ADMINISTRATIVE INFORMATION

1. TITLE

Spectacle wearing amongst children randomized to ready-made spectacles or prescription spectacles, and cost savings to programmes

2. TRIAL REGISTRATION To be registered at Clinicaltrials.gov

3. PROTOCOL VERSION 1.0

4. FUNDING Fondation L'Occitane - L'Occitane Sight Award
Vision Impact Institute

5a ROLES AND RESPONSIBILITIES

Chief Investigator:
Professor Clare Gilbert MB ChB., MSc., MD
Co-Director,
Department of Clinical Research
London School of Hygiene & Tropical Medicine
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Overall responsibility for the trial, including input to study design, detailed methodology, designing data collection instruments, data management and analysis, interpretation and dissemination of the findings.

Lead Investigator
Priya Morjaria BSc (Hons) Optom, MCOptom, MSc
Optometrist,
Department of Clinical Research
London School of Hygiene & Tropical Medicine
Email: Priya.Morjaria@Lshtm.ac.uk

Contributed to the study design, detailed methodology, designing data collection instruments. Will undertake all the field work and collection of data, data entry, analysis interpretation and dissemination of the findings.

Collaborators
Dr Jennifer Evans,

Lecturer,
Department of Clinical Research
London School of Hygiene & Tropical Medicine

Input to the study design, including sample size calculation, and support to statistical analysis and interpretation of the findings. Will contribute to dissemination of findings in peer-reviewed publications.

Dr Muralikrishnan Kartha
Centre for the Economics of Mental and Physical Health
Institute of Psychiatry, Psychology & Neuroscience
King's College London,
Box 24, The David Goldberg Centre
De Crespigny Park
London SE5 8AF

Input to the health economic component of the study including methodology, data collection and analysis and interpretation and dissemination of the findings.

Collaborating Institution
Dr. Kaushik Murali and Miss Shalini Shashidharan
Sankara Eye Care Institutions, Bangalore, India

Input to the data collection in the field and the main collaborator in India. The team will provide logistical, managerial and technical support and coordinate with the education departments to obtain permission to conduct the trial.

5b Trial Sponsor London School of Hygiene & Tropical Medicine.

Contact:
Patricia Henley,
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5c and d.Advisory Panel for the trial

An advisory panel will be established by April 2015, comprising a health economist, a statistician with expertise in clinical trials and an optometrist with research experience in low/middle income countries. The Advisory Panel will have oversight of all aspects of the trial, including study design, data collection instruments, implementation, and data management, analysis and interpretation.

The Advisory Panel will recommend whether a Data Management Team is required.

6 INTRODUCTION

6a Background and rationale

Problem statement

Uncorrected refractive errors (uRE) are the commonest cause of visual loss in children. Myopia (short sightedness) is the commonest form, which usually starts around the age of 9 to 10, progressing in severity throughout adolescence. Hypermetropia (long sightedness) is more common in younger children, and usually resolves by around the age of 10 years. Astigmatism (distorted vision) affects all age groups and does not change over time. Myopia is far more common in Asian children, particularly in SE Asia, and all types of RE are less common in African children. Myopia is more common in urban children although the reasons are not completely understood. There is an increasing body of evidence that time spent outdoors is protective although the biological mechanisms are not clear (French, 2013; Sherwin, 2012). There is very little evidence of the impact of correcting RE in children on school performance, as this is very challenging to study, but correction does improve quality of life and visual functioning.

Many countries have programmes for uRE, but approaches are not standardized and spectacle wearing rates can be very low, being higher with high uRE, and in girls (Sharma, 2012). Over-prescribing may also be a factor as protocols are rarely used. Other barriers include being teased, discomfort, no perceived benefit and beliefs about causation (Odedra, 2008). There have been three trials of interventions to improve spectacle wear: an education intervention of students in China, which had negative results, showing that educating children alone is not effective (Congdon, 2011). Another recent trial in China had a factorial design with six subgroups. Children in half the schools were randomised to a health education intervention, which involved children being shown a 10-minute documentary style video a booklet of cartoons, and classroom discussion led by teachers. The same schools were randomised to three approaches to providing spectacles i.e. free spectacles, a voucher, or children were given a prescription for spectacles. Spectacle wear was assessed by observation and self-report. Observed wear was higher in all four sub groups randomised to the health education intervention (RR 1.46 to 1.74) (Ma, 2014). The other trial was of free vs low cost spectacles in Tanzania, in which free spectacles almost doubled wearing rates (Wedner, 2008).

Recent unpublished data from a study in Bangalore (undertaken by PM) on the impact of visual acuity screening cut-off and spectacle wearing rates also analysed the prescriptions of children followed-up unannounced at 3-4 months (84). The range of spherical equivalent in the better eye of those wearing their spectacles (n=18) was -1.75 to -9.00 D compared with -0.75 to -2.25 D in the group not wearing their spectacles (n=56).

Study will be undertaken in India where children have a range of errors, including astigmatism.

Relevance

The health of school children is recognized by international health experts, policy makers, governments and international agencies as contributing to child development and learning, and hence to socio-economic development. This includes FRESH (Focus Resources on Effective School Health) whose partners includeEducation International; Partnership for Child Development; UNESCO; UNICEF; World Food Programme; WHO; World Bank.

Results of this project will be of relevance to FRESH and local, national and international agencies that support school eye health and prevention of blindness in children globally.

Main research question

Amongst eligible schoolchildren aged 11 to 15 years, do low-cost, high-quality, ready-made spectacles result in comparable rates of spectacle wear at 3 to 4 months as more expensive custom-made spectacles, and what is the cost saving to programs?

One trial has been undertaken to assess the utility of ready-made spectacles (i.e. same prescription without astigmatic correction in both eyes) in China in which all children requiring spectacles were randomized to custom-made or ready-made spectacles regardless of their uRE (Zeng, 2009). This trial could not assess the proportion of children where ready-made spectacles would be suitable nor cost savings to programmes. In addition, studies undertaken in China cannot be extrapolated to other countries as in China most children have simple myopia (i.e. without astigmatism).

