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Safety of eyeglasses wear for visual acuity among middle school students in northwestern rural China: a cluster-randomised controlled trial

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ABSTRACT

Objective To assess the effect of free eyeglasses provision on visual acuity among middle school students in northwestern rural China.

Methods and analysis Among 31 middle schools randomly selected from 47 middle schools in northwestern rural China, students were randomly allocated by school to one of two interventions: free eyeglasses (intervention group), and eyeglasses prescriptions given only to the parents (control group). The main outcome of this study is uncorrected visual acuity after 9 months, adjusted for baseline visual acuity.

Results Among 2095 students from 31 middle schools, 995 (47.5%) failed the visual acuity screening, 515 (51.8%, 15 schools) of which were randomly assigned to the intervention group, with the remaining 480 students (48.2%, 16 schools) assigned to the control group. Among these, a total of 910 students were followed up and analysed. Endline eyeglasses wear in the intervention group was 44%, and 36% in the control group. Endline visual acuity of students in the intervention group was significantly better than students in the control group, adjusting for other variables (0.045 LogMAR units, 95% CI 0.006 to 0.084, equivalent to 0.45 lines, p=0.027), and insignificantly better only for baseline visual acuity (difference of 0.008 LogMAR units, 95% CI –0.018 to 0.034, equivalent to 0.08 lines).

Conclusion We found no evidence that receiving free eyeglasses worsened visual acuity among middle school students in northwestern rural China.

Trial registration number ISRCTN17141957.

Key messages

What is already known about this subject ?

- A majority of studies have identified correlations between eyeglasses wear and uncorrected refractive error, but have not identified a causal link, especially among middle school students in northwestern rural China.

What are the new findings?

- The current study provides strong evidence for the safety of eyeglasses wear for middle school students with uncorrected refractive error in northwestern rural China.

How might these results change the focus of research or clinical practice?

- The imperfect compliance with eyeglasses wear means that the results may underestimate the true effect of eyeglasses wear on refractive power, which could be the focus of future research.

INTRODUCTION

Uncorrected refractive error can lead to a variety of broader issues. It is estimated by the WHO that uncorrected refractive error results in the global loss of hundreds of billions of US dollars each year due to reduced productivity.[1] In addition to loss of visual function,[2] refractive error is also associated with reduced educational performance in children.[3] As of 2004, 6.4 million children aged 5–15 years living in China were affected by refractive error, which accounts for 50% of all cases of refractive error in the world.[4]

Refractive error can be effectively and inexpensively treated with eyeglasses. However, among middle school students in rural China, as few as 30% of students needing eyeglasses own and wear them.[5] Studies in China suggest that factors leading to poor compliance include discomfort or inconvenience,[6] lack of perceived need[6 7] and fear of harm to vision.[6–8] More specifically, vision knowledge of children, parents and teachers was normally distributed around a low to medium average. Parents scored an average of 34% on a short knowledge test on vision care. Teachers performed slightly better, with an average score of 56%. Students had the lowest level of baseline knowledge, with an average score of only 29%.[9] Some of this low scoring may be attributed to a belief prevalent in rural China that wearing eyeglasses can worsen uncorrected visual acuity (VA).[6–8]

Previous studies[10–16] have been inconclusive about the impact of eyeglasses wear on uncorrected VA. The majority of these studies have identified correlations between eyeglasses wear and uncorrected VA, but have not identified a causal link. Only one previous trial has addressed causality between wearing eyeglasses and VA.[17] Using a cluster-randomised, investigator-masked, controlled trial, this study found no evidence that receiving free eyeglasses worsened uncorrected VA among primary school students in western rural China. However, little is known about the effects of eyeglasses wear on uncorrected VA among middle school students. In rural western China, middle school students may have higher rates of refractive error (50%[5] vs 24%[18]) and eyeglasses ownership (31%[5] vs 15%[3]) on account of their age. Additionally, unlike primary school students, middle school students are more likely to choose whether to wear eyeglasses based on peer influences and social stigma.[5] In the light of the previous finding, we sought to replicate the previously proven results in a different cohort.

