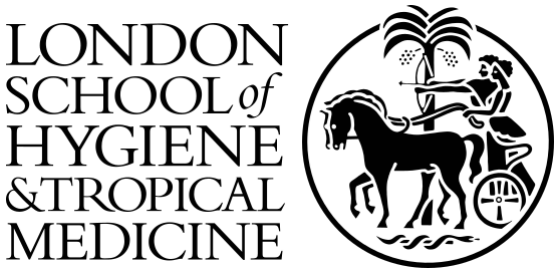

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Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

Priya Morjaria

Thesis submitted in accordance with the requirements for the degree of Doctor of Philosophy

University of London
November 2018

Department of Clinical Research
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The funders had no involvement in the study design, data collection, analysis or manuscript preparation.

Supervisor

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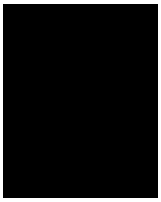
DECLARATION

I, Priya Morjaria confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been appropriately indicated in the thesis.

Signature: 

Date: 22nd Novemeber 2018

List of abbreviations

BVD	Back vertex distance
CEHJ	Community Eye Health Journal
eHealth	Electronic health
D	Dioptres
FGD	Focus group discussion
FRESH	Focus Resources on Effective School Health
IAPB	International Agency for Prevention of Blindness
ICED	International Centre for Evidence in Disability
ICEH	International Centre for Eye Health
ICER	Incremental cost effectiveness ratio
IIPHH	Indian Institute of Public Health, Hyderabad
IPD	Interpupillary distance
ISGEO	International Society of Geographical and Epidemiological Ophthalmology
ISRCTN	International Standard Randomised Controlled Trial Number
LSHTM	London School of Hygiene and Tropical Medicine
mHealth	Mobile health
NPCB	National Programme for Control of Blindness
PHFI	Public Health Foundation India
RBSK	Rashtriya Bal Swasthya Karyakram
RCT	Randomised controlled trial
REs	Refractive errors
SEH	School Eye Health

SES	School Eye Screening
Sph-Eq	Spherical equivalent
uREs	Uncorrected refractive errors
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNICEF	United Nations Children's Fund
USAID	United Sates Agency for International Development
VII	Vision Impact Institute
WCO	World Council of Optometry
WHO	World Health Organization
WOC	World Ophthalmology Council

ABSTRACT

Background

Uncorrected refractive errors (uRE) are the commonest cause of visual loss in children, accounting for 90-95% of visual impairment. Myopia is the commonest form, which usually starts around the age of 9 to 11 years, progressing in severity throughout adolescence. Hypermetropia is more common in younger children, and usually resolves by around 10 years of age. Astigmatism affects all age groups and does not change over time. Myopia is far more common in Asian children, particularly in South East Asia, and all types of refractive errors are less common in African children.

There is emerging evidence of the impact of correcting REs in children in terms of school performance, and spectacle correction improves quality of life and visual functioning. Many countries have programmes for uncorrected refractive errors among schoolchildren. However, approaches vary and subsequent spectacle wear can be very low. Over-prescribing may be a factor as protocols are rarely used. Other barriers to spectacle wear include being teased, no perceived benefit and beliefs about causation. There have been only two trials of interventions to improve spectacle wear: an education intervention of students in China and a trial of free vs low cost spectacles in Tanzania. Another trial has been undertaken in China to assess the utility of ready-made spectacles (i.e. same prescription without astigmatic correction in both eyes), which are less expensive to make and easier to dispense. This trial found that ready-made spectacles were suitable for over 90% of children who needed spectacles, but cost savings to programmes was not analysed.

Aim

The overall aim of this project is to provide evidence which could be used to improve the efficiency and effectiveness of school eye health programs for uREs in India. The project entails two randomized trials, each of which focus on a specific research question, based on reported reasons why children do not wear their spectacles: one trial addresses the cost of spectacles the other addresses negative attitudes towards spectacle wear by parents and peers.

Objectives

The project has two broad objectives; to reduce the cost and improve the efficiency of school programs for uREs by assessing the utility of ready-made spectacles, and to assess whether novel health education interventions delivered by a mobile phone application (Peek) increase spectacle wearing rates in children.

Methods:

The objectives were addressed in two randomized clinical trials.

Trial 1: The utility and cost saving of ready-made vs custom spectacles in a non-inferiority, randomized trial of eligible children aged 11-15 years.

Trial 2: The effectiveness of interventions delivered by mobile phone applications (Peek) on spectacle wear in a cluster randomized clinical trial of eligible children aged 11-15 years. The mobile phone app included images generated by PeekSim, which mimic the visual blur experienced by children with uREs which were used to educate parents, teachers, normally sighted children and children with uREs, with voice message reminders to parents about the benefits of spectacle wear.

Results

Trial 1

86.0% of children undergoing assessment were eligible for ready-made spectacles. Rates of spectacle wear in the two arms were similar i.e., 139/184 children (75.5%) in the ready-made arm and 131/178 children (73.6%) in the custom-made arm (risk difference, 1.8%; 95%CI, –7.1%to 10.8%). Cost minimisation analysis was approximately USD 2,120.00 (range 3,054-840.00) per 100 children needing spectacles.

Trial 2

701 children were prescribed spectacles (Peek arm: 376, control arm: 325). 535/701 (80%) were assessed at 3-4 months: Peek arm: 291/352 (82.7%); standard arm: 244/314 (77.7%). Spectacle wear was 156/291 (53.6%) in the Peek arm and 129/244 (52.9%) in

the standard arm, a difference of 0.7%. Among the 292 (78%) parents contacted, only 13.9% had received the PeekSim image, 70.3% received the voice message and 97.2% understood it.

Conclusions:

Trial 1

Most 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 to 4 months. The cost analysis suggests that ready-made spectacles can substantially reduce costs for school eye health programs in India without compromising spectacle wear, at least in the short term.

Implications

Use of ready-made spectacles in the delivery of school eye health programmes have the potential to increase the efficiency of a programme.

Trial 2

Spectacle wear was similar in both arms of the trial, one explanation being that health education for parents was not delivered as intended.

Implications

Health education messages to create behaviour change need to be appropriate and use an acceptable and accessible medium.

Preface (format of the thesis)

The thesis for this PhD is in the "research/review paper" format. It includes a number of papers, which have been published or are formatted for submission to peer-reviewed journals. The chapters listed in the 'Contents' page are formatted this way and include publication details in a cover sheet, which includes acknowledgement of the contributions of other people I worked with. Information and data that make the body of the thesis more coherent and not presented or covered in the papers is included as "linking material" in other chapters. I, Priya Morjaria, wrote the linking material.

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This work is dedicated to my parents and my brother who have supported this journey and continue to do so every step of the way. They keep reminding me that 'A ship in harbour is safe, but that is not what ships are made for'. Thank you for encouraging me to sail. And for bringing me up in Tanzania. It has shaped my life and career.

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There are millions of children in this world that struggle through daily life as they are not able to see clearly. I hope that in some way with this work we can continue to strive to bring school eye health to every child.

Contributors to the research presented in the thesis

Contributors to the research project besides listed authors in the manuscripts

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	Mr. Dinesh Raj	Public Health Foundation India	Project Manager
	Mr. SK Ejas	Public Health Foundation India	Project Administrator
Peek Vision	Dr. Andrew Bastawrous	Assistant Professor of International Eye Health, LSHTM and Founder of Peek Vision	Advice on study design Collaborator
	Mr. Richard Evans	Head of Software, Peek Vision	Software: development for trial and support
	Mr. Vince Hewitt	Senior Software Engineer	Software: development for trial and support

INTRODUCTION

How ideas for the thesis developed

I was brought up in Tanzania. At the age of six my career in the world of eyes began when I was given a pair of spectacles and that changed my world. I was one of the lucky few with access to an eye care professional who could correctly diagnose my high myopia, give me a pair of spectacles and also replace them when they broke. What I grew up not understanding but being affected by was the stigma surrounding a child who needs to wear spectacles, especially as a girl.

As an optometrist working as a clinician in the UK many years later, I realised that in low and middle income countries, the process of children accessing an eye care professional, is not as simple, nor is getting a pair of spectacles that a child likes to wear. In addition, I was frustrated when managing children, as there was still stigma surrounding the wear of spectacles and more often than not, parental disapproval or lack of awareness of why their child needed spectacles was still a reason for not wearing their spectacles.

I was concerned about the impact of poor vision on a child. Not only is their academic development hindered, but so is their social and emotional wellbeing. My interest in refractive errors and delivery of school eye health programs developed while working in clinics in low and middle income settings in Africa and India with organisations such as Vision Aid Overseas. The challenges faced in the delivery of school eye health programs became apparent, and the lack of standardised guidelines formed the basis of this PhD.

Although there are still many unanswered questions, I have attempted to provide evidence for the acceptability and utility of low cost, high quality, cosmetically appealing ready-made spectacles in school eye health programs and the use of an innovative mobile phone application called Peek to deliver health education to parents, teachers and children.

The structure of the thesis

The thesis for this PhD is in the "research/review paper" format.

Chapter 1. Describes the classification, epidemiology and management of refractive errors (REs) globally and REs in children. This includes a section on the epidemic of myopia, and REs in India and concludes with the public health significance of uncorrected RE (uRE) in children.

Chapter 2. This chapter introduces school eye health (SEH) programmes with a global perspective and within India. The technical and clinical methodologies implemented in programs are described to gain a better understanding of the different approaches. The topics discussed are: screening methods, measuring visual acuity (VA), the introduction of Peek (an innovative way to measure acuity, collect data and deliver health education), refraction and dispensing of spectacles. Prescribing guidelines are introduced and the importance of monitoring and evaluation for SEH programmes with a summary of compliance of spectacle wear. There are three papers included in this chapter:

- Paper 1 – Published Cochrane review

'*Vision screening for correctable visual acuity deficits in school-age children and adolescents*'[1] (February 2018)

- Paper 2 – Submitted to BMJ Global Health

'*Compliance and predictors of spectacle wear in schoolchildren and reasons for non-wear: a review of the literature*' (April 2018)

- Paper 3 – Published in the Community Eye Health Journal

'*Improving spectacle wear in school children*'[2] (June 2017)

Chapter 3. This chapter describes the rationale and objectives for both trials undertaken for this thesis.

Chapter 4. This introduces the first trial, which was a non-inferiority trial of spectacle wear in children individually randomised to ready-made or custom-made spectacles. Five papers are included in this chapter:-

- Paper 4 – Published in Trials (protocol paper)

'*Spectacle wearing in children randomised to ready-made or custom spectacles, and potential cost savings to programmes: study protocol for a randomised controlled trial*'[3] (January 2016)

- Paper 5 – Published in JAMA Ophthalmology (primary outcome)

'*Spectacle Wear Among Children in a School-Based Program for Ready-Made vs Custom-Made Spectacles in India: A Randomized Clinical Trial*'[4] (June 2017)

- Paper 6 – Submitted to JAMA Ophthalmology

'*Predictors of spectacle wear and reasons for non-wear in children randomized to ready-made or custom-made spectacles'* (June 2017)

- Paper 7 – Unsubmitted manuscript

'*A cost minimisation analysis of dispensing ready-made spectacles in a school eye health programme*'

- Paper 8 – Published in the Community Eye Health Journal

'*Use of ready-made spectacles in school eye health programmes*'[5] (June 2017)

Chapter 5. This introduces the second trial, which was a superiority, cluster randomised trial using an innovative complex health intervention (Peek), with the hypothesis that this would increase spectacle wear in schoolchildren. A section on how the health education package was developed (formative research) is included in this chapter, along with three papers:-

- Paper 9 – Published in Trials (protocol paper)

  '*Effectiveness of a novel mobile health education intervention (Peek) on spectacle wear among children in India: study protocol for a randomized controlled trial*'[6] (April 2017)

- Paper 10 – Unsubmitted manuscript

  '*Spectacle wearing in children randomized to a novel mobile health intervention (Peek) or standard care: results from a randomized superiority trial in India*'

- Paper 11 – Published in the Community Eye Health Journal

'*Helpful developments and technologies for school eye health programmes*'[7] (June 2017)

Chapter 6. This final chapter takes into account the discussion from both trials (Chapter 4 and 5). It describes the implications and findings for programmes, policy and further research. Dissemination of findings from research is important, the last section describes ways in which this has been achieved, such as the '*Standard guidelines for school eye health programmes for low and middle-income countries*'[8], which I was involved in drafting. This section also has details on the conferences and meetings I have presented findings from this thesis.