6b Choice of comparators and benefits and harms of each intervention

Prescribing according to the subjective prescription obtained following objective refraction by an optometrist is the gold standard means of correcting refractive errors. If the spectacles are well fitted i.e. so that the optical centre of each spectacle lens aligns with the optical axis of the eye, good visual acuity is anticipated without symptoms e.g., eye strain, or headaches. Spectacle frames are also chosen so that they fit the distance between the two eyes and the size of the head.

In this trial children will only be eligible for randomisation to ready-made or custom-made spectacles if they have pre-defined low levels of astigmatism and/or anisometropia (i.e. a different prescription in right and left eyes). Prescribing ready-made spectacles may lead to a slight but clinically insignificant diminution in corrected visual acuity compared with that which could be obtained with custom-made spectacles. Children will also only be eligible for randomisation if the distance between the two eyes is compatible with the frame sizes available in ready-made spectacles. No discomfort is therefore anticipated in relation to the spectacle frames.

The cosmetic appearance of spectacles is also of great importance. In both arms of the trial children will be able to select from a limited range of metal or plastic frames of different colours.

From a programmatic perspective prescribing ready-made spectacles has benefits for providers as well as parents and children as a supply of ready-made spectacles with a wide range of prescriptions and frame types can be taken to the school and dispensed immediately. In contrast, custom-made spectacles have to be individually made up in optical laboratories, marked with the child's name, and the spectacles taken back to the school and given to the correct child.

7 OBJECTIVES

7a Main Hypothesis

The proportion of children wearing spectacles 3 to 4 months after they were dispensed is similar amongst children randomised to ready-made spectacles compared with those randomised to custom-made spectacles.

7b Specific objectives

1. To estimate the proportion ofschool children aged 11 to 15 years with refractive error that might benefit from ready-made spectacles
2. To compare the proportion of children wearing spectacles among those randomised to ready-made spectacles versus custom-made spectacles at unannounced visits at 3 to 4 months
3. To assess reasons for non-spectacle wear in both arms of the trial e.g. symptoms such as eyestrain or headache and other reasons
4. To assess the cost effectiveness of dispensing ready-made spectacles compared with custom-made spectacles, and costsavings to programs using ready-made spectacles

8 TRIAL DESIGN

Randomized, non-inferiority, double masked clinical trial.

A non-inferiority design was chosen to compare ready-made spectacles with custom-made spectacles as the benefit of ready-made spectacles is the considerably lower cost and ease of dispensing which increases the efficiency of programs. As millions of children are affected by uncorrected refractive errors lower cost spectacles have the potential to increase coverage. Under these circumstances a slightly lower acceptance of spectacles, measured by spectacle wearing, might be acceptable. The non-inferiority margin of 10% was chosen to balance the considerations of efficacy and secondary benefits.

Allocation ratio approximately 1:1.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

9a Setting

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

A list of schools with pupils in the target age range will be obtained from the district education office. Information on the number of children aged 11-15 years will also be sought.

10. Eligibility criteria

Inclusion criteria

- Age 11-15 years
- Presenting visual acuity (i.e. with spectacles if usually worn) of less than 6/9 in one or both eyes
- The visual acuity with full correction improves by two or more lines in the better seeing eye

AND

- the spherical equivalent (i.e. the sum of the myopic or hypermetropic prescription in dioptres (D) plus half the astigmatic cylindrical prescription) corrects the visual acuity to equal to, or not more than one line less than best corrected visual acuity with a full prescription in the better eye

AND

- the difference between the spherical equivalents of the right and left eyes is not >1 D

AND

- the inter-pupillary distance (IPD) matches that of ready-made spectacle frames available

AND

- the spectacle frame is of acceptable size and fit

A pilot study will be undertaken to estimate the proportion of children who fulfil these eligibility criteria which is estimated to be in the range of 30 to 50%.

Exclusion criteria

- Children with other causes of visual loss
- Children whose visual acuity does not improve adequately with a spherical lens
- Children with more than 1 dioptre of anisometropia

All these children will be dispensed custom-made spectacles but will not be recruited to the trial.

Eligibility of those performing interventions

All refractions, prescribing and dispensing will be undertaken by fully qualified optometrists, including the lead investigator.

INTERVENTIONS

11a. The intervention will be ready-made spectacles. The comparator will be custom-made spectacles (standard of care).

Although ready-made spectacles are available for bulk purchase, in this study all spectacles will be made up in Sankara Eye Hospital. This is so that a) all children will have the same choice of frames, and b) so that all spectacles will be delivered to the school at the same time. This will permit masking of students.

Ready-made spectacles have exactly the same prescription in each eye.

Custom-made spectacles are those made up by a dispensing optician on the basis of a prescription from a qualified optometrist. Each eye can have a different prescription, including astigmatic correction.

11b Modification of allocation
Not applicable

11c Strategies to improve adherence
Not applicable as spectacle wearing (i.e. adherence to the intervention) at 3 to 4 months is the primary outcome of the trial.

11d. Concomitant care
Any child identified with simple eye conditions such as conjunctivitis will be treated. Children identified with more serious problems such as strabismus or lens opacities will be referred.

OUTCOMES

12a. Primary outcome

The proportion of children in each arm of the trial who are wearing their spectacles at unannounced visits 3 to 4 months after refraction.

The trial has been powered to detect ≤10% difference in the proportion of children wearing ready-made spectacles compared with custom-made spectacles. This margin of non-inferiority has been selected as a recently published superiority trial was powered to detect a 10% or greater difference in spectacle wear between intervention arms (Congdon, 2011).