To carry out this replication, we conducted a parallel cluster-randomised trial that provided free accurate eyeglasses to middle school students with refractive error in northwestern rural China. We now report an intention-to-treat (ITT) analysis of the effect of providing free eyeglasses on uncorrected (without eyeglasses) VA over the course of a school year, approximately 9 months. An advantage of the current trial is that middle school students have higher rates of refractive error and eyeglasses ownership than primary school students on account of age. Additionally, middle school students must spend more time preparing for high school entrance examinations, which involves increased reading and near work, further worsening uncorrected VA.[19 20] We hypothesise that uncorrected VA of students in the intervention group will not be worse than students in the control group, adjusted for baseline VA.

METHODS

The current study follows the methods of 'Seeing is Believing: Experimental Evidence of the Impact of Eyeglasses on Academic Performance, Aspirations and Dropout among Junior High School Students in Rural China', which have been expressed elsewhere, and are summed up for reference.[5]

Setting

The study was conducted in three nationally designated poverty counties in the Yulin Prefecture of Shaanxi Province. Yulin Prefecture was chosen for the net income (¥9730, equal to $1569) of rural residents in 2014, which was close to the Chinese national rural average income (¥9892 in 2014).[21]

Sampling and eligibility criteria

The list of middle schools from the three counties was provided by the local boards of education, from which 32 schools were randomly selected from a total of 47. One grade 7 class and one grade 8 class from each of 31 selected schools (one school departed from the study after the baseline survey) responded to questionnaires and participated in VA and refraction testing. Students in the selected classes who met any of the following criteria were eligible for the trial: uncorrected (without eyeglasses) VA ≤6/12 in either eye; refractive error as follows: myopia ≤−0.75 dioptres (D); hyperopia ≥+2.00 D, or astigmatism (non-spherical refractive error) ≥1.00 D; VA which could be improved to 6/7.5 in both eyes with eyeglasses.

Questionnaire

At baseline (September 2013, beginning of the school year), enumerators administered questionnaires to students. The questionnaire included items concerning student age,[7 18] gender,[7 18] eyeglasses usage at baseline, boarding status,[18] rural residence status,[22] only child status,[23] belief that wearing eyeglasses harms vision (a common misconception in rural China),[7 17] time spent on cellphones or computers,[20] parental migration status,[18] parental eyeglasses wear[24] and parental education level.[3 6 7 24] Students who owned eyeglasses were told to bring their eyeglasses to school on the day of the baseline examination to measure baseline eyeglasses ownership. In addition, mathematics teachers quantified their blackboard use as a portion of their teaching time (all, most, about half, little, or not at all), which was considered a possible factor driving students with uncorrected refractive error to use eyeglasses. At endline, children were asked whether they were satisfied with the style of the frames of their eyeglasses, the thickness of the lenses and the ease with which glasses could be cleaned.

VA assessment

Using an Early Treatment Diabetic Retinopathy Study chart[25] (Precision Vision, La Salle, Illinois, USA), a nurse and trained assistant carried out VA testing for each student without refraction at 4 m in a well-lit and indoor area. The top (6/60) line was tested first, and we defined VA of each eye as the lowest line in which a student could identify at least four of five optotypes correctly. If a student could not identify the top line at 4 m, the test was conducted at 1 m, and the measured VA was divided by 4.

Refraction

Students with uncorrected VA ≤6/12 in either eye experienced cycloplegia with up to three drops of cyclopentolate 1%. A refractionist, previously trained by experienced paediatric optometrists from Zhongshan Ophthalmic Center, Sun Yat-sen University, conducted automated refraction (Topcon KR-8900; Tokyo, Japan) with subjective refinement for students. Approximately 10 different styles of child-friendly frames were prepared for the children. Children were permitted to choose the frames they preferred.

