, −0.10, 95% CI, −0.14 to −0.06, compared with control group), 0.33 ± 0.16 mm in the reminder only group (MD, −0.08, 95% CI, −0.12 to −0.04, compared with control group), and 0.40 ± 0.20 mm in the control group (Table 6, Fig 3). The incidence of myopia at the 49-week follow-up was 27.8% in the control group, 21.6% in the reminder only group, and 13.3% in the reminder and feedback group, respectively

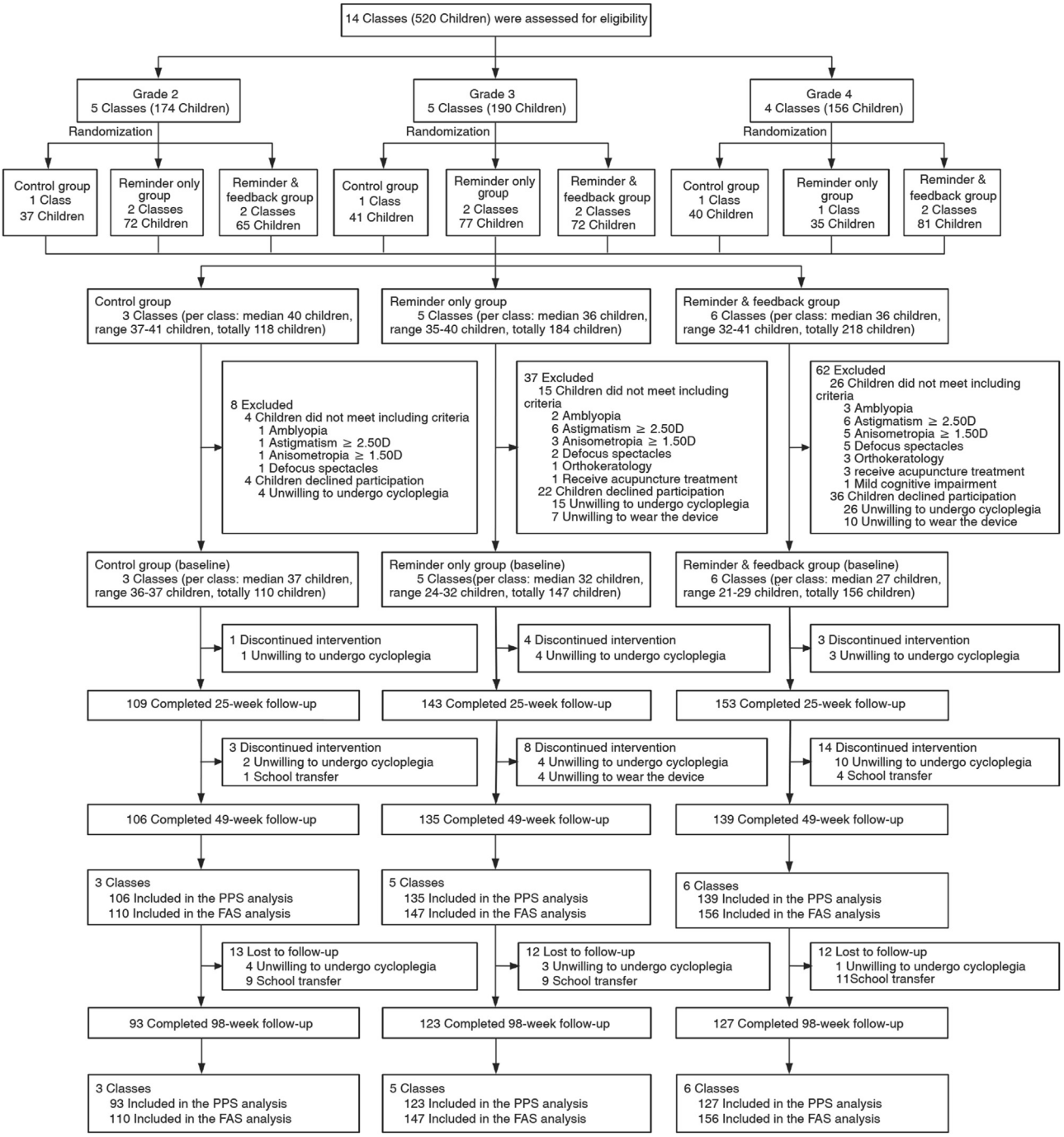


Figure 2. Flow diagram of participants according to Consolidated Standards of Reporting Trials statement.

(P for trend < 0.001), at the 49-week follow-up, but the difference was no longer significant at the 98-week follow-up. The percentages of children with fast myopic shift were 54.5% (85/156) in the reminder and feedback group, 63.3% (93/147) in the reminder only group, and 71.8% (79/110) in the control group ($P = 0.02$, P for trend < 0.001) at the 49-week follow-up (Table 6). No significant difference was observed in the proportion of good compliance among the 3 groups (Table 6).