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8. IAPB. Comprehensive School Eye Health Guidelines April 2018 [cited 2018 28 April]. Available from: https://www.iapb.org/about-iapb/iapb-work-groups/school-eye-health/.

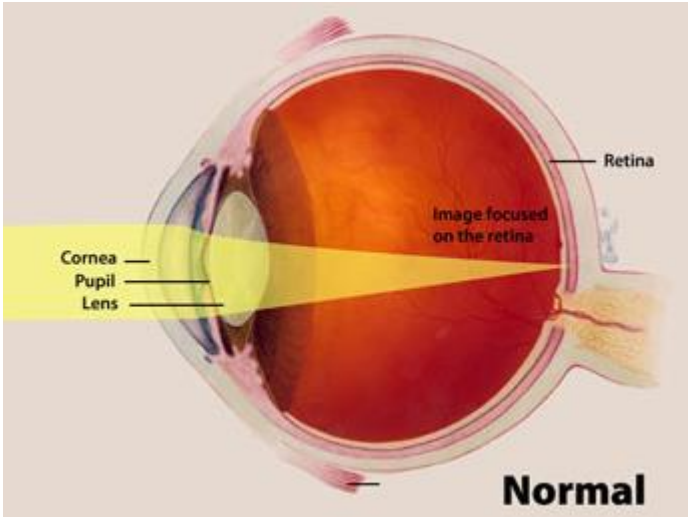
Chapter 1. Refractive errors: definition, classification, detection, management, and epidemiology

This chapter defines refractive errors (REs) and describes the epidemiology of REs in children. The table in the chapter summarises the prevalence of REs in school age children in different populations.

1.1 Definition

Refractive errors are defined as a disorder in which parallel light entering the eye from a distant object is not focussed on the retina. The retina converts the light rays into signals that are sent to via the optic nerve to the brain. The brain then interprets these signals into the images that we see. Refractive errors cause blurred vision in the affected eye(s) and can vary in severity.

Figure 1: How light focusses on the retina in a normal eye



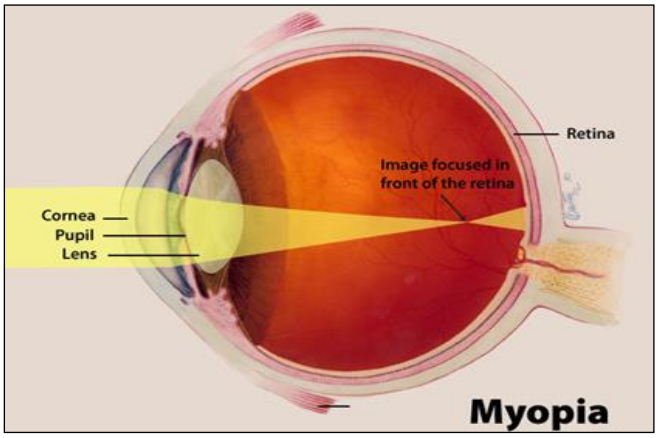
https://nei.nih.gov/health/errors/myopia

1.2 Classification

Refractive errors can result from the axial length of the eye being too short or too long, abnormalities in the curvature of the cornea or the lens. The three most common types of REs are: myopia, hyperopia and astigmatism. Presbyopia typically affects adults as part of the ageing process and is not considered further.

1. Myopia (short/near sightedness), in which objects up close appear clear but there is difficulty in seeing distant objects. In myopia, parallel light rays from distance objects enter the eye and focus in front of the retina instead of on the retina because the eye is too long. Sometimes myopia can also be the result of the cornea being too curved for the length of the eye or the lens being too thick. Myopia is the most common form of RE in children and usually starts around the age of 9 to 10 years and progresses in severity throughout childhood and adolescence into adulthood. This can vary depending on family background setting and such as, in China and other East Asian and South East Asian countries, myopia begins earlier and is prevalent in children as young as 5 years old.[1, 2]

Figure 2: How light rays from a distant object focus in a myopic eye



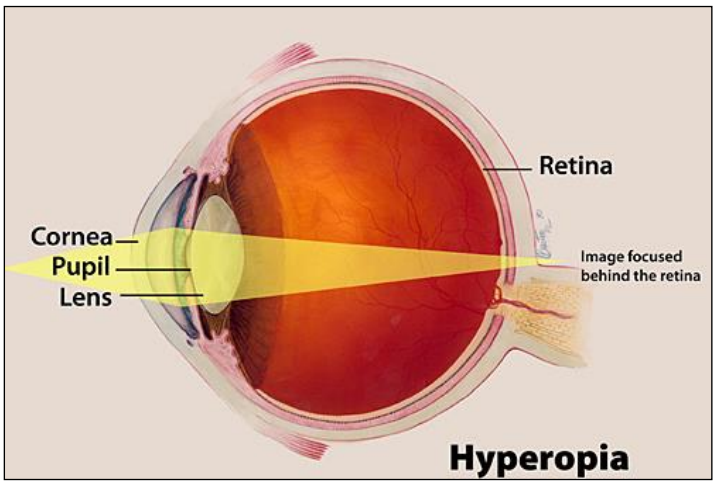
https://nei.nih.gov/health/errors/myopia

Figure 3: The world as seen by someone with myopia

http://www.essilor.ca/En/youreyes/visiondefects/Pages/Myopie.aspx

2. Hyperopia (long/far sightedness), causes difficulty in seeing objects at a close distances. Parallel light rays from a distance object enter the retina and focus behind the retina. Hyperopia is common in younger children. It usually resolves around the age of 10 years.

Figure 4: How light rays from an object focus in a hyperopic eye



https://nei.nih.gov/health/errors/hyperopia

Figure 5: The world as seen by someone with hyperopia

http://www.essilor.com/en/EyeHealth/VisionDefects/Pages/Hyperopia.aspx

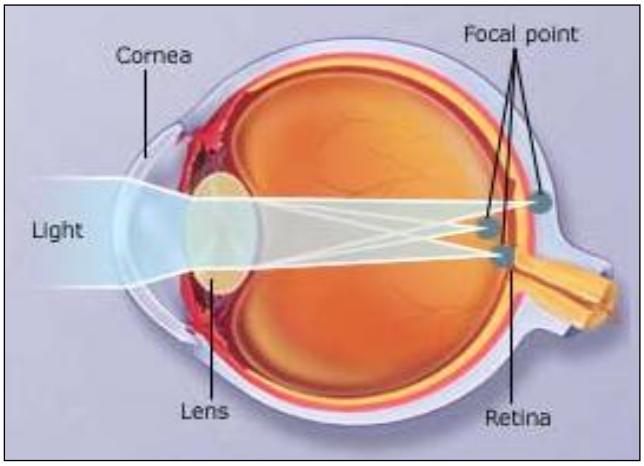
3. Astigmatism causes distorted vision as the refractive power of the cornea or the lens are not consistent in all the meridians. Parallel light rays enter the eye and are refracted unequally in different directions, which leads to lack of a sharp point of focus on the retina and burred or distorted vision. Astigmatism affects all age groups and does not change significantly with age. Astigmatism can be classified in three ways:

(i) 'with the rule' when the refractive power of the vertical meridian is the greatest

(ii) 'against the rule' when the refractive power of the horizontal meridian is the greatest

(iii) 'oblique' when the two primary meridians are neither horizontal nor vertical.

Figure 6: How light rays from an object focus in an astigmatic eye



https://nei.nih.gov/health/errors/astigmatism

Figure 7: The world as seen by someone with astigmatism

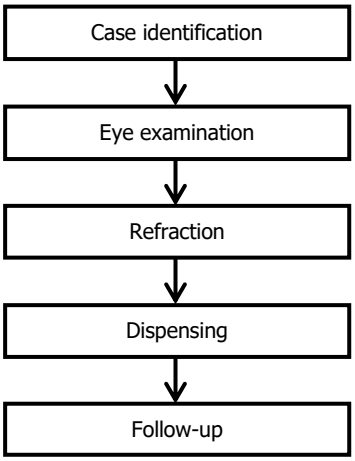
http://www.essilor.ca/En/youreyes/visiondefects/Pages/Astigmatism.aspx

1.3 Detection and management of refractive errors

The most common symptom of REs is blurred vision (Figures 3, 5 and 7). This can be accompanied by double vision, difficulty in focussing, glare or halos around bright lights, headaches from eye strain and squinting. However, many people, especially children, are not aware of these symptoms as they are not aware that they are not

able to see clearly as they should. An eye care professional can diagnose RE during a comprehensive eye exam. This includes testing the visusal acuity (VA), using a retinoscope (explained in further detail below) to objectively measure the refractive error and examine the front and the back of the eye as part of the comprehensive eye health examination.

Figure 8: Steps involved in detection and management of refractive errors

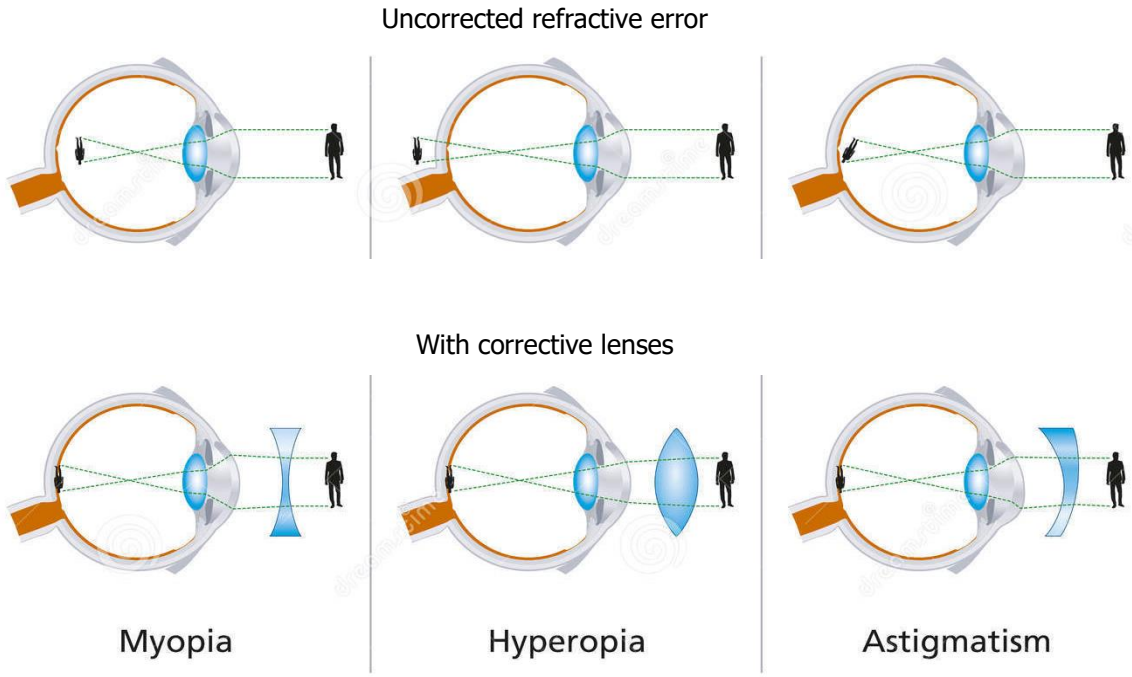


Refraction is a crucial component to detecting REs and it is not an easy skill to learn. A retinoscope is used to get an idea of the patient's prescription objectively and does not require any patient response. The practitioner shines a light into the patient's eyes (using a retinoscope) and studies the direction and speed of the light reflex as the light is moved. Based on these light reflexes, the practitioner is able to determine the type and power of the lenses that can be used in spectacles to correct the RE. This is followed by a subjective refraction to refine the prescription based on the patient's responses. In most settings, an optometrist or refractionist conducts the refraction and decides on the best way to correct the RE.