Randomisation and interventions

Schools acted as clusters in the cluster-randomised controlled trial (figure 1). In October 2013, after the

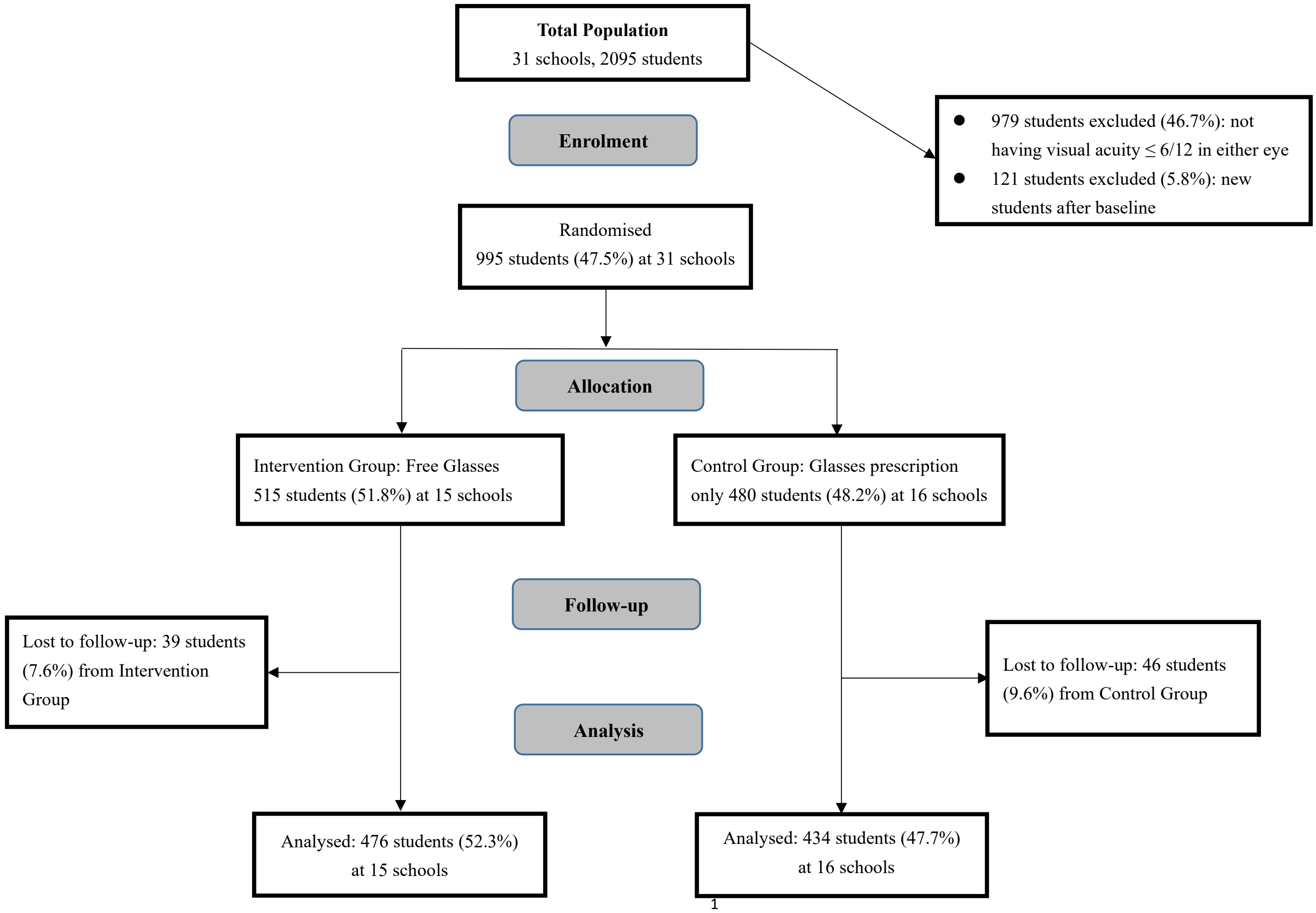

Figure 1 Flow chart for enrolment and allocation of students with refractive error in a randomised trial of free eyeglasses to promote eyeglasses wear.

baseline survey and vision screening but earlier than refraction testing, eligible students were randomised by school to receive one of two interventions (figure 1).