Distributions of the average duration of eye-use at close distance, working distance, light intensity, and head tilting angle of the study participants are shown in Table S7 (available at www.aaojournal.org) and Figure 4, respectively. During the 49 weeks, no significant changes were observed in the control group, whereas the children in the intervention groups showed significant improvement. The eye-use behaviors in the reminder and feedback group were significantly better than in the control

Table 2. Demographics of the Study Participants in the Three Study Groups

	Control Group (N = 110)*	Reminder Only Group (N = 147)*	Reminder and Feedback Group (N = 156)*	P Value
Cluster	3	5	6	
Grade 2	1	2	2	
Grade 3	1	2	2	
Grade 4	1	1	2	
Age, yrs	8.10 (0.87)	7.92 (0.80)	8.19 (0.80)	0.02
Sex, No. (%)				0.17
Male	53 (48.20%)	86 (58.50%)	83 (53.20%)	
Female	57 (51.80%)	61 (41.50%)	73 (46.80%)	
Uncorrected visual acuity,† logMAR				
Distance	0.05 (0.12)	0.05 (0.13)	0.05 (0.13)	0.96
Near	0.03 (0.06)	0.02 (0.06)	0.02 (0.05)	0.46
Cycloplegia SE, D	0.34 (1.22)	0.45 (1.15)	0.44 (1.16)	0.73
Grade 2	0.78 (1.06)	0.87 (0.84)	0.96 (1.05)	0.70
Grade 3	0.24 (1.10)	0.28 (0.96)	0.35 (1.05)	0.87
Grade 4	0.02 (1.38)	-0.02 (1.64)	0.09 (1.21)	0.94
AL, mm	23.14 (0.80)	23.34 (0.73)	23.17 (0.78)	0.07
Intraocular pressure, mmHg	17.20 (2.95)	17.77 (2.79)	17.22 (2.84)	0.16
Parents with myopia, No. (%)				0.82
0	36 (32.70%)	40 (27.20%)	57 (36.50%)	
1	45 (40.90%)	64 (43.50%)	55 (35.30%)	
2	29 (26.40%)	43 (29.30%)	44 (28.20%)	
Average duration of eye-use at close distance,‡ min	11.50 (6.93 to 16.43)	11.60 (7.88 to 17.25)	11.06 (7.73 to 14.77)	0.35
Working distance,§ cm	31.71 (3.31)	31.06 (3.33)	31.23 (3.55)	0.30
Light intensity‖ lux	293.02 (40.13)	288.64 (34.03)	297.25 (37.28)	0.13
Head tilting angle,¶ °	8.47 (6.05 to 11.93)	9.48 (6.39 to 12.73)	8.38 (4.89 to 13.96)	0.45

AL = axial length; D = diopters; logMAR = logarithm of the minimum angle of resolution; SE = spherical equivalent.
*Calculated by full analysis set analysis, including all randomized cases excluding minimally excluded cases.
†Distance visual acuity was measured at 4 m, and near visual acuity was measured at 40 cm.
‡Average duration of eye-use at close distance was measured by the Eye Monitor, expressed as median (interquartile range).
§Working distance was measured by a built-in infrared distance sensor in the Eye Monitor. The average value was used to represent the subjects' working distance from eyes to reading plane, expressed as mean (standard deviation).
‖Light intensity was measured by light sensor (measurement range 0–64 000 lux) in the Eye Monitor and represented the intensity of light entering the eyes, expressed as mean (standard deviation).
¶When working at a close distance of 10–60 cm, the angle at which the head deviates from the vertical direction was defined as the head tilting angle. It was measured through the built-in gyroscope sensor in the Eye-Monitor, expressed as median (interquartile range).

group (all $P < 0.05$, Table S7) and reminder only group (all $P < 0.05$ except for the light intensity and the head tilting angle, Table S7) at 49 weeks. Specifically, the average duration of eye-use at close distance was shorter (6.47 [4.46–9.26] minutes vs. 9.73 [6.48–14.6] minutes), working distance was larger (33.1 ± 3.81 cm vs. 31.2 ± 4.24 cm), light intensity was better (328 ± 53.6 lux vs. 303 ± 46.2 lux), and head tilting angle was smaller (6.03 [3.11 to 10.1]° vs. 8.18 [5.34 to 11.3]°) in the reminder and feedback group compared with the control group. After cessation of the intervention, most eye-use behaviors in the reminder and feedback group at 98 weeks deteriorated compared with the 49 weeks (Table S7). No children experienced intervention-related adverse reaction throughout the study (Table S8, available at www.aaojournal.org).