Categories 1 or 2 below will be defined as spectacle wearing, and categories 3 or 4 as non-spectacle wearing (Wedner, 2008):
1. Children were wearing the spectacles at the time of the unannounced visit
2. Children were not wearing the spectacles at the time of the visit but have them at school
3. Children were not wearing the spectacles at the time of the visit but said they were at home
4. Children said they no longer had the spectacles as they were broken or lost

12b. Other outcomes

Cost savings to the programme of dispensing ready-made spectacles. This analysis will only be undertaken should the trial demonstrate non-inferiority.

Reasons for non-spectacle wear.

13 Participant timeline

Eligible children will be identified in government schools in India over a 3 to 4 month period and spectacles will be dispensed within two weeks of refraction.Data on the primary outcome will be assessed at 3 to 4 months after refraction.

There will be no long-term follow-up.

14 SAMPLE SIZE

Data already obtained on uncorrected refractive errors from children aged 11-15 years in schools in the catchment area of this trial will be analyzed to determine the prevalence of significant uncorrected refractive error overall (see section 10 for the definition) andwhether the prevalence differs between urban and peri-urban schools. Data from this earlier study will also be used to estimate of the proportion of children refracted who would beeligible for the trial.

The parameters used in the sample size calculation will include a significance level of 0.05, 95% confidence interval, 90% power and 1:1 allocation. The trial will be powered to detect a non-inferiority margin ($\triangle$) of 10% or less. No increase will be required for loss to follow up as all eligible children present on the day of the visit will be recruited, and very few are likely to not take part. The communities are stable and few study children are expected to leave the school during the school year.

All calculations have been done using a one sided 95% confidence interval. The tool used to calculate sample size was Sealedenvelope (https://www.sealedenvelope.com/power/binary-noninferior/).

Power	% wearing prescription spectacles at follow up	Inferiority margin	N in each arm	Total sample size
80%	80%	10%	200	400
	70%	10%	260	520
	60%	10%	300	600
	50%	10%	310	620

Once the number of children to be recruited to each arm of the trial is known, the total number of children to be screened can be calculated using the prevalence estimates from peri-urban and urban schools together with the proportion of children eligible for recruitment. As approximately 500 children will be examined in each school, the requisite number of schools in peri-urban and urban locations can then be determined.

For example, the prevalence of uncorrected refractive error in the earlier study in Bangalore was 4%. If one third are not eligible for ready-made spectacles the effective prevalence would be 2.7%. To obtain a sample of 260 eligible children, 10,000 children would need to be screened in 200 schools. The field team will comprise two trained field workers to measure visual acuity and two study, optometrists. Screening and assessing 500 children will take approximately 3 days (two schools per week).

15. Recruitment

After obtaining written permission from the Principal of each school the requisite number of classes representing the age range of children to be included will be selected, using simple random sampling, if required.

All children in each selected class will have their presenting vision acuity measured at the 6/9 level in each eye separately. Those with a visual acuity of less than 6/9 in the better seeing eye, will be refracted by an experienced optometrist who will measure their best corrected visual acuity. Children will be recruited to the trial if they fulfil the eligibility criteria (see section 10). Children with significant refractive error who require custom-made spectacles to achieve the level of improvement in vision required for eligibility will not be recruited. They will be dispensed a pair of custom-made spectacles. All other children will be eligible for randomization.

METHODS: ASSIGNMENT OF INTERVENTIONS

Allocation

Individual children will be the unit of randomization.

In this study a proportion of children with uncorrected refractive errors in each school will not be eligible for randomization as they require custom-made spectacles. These spectacles will be delivered within two weeks of refraction. In order that head teachers and pupils are masked to the arm of the trial that each child has been randomized to, all randomized children will also have their spectacles dispensed at the same time as those who were not eligible i.e. within two weeks.

The field workers who follow up the children at 3 to 4 months to assess spectacle wearing will be masked to the arm of the trial the children were allocated to, as they will only be given a list of the school, the child's study ID number, name, class and gender. Data on the primary outcome will be entered into a separate database which will only be merged with the main database immediately prior to analysis.

All aspects of the study will be pilot tested in schools which will not be included in the main trial.

16a. Sequence generation.

The allocation sequence (using block randomization)will be computer-generated by an independent statisticiannot involved in the fieldwork who will keep the list of the allocation codes. Randomization will be stratified by school.

16b. Allocation concealment mechanism

<u>During field work</u>
Randomization codes will be placed in identical,sequentially numbered sealed envelopes, which will be taken to the school. The next envelope in this series will be opened for each eligible child and the sequential code number entered on the child's data collection form.

<u>During data management</u>
Details of the refractive error and what was prescribed will be recorded in each child's data recording form. From this information it will be possible to assess whether the child was randomized to custom-made spectacles. Concealment at this stage is, therefore, required.

Two databases will be created, and will only be merged once all the data have been entered and the data in database 1 has been cleaned.

Database 1: study ID, initials, date of birth, gender, age, school, randomization code, clinical details, including refractive error and details of the prescription dispensed.

Database 2: study ID, initials, date of birth, gender, school, primary outcome

16c. Implementation

Experienced trained field workers will measure visual acuity, to identify children requiring refraction. Trained optometrists will identify children eligible for recruitment to the trial after standard refraction, measurement of corrected visual acuity testing, and assessment and comparison of the type and degree of refractive error in each eye.

Another fieldworker will recruit eligible children and allocate them a unique study number. Immediately after recruitment each eligible child will be randomized.

17a. Masking

The following individuals will be masked to the allocation

- Children
- Head teachers
- Class teachers
- Field workers who deliver the spectacles to the school
- Field workers collecting primary outcome data

The following individuals will be not masked to the allocation

- The optometrist who refracts the child and prescribes spectacles according to the randomization code

17b Unmasking

There are no circumstances under which unmasking is envisaged.

METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

18a. Data collection methods

See appendices for flow chart and data collection instruments.

