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Manuscript title

Spectacle wearing in children randomized to ready-made or custom-made spectacles: results from a randomized non-inferiority trial

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Key points

Question: What is the proportion of children wearing spectacles at 3-4 months who are randomized to ready-made or custom-made spectacles?

Findings: In this randomized clinical trial that included 460 children, the proportion of children wearing spectacles in both arms was similar, 75% in the ready-made arm vs. 74% in the custom-made arm.

Meaning: This suggests that in school eye health programs, ready-made spectacles could be used instead of the more expensive custom-made spectacles.

Importance:

Uncorrected refractive errors are the commonest cause of visual impairment in children despite correction being highly cost effective.

Objective:

To determine whether lower cost ready-made spectacles give comparable rates of spectacle wear at 3-4 months as more expensive custom-made spectacles amongst eligible school children aged 11-15 years.

Design:

Non-inferiority, double masked, randomized controlled trial. Recruitment occurred between January-July 2015, and follow-up between March and October 2015.

Setting:

Government schools in urban and peri-urban areas surrounding Bangalore, India.

Participants:

Children eligible for ready-made spectacles i.e., who failed vision screening at the 6/9 level in each eye; where refraction was indicated; whose acuity improved with correction by two or more lines in the better seeing eye and the corrected acuity with the spherical equivalent was not more than one line less than with full correction; anisometropia <1.0 dioptre and appropriate frame available.

Intervention:

Eligible children were randomized to ready-made or custom-made spectacles.

Main Outcome(s) and Measure(s):

Proportion of children wearing their spectacles at unannounced visits 3-4 months.

Results:

23,345 children aged 11-15 years were screened. 694 failed screening, 535 of whom were assessed for eligibility. 460 (49.3% female) children eligible for ready-made spectacles (2.0% of those screened; 86.0% of those assessed) were randomized to ready-made (232) or custom-made (228) spectacles. Follow-up rates at 3-4 months were similar (79.3% ready-made; 78.1% custom-made). Spectacle wear in the two arms were similar: 139/184 (75.5%) ready-made arm; 131/178 (73.6%) custom-made arm (risk difference 1.8%; 95% confidence interval -7.1-10.8%).

Conclusions and Relevance:

The majority of children were eligible for ready-made spectacles, and the proportion wearing ready-made spectacles was not inferior to the proportion wearing custom-made spectacles at 3-4 months. These findings suggest ready-made spectacles could substantially reduce costs for school eye health programs in India without compromising spectacle wear, at least in the short run.

Trial Registration: www.isrctn.com Identifier: ISRCTN14715120

The proportion of visual impairment due to uncorrected refractive errors (uRE) in children aged 3-15 years varies from 72.6% in Australia,¹ 82% in India² and 97.1% in China.³ Uncorrected REs are the commonest cause of visual impairment in children in all regions, affecting an estimated 12.4 million children,⁴ despite correcting RE being highly cost effective.⁵⁻⁷ Incidence of myopia in children is increasing globally in what is now an 'epidemic' in East Asia, Europe and United States.⁸ In Singapore, China, Taiwan, Hong Kong, Japan and Korea, 80-90% of children completing high school are now myopic.^{8,9} Variation in prevalence of uRE in children by age and urban/rural location is evident in India too.^{2,10,11} In a 2002 study in urban India, 7.4% children aged 5-15 years were myopic, and 82% of visual impairment was due to uRE.¹² In a similar study in rural India 4.1% of children aged 7-15 years were myopic and 61% of visual impairment was due to uRE.¹⁰ In both studies older children had a higher prevalence of uRE than younger children.

Complex refractions require spherical and astigmatic correction and in clinical practice these are usually fully corrected. In this trial these are referred to as "custom-made" spectacles. Simple REs, where there is low or no astigmatism and minimal difference in spherical correction between the two eyes, can be corrected using low cost spectacles which have the same spherical equivalent (SE) in both eyes. These are referred to as "ready-made" spectacles. Two broad criteria need to be fulfilled prior to dispensing ready-made spectacles: prescription is suitable, and frames available are of the correct size and fit.