Control group: An eyeglass prescription was given to parents of students on completion of refraction testing. The students in the control group were given free eyeglasses after finishing the endline survey, which was masked to students and teachers in control schools at the beginning of the study.

Intervention group: Based on student refractive power, as tested at school by the optometrist, free eyeglasses were given to the students in the intervention group on completion of refraction testing.

R software (R Foundation for Statistical Computing, Vienna, Austria) was used to generate blocks and assign schools at random within each block to the intervention arm at Stanford University (Palo Alto, California, USA). Participants (students, parents and teachers) and enumerators were unaware of the overall design of the study and the explicit intervention arm assignment.

Outcome assessment

At endline, students' VA was reassessed by using the protocol and vision chart described above. The main outcome measure of this study is uncorrected LogMAR VA after 9 months, adjusted for baseline VA. Higher values on the LogMAR scale indicated worse vision. Two methods were used to evaluate students' eyeglasses wear. Nine months after eyeglasses distribution, trained enumerators, unaware of group assignment, went to observe eyeglasses wear during class, which was masked to sampled students. Additionally, enumerators also asked all sampled students in both control and intervention schools to describe their eyeglasses wear as 'most of the time', 'sometimes', 'rarely' or 'never'. Positive self-reported wear was defined as wearing eyeglasses 'most of the time' and 'sometimes'.

Statistical methods

Baseline eyeglasses ownership was defined as the ability to produce eyeglasses at school at the time of the baseline survey. Refractive power was defined throughout as the spherical equivalent (spherical power plus half the cylindrical power).[26]

We performed analysis in ITT fashion using multivariate regression models in Stata V.14.2 (StataCorp, College Station, Texas, USA), which calculated robust SEs to adjust for clustering at school level. In the analysis, we use multivariate regression models to assess the correlation between baseline variables, and endline uncorrected VA adjusted for baseline VA. All the variables (baseline uncorrected VA, assignment to the intervention group, gender, baseline eyeglasses ownership, only child status, time spent on computers, refractive error and blackboard use) were included in the multivariate regression models with p≤0.20 in the univariate analysis.[3 17 27 28]

Missing data: To reduce the inefficiency of estimation due to missing values, multiple imputation in Stata was used to impute data for several variables at baseline, including total time spent on phone (n=2), belief that wearing eyeglasses harms vision (n=1), parental migration status (n=9), parental eyeglasses wear (n=3), rural residence status (n=1), parental education level (n=1) and refractive error (n=32).

RESULTS

Among 2095 students screened at 31 selected schools, 995 (47.5%) failed VA screening and were randomised (figure 1). A total of 15 schools (515 students, 51.8%) were randomly assigned to the intervention group (free eyeglasses) and the remaining 16 schools (480 students, 48.2%) were assigned to the control group (only eyeglasses prescriptions given to the parents). A total of 39 students (absent at endline survey) were excluded from the intervention group and 46 (absent at endline survey) from the control group, leaving 476 students (52.3%) at 15 schools allocated to intervention group and 434 children (47.7%) at 16 schools allocated to control group (figure 1). Therefore, 910 students underwent analysis.