In the schools selected for the trial trained field workers will measure visual acuity at the 6/9 level in each eye and with both eyes open, with spectacles if the child usually wears them. An illuminated LogMar cabinet with a LogMar chart will be used at the recommended test distance to overcome the limitation of variable illumination in the classrooms.

All children who fail screening will undergo objective and subjective refraction by an optometrist. The following information will be recorded

- objective refraction and corrected visual acuity in each eye
- subjective refraction and record best corrected visual acuity in each eye
- the spherical equivalent will be calculated for each eye using the sum of the sphere plus half of any astigmatic correction (cylinder)

- visual acuity using the spherical equivalent will be measured and recorded for each eye

On the basis of these findings the optometrist will decide whether the child is eligible for the trial.

Children not eligible for the trial will be dispensed custom-made spectacles and the prescription will be recorded. Children will choose the spectacle frames they prefer from a selection of 6 to 7 frames

Eligible children

Children in both arms of the trial will go through identical procedures regardless of their allocation.

A fieldworker will interview children to collect the following data: age, gender, class, and whether one or both parents wear spectacles for distance. Limited information will be collected on the educational level and occupation of their parents and on a limited number of assets, taken from National Household Survey questionnaires.

Children randomly allocated to custom-made spectacles will be dispensed custom-made spectacles and the prescription will be recorded. Children will choose the spectacle frames they prefer from a selection of 6 to 8 frames.

Children randomly allocated to ready-made spectacles will be dispensed ready-made spectacles using the spherical equivalent which gives the best corrected visual acuity in either eye. Children will choose the spectacle frames they prefer from a selection of 6 to 7 frames.

To ensure children receive the correct spectacles each pair of spectacles will be labelled with the child's name, age, school, class and study ID. This will be checked by two members of the project team. Each class teacher will be given a list of the names and study IDs of children in the trial. The teacher will ensure that the correct child was issued with the correct spectacles. A field worker will assess the visual acuity of each child given spectacles to ensure that they can see 6/9 with both eyes open.

Primary outcome data

Trained field workers will visit each study school 3 to 4 months after the children were refracted. This will be an unannounced visit. Fieldworkers will ask permission from the head teacher to visit the classrooms of all children in the trial when they will ascertain spectacle wear according to the four categories indicated above.

Other outcomes

Children in categories 3 and 4 will be asked an open ended question to explore why they were not wearing their spectacles. Children will be allowed to give more than one reason. Responses will be categorised as follows:

1. Never received them
2. Lost
3. Broken or scratched
4. Do not like wearing them – teased
5. Do not like wearing them – appearance
6. Do not like wearing them – headache or eyestrain
7. Parents do not like the child to wear them
8. Did not notice an improvement in vision i.e. no benefit
9. Other, specify

18b Plans to complete follow up

If children are not present in the school on the day of the unannounced visit the school will be revisited on at least one further occasion.

Fieldwork will be planned such that the initial assessment, and follow-up 3 to 4 months later does not coincide with a long school holidays, nor the end of the school year when children may leave school. Refraction and follow-up will also avoid school examination periods.

Economic data collection

The cost per pair custom-made spectacles delivered to the school will be calculated using the cost of frames and lenses, salary time of dispensing optician staff to make up each pair of spectacles, and the cost of delivering the spectacles to individual children in school. The cost of ready-made spectacles will be obtained from local suppliers. Under non-trial conditions the ready-made spectacles would be dispensed at the time of refraction, and so the cost of delivering them will not be included.

19. DATA MANAGEMENT

All field staff will undergo rigorous training for the trial, including inter-observer agreement studies for visual acuity measurement and refraction, and how to record data.

Two password protected databases will be created in Access, one for the primary outcome data and the other for all other data. Consistency and range checks will be built in. Data will be double entered by the lead investigator.

All data recording forms will be kept in a locked cupboard or filing cabinet in Sankara Eye Hospital.

20. STATISTICAL METHODS

To assess the comparability of the two groups,the characteristics of children in the intervention and comparator arms will be compared i.e. age, gender, degree of uncorrected refractive error, presenting visual acuity in the better eye, peri-urban/urban school and whether they were previously wearing spectacles which required replacement,

20a. Methods for analysing primary and secondary outcomes

Primary outcome:

Analysis will be in the groups to which the children were randomly allocated. We expect all children will be given the spectacles that they are allocated. . The proportion of children wearing or having their spectacles with them at school at 3 to 4 months will be compared between the intervention and comparator arms using the risk ratio with 95% confidence intervals.

A separated analysis using logistic regression will also be undertaken to adjust for factors that may affect spectacle wearing such as gender, age, degree of refractive error in the better seeing eye, previously wore spectacles, and parental spectacle wear and education.

The randomization code will only be broken once the analysis is complete.

There will be no subgroup analysis.

Secondary outcomes

Analysis of cost saving to programmes of ready-made spectacles will only be undertaken if the clinical trial demonstrates non-inferiority.

The unit cost of ready-made ($Cost_{RM}$) and custom-made spectacles ($Cost_{CM}$) will be calculated.

The cost of dispensing spectacles to two groups of children in the study will be determined:

A = not eligible for the trial and dispensed custom-made spectacles
B = eligible for randomization i.e. suitable for ready-made spectacles

The cost to programmes without ready-made spectacles $Cost^{CM\ only} = A*Cost_{RM} + B*Cost_{CM}$

The cost to programmes with ready-made spectacles $Cost^{RM\ used} = A*Cost_{CM} + B*Cost_{RM}$

The cost saving to programs = $Cost^{CM\ only} - Cost^{RM\ used}$

Reasons for non-spectacle wear

Reasons for non-spectacle wear will be compared in children who were not wearing custom-made spectacles and ready-made spectacles, using z-tests.

METHODS: MONITORING

21a and b Data monitoring

A data monitoring committee will not be required.