The high levels of visual impairment due to uRE have led to school programs for RE in many countries, and organizations are supporting large scale programs, including in India.¹³ However, approaches are not standardized and most do not use guidelines or prescribing protocols, nor is spectacle wear usually monitored.¹⁴ Available evidence suggests spectacle wear among children with RE can be low in all settings, 13% in Mexico,¹⁵ 29.4% in rural areas near Delhi¹⁶ and 33.2% among native American students.¹⁷ Spectacle wear is higher in children with more severe uRE¹⁹ and in girls,²⁰ but associations between socioeconomic status or parental education are

inconclusive.^{14,17,21} In a recent study in India only 30% of children dispensed spectacles were wearing them at 6-12 months, being higher amongst girls, those with higher REs and poor uncorrected visual acuity (VA), and whose fathers were better educated.²²

To our knowledge, school eye screening programs in India dispense custom-made spectacles regardless of severity or type of RE. These spectacles are more expensive to dispense than ready-made spectacles, requiring the time of dispensing opticians, and cannot be dispensed immediately in schools, they must be delivered which increases costs. Costs are therefore likely to be higher for parents and providers if custom-made spectacles are used rather than ready-made.

We have identified two trials which have compared ready-made with custom-made spectacles for children with uRE, both undertaken in China.²³ The trial by Zeng had a superiority design and children with high degrees of astigmatism or anisometropia were excluded. Children were individually randomized to custom-made or ready-made spectacles. Spectacles were prescribed based on RE and level of uncorrected VA but not corrected VA or improvement in VA, factors known to increase spectacle wear.^{17-20,22} Subsequent spectacle wear was defined as children observed to be wearing their spectacles at an unannounced visit. At one month, similar proportions of children were wearing their spectacles (46.9% ready-made vs 51.5% custom-made spectacles, a difference of 5.4%, $p = 0.23$). The purpose of the other trial, which had a non-inferiority design, was to assess the impact of spectacle correction on quality of life.²⁴ Self-reported spectacle wear was high (>94.7%) in all groups, including those dispensed ready-made spectacles.

In our trial a non-inferiority design was used with the null hypothesis being that the proportion of children wearing their ready-made spectacles (intervention) at 3-4 months would not be inferior to the proportion wearing custom-made spectacles (standard care). A non-inferiority design was chosen as benefits of ready-made spectacles are considerably lower cost and ease of dispensing which would increase program efficiency. Under these circumstances a slightly lower acceptance of ready-made spectacles, measured by observed spectacle wear, might be acceptable. The non-

inferiority margin of 10% was chosen based on the trial by Zeng outlined above²³ to balance considerations of efficacy and secondary benefits, and the maximum difference we were prepared to tolerate if ready-made spectacles were not to be considered clinically inferior.²⁷ The trial protocol was published in January 2016.²⁸

This prospective, randomised controlled trial was undertaken in government schools in and around Bangalore, India. Reporting follows the CONSORT 2010 Checklist for non-inferiority and equivalence trials.²⁹

METHODS

The study adhered to the Declaration of Helkinki. The trial was approved by the Interventions and Research Ethics Committee, London School of Hygiene & Tropical Medicine, and the Institutional Review Board of Sankara Eye Hospita. All parents of children eligible to be recruited to the trial provided written informed consent and assent was provided by children. Children requiring further examination or spectacles for complex REs were not recruited and referred to Sankara Eye Hospital, Bangalore for free examination, and spectacles if required.

A list of government secondary schools in urban and peri-urban areas surrounding Bangalore, Karnataka State, was obtained from the District Education Officer. Schools were excluded if eye screening had taken place within two years. Schools were stratified by location (urban/rural) and size (more or less than 200 children aged 11-15 years) then randomly selected using block randomization. The Principal of each selected school was visited by a field worker who obtained written informed consent for school participation. An information sheet in the local language was given to each child aged 11-15 years to take home, for parents to sign if they did not want their child to be screened and given spectacles, if required.

Field workers who were part of an earlier study, were recruited and underwent further training in VA screening, including assessment of inter-observer agreement.

Participants and eligibility

Recruitment took place between 12 January-31 July 2015. Screening was offered to all children aged 11-15 years present at school at time of screening, using the 6/9 row of 5 tumbling Es on an illuminated, distance acuity logMAR chart, testing each eye separately. To pass children had to correctly identify four or five Es. Children who failed screening i.e. presenting VA of less than 6/9 in each eye, were referred to study optometrists who retested their VA using a full logMAR chart. If a child could see 6/9 in both eyes on repeat testing no further action was taken. Children confirmed with a VA less than 6/9 in both eyes underwent objective and subjective refraction and assessed for frame size to ascertain if they fulfilled eligibility criteria for the trial. As ready-made spectacles have only spherical lenses, SE was calculated for each eye. All children with a VA of less than 6/9 also had a basic eye examination.