Discussion

Our study demonstrated that interventions aimed at promoting improved eye-use behaviors can delay the onset and progression of myopia in children. This is one of the earliest studies to use simultaneous monitoring combined with tailored feedback from teachers, schools, and parents, which proved to be the most effective strategy in promoting sustained behavior change. It is noted that after ceasing the intervention, inter-group differences in visual behaviors and myopia outcomes disappeared, indicating that such behavioral interventions should be conducted over the long term. Future studies should explore sustainable models of multilevel long-term intervention, potentially integrating these strategies into everyday school and home routines, and social environment for children in improving eye-use behaviors to ensure ongoing effectiveness.

Increased time outdoors and low-dose atropine are 2 widely used interventions for children to delay myopia onset.[22–24] For slowing myopia progression, clinicians often use multifocal spectacles, orthoketatology lenses, low-dose atropine eyedrops, or a combination of these interventions.[25] Near work has generally been regarded as an important myopia-related risk factor. Recently, a 2-year prospective, observational population study suggested that longer distance at near work and discontinuing near work every 30 minutes were protective behaviors for myopia

Table 3. Changes in Spherical Equivalent over 98 Weeks

	Control Group (1)		Reminder Only Group (2)		Reminder and Feedback Group (3)			(2) vs. (1)		(3) vs. (1)		
	No. of Children	*Mean ± SD*[‡]	*No. of Children*	*Mean ± SD*[‡]	*No. of Children*	*Mean ± SD*[‡]	**P Value**[§]	*MD (95% CI)*[§]	*Adjusted P Value*[§]	*MD (95% CI)*[§]	*Adjusted P Value*[§]	**P for Trend**[§]
Changes in SE, D*												
25 wks	110	0.39 ± 0.32	147	0.33 ± 0.33	156	0.32 ± 0.31	< 0.001	−0.04 (−0.11 to 0.04)	0.37	−0.07 (−0.15 to 0.01)	0.09	< 0.001
49 wks	110	0.73 ± 0.48	147	0.59 ± 0.43	156	0.52 ± 0.35		−0.12 (−0.22 to −0.02)	0.02	−0.21 (−0.31 to −0.12)	< 0.001	
98 wks	110	1.37 ± 0.68	147	1.15 ± 0.69	156	1.01 ± 1.54		−0.19 (−0.35 to −0.04)	0.02	−0.35 (−0.49 to −0.20)	< 0.001	
Changes in SE, D[†]												
25 wks	106	0.39 ± 0.32	135	0.33 ± 0.32	139	0.30 ± 0.29	< 0.001	−0.04 (−0.12 to 0.04)	0.33	−0.07 (−0.15 to 0.01)	0.09	< 0.001
49 wks	106	0.73 ± 0.47	135	0.60 ± 0.43	139	0.50 ± 0.31		−0.11 (−0.21 to −0.01)	0.03	−0.21 (−0.31 to −0.12)	< 0.001	
98 wks	93	1.33 ± 0.69	123	1.13 ± 0.71	127	0.98 ± 0.48		−0.20 (−0.37 to −0.03)	0.02	−0.35 (−0.50 to −0.20)	< 0.001	

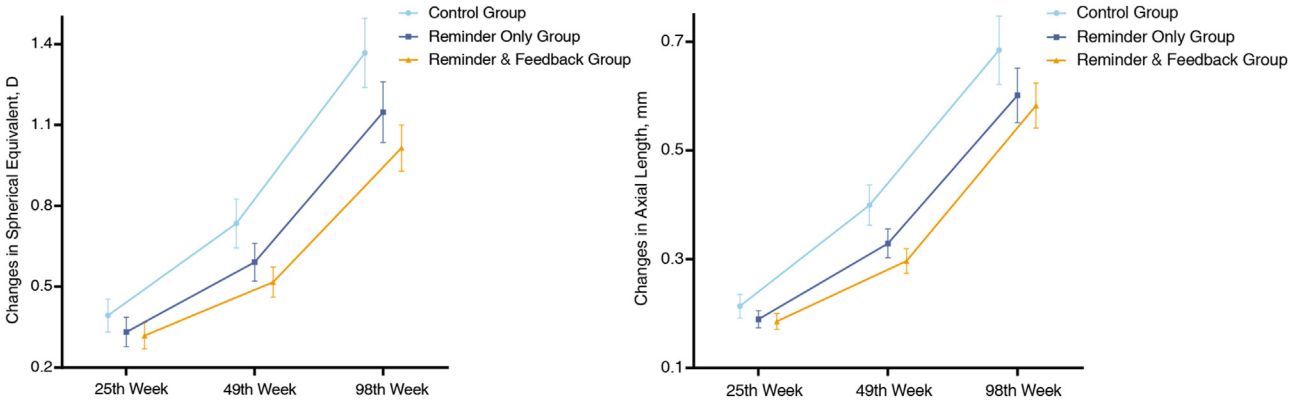
D = diopter; MD = mean difference; SD = standard deviation; SE = spherical equivalent.