Both the intervention and comparator arms are not novel procedures and are in common use. There is no reason to expect significant adverse effects. Interim and subgroup analyses are not planned and there will be no stopping rules.

22 Harms

Inaccurate prescribing or fitting of spectacles can give rise to blurred vision and/or symptoms of eyestrain or headache whilst wearing the spectacles. All refractions in this trial will be undertaken by highly experienced optometrists and so inaccurate prescribing is highly unlikely. In addition, children who have refractive errors not suitable for readymade spectacles will not be eligible for the trail, so reducing the risk of symptoms arising through under correction.

Children will not be specifically asked whether they have these symptoms but will be offered the opportunity to say whether symptoms were the reason why they discontinued wearing spectacles at the time of the unannounced visit. Any child who says that blurred vision, eyestrain or headaches were why they did not wear their spectacles will be refracted again and given a new pair of spectacles, if required. .

ETHICS AND DISSEMINATION

24 Research ethics approval

Ethical approval will be obtained from the Interventions Research Ethics Committee of LSHTM and the IRB of Sankara Eye Institute.

25 Protocol amendments

Important protocol modifications, such as eligibility criteria, will be reported to the Interventions Research Ethics Committee of LSHTM and the IRB of Sankara Eye Institute.

26a Consent

Approval will be sought from the relevant school authorities and school head teachers. Written informed consent will be sought from the parents. Parents of the children will be sent an information sheet regarding the study and explaining the study procedure along with the consent form prior to the screening.
Guidelines followed for school screening in India and by the collaborating institute state that before starting the screening at each school, the children are given verbal information and an explanation of the procedures by trained field workers. This gives the children an opportunity to ask any questions. At this stage, if the children are eligible for the trial, they will be given an assent form and health education on how to look after their spectacles and the health of their eyes.

Written informed consent will be obtained from each school authority, head teacher and/or the school administrator to allow the school to participate in the study. All the information sheets and consent forms will be translated into local languages.
The lead collaborator in India will obtain written informed consent from school authorities and school head teachers.

27 Confidentiality

Data will be kept confidential and no identifiers will be entered into the databases. Data will be anonymised by allocating a unique study ID for each participant. The unique study ID and other identifiers will be used to merge the database with the primary outcome and the database at containing all the other data.

Paper records will be stored in a locked filing cabinet at LSHTM and the data will only be made available to those involved in the study. The databases created will be password protected. At the end of the study, the data will be archived at LSHTM.

28 Declaration of interests

None of the investigators have any competing interests.

29 Access to data

Only investigators at LSHTM and the lead investigator at Sankara Eye Hospital will have access to the final trial dataset. A memorandum of understanding will be drawn up between the two institutions highlighting intellectual property issues, which will include data sharing and making the database available online.

30. Ancillary and post-trial care

Not applicable.

31a-c Dissemination policy

All investigators will contribute to the dissemination strategy which is likely to include a summary of the findings for head teachers, a report for the website of both institutions, publications in peer-reviewed journals, presentation at national (UK and India) and international conferences.

Recognized authorship eligibility guidelines will be followed. Professional writers will not be used.

References

Congdon N, Li L, Zhang M, Yang A, Gao Y, Griffiths S, Wu J, Sharma A, Lam DS. Randomized, controlled trial of an educational intervention to promote spectacle use in rural China: the see well to learn well study.Ophthalmology. 2011 Dec;118(12):2343-50. doi: 10.1016/j.ophtha.2011.06.016. Epub 2011 Sep 1.

French AN[1], Ashby RS, Morgan IG, Rose KA. Time outdoors and the prevention of myopia. Exp Eye Res. 2013 Sep;114:58-68. doi: 10.1016/j.exer.2013.04.018. Epub 2013 May 2.

Ma X, Zhou Z, Yi H, Pang X, Shi Y, Chen Q, Meltzer ME, le Cessie S, He M, Rozelle S, Liu Y, Congdon N. Effect of providing free glasses on children's educational outcomes in China: cluster randomized controlled trial.BMJ. 2014 Sep 23;349:g5740. doi: 10.1136/bmj.g5740.

Odedra N, Wedner SH, Shigongo ZS, Nyalali K, Gilbert C. Barriers to spectacle use in Tanzanian secondary school students.Ophthalmic Epidemiol. 2008 Nov-Dec;15(6):410-7. doi: 10.1080/09286580802399094.