Spectacles are the commonest method of correction as they simple, safe and cost effective. Other ways to correct REs are contact lenses and refractive surgery but these methods are generally not available in low and middle income countries (LMICS), and are not appropriate for children. After refraction, the eye care professional prescribes the appropriate lenses that give the patient their optimal vision and which is comfortable for them. Depending on the RE, different types of lenses are required to correct the prescription. Refractive errors are measured on a continuous scale in dioptres (D). Myopia is corrected using spherical concave (minus)

lenses, hyperopia requires spherical convex lenses (plus) and astigmatism is corrected using a toric lens, which is a combination of a spherical and cylindrical lens. The term 'spherical equivalent' (SE) is often used to summarize the dioptric measurements. The SE describes the full spherical correction plus half the cylindrical correction.

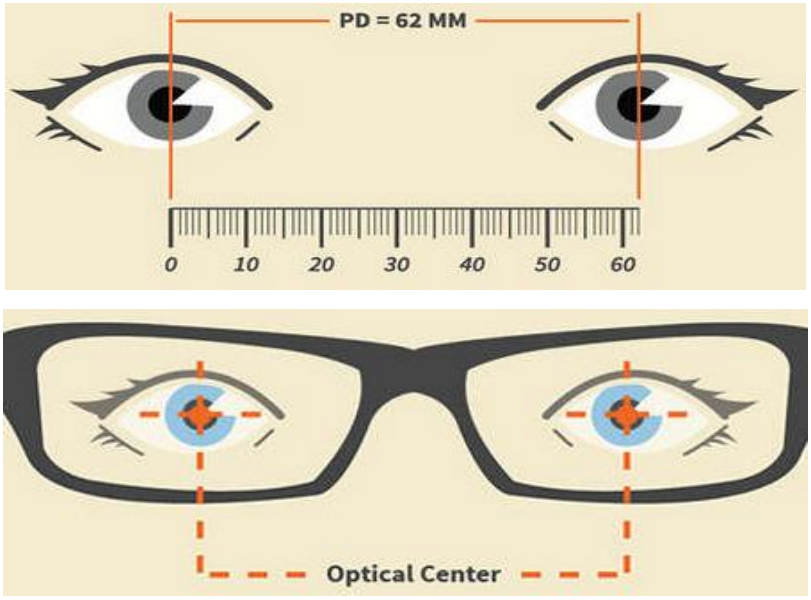
Figure 9: Correction of the different refractive errors using appropriate lenses



http://adelsoneye.com/?page_id=427

The patient then choses a spectacle frame of their preference and measurements are taken to ensure the frame fits the patient. One of the measurements is the interpupillary distance (IPD) which is unique to each person. The IPD is the distance between the centres of the pupils of the two eyes (Figure 10). This measurement is used to position the lenses correctly in the spectacle frames so that the optical centre of the lenses are aligned with the visual axes of the eyes. Incorrect IPD measurements can cause a prismatic effect and visual discomfort. The spectacles are glazed and dispensed ensuring they fit correctly, give optimal vision and are comfortable.

Figure 10: How to measure interpupillary distance and optical centres



http://endmyopia.org/how-to-measure-pd-pupillary-distance/

1.4 Types of spectacles

In clinical practice simple myopic REs are usually fully corrected, using a prescription that is comfortable for the patient and gives them best visual acuity (VA). This can vary for hyperopic and astigmatic prescriptions. For the sake of consistency throughout the thesis, these spectacles are called 'custom-made' (CM) spectacles. Other types of spectacles can be used for people with simple REs in which there is no or minimal astigmatism in both eyes, and where there is minimal difference in the SE between eyes i.e. low anisometropia. These spectacles can be mass-produced at a very low cost, again to maintain consistency throughout this thesis, these spectacles are called 'ready-made' (RM) spectacles.

Diagnosing and managing REs in adults and children follow a similar process. However, children require more frequent follow-up as their prescription can change over time, and their faces grow.

1.5 Epidemiology of refractive errors

1.5.1 Prevalence and magnitude in all ages

Data from the Global Burden of Disease Study estimate that there are 6.6 million people who are blind (presenting visual acuity (VA) worse than 3/60 in the better eye) and 101.2 million are visually impaired (presenting VA worse than 6/18 in the better eye), simply because they do not have a pair of spectacles.[3] The World Health Organization (WHO) estimates that the cause of 43% of blindness is uncorrected refractive errors (uREs).[4]

Refractive errors affect people of all ages, gender, ethnicities and in all settings, i.e. urban or rural and low, middle and high income. For example, in the United States, half the population over the age of 20 years has a RE.[5] And in Asia there is a much higher prevalence of uREs because of the myopia epidemic.[6]

The refractive state of the eye changes throughout childhood and adolescence. This has an impact on the type of RE that manifests. At birth, the eyes are usually hyperopic with a shift towards emmetropisation over the first few years of life as the eyes grow. In most children the eyes remain emmetropic but in some there can be a shift towards myopia during the school years, followed by a rapid period of myopisation that plateaus in the mid to late teenage years.

1.5 2 Refractive errors in children

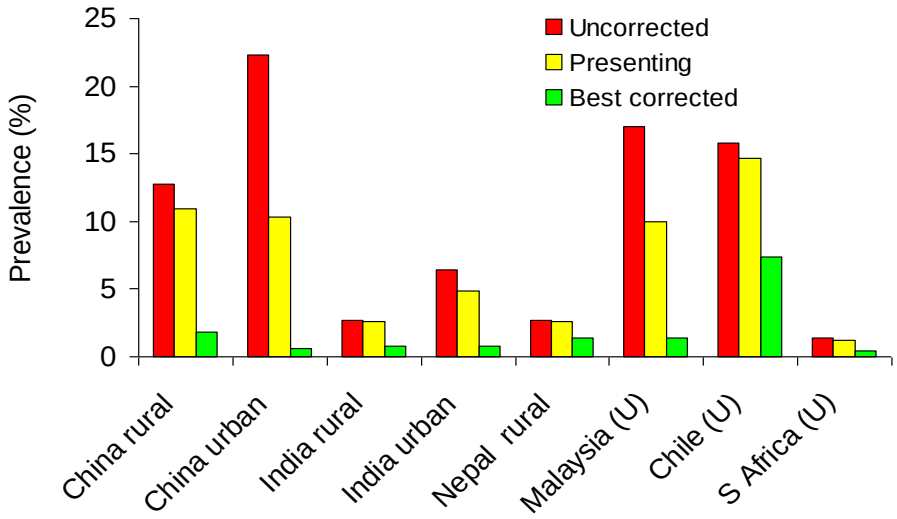
Despite the correction of refractive errors being highly cost effective[7-9], uREs are the most common cause of visual impairment in children. Global estimates in 2004 indicated there were 12.8 million children visually impaired from uREs.[10] This translates into 1% of all children, and given the current global trends in myopia, this is set to rise.

The proportion of visual impairment due to uREs in studies of children in the age range 3 to 15 years varies from 56.3% in Chile,[11] 72.6% in Australia,[12] 76.8% in Brazil,[13] 82.0% in India[14] to 97.1% in China.[15]

The prevalence of REs in children can vary by ethnicity and by cultural setting. It is quite difficult to compare the prevalence in different regions as definitions of myopia, hyperopia and astigmatism are not uniform in the studies, the age groups are dissimilar and procedures to measure VA and refractive status are also different. The

Refractive Error Study in Children (RESC) is a set of eight population-based (not school based) cross-sectional studies of children aged 5 (or 7) to 15 years conducted using a standardised methodology to estimate the prevalence of REs in different ethnic groups and cultural settings.[16] Consistent definitions and common methods were used in each if the eight locations: Nepal,[17] India (urban[14] and rural[18]), Chile,[11] Malaysia,[19] South Africa[20] and China (urban[21] and rural[15]). The results from these studies confirm that there is significant variation in the prevalence in different regions. Within countries there is also variation between urban and rural settings such as India and China (Figure 11). In figure 11, the difference between presenting VA and best corrected VA is the unmet need for spectacle correction.

Figure 11: Prevalence of refractive errors from eight standardised RECS studies



As mentioned previously, the type of RE can vary in different age groups. There is evidence that the majority of myopia usually develops in children aged 8 to 14 years[22] and stabilises during adolescence. Myopia can occur in the later in life but it is not as severe as myopia with an onset in chidhood.[23] Studies have generally found that the prevalence of hyperopia in children can be low with some variability in different populations.[15, 24-27] It is difficult to compare studies that report on prevalence of hyperopia again due the different definitions used. Table 1 includes studies that define hyperopia as a SE ≥2.00, which is a clinically significant measure. Population based data on astigmatism in children are limited and it appears to be more prevalent in infants and very young children. Using the definition of astigmatism as a cylindrical power ≥0.75 in either eye, the range of prevalence is over 40% in Singapore

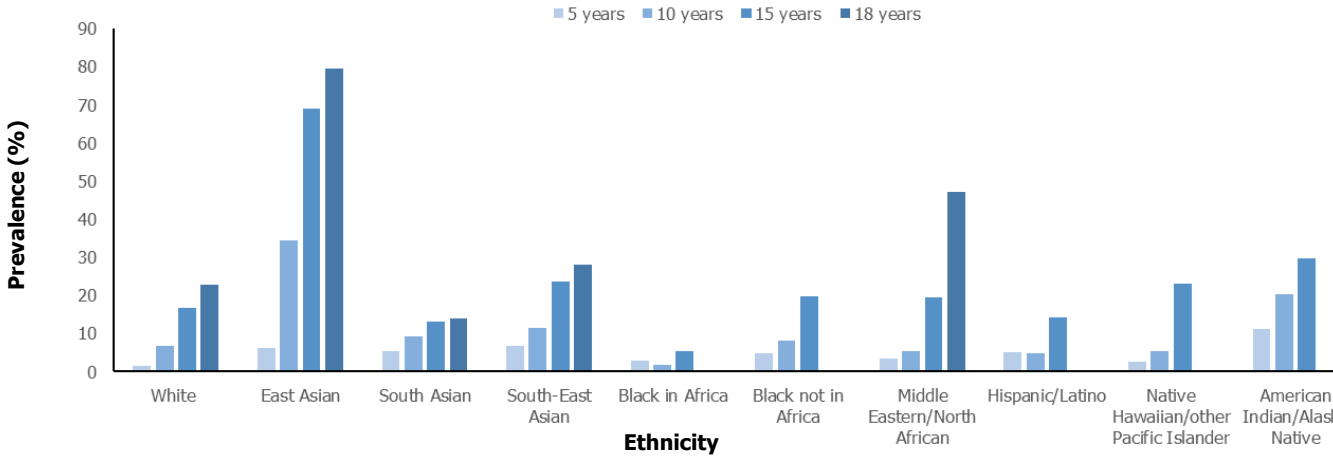
(7-9 years old)[27] and urban China (5-15 years old)[21] to a low of 9.5% in rural China (5-15 years old)[28] and 9.8% in rural India (7-15 years old).[18]