*Calculated by full analysis set analysis, including all randomized cases excluding minimally excluded cases. The changes in SE were the absolute values of the difference from baseline to 25, 49, and 98 weeks, respectively.

[†]Calculated by per protocol set analysis, including only children who completed the 49-week intervention. The changes in SE were the absolute values of the difference from baseline to 25, 49, and 98 weeks, respectively.

[‡]Calculated with data from right eyes.

[§]*P* value and *P* for trend represented the comparison among 3 groups. Estimated by the generalized estimating equation (GEE) model with the adjustment of baseline age, sex, baseline SE, outdoor time, head tilting angle, light intensity, working distance, average duration of eye-use at close distance, parental myopia, and cluster.



Note: The changes in Spherical Equivalent and Axial Length were the absolute values of the differences from baseline to 25, 49, and 98 weeks, respectively.

Figure 3. Changes in spherical equivalent (SE) and axial length (AL) over 98 weeks.

onset and progression.[26] It has been found that children with fast annual myopia progression was associated with a shorter reading distance for doing near work and the lack of a 10-minute rest period after 30 minutes of near work by Hsu et al[27] in a population-based cohort study. Limited evidence has supported the protective effect of increased indoor light and improved the head titling angle against myopia onset and progressive.[28–30] More longitudinal studies are needed to confirm the relationship between the 2 factors with the development of myopia. Our daily behaviors direct intervention study results further implicated that the improved eye-use behaviors in the reminder and feedback group were helpful in delaying the onset and progression of myopia in children.

Despite the widely acknowledged link between behavioral risk factors and myopia, interventions aimed at health promotion have received less attention than therapeutic interventions in terms of myopia prevention and control. Health promotion is the science of helping people change their behavior to achieve better health. Behavior change can be facilitated through a combination of efforts to increase awareness and create environments that support good health practices.[31] One key recommendation from the World Report on Vision (2019) was the vital role that health education campaigns play in the management of myopia and its associated complications.[32]

To encourage more outdoor activities and improved eye-use behaviors in children, there is a need to enhance parents' and teachers' awareness and knowledge, because school-aged children spend most of their time at home or school. Previous randomized controlled trials sought to promote healthy behaviors for better myopia control through family health education. Li et al[33] provided school-based family health education weekly via the social media platform WeChat. In another study,[34] parents of children were sent text messages twice daily for 1 year to remind them to take their children outdoors. Unlike these 2 studies,[33,34] the current report used an objective device to offer simultaneous eye-use monitoring and alerts, and tailored behavior change recommendations for each child. By engaging families and schools, we effectively encouraged children to develop and maintain improved eye-use habits. This strategy lays a foundation for fostering healthy behaviors in the management and prevention of myopia among school-aged children.

Our study intervention not only includes health education but also was based on the concept of health promotion. Effective health promotion strategies for childhood myopia should act on behalf of children rather than manipulate them. It is essential for interventions to occur concurrently at the government, school, and family levels to establish an environment conducive to myopia prevention and control. In contrast to the reminder only group that received only vibration alerts, the reminder and feedback group benefited from an environment fostered by feedback from teachers, schools, and parents, encouraging children to adopt and maintain healthy eye-use habits. Furthermore, to support sustained alteration in unhealthy excessive near work, interventions also concentrated on enhancing children's self-esteem and empowerment through a psychological reward system. It should be noted that our current Eye-Use Monitor does have certain costs and is not convenient for daily wear, which affects its sustainability and scalability. However, the primary goal of our study is to demonstrate that monitoring and improving eye-use behavior significantly benefits myopia prevention and control, especially through implementation in schools. In the future, the development of more portable eye-use behavior promotion technologies could result in a more realistic and practical model for broader use.