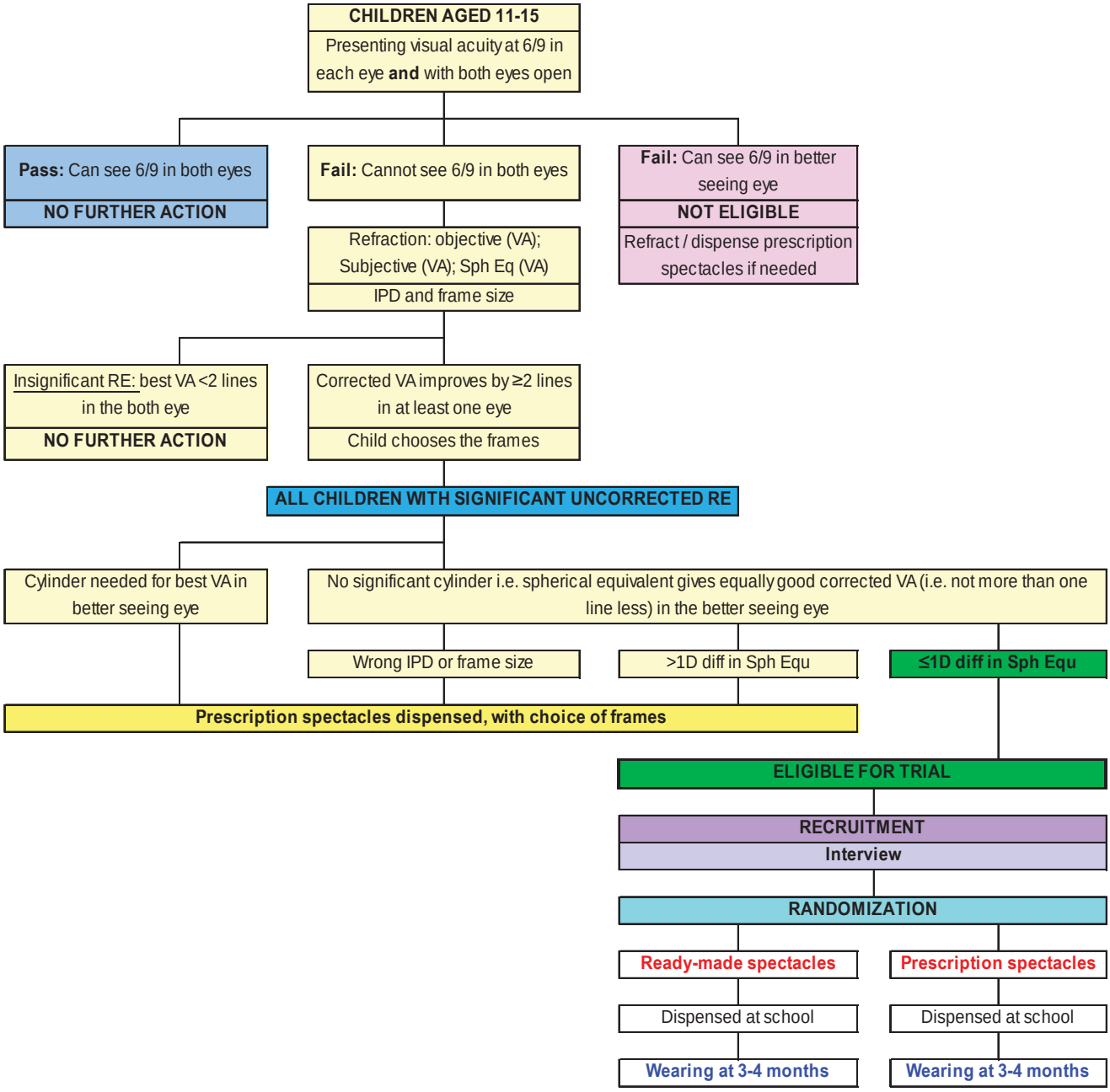
Sharma A, Congdon N, Patel M, Gilbert C. School-based approaches to the correction of refractive error in children.Surv Ophthalmol. 2012 May-Jun;57(3):272-83. doi: 10.1016/j.survophthal.2011.11.002. Epub 2012 Mar 6. Review.

Sherwin JC[1], Reacher MH, Keogh RH, Khawaja AP, Mackey DA, Foster PJ. The association between time spent outdoors and myopia in children and adolescents: a systematic review and meta-analysis. Ophthalmology. 2012 Oct;119(10):2141-51

Wedner S, Masanja H, Bowman R, Todd J, Bowman R, Gilbert C. Two strategies for correcting refractive errors in school students in Tanzania: randomised comparison, with implications for screening programmes.Br J Ophthalmol. 2008 Jan;92(1):19-24.

Zeng Y, Keay L, He M, Mai J, Munoz B, Brady C, Friedman DS. A randomized, clinical trial evaluating ready-made and custom spectacles delivered via a school-based screening program in China.Ophthalmology. 2009 Oct;116(10):1839-45. doi: 10.1016/j.ophtha.2009.04.004. Epub 2009 Jul 9.

APPENDIX 1. Flow chart



APPENDIX 2 Timeline of activities

Project activities		Months of project											
Preparatory:		1	2	3	4	5	6	7	8	9	10	11	12
Ethical approval (x2)													
MOUs being finalised													
Detailed planning													
Develop data collection instruments													
Field work in India:													
Set up; train staff etc													
Pilot test data collection instruments													
Baseline data collection													
Follow up visit and data collection:													
Assessment of spectacle wearing rates													
Analysis and writing up:													
Data entry													
Data analysis													
Write up reports; publications													
Dissemination meetings													

APPENDIX 3 Data collection instruments

Spectacle wearing amongst children randomized to ready-made spectacles or prescription spectacles, and cost savings to programmes

Recruitment form **Study number** ☐☐☐

Randomization Code ☐☐ ☐☐☐ *(if eligible)*

1 Date ☐☐ *Day* ☐☐ *Month* 2 0 ☐☐ *Year*

2 School name _____ **3** Level 1 Primary / 2 Secondary

3 Location 1 Rural / 2 Urban / 3 Peri-urban

4 Name _____ **5** Class ☐☐

6 Age ☐☐ **7** Gender 1 Male / 2 Female

8 Presenting VA measured with own spectacles 1 Yes / 0 No

9 Visual acuity (VA) Can see **6/9**

	Right eye	**Left eye**	**Binocularly**
	1 Yes / 0 No	1 Yes / 0 No	1 Yes / 0 No

10 **Cannot see 6/9 in both eyes** / **Can see 6/9 in one eye** 1 Yes / 0 No — May be eligible for the trial / NOT eligible for recruitment — **Complete ALL except Q 16 and 17** / ***Complete Q 11 to 17 ONLY***

Refraction and visual acuity

	Presenting visual acuity	**Right eye**	**Left eye**
11	Smallest logMAR line seen (4 or more)	☐☐	☐☐
12	*Objective*	☐ +/-	☐ +/-
	Sphere	☐☐ . ☐☐	☐☐ . ☐☐
	Cyl	☐ . ☐☐	☐ . ☐☐
	Axis	☐☐☐	☐☐☐
13	Smallest logMAR line seen (4 or more)	☐☐	☐☐
14	*Subjective*	☐ +/-	☐ +/-
	Sphere	☐☐ . ☐☐	☐☐ . ☐☐
	Cyl	☐ . ☐☐	☐ . ☐☐
	Axis	☐☐☐	☐☐☐
15	Smallest logMAR line seen (4 or more)	☐☐	☐☐