Among the 910 students allocated to the study, students in the intervention and control groups did not differ significantly in any individual-level or cluster-level variables at baseline, including baseline uncorrected VA (mean 0.64 in both groups, table 1). Endline eyeglasses

Table 1 Baseline characteristics of 910 students with correctable myopia allocated in a trial of eyeglasses provision, by intervention group assignment

Variable	Control group (n=434* at 16 schools)	Intervention group (n=476* at 15 schools)	P value, control versus intervention	Missing data, n (%)
Age (years), mean (SD)	13.64 (1.19)	13.49 (1.08)	0.219	0
Baseline uncorrected visual acuity (LogMAR)†	0.64 (0.25)	0.64 (0.26)	0.974	0
Total time spent on phone (hours/day)	0.87 (1.05)	0.97 (1.27)	0.526	2 (0.22)
Total time spent on computer (hours/day)	0.62 (1.02)	0.51 (1.03)	0.384	0
Male gender, n (%)	193 (44.47)	211 (44.33)	0.969	0
Only child in family, n (%)	42 (9.68)	34 (7.14)	0.237	0
Believes wearing eyeglasses harms vision, n (%)	168 (38.71)	218 (45.80)	0.173	1 (0.11)
Baseline eyeglasses ownership, n (%)‡	145 (33.41)	192 (40.34)	0.314	0
VA <6/18 both eyes, n (%)	314 (72.35)	353 (74.16)	0.692	0
Boarding at school, n (%)	306 (70.51)	371 (77.94)	0.155	0
Both parents migrant out, n (%)	25 (5.76)	25 (5.25)	0.754	9 (0.99)
At least one family member wearing eyeglasses, n (%)	123 (28.34)	157 (32.98)	0.161	3 (0.33)
Rural residence, n (%)	401 (92.40)	459 (96.43)	0.091	1 (0.11)
At least one parent with ≥9 years of education, n (%)	399 (91.94)	449 (94.33)	0.290	1 (0.11)
Mean (SD) refractive error (dioptres), n (%)			0.231	32 (3.52)
≤−2	223 (51.38)	274 (57.56)		
−2 to −0.5	181 (41.71)	179 (37.61)		
0.5–0.5	19 (4.38)	16 (3.36)		
≥0.5	11 (2.53)	7 (1.47)		
Blackboard use, n (%)			0.676	0
<Half of teaching	213 (49.08)	196 (41.18)		
Half of teaching	96 (22.12)	129 (27.10)		
>Half of teaching	125 (28.80)	151 (31.72)		

*Data are presented as mean (SD) or number (%) unless otherwise stated.
†0.1 change in LogMAR indicates 1 line change on the vision chart.
‡Defined as being able to produce eyeglasses at school, having been told the day before to bring them.
LogMAR, logarithm of the minimum angle of resolution; VA, visual acuity.

Table 2 Effect of intervention arm in a trial of eyeglasses provision on final uncorrected visual acuity (LogMAR) of both eyes

Intervention group	n	Mean baseline uncorrected LogMAR visual acuity (SD)	Mean endline uncorrected LogMAR visual acuity (SD)	Unadjusted change in LogMAR visual acuity (95% CI)	Effect of interventions on endline uncorrected visual acuity adjusted for baseline acuity (95% CI)*
Total	910	0.644 (0.251)	0.728 (0.237)	−0.085* (−0.098 to 0.072)	–
Control	434	0.644 (0.246)	0.733 (0.235)	−0.089* (−0.108 to 0.070)	(Reference)
Intervention	476	0.643 (0.255)	0.724 (0.239)	−0.081* (−0.099 to 0.062)	0.008 (−0.018 to 0.034)

Though higher values on the LogMAR scale indicate worse vision, we have followed the convention in this table that negative change indicates worsening and positive change indicates improvement.
*P<0.05.
LogMAR, logarithm of the minimal angle of resolution.

wear was 44% (observed: 209/476) to 71% (self-reported: 339/476) in the intervention group, and 36% (observed: 157/434) to 50% (self-reported: 215/434) in the control group. In the treatment group, over 75% of children were satisfied with the style of their frames (77.0%), thickness of the lenses (88.2%) and ease with which the glasses could be cleaned (76.5%).