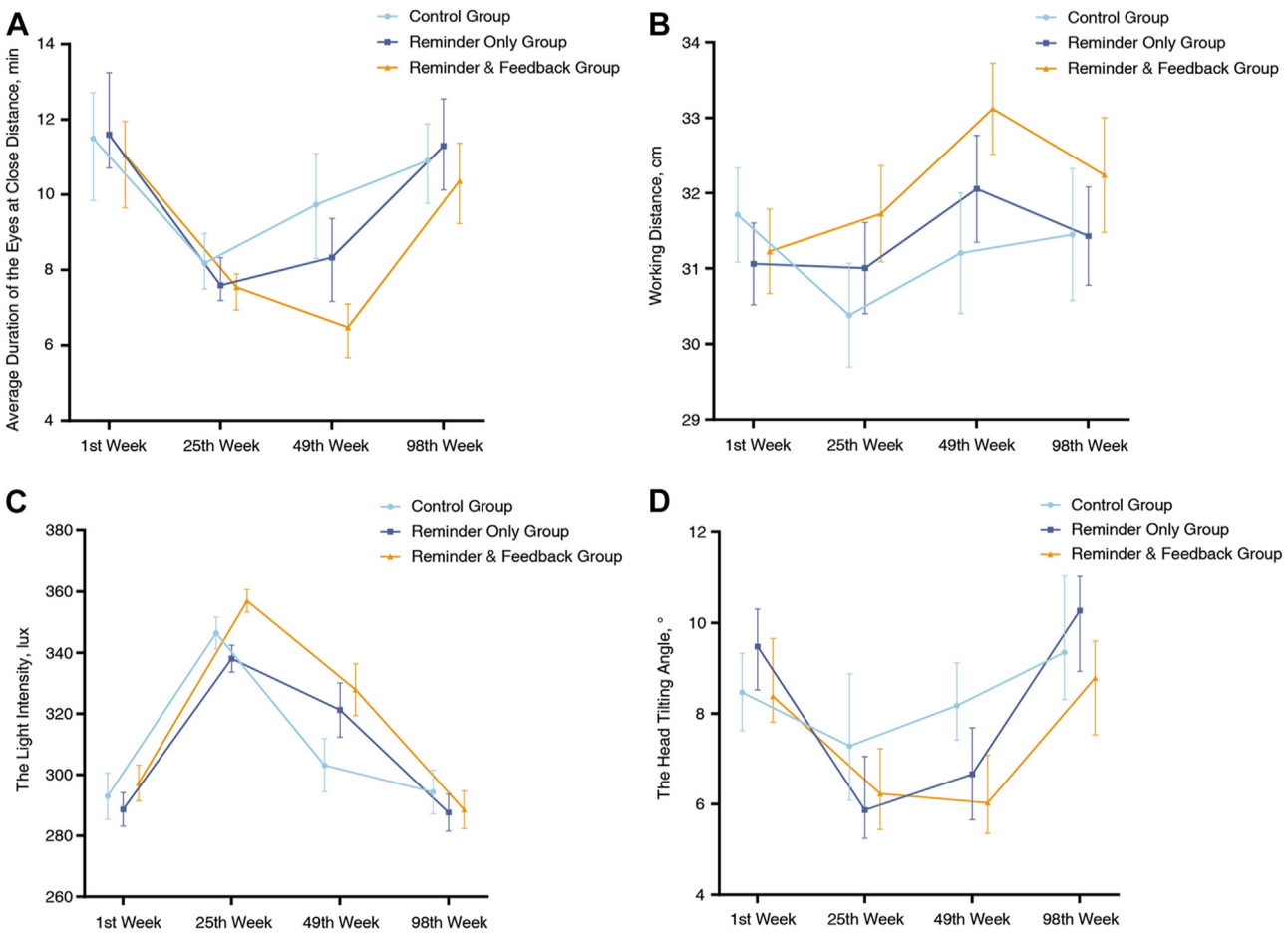
Limitations

This study had several limitations. First, the sample size was calculated on the basis of the primary outcome; thus, the secondary outcomes may not be adequately represented. Second, this study was conducted at schools in China, and the lack of ethnic diversity among participants limits the applicability of the findings to other settings and ethnic groups. Further multicenter studies with a larger sample size are needed. Third, because of the nature of the

Table 6. Changes in Axial Length, Myopia Incidence,* and Percentages of Participants with Fast Myopic Shift over 98 Weeks of Follow-up†