Table 1: Refractive errors in school age children in different populations

					Prevalence (%)		
Author, year of publication	**Country/Subgroup**	**Age (years)**	**Year of study**	**Sample size**	**Myopia SE ≤ -0.50D**	**Hyperopia SE ≥2.00D**	**Astigmatism (cyl ≥ 0.75D in either eye)**
Zhao, 2000[28]	China (Shunyi District)	5-15	1988-1998	5,884	21.6	2.7	15.0
Dandona, 2002[18]	Rural India (Andhra Pradesh)	7-15	2000-2001	4,074	5.6	0.68	9.8
Murthy, 2002[14]	Urban India (New Delhi)	5-15	2000-2001	6,447	7.4	7.4	14.6
Kleinstein, 2003[29]	US	5-17	1997-1998	2,523	10.5		
	African-American			534	8.6		
	Asian			491	19.8		
	Hispanic			463	14.5		
	White			1.035	5.2		
Naidoo, 2003[20]	Durban, S. Africa	5-15	2002	4,890	4.0	2.6	14.6
Fan, 2004[24]	Hong Kong	5-16	1998-2000	7,560	36.7	4	
He, 2004[21]	Urban China (Guangzhou)	5-15	2002-2003	4,364	38.1	4.6	42.8
Goh, 2005[19]	Malaysia	7-18	2003	4,634	20.7	1.6	15.7
	Malay			3,257	15.4	1.5	
	Chinese			764	46.4	1.1	
	Indian			412	16.2	2.0	
Ojaimi, 2005[30]	Australia	5.5-8.4	2003-2005	1,765	1.43	91.0	
Saw, 2006[27]	Singapore	7-9	1999-2001	1,962	36.3	1.7	42.6
	Malay			1,254	22.1	3.4	44.3
	Chinese			285	40.1	1.2	42.5
	Indian			152	34.1	2.4	41.3
	Malaysia	7-9	1999-2001	1,752	13.4	2.9	22.2
	Malay			348	9.2	2.9	18.7
	Chinese			1,467	30.9	1.8	34
	Indian			126	12.5	3.9	22.4
He, 2007[15]	China (Yangxi)	12-18	2005	2,454	42.4	1.2	25.3
	Urban				50	1.51	26.6
	Rural				33	0.82	23.6
Congdon, 2008[30]	Rural China (Xichang)	11-17	2007	1,892	62.3	0.2	1.7
Huynh, 2007[32]	Australia	11.1-14.4	2003-2005	3,144	12.8	5.0	13.6
Ip, 2008[31]	*Younger*	5-8		1,724	1.43	13.2	
Ip, 2008[25]	*Older*	11-15		2,340	11.9	5	13.6

In 2016, Rudnicka et al published a review to quantify the global variation in childhood myopia prevalence taking account of ethnicity, age and the study design. Rudnicka et al state that there are noticeable differences in prevalence by ethnicity and these differences increase with age[31] (Figure 12). East Asians as categorised in this review have the highest prevalence of myopia reaching 80% by 18 years of age compared to black children in Africa in late adolescence where 5.5% of 15 year olds are affected. Also, children who predominantly live in urban areas are 2.6 times more likely to be myopic than children living in rural environments.

Figure 12: Prevalence of myopia in children by ethnicity and age



1.6 Refractive errors in children in India

The prevalence of uRE in children varies by country, age, and urban/rural location, including in India.[14, 18, 32] In the population based surveys of children in India outlined above (Table 1) in 2003, 4.1% of children in rural areas aged 7-15 years were myopic, and 61% of visual impairment was due to uRE.[18] In the survey in urban India 7.4% of children aged 5-15 years were myopic and 82% of visual impairment was due to uRE[14] (see Table 1). In both studies, older children had a higher prevalence of uRE than younger children.

In studies conducted in schools in India, the prevalence of RE ranges from 13.1% in urban Delhi,[33] 25.1% in Kolkata[34] to 59.5% in Odisha.[35] Furthermore, one study found that only 1.06% of children were wearing their spectacle correction.[36]

1.7 Aetiology and risk factors for myopia

The aetiology of myopia is complex entailing complex interactions between retinal and optical, and genetic and environmental factors.[37] Genetic predisposition, environmental factors associated with urbanisation, increased near work and lack of time spent outdoors are thought to be risk factors associated with myopia.[38, 39]

The role of genetics is complicated and genome wide association studies have isolated many genes associated with myopia. These affect different parts of the pathways, which influence eye growth. Numerous studies have tried to identify a specific gene link, while a loci for high myopia has been identified, there are no conclusions on a loci for moderate levels of myopia.[40]

The role of genetics on myopia has been explored in multiple familial aggregate studies, twin and sibling studies, school-based samples and population-based samples. One myopic parent increases the risk of the child being myopic by 2-3 times; two myopic parents increases the risk up to 6 times and twin studies show high heritability for myopia.[41]

Increased near work has been associated with a higher prevalence of myopia for example in students, tailors etc. Accommodative lag has been studied extensively in relation to near work, as it contributes to hyperopic defocus so promoting eye growth. Myopes have greater accommodative lag than emmetropes. However, it is unclear whether myopia comes first or the accommodative lag.[42, 43] Hyperopic defocus on the peripheral retina is suggested as a risk factor for myopia progression. The concept that the eye is not focus across the entire retina and the peripheral retina can be out of focus is important. The Study of Theories about Myopia Progression (STAMP) was a 2-year, double-masked randomized clinical trial designed to evaluate hyperopic retinal blur caused by a high lag of accommodation during near work accelerates axial elongation.[44, 45] Results from this trial concluded that children with myopic superior defocus had significantly less myopia progression. These findings support the continued investigation of optical designs that create peripheral myopic defocus as a means of slowing the progression of myopia.[46]

A range of studies of different designs have suggested that greater time spent outdoors is effective in preventing the onset of myopia and slowing the myopic shift in non-myopic children. However, a recent meta-analysis[47] of three clinical trials showed that greater time outdoors is not effective at slowing progression in eyes that are already myopic.[48-50] There are a number of explanations why higher levels of light encountered outdoors and spectral composition of natural light are protective.[39] Individual factors such as smaller pupils, relaxed accommodation, reduced dioptric variation also play a role combined with the light levels outdoors.[51] Higher light levels increase dopamine and slows down eye growth in animals, but this has not been validated in human myopia.[52, 53] In one study in China, the progression of myopia was approximately 60% less in the summer than the winter and axial elongation was also significantly less in the summer. However, it is not conclusive whether more time spent outdoors in summer vs. winter is a contributing factor, or the difference in progression rates is a result of "seasonal" variations in the intensity or amount of close work performed.[54] There is a hypothesis that myopes have a lower level of vitamin D but whether this influences the onset or progression of myopia is not very clear. Outdoor exposure is a protective factor for onset of myopia, and vitamin D can serve as a biomarker of outdoor exposure.[55]

Several studies implicate the role of prolonged near-work in the aetiology of myopia, but the relationship between genetic, and environment factors is difficult to disentangle and remains unclear.

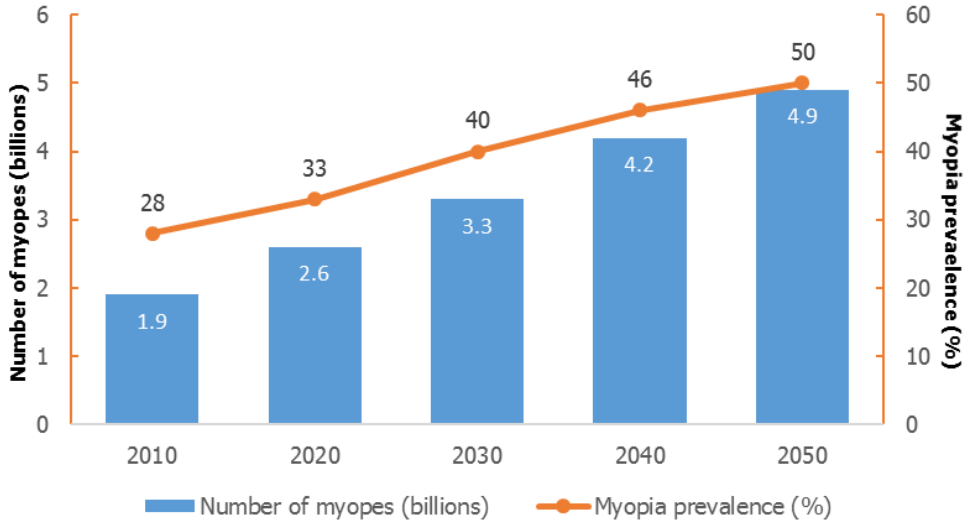
1.8 Epidemic of myopia

The prevalence of myopia is significantly increasing and in the developed countries of East and Southeast Asia the prevalence of myopia is now 80-90% in children completing secondary school at the age of 17-18.[56] In comparison, the prevalence in developed western countries is in the region of 20-40%.[38, 57-59] It is interesting to note that in the less developed countries with education systems are not as developed the prevalence of myopia is often less than 5-10%.[60-64] The cluster of countries where there is a high prevalence of myopia is in East and Southeast Asia and many of these countries have a populations of Chinese ancestry but the high prevalence is not limited to these popluations, it is also high in South Korea[65] and Japan.[66] Although

the myopia epidemic is commonly described as an Asian problem, 'it is an epidemic that crosses ethnic boundaries but tightly localised geographically'.[56]

A recent systematic review and meta-analysis suggests that between 2010 and 2050 the number of people with myopia globally will increase from 1.9 billion to almost 5 billion, 1 billion of who will have high myopia.[6] (Figure 13)

Figure 13: Myopia progression between 2010 and 2050



The projections were based on existing data and assumed that current lifestyle patterns would continue. Currently, there is an increasing prevalence of myopia, which means that vision impairment from uncorrected myopia is also increasing; accurate data for this however, is limited from certain regions. For example, Taiwan[66, 67] and some less systematic data from Singapore.[68-70] These findings, together with the lack of consensus on standard definitions for myopia and high myopia and insufficient attention from a public health perspective, led to a global scientific meeting on myopia in March 2015, which was led by WHO and the Brien Holden Vision Institute. Participants at the meeting were scientific and clinical experts in myopia from six different WHO regions, and they published a report called 'The Impact of Myopia and High Myopia.'[71] Some of the main outcomes of the meeting are as follows:

1. An agreed definition of myopia and high myopia.

- Myopia: a condition in which the spherical equivalent objective refractive error is ≤ –0.50 dioptre in either eye.
- High myopia: a condition in which the spherical equivalent objective refractive error is ≤ –5.00 dioptre in either eye.

2. A clinical definition of myopic macular degeneration (MMD) and the need to use clinically and in research
   - A vision-threatening condition in people with myopia, usually high myopia, which comprises diffuse, patchy macular atrophy with or without lacquer cracks, choroidal neovascularization and Fuchs spot.
   - The term MMD should be used clinically and in research to categorize the blinding retinal diseases associated with high myopia. Currently, a number of terms are used, including MMD, myopic maculopathy, myopic retinopathy and myopic choroidal neovascularization.
3. A call for clinical and epidemiological research on myopia using standardised methodologies.
   - A cycloplegic agent should be used in clinical or epidemiological studies of children under the age of 18 years.
   - In surveys and studies, the continuous distribution of age and refractive errors should be reported for people up to the age of 25 years.
   - The ocular history of individuals should include interventions such as refractive surgery and other procedures to reduce refractive error, but not necessarily the consequences of axial eye elongation.
   - The use of cycloplegic refractions and its inclusion in survey protocols for both young adults and adults should be investigated further.
4. The inclusion of myopia and high myopia and myopic macular degenerations as attributable causes of vision impairment in epidemiological surveys.
   - The term “myopic macular degeneration” should be used to define the retinal condition that causes vision impairment in myopia, because it is clearly defined and easily categorized for rapid assessment of avoidable blindness, in the WHO survey protocol and others.
5. Evaluation of the evidence on myopia control strategies e.g. increasing time spent outdoors, atropine, spectacle/contact lens.
6. Evaluation of the evidence on environmental, optical and therapeutic factors on myopigenisis.