Endline VA adjusted for baseline VA in the intervention group was better than that of control students (difference: 0.008 LogMAR units, 95% CI −0.018 to 0.034, 0.08 lines on

Table 3 Linear regression model of potential predictors of final uncorrected LogMAR visual acuity

Variables	Model adjusted only for baseline visual acuity (n= 910)		Full model* (n=910)	
	Regression coefficient†‡ (95% CI)	P value	Regression coefficient‡ (95% CI)	P value
Baseline uncorrected visual acuity (LogMAR)	0.335 (0.284 to 0.386)	<0.001	0.414 (0.340 to 0.487)	<0.001
Intervention group	0.034 (−0.012 to 0.080)	0.142	0.045 (0.006 to 0.084)	0.027
Age	−0.001 (−0.012 to 0.010)	0.839		
Male gender	0.022 (0.003 to 0.041)	0.025	0.023 (0.003 to 0.043)	0.026
Only child in family	−0.045 (−0.099 to 0.009)	0.097	−0.041 (−0.091 to 0.009)	0.102
Believes wearing eyeglasses harms vision	−0.003 (−0.028 to 0.021)	0.776		
Baseline eyeglasses ownership†	−0.054 (−0.079 to −0.028)	<0.001	−0.042 (−0.067 to −0.016)	0.002
VA <6/18 both eyes	−0.005 (−0.049 to 0.039)	0.824		
Both parents migrant out	0.014 (−0.020 to 0.049)	0.41		
Total time spent on phone (hours/day)	0.001 (−0.010 to 0.012)	0.869		
Total time spent on computer (hours/day)	0.015 (0.001 to 0.029)	0.037	0.012 (−0.002 to 0.027)	0.083
Rural residence	−0.005 (−0.059 to 0.049)	0.843		
At least one parent with ≥9 years of education	0.015 (−0.031 to 0.061)	0.512		
Boarding at school	−0.014 (−0.044 to 0.016)	0.35		
At least one family member wearing eyeglasses	−0.005 (−0.025 to 0.014)	0.572		
Mean (SD) refractive error (dioptres) (−0.5 to 0.5 D as reference)				
≤−2	−0.093 (−0.166 to −0.021)	0.013	−0.083 (−0.155 to −0.011)	0.025
−2 to −0.5	−0.041 (−0.098 to 0.016)	0.155	−0.040 (−0.098 to 0.019)	0.178
≥0.5	0.060 (−0.051 to 0.171)	0.28		
Blackboard use (less than half as reference)				
Half of teaching	−0.044 (−0.082 to −0.006)	0.024	−0.048 (−0.083 to −0.013)	0.009
>Half of teaching	0.007 (−0.050 to 0.066)	0.787		

*Including variables associated with visual acuity p≤0.20 in the model only adjusted for baseline visual acuity.
†Except for the regression coefficient for baseline visual acuity (simple regression), coefficients for the different variables are for multivariate regression models with endline visual acuity as dependent variable, adjusted for baseline visual acuity.
‡A negative regression coefficient indicates an association with worse endline visual acuity.
LogMAR, logarithm of the minimum angle of resolution; VA, visual acuity.

the VA chart) (table 2). In multivariate regression models (table 3), better uncorrected endline VA was associated with the following: better baseline VA (0.414 LogMAR units, 95% CI 0.340 to 0.487, p<0.001), assignment to the intervention group (0.045 LogMAR units, 95% CI 0.006 to 0.084, p=0.027), male gender (0.023 LogMAR units, 95% CI 0.003 to 0.043, p=0.026), lack of eyeglasses usage at baseline (−0.042 LogMAR units, 95% CI −0.067 to 0.016, p=0.002), lack of myopic refractive error (≤−2 D: −0.083 LogMAR units, 95% CI −0.155 to 0.011, p=0.025) and blackboard use (half of teaching: −0.048 LogMAR units, 95% CI −0.083 to 0.013, p=0.009). Age, only child status, belief that wearing eyeglasses harms vision, uncorrected VA <6/18 in both eyes, parental migration status, total time spent on phone, total time spent on computer, rural residence status, parental education level, boarding status and parental eyeglasses wear were not significantly associated with endline VA in multivariate regression models.