Follow-up	No./Total No. (%)			P value‡	(2) vs. (1)		(3) vs. (1)		P for Trend‡
	Control Group (1)	*Reminder Only Group (2)*	*Reminder and Feedback Group (3)*		*MD/OR (95% CI)‡*	*Adjusted P Value‡*	*MD/OR (95% CI)‡*	*Adjusted P Value‡*	
Changes in AL (Mean ± SD, mm)									
25 wks	0.21 ± 0.12	0.19 ± 0.10	0.19 ± 0.09	<0.001	−−0.03 (−0.06 to −0.01)	0.02	−0.02 (−0.05 to 0.00)	0.10	< 0.001
49 wks	0.40 ± 0.20	0.33 ± 0.16	0.30 ± 0.14		−0.08 (−0.12 to −0.04)	< 0.001	−0.10 (−0.14 to −0.06)	< 0.001	
98 wks	0.68 ± 0.33	0.60 ± 0.31	0.58 ± 0.26		−0.09 (−0.17 to −0.01)	0.02	−0.10 (−0.17 to −0.02)	0.01	
Cumulative Myopia Incidence Over 98 Wks (n/N, %)									
25 wks	17/90 (18.89%)	11/125 (8.80%)	9/128 (7.03%)	0.01	0.24 (0.08 to 0.74)	0.01	0.25 (0.08 to 0.79)	0.02	< 0.001
49 wks	25/90 (27.78%)	27/125 (21.60%)	17/128 (13.28%)		0.57 (0.21 to 1.54)	0.27	0.22 (0.08 to 0.62)	0.004	
98 wks	41/90 (45.56%)	51/125 (40.80%)	48/128 (37.50%)		0.82 (0.28 to 2.38)	0.71	0.54 (0.22 to 1.35)	0.19	
Participants with Fast Myopic Shift (Defined as SE Myopic Shift ≥0.50 D Over 49 Wks and ≥1.00 D over 98 Wks, n/N, %)									
49 wks	79/110 (71.82%)	93/147 (63.27%)	85/156 (54.49%)	0.02	0.74 (0.42 to 1.30)	0.29	0.45 (0.25 to 0.78)	0.01	< 0.001
98 wks	77/110 (70.00%)	82/147 (55.78%)	87/156 (55.77%)		0.57 (0.33 to 0.98)	0.04	0.52 (0.30 to 0.92)	0.02	
Overall Good Compliance during Study Period (n/N, %)§									
25 wks	100/110 (90.91%)	131/147 (89.12%)	139/156 (89.10%)	0.87					
49 wks	96/110 (87.27%)	122/147 (82.99%)	126/156 (80.77%)	0.37					

D = diopters; MD = mean difference; OR = odds ratio; SD = standard deviation.
*Myopia incidence was calculated as the number of children with newly developed myopia in the right eye/total number of children without myopia at baseline.
†The full analysis set, including all randomized cases excluding minimally excluded cases.
‡*P* value and *P* for trend represented the comparison among 3 groups. Estimated by the GEE model with the adjustment of baseline age, sex, SE, outdoor time, head tilting angle, light intensity, working distance, average duration of eye-use at close distance, number of myopic parents, and cluster.
§*P* value was estimated by Pearson's chi-square test.



Note: This chart is drawn by means or medians (95%CI). Reminder only group refers to Eye-Monitor vibration intervention group. Reminder & feedback group refers to Eye-Monitor vibration combined with eye-use behaviors feedback intervention group.

Figure 4. Changes of eye-use behaviors among the 3 study groups.

study intervention, masking was not possible, which could introduce bias. Parents, knowing their children were participating in a study might have adjusted both their own and their children's eye-use behavior. Furthermore, wearing the device could have served as a reminder for participants to adopt healthier eye-use habits, thereby influencing their behavior. Fourth, the Eye-Use Monitors were only used for selected periods (2 hours during school and 1 hour at home when doing near work). Future research is encouraged to further expand the wearing duration. Although contamination bias is a potential concern because of the class-based randomization within a single school, the structured class environment and limited inter-class communication likely minimized its impact. In addition, data on time spent outdoors were collected from questionnaires, which were susceptible to recall bias. Studies that objectively measure time spent outdoors are encouraged in the future.

Conclusions

This study highlights the potential of behavioral interventions in myopia control, suggesting that managing daily eye-use behaviors can be an effective complement to existing strategies. Integrating family and school efforts to foster reductions in near work and use of low-light settings, coupled with an objective and simultaneous behavior monitoring and alert system, significantly slowed the onset and progression of myopia in children. However, further research is needed to explore long-term sustainability and optimize the intervention for broader application.

Acknowledgments

The authors thank the Huantai Education Bureau and Maqiao Experimental School for helping organize the survey, and Yizhuo Gong, Xianwei Yao, Tingting Qiu, Zheng Liu, and Xiaohui Ma for helping collect data.

Footnotes and Disclosures

Originally received: September 16, 2024.
Final revision: December 19, 2024.
Accepted: January 2, 2025.
Available online: ■■■. Manuscript no. OPHTHA-D-24-01980.

[1] Affiliated Eye Hospital of Shandong University of Traditional Chinese Medicine, Shandong Academy of Eye Disease Prevention and Therapy, Shandong Provincial Key Laboratory of Integrated Traditional Chinese and Western Medicine for Prevention and Therapy of Ocular Diseases, Shandong Provincial Clinical Medical Research Center of Optometry and Children Visual Impairment Prevention and Control, Shandong Engineering Technology Research Center of Visual Intelligence, Shandong Institute of Children Health and Myopia Prevention and Control, Shandong, China.

[2] Shandong University of Traditional Chinese Medicine, Shandong, China.

[3] State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, SunYat-sen University, Guangdong Provincial Key Laboratory of Ophthalmology and Visual Science, Guangdong Provincial Clinical Research Center for Ocular Diseases, Guangzhou, China.