1.9 Public health significance of refractive errors in children

There is evidence that providing spectacles to myopic children significantly improves their academic performance,[72] visual functioning, behavioural development[73] and quality of life.[9] A study in Mexico showed evidence of improvement in self-reported visual function after spectacle wear.[74] There is some evidence from an Australian study that children who failed vision screening had significantly lower academic achievements than their peers who passed screening.[75] An American study demonstrates a positive impact on academic performance and psychosocial wellbeing in children given spectacles.[76]

The high levels of uRE has led to school programs in many countries, and organizations are supporting large scale programs, including in India.[77] However, the approaches have not been standardized and most do not use guidelines or prescribing protocols, nor is spectacle wear usually monitored.[78]

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Chapter 2. School eye health programmes and vision screening

This chapter describes the different models of school eye health programmes (SEH) globally and outlines programmes in India and how they vary. Different methods of vision screening for children are described, including Peek Acuity which has a suite of smartphone based applications and a data management system. Different components of SEH are described along with the challenges of implementing, monitoring and evaluating them.

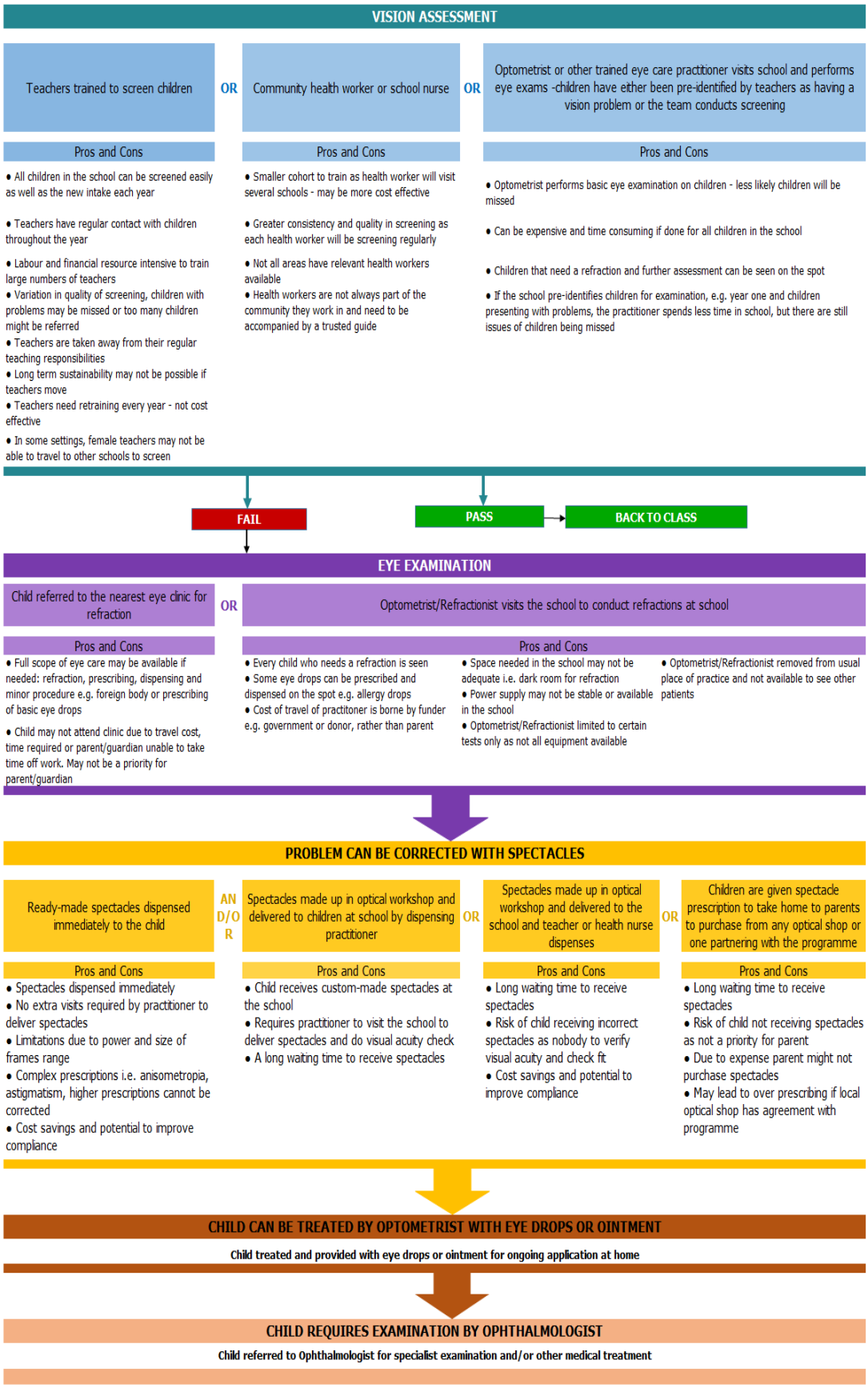
2.1 School eye health programmes: globally

Globally it is normal practice in many countries for children to have their vision measured at school. This is usually a screening test and does not constitute or replace a comprehensive eye examination. School based programmes are common in settings where the prevalence of uREs are high, e.g. in India and China, where there is limited access to optometric services, and potential for children to have a severe vision impairment that would affect school performance. There is evidence that providing free spectacles as a part of a screening programme increase the number of children possessing and wearing their spectacles and also has the potential to improve educational outcomes in children.[1]

As expected, in all the settings where SEH programmes are implemented, they vary in purpose, design and how they are implemented. The components of SEH programmes depend on the setting and whether they focus narrowly on RE, or health education and/or other eye diseases of childhood are included. Different cadres are also involved in these programmes e.g. field workers, community health workers, teachers, refractionists, optometrists, and ophthalmic technicians.

Figure 14 illustrates some of the common strategies for delivering SEH, including some of the advantages and disadvantages of the different methods. The infographic is a version that I have modified from an unpublished report titled 'A Situational Analysis of Child Eye Health' which was commissioned by the World Bank via a school health project that was sponsored by the Global Partnership for Education. The research and reporting was by a team at the Brien Holden Vision Institute.

Figure 14: Description of common approaches for delivery of school eye health



2.2 **School eye health programmes: India**

School eye health was embedded within the National Programme for Control of Blindness as 'School Eye Screening' (SES) in 1994 after successful implementation in five pilot districts.[2] The focus of the programme was screening children for uREs in middle and secondary schools. Table 2 describes the activities undertaken within the SES programme.

Table 2: Activities in the School Eye Screening programme in India

1	Collect information on number of students and teachers
2	Collect information on number of screening and referral centres
3	Training of school teachers to screen and identify referrals
4	Training of general health care professionals
5	Confirmation of referred students by ophthalmic assistant/ophthalmologist
6	Agreement between District Health Centre and local optical shops to supply low cost quality spectacles (acetate frames with lenses)
7	Prescription of spectacles
8	Provision of free spectacles for students

Despite a very large number of children receiving spectacles, the SES programme in India had a number of challenges, as in other countries, including lack of trained personnel to provide refractive and surgical services for children; the cost of spectacles; low community awareness about the condition; reaching children out of school and lack of low vision and rehabilitation services.[3]

In 2013 the Ministry of Health and Family Welfare, Government of India, under the National Health Mission, launched the Rashtriya Bal Swasthya Karyakram (RBSK) programme, which is an initiative for a systematic approach to 'Child Health Screening and Early Intervention Services'. The programme entails early identification with referral to relevant care, support and treatment. The RBSK programme absorbed the earlier SES initiative. Under the RBSK, 30 health conditions prevalent in children under the age of 18 years have been identified for early detection and management. These conditions fall under the 4Ds:-

(i) Defects of birth
(ii) Diseases in children, which includes refractive errors
(iii) Deficiency conditions
(iv) Developmental delays including disabilities, which includes visual impairment

The policy is that children aged 6 to 18 years enrolled in government and government-aided schools are screened by RBSK Mobile Health teams for these conditions at least once a year. However, no data is available on the coverage of this programme.

Along with the government programme, a large number of non-governmental eye care organisations (NGOs) and service providers in India include SEH programmes as part of their strategy. However, the lack of local coordination between providers can lead to duplication of effort in some districts or regions where multiple screening activities occur (unpublished MSc dissertation).[4]

Models of school eye health in India

There are a number of ways that SEH activities are implemented in India. Four models of SEH programmes have been identified from discussions with personnel in the government and NGO sectors in India (Table 3).

Table 3: How school eye health programmes are implemented in India

<table>
<tr><th>Model</th><th>Preliminary screening</th><th>Children who require refraction</th><th>Specialist examination</th><th>Delivery and financing of spectacles</th></tr>
<tr><td>1</td><td>Trained teachers screen children at school and identify those who need further examination</td><td>Detailed examination by ophthalmic assistants - at school or primary health centre. Simple refractive errors managed</td><td>Children referred to the base hospital for specialist examination and cycloplegic refractions</td><td rowspan="4">(i) Free spectacles are given to children from poor socioeconomic backgrounds in government schools. They are supplied by local partner optical shops and the District Blindness Control covers the costs.

(ii) Free spectacles are provided to all children. They are supplied by the local partner optical shops and costs are covered by donors such as the NGOs e.g. Rotary, Lions and international NGOs

(ii) Parents are given prescriptions and they purchase he spectacles directly from private optical shops

(iv) Spectacles are provided at a subsidised cost by the screening organisation - the cost is shared by parents and the organisation</td></tr>
<tr><td>2</td><td>Screening takes place at school by optometrists</td><td colspan="2">Detailed examination with refraction done at the base hospital; spectacle dispensing; cycloplegic refractions</td></tr>
<tr><td>3</td><td>Screening and simple refraction at the school by mid-level ophthalmic personnel</td><td colspan="2">Complicated and cycloplegic refractions referred to the base hospital</td></tr>
<tr><td>4</td><td colspan="3">Parents are informed about screening and advised to bring their children to the hospital where screening, diagnosis and treatment take place</td></tr>
<tr><td colspan="5">Some programmes allow children to choose their spectacle frames and some provide a standard frame that is given to all children</td></tr>
</table>

In India, teacher led screening has been successful in some settings. Teachers are trained to identify children with VA <6/12 in either eye or with obvious ocular abnormalities, who are referred to an ophthalmic team consisting of refractionists and ophthalmologists who visit the school and provide treatment and prescriptions for spectacles.[5] However, the evidence for such teams to visit schools is limited and cannot be translated across India due to the cultural variation between States and the trained personnel available. Screening correctly is an important issue to address, as a major cost to SEH programmes is the cost of providing services after a child fails screening. If screening is not done accurately, then the number of false positives and false negatives increase. If children who require spectacles and/or treatment are not identified appropriately and in a timely manner, it can have long term implications for the child. False positives can increase the burden on clinical staff.[6] What is

apparent in India is that the majority of SEH programmes are NGO led with enormous variation across the country.

Some of the questions that need to be addressed for implementing SEH programmes have been identified universally (Table 4).