To be eligible for recruitment the following criteria had to be met: a) VA with full correction improved in the better seeing eye by two or more lines, b) the SE corrected the VA to not more than one line less than best corrected VA with a full prescription in the better eye, c) the difference between SE of right and left eyes was not more than 1.0D, d) inter-pupillary distance matched that of ready-made spectacle frames available (i.e. 54 to 62mm) and e) spectacle frames were of acceptable size and fit. Exclusion criteria: children with other causes of visual impairment and where parental consent was not obtained. Ineligible children were either prescribed custom-made spectacles or referred to Sankara Eye Hospital.

Eligible children were recruited by optometrists and given a unique identifier (ID) and a red card with the child's name and ID, class and their father's name.

Interventions

The intervention was ready-made spectacles i.e., same spherical correction in each eye. The comparator was custom-made spectacles i.e., dispensed on basis of a prescription from study optometrists. In this study all spectacles were made at Sankara Eye Hospital. All children had same choices of frames and all spectacles were delivered to the school at the same time. The latter was to mask students to the arm they were allocated to.

Children recruited to the trial select the frames they preferred from a range of six different coloured plastic and metal frames. Ready-made and custom-made spectacles were delivered to each school by a field worker and optometrist on the same day, within two weeks of refraction, to maintain masking. Each child's identity was confirmed by the teacher and checked against the red card. Spectacle fit was assessed and corrected distance VA was measured in each eye.

Outcome and ascertainment of primary outcome

Spectacle wear was categorised as follows: children were a) wearing their spectacles at time of the unannounced visit; b) not wearing their spectacles but had them at school; c) were not wearing their spectacles but said they were at home; and d) children said they no longer had the spectacles as they were broken or lost.¹⁴ Categories a) and b) were defined as wearing and categories c) and d) as non-wearing.

Field workers made unannounced visits to study schools 3-4 months after spectacles were delivered, to assess the proportion of children wearing their spectacles. They were given a list of children dispensed spectacles and they went to the relevant classrooms where teachers identified each child. Whether the child was wearing their spectacles was noted. If they were not, the child was interviewed in another room to explore whether they had their spectacles with them, which they were asked to show field workers.

Sample size calculation

Sample size was calculated using *Sealedenvelope*³⁰ assuming a non-inferiority margin (Δ) of 10%, considering a difference of 10% or less in spectacle wear would be acceptable. Other parameters included were 95% confidence level, 80% power, and 1:1 allocation. Sample size was not increased to allow for loss to follow-up, high follow-up at 3-4 months was anticipated as communities are stable and few study children were expected to leave school during the academic year.

Randomisation and masking

After recruitment children were randomly assigned individually to ready-made or custom-made spectacles in a ratio of 1:1. Block randomization with variable block sizes, stratified by school, was computer generated by an epidemiologist away from the study site. Sequentially numbered, sealed,

stamped opaque envelopes containing labels with unique study ID numbers and random allocation were prepared by persons not involved in the trial. At the study site the optometrist opened the envelopes.

Children, teachers and parents were masked to the allocation arm. To maintain masking a field worker and optometrist not previously involved in the trial were trained to assess the primary outcome.

Statistical analysis

Data were double entered by the lead investigator at regular intervals to monitor recruitment. After data cleaning, range and consistency checks, primary analysis was undertaken to compare spectacle wear in both arms. Characteristics of children in both arms were compared. All analyses were undertaken according to the group to which the child had been allocated. The outcome is presented as the difference in the proportion wearing spectacles and 95% confidence interval of the difference. Analyses were pre-specified.²⁸ All analyses were performed using STATA 14.1 (StataCorp, Texas, USA).

RESULTS

All school principals approached agreed that their school take part in the trial and no parent or child refused consent. 23,345 children were screened in 112 government schools (Figure 1), 694 (3.0%) of whom failed the screening test i.e. they had a presenting VA <6/9 in each eye. 39 children were excluded as their VA was 6/9 or better in one or both eyes on retesting. A further 120 were excluded after refraction and basic eye examination: 45 required specialist refraction, 38 their VA did not improve by two or more lines, 33 had pathology that required specialist examination and four were excluded: one wanted contact lenses. one refused spectacles, two had learning disabilities. Among the 535 children assessed for eligibility for ready-made spectacles, 75 (14.1%) children were excluded as they did not meet all requirements for ready-made spectacles, mainly their VA with SE

was more than one line worse than with a full prescription (55 children). 86.0% of children assessed were, therefore, eligible for ready-made spectacles.