[4] Centre for Public Health, Queen's University Belfast, Belfast, United Kingdom.

[5] Ophthalmology and Optometry Medical School, Shandong University of Traditional Chinese Medicine, Shandong, China.

[6] Affiliated Yongchuan Hospital of Chongqing Medical University, Chongqing, China.

[7] Centre for Evidence Based Chinese Medicine, Beijing University of Chinese Medicine, Beijing, China.

[8] Research Centre for SHARP Vision, The Hong Kong Polytechnic University, Hong Kong, China.

Disclosure(s):

All authors have completed and submitted the ICMJE disclosures form.

The author(s) have made the following disclosure(s): N.C. had a contract until recently with Belkin Vision for development of a glaucoma laser product; consulting fees from Belkin Vision; and participation for testing of the EAGLE device for Belkin Vision.

This study was supported by the National Key Research and Development Program, China (No. 2019YFC1710200), Shandong Province Integrated Traditional Chinese and Western Medicine Disease Prevention and Control Project (YXH2019ZXY001), Key Research and Development Program of Shandong Province (No. 2021LCZX09), and Shandong Provincial Natural Science Foundation (No. ZR2021LZY045). The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. Dr Bi and Dr He had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Dr Bi is the primary corresponding author. Dr Bi and Dr He contributed equally as corresponding authors. The Article Publishing Charge (APC) for this article was paid the Affiliated Eye Hospital of Shandong University of Traditional Chinese Medicine.

HUMAN SUBJECTS: Human subjects were included in this study. Ethical approval has been received from the Medical Ethics Committee of Affiliated Eye Hospital of Shandong University of Traditional Chinese Medicine (HEC-HY-2021002KY, HEC-KS-2021002KY01,02,03). All research adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from parents or legal guardians of all participants, and verbal assent was collected from children themselves.

No animal subjects were used in this study.

Author Contributions:

Conception and design: Hu, He, Bi

Data collection: Hu, Wu, Huo

Analysis and interpretation: Hu, Yu, J. Liu, Z. Liu, Huo, He, Bi

Obtained funding: Bi; Study was performed as part of regular employment duties. No additional funding was provided.

Overall responsibility: Hu, Yu, Han, Congdon, J. Liu, Z. Liu, He, Bi

Abbreviations and Acronyms:
AL = axial length; **D** = diopters; **GEE** = generalized estimating equation; **MD** = mean difference; **SE** = spherical equivalent.

Keywords:
Children, Cluster randomized controlled trials, Eye-use behaviors, Myopia, Spherical equivalent.

Correspondence:
Hongsheng Bi, MD, PhD, Affiliated Eye Hospital of Shandong University of Traditional Chinese Medicine, Shandong, China 250002. E-mail: hongshengbi@126.com; and Mingguang He, MD, PhD, Research Centre for SHARP Vision, The Hong Kong Polytechnic University, Hong Kong, China 999077. E-mail: mingguang_he@yahoo.com.

References

1. Morgan IG, Ohno-Matsui K, Saw SM. Myopia. *Lancet*. 2012;379(9827):1739–1748.
2. Dolgin E. The myopia boom. *Nature*. 2015;519(7543):276–278.
3. Holden BA, Fricke TR, Wilson DA, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *Ophthalmology*. 2016;123(5):1036–1042.
4. Sankaridurg P, Tahhan N, Kandel H, et al. IMI impact of myopia. *Invest Ophthalmol Vis Sci*. 2021;62(5):2.
5. Morgan IG, French AN, Ashby RS, et al. The epidemics of myopia: aetiology and prevention. *Prog Retin Eye Res*. 2018;62:134–149.
6. Morgan IG, Wu PC, Ostrin LA, et al. IMI risk factors for myopia[J/OL]. *Invest Ophthalmol Vis Sci*. 2021;62(5):3.
7. Saw SM, Hong CY, Chia KS, et al. Nearwork and myopia in young children. *Lancet*. 2001;357(9253):390.
8. Rose KA, French AN, Morgan IG. Environmental factors and myopia: paradoxes and prospects for prevention. *Asia Pac J Ophthalmol (Phila)*. 2016;5(6):403–410.
9. Lanca C, Yam JC, Jiang WJ, et al. Near work, screen time, outdoor time and myopia in schoolchildren in the Sunflower Myopia AEEC Consortium. *Acta Ophthalmol*. 2022;100(3):302–311.
10. French AN, Morgan IG, Mitchell P, et al. Risk factors for incident myopia in Australian schoolchildren: the Sydney adolescent vascular and eye study. *Ophthalmology*. 2013;120(10):2100–2108.
11. Lin Z, Vasudevan B, Mao GY, et al. The influence of near work on myopic refractive change in urban students in Beijing: a three-year follow-up report. *Graefes Arch Clin Exp Ophthalmol*. 2016;254(11):2247–2255.
12. Guo Y, Liu LJ, Tang P, et al. Outdoor activity and myopia progression in 4-year follow-up of Chinese primary school