Table 4: Questions to address when implementing School Eye Health programmes

Screening	Which age group to screen?	**Refraction Dispensing of spectacles**	Definition of refractive error	**Follow-up & other aspects**	When to follow-up on compliance of spectacles?
	Who does the screening?		What spectacles to prescribe?		How to address low spectacle compliance?
	When to do the screening?		Where to do the refraction? e.g. school/health centre		How to address poor monitoring & evaluation for spectacle compliance and referrals?
	How to screen?		Who does the refraction?		Teacher's eye health needs
	Where to do the screening?		When to prescribe ready-made spectacles?		When to re-screen children?
	How to screen out-of-school children?		Where to dispense the spectacles? e.g. at school, optical shop		Other aspects of eye health to address
	What screening acuity cut-off to use?		Should visual acuity be re-measured at spectacle dispensing?		Embedding with other child/school health programmes

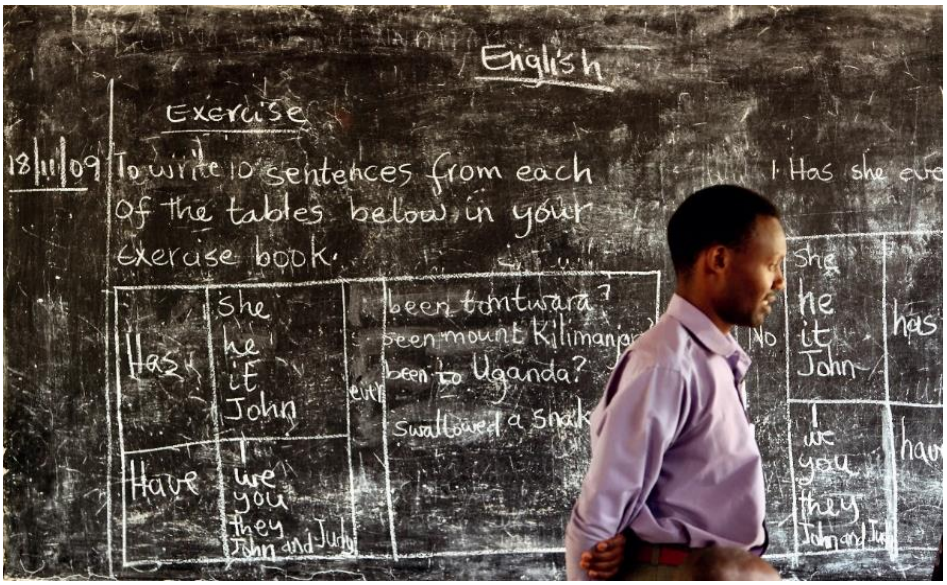
2.3 Screening

2.3.1 Methods of measuring visual acuity

The measurement of VA is usually the first step to assess the visual system and is used in SEH programmes. This requires a VA chart and a VA cut-off to identify children who require refraction and/or further specialist examination.[7] However, there is no set VA cut-off and programmes use either 6/9 or 6/12. The test chart should be adequately illuminated and each eye tested separately. The use of 6/12 is recommended by some, as in one study it reduced the number of children who screened positive by 50% compared to testing at 6/9.[8] However, there needs to be more evidence to determine optimal VA cut-off in each context. It is important to ensure that all children who could have a potential vision impairment are identified and thus, it is recommended to screen at 6/9. Also, in the majority of settings where SEH programmes are conducted, most teaching uses blackboards which are often of

poor quality and contrast (Figure 15), the classrooms are not adequately lit and thus a better level of vision is required for distance viewing.

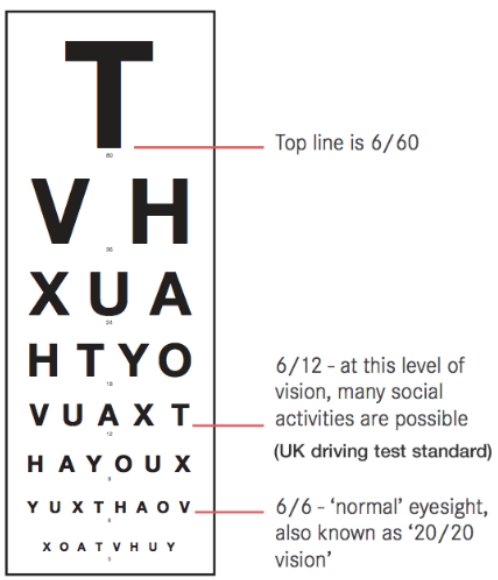
Figure 15: Example of a blackboard of poor quality in some of the classrooms



There is no universal vision chart that is currently used in SEH programmes and many charts are available, using different optotypes.[9] Some programmes use a Snellen chart, while some use a one line optotype of tumbling Es. In India, some programmes have implemented a pocket screener.[10] (Figure 16)

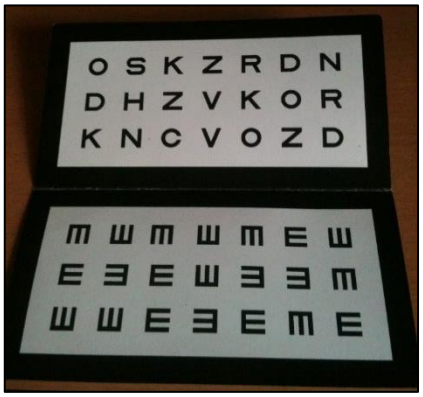
The World Health Organization, in 1988 set out guidelines on what constitutes a pass for a Landolt C or Snellen E chart, the criteria is 4 out 5 correct identification at a consecutive showing of the optoype.[11] One of the challenges when screening using different vision charts is that there is no standardization on whether a screen fail at any given level of acuity on one type of chart is equivalent to a screen fail when using a different chart. There are also concerns around children remembering the orientation of the E's and if a Snellen chart is used, children tend to memorise the letters while queuing up to be screened.

Figure 16: Examples of the different charts used to measure visual acuity



Snellen chart

Tumbling 'E'



Pocket Screener

The pocket screener is a compact chart for screening that incorporates the principles of a logMAR chart and can be used for large scale vision screening programmes. It is used to screen at the 6/9 cut off level. Mobile phone applications can also be used, but these need to be validated (see below).

2.3.2 Who should screen?

Who does the screening depends on many factors, and can be done by health/eye care professionals or non-health personnel such as field workers or teachers after rigorous training. Figure 14 explains some of the advantages and disadvantages of three different personnel who can screen: (i) teachers, (ii) community health workers, school nurses or other field workers and (iii) optometrist, ophthalmic technician, ophthalmic nurse or other eye care professional.

Several studies have attempted to validate the accuracy and effectiveness of teachers as screeners in schools. A study in India provides evidence that training all class teachers in a school is more cost effective and efficient than training selected teachers to screen, and it also improved compliance with hospital referral.[5] Although using teachers as screeners is cost effective and reduces the workload of the eye care personnel, there is evidence of large variability among teachers and high false positive

and false negative rates and reduced accuracy.[12–14] Other studies have commented on teacher participation being satisfactory[15] and the lack of knowledge of REs amongst teachers.[16] A school-based screening programme in Vietnam found that teachers were more accurate when they screened uncorrected VA compared to presenting VA.[17]

Vision screening by teachers and other non-eye health personnel such as teachers and parents is carried out in many settings. Nurses, optometry students and other allied health professionals often screen in school eye health programmes.[18] Results vary widely between different personnel, for example, 'nurses and lay screeners achieved sensitivities of 37% to 71% at specificities of 70% to 90% in detecting visual impairment' and the accuracy is better amongst older compared to younger children.[19]

Teachers are in a unique position in that they are able to screen all the children in the school, including the new intake every academic year. However, teachers also have their teaching and other responsibilities, and they require the time and motivation to continue to screen at regular intervals. In some settings, it may be difficult for teachers to gain permission from the local education authorities to take on this responsibility as it also requires continuous refresher training. This is not a sustainable model as teachers may transfer schools or move out of the area. This is not a sustainable model in some regions as teachers may transfer schools or move out of the area and the attrition of teacher's especially female teachers.

Community health workers or school nurses can be trained to screen and visit several schools. This can be cost effective and consistent quality of screening can be maintained. However, such a cadre may not be available in all areas. One other group of screeners are fieldworkers who are not healthcare workers. These function in a similar way to community health workers and visit several schools in their catchment area. However, for subsequent screening, new field workers would need to be recruited and this is not sustainable.

Optometrists or other eye care personnel, such as ophthalmic/vision technicians are another group of personnel who can screen. In a setting where a high number of eye care personnel are available, this can be an option. This cadre can also perform an eye examination at the school and refer children who need specialist examination.

However, eye care professionals are an expensive resource as it is time consuming to screen children and there are opportunity costs for providers. An option is for teachers to pre-identify children who have symptoms but this can mean some children who have eye problems are missed.

Any personnel who screens requires high levels of competency for all the relevant steps of screening i.e., to prepare the screening location (lighting, distance), adequately explain the screening process to the child, elicit from the child if they already use spectacles or have any eye concerns, accurately measure VA, document the findings correctly and identify children who require referral.

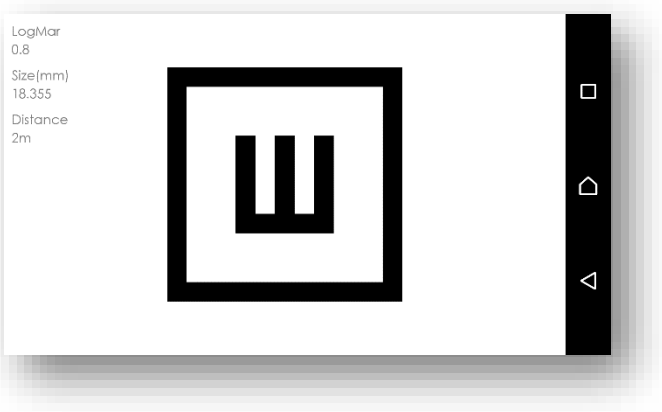
2.4 Peek Solutions

New technology and innovative medical devices along with the use of smartphones are becoming increasingly popular in clinical practice and research. One such innovation is Peek Solutions, which has a smartphone-based web technology primarily deployed in Android to measure VA, called Peek Acuity. Peek Acuity was developed by Dr. Andrew Bastawrous and colleagues and it has been validated for clinical practice and community-based vision screening.[20] The validation study showed Peek Acuity to be comparable to the Early Treatment Diabetic Study (ETDRS) logMAR chart and to Snellen VA screening in terms of repeatability and speed. Peek Acuity used in the community by a community health care worker had 85% sensitivity and 98% specificity.[20] . In addition, Peek Acuity can be used by non-health professionals to obtain accurate measurements.[20]

<u>How Peek Acuity works</u>

Peek Acuity uses E optoypes of varying size and orientation which obey the principles of the standard ETDRS chart design (Figure 17). Four orientations are used in total. The crowding effect of a standard ETDRS chart is also simulated by a bounding box with thickness equivalent to the limb of the optotype and spacing between the optotype and crowding bar equal to twice the thickness of the limb. The screen shows one E optotype at a time which is known to reduce confusion.

Figure 17: The E optotype with the bounding box as it appears in Peek Acuity



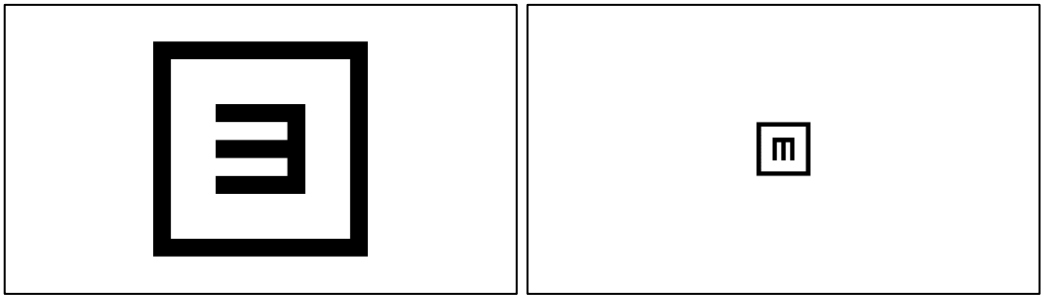
Peek Acuity can configure the test distance, and the practitioner can chose between 2 or 3 metres. During VA screening, the subject being tested points in the direction the arms of the E are pointing and the screener uses the touch screen on the device to swipe in that direction. The practitioner is masked and does not know whether the patient is correct or incorrect, which reduces practitioner bias The software records the number of optotypes correctly seen at any given level of VA screening. If the patient shakes their head or hand or indicates they cannot see the optotype, the examiner shakes the handset which records a “not seen” at that size. (see YouTube video; https://www.youtube.com/watch?v=Xw3qMLjdpfM.)

Screening starts with the largest optotype that fits the screen (configured to the equivalent of 6/60 for use in school screening), but this can be configured to 6/120 if required. If the child’s VA is less than this, the practitioner is prompted to reduce the test distance. Jf all the tests are positive the software automatically brings up the next smallest series of optotpyes in a randomly generated orientation. The process of testing is repeated until the correct number of errors is reached for any given level of acuity, at which point the device vibrates and makes a sound to indicate that the screening has concluded. The screen orientation is locked during the test to avoid confusing reorientation.