A total of 460 children eligible for ready-made spectacles were recruited between January-July 2015, 49.3% of whom were female. 232 children were randomized to ready-made and 228 to custom-made spectacles. All children received the correct spectacles and had a corrected VA of at least 6/9 in each eye with their new spectacles at the time of delivery two weeks later. The mean SE was similar in both arms of the trial (ready-made: -1.51D; custom-made: -1.42D, but the range of SE in the better eye was wider in the custom-made arm than ready-made arm (Table 1). All other baseline variables were similar in both arms.

Overall 78.7% (362/460) of children were identified in their schools at follow-up (Table 2). Follow-up was similar in both arms: 184/232 (79.3%) ready-made and 178/228 (78.1%) custom-made. All children not traced in school (98) had changed schools and moved to a different area. Children not followed up in the ready-made arm were more likely to be male, and have parents who did not wear spectacles. Children not followed up in the custom-made arm were more likely to have a literate father and better presenting VA.

Overall 74.6% (270/362) of children were wearing their spectacles or had them at school, ready-made:75.5% (139/184) and custom-made:73.6% (131/178). The risk difference between the two arms was 1.8% (95% confidence interval -7.1 to 10.8%). The proportion of children given spectacles and wearing them were 68.5% (ready-made) and 62.9% (custom-made). Other children had their spectacles with them (7.1% (ready-made) and 10.7% (custom-made).

DISCUSSION

In our trial majority of children assessed were eligible for ready-made spectacles, as reported in the two other studies.^{23,24} At the 3-4 month follow-up spectacle wear was similar in both arms. These are important findings, suggesting that ready-made spectacles, which can be purchased in bulk at very

low cost, would be suitable for majority of children with uRE in this setting without compromising spectacle wear. In addition to lower purchase cost, ready-made spectacles can be dispensed on site at the time of refraction, which reduces the cost of dispensing optician's time and visits to schools by service providers. In some programs children are given a prescription for spectacles which parents collect from the opticians or eye department. Ready-made spectacles delivered on site would, therefore, reduce travel and opportunity costs for parents. However, dispensing ready-made spectacles in schools would require a relatively large inventory of frames (sizes, colours, shapes) with a range of powers. A recent innovation, called "clip-and-go" spectacles, would reduce the inventory required. Lenses of the same shape are used for each eye and lenses of relevant powers are clipped into frames. Pilot studies could provide information on frame preference, sizes needed and range of powers required, all of which are likely to be context dependent.

Spectacle wear in our trial was much higher than in other studies of children of similar ages.^{12,15,18,19,22 16}. There could be several reasons for this. Firstly, in our trial only children with significant uRE who had improvement of two or more lines in VA in the better seeing eye were prescribed spectacles, unlike in the trial by Zeng et al. Second, children were refracted only if both eyes had a presenting VA of less than 6/9. Most other studies define screening failure as a reduced VA in one or both eyes, and in the absence of prescribing guidelines, many children are prescribed spectacles when they already have good VA in one eye. This lowers spectacle wear as children do not perceive any benefit. How screening failure is defined and use of prescribing guidelines are important to ensure that children are only prescribed spectacles if they have the potential to benefit. Another difference was children were given the opportunity to choose spectacle frames they preferred. Studies frequently report that if children do not like the appearance of their spectacles they are less likely to wear them.^{15,18,25} Comparison with other studies is difficult, as definitions of spectacle wear and time intervals between dispensing and follow-up vary between studies. The Zeng et al trial, had a superiority design and was powered to detect a 15% difference in spectacle wear, it had short follow-up, and definition of significant RE was not based on improvement in VA

with correction. In our trial significant RE was clearly defined, follow-up was longer (3-4 months) and used more established ways of assessing spectacle wear.^{14,15,18,19,22,25,26}

Other strengths of our study include the non-inferiority design, the large sample size which was representative of the school-going population in the study area and primary outcome was assessed by direct observation, as in other studies,^{14,15,18} rather than self-report which may induce response bias, particularly as the trial involved children. The findings can, therefore, be extrapolated to other school-going children aged 11-15 years in this part of India. However, the proportion of children eligible for ready-made spectacles is likely to vary across India, as the type and degree of REs vary.^{10,16}

A limitation of this study was loss to follow-up of children who had left or moved to another school in a different location. However, characteristics of those followed-up and those lost to follow-up are similar. Another limitation was spectacle wear was assessed at 3-4 months rather than a longer time. Although longer follow-up would be desirable this is challenging as children often move school at the end of the academic year making follow-up difficult.