children: The Beijing Children Eye Study. *PLoS One*. 2017;12(4):e0175921.
13. Pärssinen O, Lyyra AL. Myopia and myopic progression among schoolchildren: a three-year follow-up study. *Invest Ophthalmol Vis Sci*. 1993;34(9):2794–2802.
14. Huang HM, Chang DS, Wu PC. The association between near work activities and myopia in children-a systematic review and meta-analysis. *PLoS One*. 2015;10(10):e0140419.
15. Saw SM, Nieto FJ, Katz J, et al. Factors related to the progression of myopia in Singaporean children. *Optom Vis Sci*. 2000;77(10):549–554.
16. Saw SM, Chua WH, Gazzard G, et al. Eye growth changes in myopic children in Singapore. *Br J Ophthalmol*. 2005;89(11):1489–1494.
17. Jones-Jordan LA, Sinnott LT, Cotter SA, et al. Time outdoors, visual activity, and myopia progression in juvenile-onset myopes. *Invest Ophthalmol Vis Sci*. 2012;53(11):7169–7175.
18. Williams R, Bakshi S, Ostrin EJ, et al. Continuous objective assessment of Near work. *Sci Rep*. 2019;9(1):6901.
19. Wen L, Cao Y, Cheng Q, et al. Objectively measured near work, outdoor exposure and myopia in children. *Br J Ophthalmol*. 2020;104(11):1542–1547.
20. Glasman LR, Albarracín D. Forming attitudes that predict future behavior: a meta-analysis of the attitude-behavior relation. *Psychol Bull*. 2006;132(5):778–822.
21. Ang M, Flanagan JL, Wong CW, et al. Review: Myopia control strategies recommendations from the 2018 WHO/IAPB/BHVI Meeting on Myopia. *Br J Ophthalmol*. 2020;104(11):1482–1487.
22. 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 J. *JAMA*. 2015;314(11):1142–1148.
23. He X, Sankaridurg P, Wang J, et al. Time outdoors in reducing myopia: a school-based cluster randomized trial with objective monitoring of outdoor time and light intensity [J]. *Ophthalmology*. 2022;129(11):1245–1254.
24. Yam JC, Zhang XJ, Zhang Y, et al. Effect of low-concentration atropine eyedrops vs placebo on myopia incidence in children: the LAMP2 randomized clinical trial. *JAMA*. 2023;329(6):472–481.
25. Wolffsohn JS, Whayeb Y, Logan NS, et al; International Myopia Institute Ambassador Group*. IMI-Global Trends in Myopia Management Attitudes and Strategies in Clinical Practice-2022 Update. *Invest Ophthalmol Vis Sci*. 2023;64(6):6.
26. Huang PC, Hsiao YC, Tsai CY, et al. Protective behaviours of near work and time outdoors in myopia prevalence and progression in myopic children: a 2-year prospective population study. *Br J Ophthalmol*. 2020;104(7):956–961.
27. Hsu CC, Huang N, Lin PY, et al. Risk factors for myopia progression in second-grade primary school children in Taipei: a population-based cohort study. *Br J Ophthalmol*. 2017;101(12):1611–1617.
28. Hua WJ, Jin JX, Wu XY, et al. Elevated light levels in schools have a protective effect on myopia. *Ophthalmic Physiol Opt*. 2015;35(3):252–262.
29. You X, Wang L, Tan H, et al. Near work related behaviors associated with myopic shifts among primary school students in the Jiading District of Shanghai: a school-based one-year cohort study. *PLoS One*. 2016;11(5):e0154671.
30. Zhu Z, Chen Y, Tan Z, et al. Interventions recommended for myopia prevention and control among children and adolescents in China: a systematic review. *Br J Ophthalmol*. 2023;107(2):160–166.
31. Viner R, Macfarlane A. Health promotion. *BMJ*. 2005;330(7490):527–529.
32. World Health Organization. World Report on Vision. https://www.who.int/publications-detail/world-report-on-vision; 2019. Accessed November 16, 2023.
33. Li Q, Guo L, Zhang J, et al. Effect of school-based family health education via social media on children's myopia and parents' awareness: a randomized clinical trial. *JAMA Ophthalmol*. 2021;139(11):1165–1172.
34. Li SM, Ran AR, Kang MT, et al. Effect of text messaging parents of school-aged children on outdoor time to control myopia: a randomized clinical trial. *JAMA Pediatr*. 2022;176(11):1077–1083.