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Spectacle wearing among children given ready-made spectacles or prescription spectacles, and cost savings to programmes

Submission date 26/01/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 04/02/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 07/03/2023	**Condition category** Eye Diseases	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Uncorrected refractive errors in children account for 90–95% of vision loss. The proportion of children aged 10–15 years with significant uncorrected refractive errors is less than 1% in Africa to over 70% in China. Shortsightedness (myopia) is the most common refractive error. Worldwide, more than 12 million children are visually impaired from uncorrected refractive errors. Many organisations support school vision testing initiatives, but there are gaps in the evidence about many aspects of these programmes. In most programmes, children are refracted by optometrists and those needing correction are given or sold prescription glasses (i.e., that fully correct the refractive error in both eyes), which are much more expensive than are ready-made spectacles (i.e., that have the same prescription in both eyes and do not correct astigmatism). The aim of this study is to find out whether low-cost, high-quality, ready-made spectacles result in similar rates of wear compared with more expensive prescription spectacles, and to assess the cost saving.

Who can participate?
Children age 11–15 at school with uncomplicated uncorrected refractive errors

What does the study involve?
Children are randomly allocated to high-quality, low-cost ready-made spectacles or prescription spectacles. At 3–4 months, they are classified as wearing or not wearing their spectacles. All children needing glasses receive them free of charge from the project and have an eye examination done for other diseases. If children require further tests or specialist referrals, then they are referred to the Sankara Eye Hospital (Bangalore) where they are seen free of charge.

What are the possible benefits and risks of participating?
Benefits not provided at time of registration. Children can occasionally take a little while to become accustomed to new spectacles, but eye strain and headache are uncommon.

Where is the study run from?
Sankara Eye Hospital (India)

When is the study starting and how long is it expected to run for?
December 2014 to June 2015

Who is funding the study?
L'Occitane Fondation (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
Spectacle wearing among children in India given ready-made spectacles or prescription spectacles, and cost savings to programmes: a randomised controlled study

Acronym

N/A

Study objectives

1. Several studies report that a high proportion of children given or who purchase spectacles do not wear them. One factor associated with spectacle wear is the degree of refractive error, with children having higher refractive errors being more likely to wear their spectacles. Other barriers to spectacle wear have been investigated, but few interventions have been assessed. To our knowledge there has only been one study of cost-effectiveness of screening for refractive errors and this study compared school-based programmes with primary health-care programmes (Frick, 2009). No studies have addressed cost effectiveness or cost savings of different approaches. 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. By contrast, prescription 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. The value of ready-made spectacles compared with prescription spectacles are that they are far less expensive (i.e. US$ 2–3 compared with US$10–15 in most low-income countries. High-quality, low-cost, ready-made spectacles suitable for children are readily available and can be purchased in bulk. Ready-made spectacles are also far easier to dispense because they do not have to be made up by trained dispensing opticians for each individual child. The low cost of ready-made spectacles means that they can replaced at little extra cost, or children can be given two pairs to replace those that get broken, scratched or lost. In view of the very large number of children in low-income and middle-income countries who require spectacles at a cost saving of approximately US$10 per child would lead to huge cost savings either to those providing the service or to parents (in settings where they have to buy them).
There has been an earlier trial of ready-made versus prescription spectacles in school children but in this trial all children with uncorrected refractive errors were randomly allocated to ready-made or prescription spectacles irrespective of their refractive error. We feel this is not justifiable as some children have complex refractive errors and require prescription glasses. In our study children with complex refractive errors will be excluded. The earlier trial did not address cost savings.
2. Our study is powered to detect ≤10% difference in the proportion of children wearing ready-made spectacles compared with prescription spectacles. This margin of non-inferiority has been selected because a recently published superiority trial was powered to detect a 10% or greater difference in spectacle wear between intervention arms (Congdon, 2011).
3. Hypothesis: similar proportions of children will wear spectacles 3–4 months after they are dispensed irrespective of whether they are ready-made or prescription spectacles.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. London School of Hygiene and Tropical Medicine (UK): Observational/interventions Research Ethics Committee, 09/01/2015, ref: 8827
2. Ethics Committee Institutional Review Board, Sankara Eye Hospital, Bangalore (India), 27/12 /2014

Study design

Randomised non-inferiority double-blind study

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Spectacle wearing in children with uncorrected refractive errors

Interventions
Children will be randomly allocated to one of two arms:
1. Intervention: ready-made spectacles with the same prescription in each eye
2. Comparator: prescription spectacles (standard of care), made up by a dispensing optician in accordance with a prescription from a qualified optometrist; each eye can have a different prescription, including astigmatic correction.

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

Intervention Type
Device

Primary outcome measure
Proportion of children in each arm of the trial who are wearing their spectacles at unannounced visits 3–4 months after refraction:
1. Children wearing spectacles at the time of the unannounced visit
2. Children not wearing spectacles at the time of the visit, but have them at school
3. Children not wearing spectacles at the time of the visit, but say they are at home
4. Children say they no longer have the spectacles because they are broken or lost

Categories 1 or 2 will be defined as spectacle wearing, and categories 3 or 4 as non-spectacle wearing (Wedner, 2008).

Secondary outcome measures
1. Cost savings to the programme of dispensing ready-made spectacles: this analysis will only be undertaken should the trial demonstrate non-inferiority
2. Reasons for not wearing spectacles, assessed at 8 weeks with a simple questionnaire

Overall study start date
01/12/2014

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Age 11–15 years
2. Visual acuity (i.e., with spectacles if usually worn) of less than 6/9 in one or both eyes
3. Visual acuity with full correction improves by two or more lines in the better seeing eye
4. 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
5. Difference between the spherical equivalents of the right and left eyes is not >1 D
6. Inter-pupillary distance matches that of ready-made spectacle frames
7. Spectacle frame is of acceptable size and fit

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
520

Key exclusion criteria
1. Other causes of visual loss
2. Visual acuity does not improve adequately with a spherical lens
3. >1 D of anisometropia
These children will be dispensed prescription spectacles, but will not be recruited to the trial.

Date of first enrolment
05/01/2015

Date of final enrolment
01/03/2015

Locations

Countries of recruitment

India

Study participating centre
Sankara Eye Hospital
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ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
L'Occitane Fondation (UK)

Funder Name
Vision Impact Institute

Results and Publications

Publication and dissemination plan
1. All results will be disseminated and a summary of findings will be reported to the head teachers and education officers.
2. The results of spectacle wear at the follow-up visit and cost savings will be published in peer reviewed journals at the end of the trial.
3. Reasons for non-spectacle wear will form a separate publication.
4. A report will be written for the websitse of both institutions, and presentation at national (UK and India) and international conferences; anticipated date for this is August 2015.

Intention to publish date
31/08/2015

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/01/2016		Yes	No
Results article	results	01/06/2017		Yes	No
Results article	results	01/04/2019	01/02/2019	Yes	No
Protocol (other)			07/03/2023	No	No