Figure 18: The child uses hand gestures to indicate the direction of the E

Peek Vision: Teacher screening a child in the classroom in Kenya

Figure 19: The E optotype changes in size according to the stair-casing algorithm

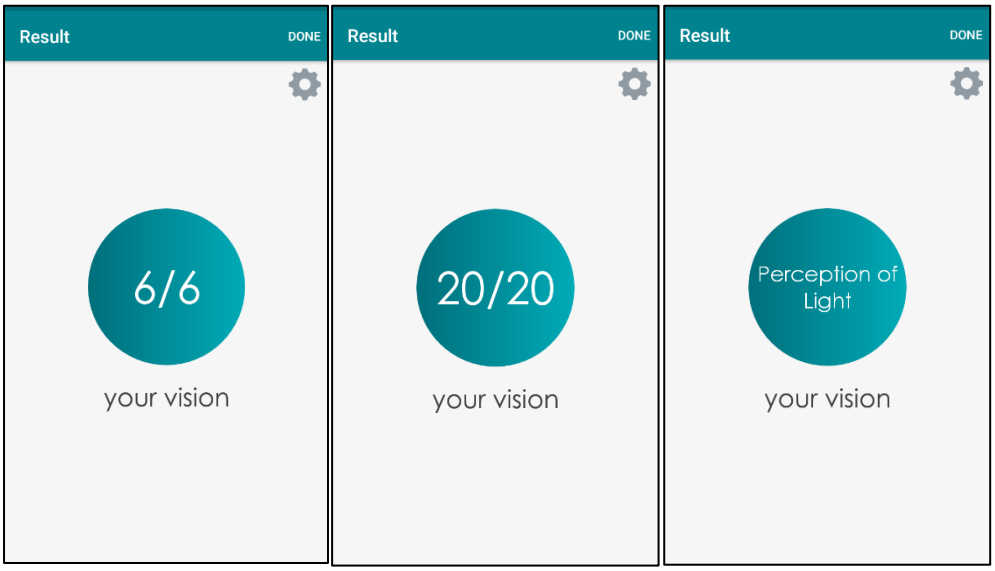


Peek Acuity also allows for the measurements of counting fingers, hand movements and light perception in a standardised manner. Counting fingers is measured by randomly presenting between two and four bars. The response is recorded on the screen as correct or incorrect. Hand movement is measured using a solid black box half the width of the screen, the box moves back and forth across the screen. For light perception Peek Acuity automatically switches on the device's LED flashlight. The child identifies when they see the light come on and go off.

The logic of the application is based on the logMAR scale, but each level can be associated with a display label, which may be logMAR, metric or imperial Snellen value or indeed any appropriate value like "Pass" or "Fail." When the test concludes,

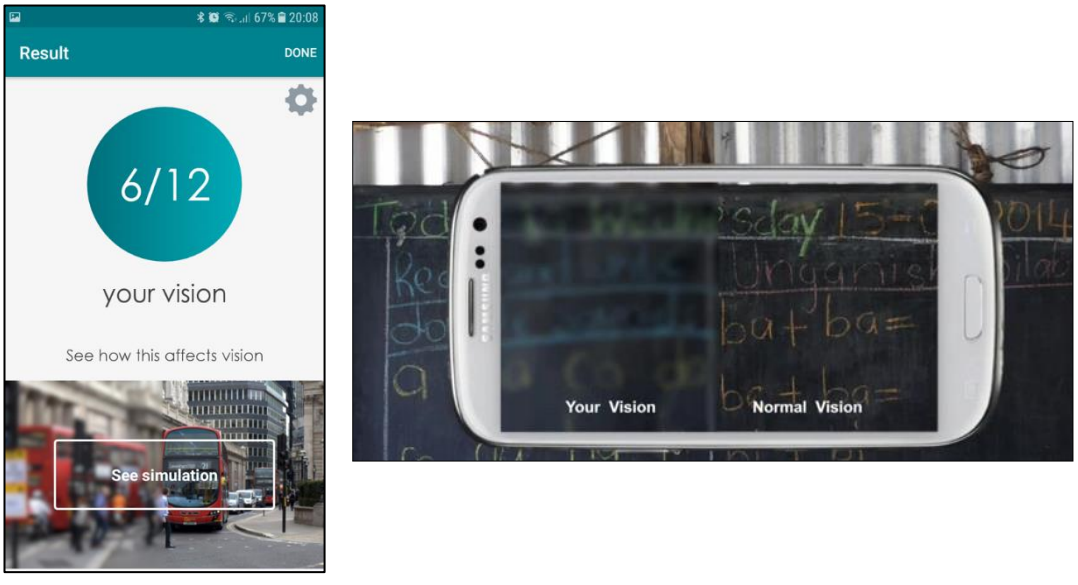
the widget displays the label of the top pass, if the test was passed, or the label of the bottom level otherwise. These labels are defined and configured to meet the needs of a project. Results from the test are displayed on the screen and the screener has the option to choose the units they are displayed in. (Figure 20).

Figure 20: Results from Peek Acuity in the different units



Another application in Peek Solutions simulates the visual blur caused by the level of vision equivalent to the result of the vision test (PeekSim) (Figure 21). This image can be shared via email or SMS and is valuable as an awareness creating tool.

Figure 21: Simulation using PeekSim to mimic visual blur



Peek Acuity is available as a free download from the Google Play Store, and has been downloaded in 160 countries.

Peek Solutions also has a retinal imaging system, Peek Retina. This is hardware that can be used by non-clinicians to get a satisfactory to view the retina, through a dilated pupil, using their smartphones. Peek Retina was validated, and non-clinicians using the Peek Retina adapter were able to acquire optic nerve images comparable to those using a desktop retinal camera by an ophthalmic assistant.[21]

The acceptability of and adoptability of both Peek Retina and Peek Acuity was assessed by qualitative interviews with patients, examiners and other stakeholders and it was found to be acceptable in Kenya. 'Peek is an acceptable solution, as it provides a beneficial service, supports patients' needs, and fulfils health care providers' roles, overall contributing to strengthening eye health.'[22]

Peek Solutions for School Eye Health

The aspiration for Peek Acuity and Peek Retina was to create tools that can be incorporated into programmes and health systems. Peek Acuity is a a standalone VA test; it is integrated into a system of digital data collection tools for SEH – Peek Solutions which means that data are captured and made available along the patient pathway. For example, lists of children who fail VA screening are generated and sent to head teachers and optometrists; SMS messages can be sent to all the parents of children who fail screening, and data are continuously updated so that programme managers can monitor and evaluate their programmes in real time.

Peek Solutions has been used in a school screening programme in Kitale, Kenya where earlier studies had shown very low uptake of referral by children who had failed vision screening. Trained school teachers used Peek Acuity to screen children at school. Those who were screen positive had their details collected and the Peek system sent automated text messages to their parents/guardians, notifying them to bring their child to the hospital for further assessment. This study was conducted as a cluster randomized control trial. In the control arm children had their vision assessed using a card based vision test and referral letters were sent home to their parents. In

the Peek intervention arm, the adherence to uptake of referral was 52% compared to 21% in the control arm (publication in press Lancet Global Health).

Additional apps and features are also being developed, for contrast sensitivity and near vision for example, to provide a comprehensive system for screening visual function in schools and communities and in population surveys.

In the linking material for trial 2 (Peek trial), chapter 3 I will describe how the software was used in the trial.

2.5 Refraction

Not all children who fail screening require spectacles as some may have mild REs that do not require correction and others may have other ocular pathology, such as allergies, strabismus, traumatic eye injuries etc., which require referral for specialist management. Other children will be false positives.

After a child is identified as having failed screening, they need to be seen by an eye care practitioner who is recognised within the health system (public/private), and who has the necessary competencies and experience of refracting children.

Refraction can be done at the school or the child is referred to an identified eye care facility. This is to ensure that the refraction is of good quality and there is access to appropriate spectacles for children. If the refraction is conducted at school, the child does not have to travel. However, all children who require a cycloplegic refraction usually must be referred as parental consent is required. This can mean that some children do not receive the spectacles as parents are not able to bring them to the eye facility for the cycloplegic refraction. In settings where there is a high number of eye care personnel who can refract, the refraction can be done at the school. But when there are a limited number of refractionists children are usually referred to an eye facility.

An objective refraction is done using a retinoscope, followed by a subjective refraction. Some programmes also use an autorefractor, but this should only be done

if the model has been validated for use in children, and is followed by a subjective refraction.

2.5.1 Cycloplegic refraction

The primary indication for a cycloplegic refraction is the young age of a child. Other indications for cycloplegic refraction are as follows: the child cannot cooperate; there is a variable or inconsistent end-point to refraction; refraction is difficult because of media opacities or irregular corneas and in the presence of strabismus or suspected amblyopia.

Wet cycloplegic refraction is done after instilling cycloplegic drops which temporarily dilate the pupil and prevent accommodation by paralysing the ciliary muscles. There has been considerable debate around cycloplegic versus non-cycloplegic refraction, with cycloplegic refraction being considered the gold standard for epidemiological studies.[23] However, outside of epidemiological studies it is regarded as standard clinical practice to conduct cycloplegic refractions in young children. There is some evidence that the greatest difference between results from non-cycloplegic and cycloplegic refraction is in the range -1.00D to +1.00D and that there is less variability in children with visual loss from RE.[24] A cycloplegic refraction is carried out in children to eliminate the concern about over correcting minus (myopic) prescriptions.

It is crucial to note that parental consent is often required to instil drops into a child's eyes and the practitioner carrying out a cycloplegic refraction must be experienced in undertaking the refraction and being able to interpret and prescribe spectacles based on the results.

2.6 Detection of hyperopia

The prevalence of hyperopia is higher than myopia in the young, pre-school age children,.[25] There is no global consensus on how to screen for hyperopia in schoolchildren and some studies indicate that where there are efficient vision screening programmes and services for pre-school children, screening for hyperopia for school-age can be omitted.[26] There is evidence that higher degrees of hyperopia

are associated with poorer progress in education, particularly reading ,[27, 28] and children with severe hyperopia may also have other problems, particularly of the central nervous system. The current consensus is that poorer progress in education is due to these problems, which can be difficult to detect, and are not entirely attributable to uncorrected hyperopia.[29]
Mild hyperopia is common in children (+2.00 to +4.00D) and generally does not interfere with their vision or education. Hence, school vision screening usually tests distance VA and assumes that if a child has hyperopia that affects their educational development then it will be detected when testing their distance VA. There is however, a lack of consensus on vision screening standards and protocols for hyperopia.[30-32]

One approach to screening for hyperopia includes "fogging".[26] In emmetropic eyes a +2.00D lens gives a fogging of the vision equivalent to 2D of myopia. Hence an emmetropic child aged above 8 years will fail distance VA screening if they are screened wearing a pair of +2.00 D spectacles. However, in hyperopic children the +2D lenses will reduce the amount of accommodation required, which is likely to improve their vision and they will pass the test. Depending on the age of the child, the amplitude of accommodation varies. Younger children have higher amplitude of accommodation and the strength of the fogging lens should increase. For example in children around the age of 6 years, a +4.00D lens is used as children with more than slight hyperopia would not be able to sufficiently relax their accommodation to see through the lens of this strength.[29]

Due to the complexities of screening and managing hyperopia in children, it is important that hyperopia screening is only part of SEH after taking into consideration if resources permit and there are trained eye health personnel available, the age of the children being screened and expected local prevalence.

2.7 Prescribing guidelines

In addition to the lack of standard approaches to screening, there are also no guidelines for prescribing spectacles, nor for referral or follow-up in SEH initiatives.

Lack of prescribing guidelines can result in the over prescribing of spectacles i.e., children are dispensed low power spectacles that they will not benefit from, adding costs to a programme and increasing expenditure for parents. Prescribing guidelines are a way to objectively prioritise refractive care and avoid unnecessary prescribing of spectacles in settings with limited resources. There is an emerging consensus that prescribing should be based on improvement of VA rather than the degree of RE, and improvement of VA by two or more lines in the better seeing eye has been recommended.[33-35]

Children who fail the screening test should be referred to an eye care facility/optical centre that is part of the programme. This ensures that the quality of refraction and the spectacles dispensed can be monitored. Poor quality refraction can lead to over prescribing. Spectacle dispensing is monitored so that children are dispensed good quality spectacles appropriate for them.