DISCUSSION

Results from the ITT analysis of the randomised trial show no evidence that receiving free eyeglasses worsened uncorrected VA among middle school students in northwestern rural China. The worsening of VA happened in both groups, and providing free eyeglasses slightly slowed the deterioration of VA rather than promoting it.

This study replicates the conclusion of a previously proven study in which free eyeglasses were distributed to primary school students in western rural China.[17] This study provides strong evidence for the visual safety of eyeglasses wear for middle school students in northwestern rural China. The mean beneficial impact of providing free eyeglasses on final VA, over all students in the intervention group, was 0.045 LogMAR units (0.45 lines on the VA chart) over a school year. Eyeglasses wear was 44%–71% in the intervention group and 36%–50% in the control group. Thus, improving the eyeglasses wear of middle school students makes a positive difference in vision protection.

We searched the PubMed database in June 2020 for articles describing randomised trials in any language published since 1970, using the terms 'correction', 'glasses' and 'spectacles' cross-indexed with 'refractive error' and 'myopia'; 'change', 'decline', 'effect' and 'impact'; and 'vision' and 'visual acuity'. Apart from the article[17] mentioned above, two previous studies[11 12] assessed the effect of eyeglasses on change in refractive power. These studies used glasses which fully corrected refractive error over a period of 18–24 months, resulting in improvements in vision between 0.5 and 0.75 D. These studies also found less progression of refractive error in the full-power group by 0.15 D,[11 12] consistent with our study. When the results were pooled in a subsequent Cochrane review, the effect was significant. However, the samples in the two studies totalled less than 200 students, and the studies were not randomised into intervention and control groups, without reporting on VA.

The strengths of the current study include randomised design, high follow-up rates (>90%) and population-based sampling, increasing confidence in the results. Two main limitations of the current study are presented as follows. First, the study was carried out in one poor region of northwestern China, therefore the application of these results to other settings must be made with caution. Second, compliance with eyeglasses wear was imperfect, which means that the results may underestimate the true effect of eyeglasses wear on refractive power.

The leading cause of visual impairment is uncorrected refractive error among students worldwide.[4] The current study provides strong evidence for the safety of eyeglasses wear for middle school students with uncorrected refractive error. Considering that the main trial result shows statistically significant improvements in academic performance, aspirations and dropout with eyeglasses provision,[5] the current result provides further impetus for programmes to distribute eyeglasses for students requiring them, whether they are in primary or middle school.

Recently, Chairman Xi Jinping made important instructions regarding the problem of myopia in children in August 2018, in light of China having the highest prevalence of myopia in the world.[29] Previous trials in China,[17] in addition to the current study, have demonstrated the safety of eyeglasses on students with myopia in primary and middle schools in rural western and northwestern China, respectively, which is of practical significance in aiding the Chinese government's efforts against myopia.

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Contributors Conceptualisation: YM. Data curation: YM. Formal analysis: XZ. Investigation: YM. Methodology: XM and XP. Project administration: YM. Supervision: NC, MZ and SR. Writing—original draft: XZ, HL and YM. Writing—review and editing: DF, YM and NC.

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Disclaimer XZ and YM conducted and are responsible for the data analysis.

Competing interests Prof Congdon is Director of Research for Orbis International, a non-governmental organization which delivers children's refraction among other services in China and other countries.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval The protocol of this study was approved by the Stanford University Institutional Review Board. Permission was received from local boards of education in each county, and the principals of participating schools. We adhered to the principles of the Declaration of Helsinki throughout the study.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon request.

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