For children NOT eligible for recruitment

16 Spectacles required 1 Yes / 0 No

17	Prescription needed	☐ +/-	☐ +/-
	Sphere	☐☐ . ☐☐	☐☐ . ☐☐
	Cyl	☐ . ☐☐	☐ . ☐☐
	Axis	☐☐☐	☐☐☐

For children NOT eligible for recruitment can now be discharged

All other children

18	Spherical equivalent	☐☐ . ☐☐	☐☐ . ☐☐
19	Smallest logMAR line seen (4 or more) with spherical equivalent	☐☐	☐☐

20 VA with SphE is equal to or not more than one line worse than best corrected VA

1	Yes
0	No

21 SphE is equal to or less than 1D difference between eyes

1	Yes
0	No

22 Interpupillary distance ____ ____ *mm*

23 IPD between 60 and 64mm

1	Yes
0	No

24 Cyclinder not greater than -0.75 in either eye

1	Yes
0	No

25 Yes to ALL 4 questions above

1	Yes	*Eligible for recruitment*
0	No	*NOT eligible. Prescribe spectacles if needed and discharge*

Ask the child the following questions

26 What job does you father / mother have

	Father	Mother
1	Professional	Professional
2	Clerk	Clerk
3	Service / Sales	Service / Sales
4	Craft trade	Craft trade
5	Skilled worker	Skilled worker
6	Labourer	Labourer
7	Unemployed	Unemployed
8	Other	Other

27 Do your mother and/or father own a mobile phone?

0	Neither
1	Father only
2	Mother only
3	Both

28 Do your mother and/or father wear spectacles for walking around?

0	Neither
1	Father only
2	Mother only
3	Both

29 Do you have any of the following in your house?

Yes	No	
1	0	Radio
1	0	TV
1	0	Computer
1	0	Bicycle
1	0	Car

30 Can your father read and write easily

1	Yes
0	No
9	Not applicable

31 Can your mother read and write easily

1	Yes
0	No
9	Not applicable

32 Randomization code

School code *Child code*

33 Randomized to

1	Ready-made
2	Prescription

34 If randomized to ready-mades

Right and left eyes

	.		D

35 If randomized to prescription glasses, prescription needed

+/-				+/-			
Sphere			.		Sphere		.	
Cyl		.			Cyl		.	
Axis					Axis			

36 Date spectacles given

				2	0		

Day *Month* *Year*

Refraction done by _____ [ ]

718

Spectacle wearing amongst children randomized to ready-made spectacles or prescription spectacles, and cost savings to programmes

Follow-up of students

Study number ☐☐☐

Randomization Code ☐☐ ☐☐☐

1 Date ☐☐ (*Day*) ☐☐ (*Month*) 2 0 ☐☐ (*Year*)

2 School name _____ **3** Level 1 Primary; 2 Secondary

4 Location 1 Rural; 2 Urban; 3 Peri-urban

5 Name _____ **6** Class ☐☐

7 Age ☐☐ **8** Gender 1 Male; 2 Female

9 Date spectacles given ☐☐ (*Day*) ☐☐ (*Month*) 2 0 ☐☐ (*Year*)

10 Date of follow-up visit ☐☐ (*Day*) ☐☐ (*Month*) 2 0 ☐☐ (*Year*)

11 Child at school 1 Yes; 2 No

12 Spectacle wear status

1 Wearing at time of visit
2 Not wearing at time of visit but have them at school
3 Not wearing at time of visit but have them at home — *Go to Q13*
4 No longer have spectacles as they are broken or lost — *Go to Q13*

13 Reasons for non-wear

First reason	Second reason (if more than one mentioned)
1	1 Never received them
2	2 Spectacles broken or scratched
3	3 Spectacles lost
4	4 Do not like wearing them - teased
5	5 Do not like wearing them - appearance
6	6 Do not like wearing them - headaceh or eyestrain
7	7 Parents do not like child to wear them
8	8 Did not notice an improvement in vision i.e. no benefit
9	9 Other, specifiy _____

Name of field worker _____ ☐

719

720

721

APPENDIX 3 Summary Budget

Personnel	UK salaries:	
	Priya Morjaria full time 4 months	£10,000.00
	Priya Morjaria 50% time 4 months	£6,250.00
	Grant Administration	£1,000.00
	India salaries	
	Optometrist	£900.00
	Research Assistants	£500.00
Equipment:	Logmar Charts x2	£304.00
	Computer x1	£750.00
	Equipment for refraction is available	£0.00
Travel:	Return flights to India x2	£1,800.00
	Accommodation & subsistence in India for 12 weeks	£2,000.00
	Local travel in India to schools	£1,500.00
Other:	Presbyopic for Teachers x100	£150.00
	Ready-made specs x240	£480.00
	Prescription Specs x240	£1,920.00
	Printing data recording forms	£250.00
	Tetracycline eye ointment	£20.00
	Letters to parents; mobile phone credit for SMS messages	£250.00
	ICEH Office costs and administration	£500.00
	Information sheets for teachers about glaucoma/DR	
	Information sheets for teachers about refractive errors in children	
	Dissemination of findings: publication and conferences	
Subtotal		***£28,574.00***
	Indirect costs for LSHTM @20% of UK salary	£3,450.00
	TOTAL	**£32,024.00**

APPENDIX 4 Information sheets and consent forms

Information sheet for head teachers

Project: **A comparison of two different types of spectacles for children with refractive errors**

Institution: London School of Hygiene and Tropical Medicine
Keppel Street
London, WC1E 7HT, UK

Researchers: Miss. Priya Morjaria
priya.morjaria@lshtm.ac.uk
Tel: +44 7732055398

Shalini Shashidharan
blr.nannakannu@sankaraeye.com
Sankara Eye Care Institutes, Bangalore
Tel: +91 97 39 777726

We would like to involve several of the students in your school to participate in a research project. Before you decide whether they should participate, it is important you understand what the research is about. Kindly please read through the information below carefully. I will be happy to discuss any questions that you may have. If you decide that the pupils in your school can participate in the study, please sign the informed consent form attached to this sheet.