Ours is the first study to our knowledge to use clearly defined prescribing guidelines, which may be one explanation for high rates of spectacle wear at follow-up. However, as this approach was used in both arms other factors may also have been important. Further studies may be of value to address the effect of prescribing guidelines on spectacle wear amongst children.

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Author contributions

PM: Conception and design; data collection; manuscript writing and final approval of the manuscript. The corresponding author had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

CG: Conception and design; revising draft for important intellectual content; final approval of the manuscript.

JE: Design; revising draft for important intellectual content; final approval of the manuscript;

KM: Design; revising draft for important intellectual content; final approval of the manuscript.

Conflict of interest disclosures

None declared.

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Role of the funding source

The study was designed by the principal investigator (PM) and CG in collaboration with the other authors. The funders of the study had no role in the data analysis, data interpretation, or writing the report.

The funding sources 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.

PM had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Table 1: To show the baseline characteristics of children randomized

	Ready-made spectacles		Custom-made spectacles	
Socio-demographic variables	Mean (SD)	Range	Mean (SD)	Range
Age	13.4 (1.28)	11-15	13.6 (1.28)	11-15
	N	%	N	%
Gender - female	111	47.8	116	50.9
Location - rural	73	31.5	70	30.7
Parental literacy				
Father only	38	16.4	57	25.0
Mother only	38	16.4	42	18.4
Both parents	90	38.8	80	35.1
Neither parent	66	18.5	49	21.5
Parental spectacle wear				
Father only	25	10.8	29	12.7
Mother only	18	7.8	19	8.3
Both parents	6	2.3	3	1.3
Neither parent	183	78.9	177	77.6
Clinical characteristics				
Presenting VA in better eye				
<6/9 - 6/12	62	49.6	63	50.4
<6/12 - 6/18	75	51.0	72	49.0
<6/18 - 6/60	91	51.7	85	48.3
<6/60	4	33.3	8	66.7
	Mean (SD)	Range	Mean (SD)	Range
Spherical equivalent (better eye)	-1.51(0.92)	+0.50 to -5.50	-1.42 (1.20)	+2.25 to -9.50

Table 2: Characteristics of children in both arms of the trial followed up and lost to follow-up

Randomized to	Ready-made n=232				Custom-made n=228			
	Followed up n=184		Lost to follow-up n=48		Followed up n=178		Lost to follow-up n=50	
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
Socio-demographic variables								
Age	13.3	11-15	13.8	11-15	13.6	11-15	13.7	11-15
	N	%	N	%	N	%	N	%
Female	93	50.5	18	37.5	87	48.9	29	58.0
Rural school	56	30.4	17	35.4	56	30.4	17	35.4
Parental literacy								
Father only	31	16.9	7	14.6	41	23.0	16	32.0
Mother only	31	16.9	7	14.6	33	18.6	9	18.0
Both parents	70	38.0	20	41.7	63	35.4	17	34.0
Neither parent	52	28.3	14	29.2	41	23.0	8	16.0
Parental spectacle wear								
Father only	21	11.4	4	8.3	21	11.8	8	16.0
Mother only	17	9.3	1	2.1	15	8.4	4	8.0
Both parents	6	3.3	0	0.0	2	1.1	1	2.0
Neither parent	140	76.1	43	89.6	140	78.7	37	74.0
Presenting visual acuity in the better eye								
<6/9 - 6/12	47	25.5	15	31.3	46	25.8	17	34.0
<6/12 - 6/18	61	33.2	14	29.2	57	32.0	15	30.0
<6/18 - 6/60	73	39.7	18	37.5	68	38.2	17	34.0
<6/60	3	1.6	1	2.1	7	3.9	1	2.0
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
Spherical equivalent (better eye)	-1.49 (0.88)	+0.50 to -4.50	-1.58 (1.07)	-0.50 to - 5.50	-1.46 (1.28)	+2.50 to -9.50	-1.30 (0.93)	+2.00 to -3.50

Figure 1. Study flow chart