What is the purpose of this study?

To compare two different types of high quality spectacles for children aged 11 to 15 years who are visually impaired from uncorrected refractive errors (long sightedness, shortsightedness, or astigmatism). Both types of spectacles will be provided by the project. The results will be used to improve the efficiency and reputation of school screening programs.

Why was this school chosen?

We are inviting certain schools to take part in this study which have students aged between 11-15 years. We have chosen this age group as refractive errors are more common at this age than in younger children. In this study we want to compare children from rural areas with children from peri-urban areas who attend government schools. Your school has been selected at random from a list of schools provided by the local authorities.

What is involved in the study?

All children will be screened using a vision testing chart on a mobile phone. Children who fail the screening test will then be examined in detail by a fully qualified optometrist who will decide which type of spectacles each child is eligible for. Children with uncomplicated refractive errors will be randomly allocated to high-quality, ready-made spectacles (i.e. spectacles that do not need to be made up by an optician) or spectacles that do need to be made up by an optician. Both groups of children will be able to select the spectacle frames they prefer. All children needing spectacles will be given a letter to take home to their parents to explain that their child needs spectacles. The letter will also explain the study in simple language (see below). All children needing glasses will receive them free of charge from the project 2 to 3 weeks after our initial visit, as the glasses need to be made up in Sankara Eye Hospital in Bangalore. After 3 to 4 months a member of the research team will come back to the school to follow up on the children who were given both types of spectacles. The researchers will ask them a few simple questions.

In each school we plan to examine approximately 500 children, which may mean randomly selecting classes. We are very aware that this can be disruptive to teachers as well as children. If you are agree that children in your school can take part we will discuss with you when might be the best time for the research team to come to the school. We anticipate being in the school for no more than 3 to 4 days.

None of the procedures that will be used in the study will cause any distress or harm to the pupils as the research team will be using standard methods and all children will be given high quality spectacles.

We are also aware that teachers may have eye problems that they are either not aware of or which have not been treated. We will ask all the teachers in the school if they would like to have their vision tested and their eyes examined. For some teachers we may need to instill eye drops so as to obtain a better view of the retina. This can lead to blurring of vision for a few hours. We will administer an information sheet and consent form like this one to each individual teacher to ensure we have their consent to participate. However, this too might be very disruptive, and if you are willing for teachers in your school to be involved, we will discuss with you what the best timing might be. Any teacher found to have a problem will be referred to a specialist eye department or hospital. All teachers needing reading spectacles will be given a pair.

Findings from this part of the study are also important as clear vision is essential for teachers.

Does the school have to take part?

No, this is entirely your own decision. The school is under no obligation to be a part of this study and can withdraw from it at any time without giving any reason.

Confidentiality of data

All the information we collect will be recorded on paper records, which will be kept in locked filing cabinets in Sankara eye hospital initially and then at the London School of Hygiene and Tropical Medicine in London. Data will be entered into the database in a computer which will be password protected. No-one other than the researchers will have access to this data, and no names will be used in analysis. We will also give each participating school a code so that individual schools cannot be identified in any reports.

How the findings will be used

At the end of the study we will write a report which will be sent to all teachers in participating schools. If you have any questions or concerns about the findings we would be happy to discuss them with you. We also plan to present the findings at meetings and conferences, and to write them up for publication.

Thank you very much for your attention today.

Consent sheet for head teachers

Project: **A comparison of two different types of spectacles for children with refractive errors**

Institution: London School of Hygiene and Tropical Medicine
Keppel Street
London, WC1E 7HT, UK

Researchers: Miss. Priya Morjaria
priya.morjaria@lshtm.ac.uk
Tel: +44 7732055398

Shalini Shashidharan
blr.nannakannu@sankaraeye.com
Sankara Eye Care Institutes, Bangalore
Tel: +91 97 39 777726

To confirm that you would like the students in the school to participate in this study, you must sign this form.
By signing this form, I am confirming the following:-

	Yes	No
I have read the patient information sheet and understand what is required of the students	☐	☐
All my questions have been answered and clarified to my satisfaction.	☐	☐
I agree that students in this school can participate in this study and will provide the necessary information required from me.	☐	☐
I am agree that teachers wishing to take part in this study are free to do so if this is what they wish.	☐	☐

_____

Headteacher's name (in block capitals) Signature of Head teacher Date (dd/mm/yy)

_____

Name of researcher(in block capitals) Signature of researcher
Date (dd/mm/yy)

_____

Name of witness (in block capitals) Signature of witness Date (dd/mm/yy)

Information sheet for parents

From Shalini Shashidharan
Co-ordinator
Sankara Eye Hospital
Bangalore
blr.nannakannu@sankaraeye.com
Tel: +91 97 39 777726

And Miss Priya Morjaria
London School of Hygiene and Tropical Medicine, London
priya.morjaria@lshtm.ac.uk

Dear Parent,

The head teacher at {……} school has given permission for some of the students to take part in a study of children's vision. We are writing to you to let you know that the vision of your child was recently tested and your child was found to benefit from spectacles.

The study is being run by eye specialists in Sankara eye hospital in Bangalore and they have agreed that all children who need spectacles will be given a pair of high quality spectacles free of charge. These spectacles will be delivered to the school in 7 to 10 days time.

Most children who need spectacles have slightly blurred vision, which may make it difficult for them to see detail such as writing on the blackboard. In other respects the eyes are entirely healthy.

If you would like further information about your child's vision for the study please contact Shalini Shashidharan at Sankara eye hospital.