2.8 Dispensing spectacles

In Chapter 1 the different types of spectacles were described, i.e., ready-made and custom-made, and the definition of spherical equivalent. This section describes what is involved in dispensing spectacles to children. All the aspects described below are applicable to both ready-made and custom-made spectacles. The main difference between the two types of spectacles is that ready-made spectacles can be fitted and dispensed at the time of refraction whereas custom-made spectacles need to be made up in the laboratory and either delivered to children in school, or patients have to collect them.

When dispensing spectacles to children the frame measurements and fitting are very important. The first step is to ensure a good frame fit as the frame size has to be appropriate for the child – a frame that is too wide or too narrow can be uncomfortable and compromise the child's vision. The practitioner must also check the child's IPD and check that the back vertex distance (BVD). This is the distance from the back of the lens to the apex of the cornea. On average, it is assumed at 12mm if not indicated otherwise. The BVD is important because if there is a difference between the vertex distance that the refraction took place at and where the final

spectacle frame will sit, an adjustment needs to be made to the prescription. The BVD also prevent the eyelashes being in contact with the lens.

Different aspects of the frame must also be checked: head width, sides, length to bend, length of side and angle of drop. Bridge fitting is also extremely important as it often it is the deciding factor between a good or ill-fitting spectacle frame. The nasal bridge starts to form at approximately nine years of age and it is almost completely formed by the age of 13 years.

Both the frame and prescription should be verified to prevent errors. At the time of delivering the spectacles personnel must ensure that the spectacles fit the child and have the intended visual outcome.

Part of the challenge of dispensing spectacles to children is being able to explain to the child why they need to wear spectacles and when to wear them. Appropriate attention to the fitting details will improve wearing compliance and ensure the best visual outcome for the child.

2.9 Compliance of spectacle wear in children and reasons for non-wear

Several studies have investigated compliance of spectacle wear in children and the reasons for non-compliance. Issues with spectacle compliance is a common problem in all settings.

Reasons why children do not wear their spectacles include loss/breakage,[36-39] misconceptions that using spectacles will make their vision worse,[33, 40, 41] parental disapproval,[42, 43] being teased,[36, 37, 40, 41, 43, 44] and forgetfulness.[33, 37, 38, 43] In a recent study in India, reasons for not wearing spectacles included being teased (19.8%), the spectacles were broken (17.4%) or lost (9.3%), and the child did not like their spectacles (12.0%).[45]

2.10 Monitoring and evaluation

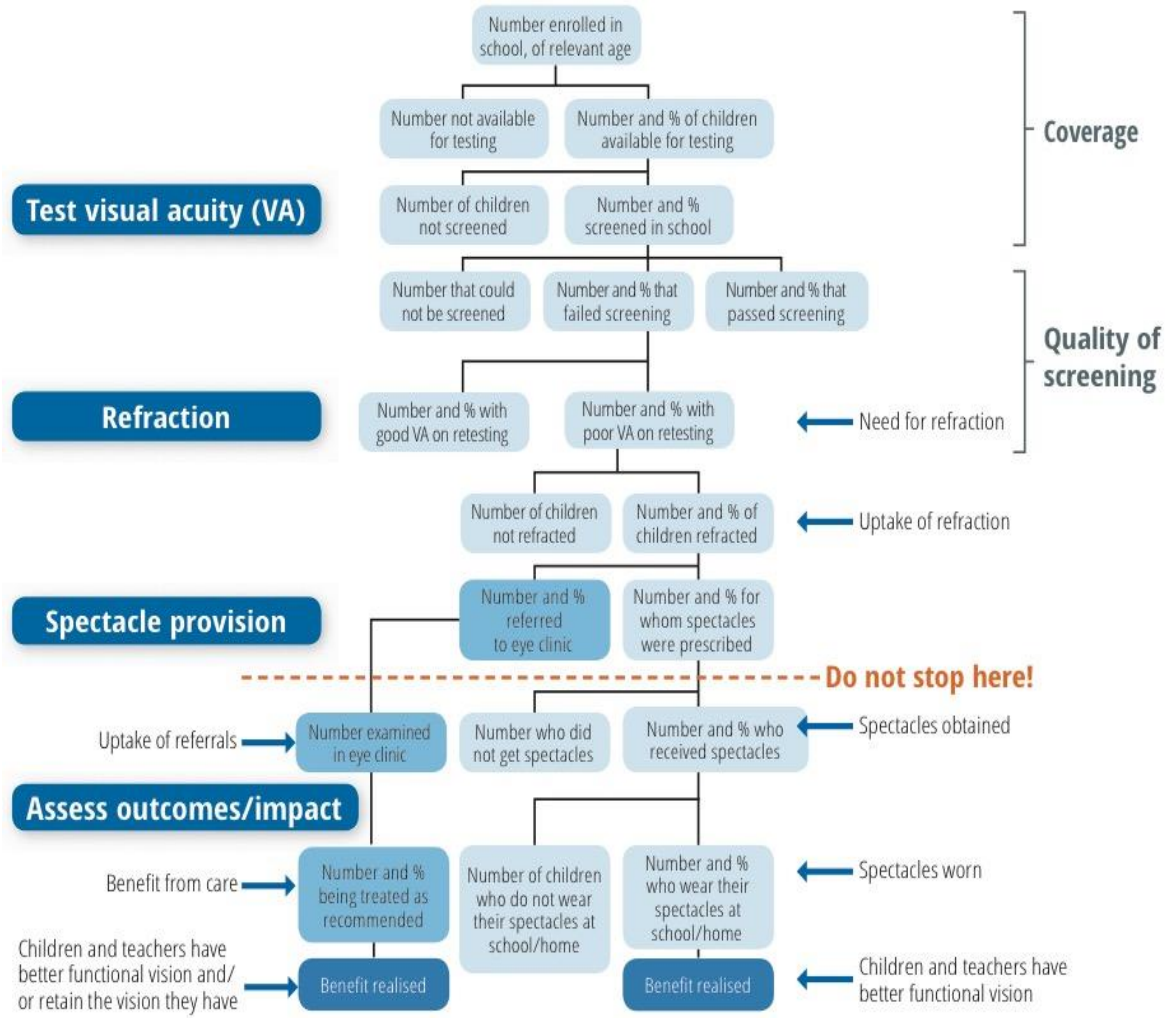
The best practice for a programme is to have a system or plan for evaluation developed at the outset of a programme. Inadequate monitoring and evaluation of SEH programmes can lead to inefficiencies and poor assessment of the outcomes and impact.

Before starting a SEH programme the goal of the programme must be clearly identified and all components of the programme aligned before beginning implementation. After defining the goal, a strategy is to work backwards, with specific (SMART) objectives for each outcome, i.e. which are Specific, Measureable, Attainable, Relevant and Time-bound. Each objectives requires activities and indicators.

Traditionally the indicators collected in a SEH programme are the number of children screened and number of pairs of spectacles dispensed. However, these do not assess the impact of a programme. It is important to know how many children obtain spectacles and how many subsequently wear them. A step beyond that is to assess the impact of spectacles on a child's visual function and quality of life

Programme decisions should be driven by data and hence evidence based. Thus, information on the different indicators should be collected at different stages of the programme. Figure 22 from the 'School Eye Health' issue of the Community Eye Health Journal,[46] illustrates data that can be collected to monitor and evaluate SEH programmes at each stage. Amongst other things, this will ensure screening accuracy, spectacle adherence and uptake of referrals.

Figure 22: Data to be collected to monitor and evaluate at each stage of the programme



Assumptions are often made that children will obtain and wear their spectacles and that this will improve their visual function and quality of life. Data on the above indicators and regularly monitoring them can be used to assess if a programme is meeting its targets and to identify if any changes need to be made.

The next section is a manuscript which has been submitted for publication which reviews rates of compliance and predictors of spectacle wear, and reasons for non-compliance in school children. The manuscript incudes recommendations for improving spectacle wear, which include the use of prescribing guidelines, health education, and allowing children to select the frames they prefer.

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Student	Priya Morjaria
Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

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[Intervention Review]

Vision screening for correctable visual acuity deficits in school-age children and adolescents

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ABSTRACT

Background

Although the benefits of vision screening seem intuitive, the value of such programmes in junior and senior schools has been questioned. In addition there exists a lack of clarity regarding the optimum age for screening and frequency at which to carry out screening.

Objectives

To evaluate the effectiveness of vision screening programmes carried out in schools to reduce the prevalence of correctable visual acuity deficits due to refractive error in school-age children.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) (2017, Issue 4); Ovid MEDLINE; Ovid Embase; the ISRCTN registry; ClinicalTrials.gov and the ICTRP. The date of the search was 3 May 2017.

Selection criteria

We included randomised controlled trials (RCTs), including cluster-randomised trials, that compared vision screening with no vision screening, or compared interventions to improve uptake of spectacles or efficiency of vision screening.

Data collection and analysis

Two review authors independently screened search results and extracted data. Our pre-specified primary outcome was uncorrected, or suboptimally corrected, visual acuity deficit due to refractive error six months after screening. Pre-specified secondary outcomes included visual acuity deficit due to refractive error more than six months after screening, visual acuity deficit due to causes other than refractive error, spectacle wearing, quality of life, costs, and adverse effects. We graded the certainty of the evidence using GRADE.

Main results

We identified seven relevant studies. Five of these studies were conducted in China with one study in India and one in Tanzania. A total of 9858 children aged between 10 and 18 years were randomised in these studies, 8240 of whom (84%) were followed up between one and eight months after screening. Overall we judged the studies to be at low risk of bias. None of these studies compared vision screening for correctable visual acuity deficits with not screening.

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Two studies compared vision screening with the provision of free spectacles versus vision screening with no provision of free spectacles (prescription only). These studies provide high-certainty evidence that vision screening with provision of free spectacles results in a higher proportion of children wearing spectacles than if vision screening is accompanied by provision of a prescription only (risk ratio (RR) 1.60, 95% confidence interval (CI) 1.34 to 1.90; 1092 participants). The studies suggest that if approximately 250 per 1000 children given vision screening plus prescription only are wearing spectacles at follow-up (three to six months) then 400 per 1000 (335 to 475) children would be wearing spectacles after vision screening and provision of free spectacles. Low-certainty evidence suggested better educational attainment in children in the free spectacles group (adjusted difference 0.11 in standardised mathematics score, 95% CI 0.01 to 0.21, 1 study, 2289 participants). Costs were reported in one study in Tanzania in 2008 and indicated a relatively low cost of screening and spectacle provision (low-certainty evidence). There was no evidence of any important effect of provision of free spectacles on uncorrected visual acuity (mean difference -0.02 logMAR (95% CI adjusted for clustering -0.04 to 0.01) between the groups at follow-up (moderate-certainty evidence). Other pre-specified outcomes of this review were not reported.

Two studies explored the effect of an educational intervention in addition to vision screening on spectacle wear. There was moderate-certainty evidence of little apparent effect of the education interventions investigated in these studies in addition to vision screening, compared to vision screening alone for spectacle wearing (RR 1.11, 95% CI 0.95 to 1.31, 1 study, 3177 participants) or related outcome spectacle purchase (odds ratio (OR) 0.84, 95% CI 0.55 to 1.31, 1 study, 4448 participants). Other pre-specified outcomes of this review were not reported.

Three studies compared vision screening with ready-made spectacles versus vision screening with custom-made spectacles. These studies provide moderate-certainty evidence of no clinically meaningful differences between the two types of spectacles. In one study, mean logMAR acuity in better and worse eye was similar between groups: mean difference (MD) better eye 0.03 logMAR, 95% CI 0.01 to 0.05; 414 participants; MD worse eye 0.06 logMAR, 95% CI 0.04 to 0.08; 414 participants). There was high-certainty evidence of no important difference in spectacle wearing (RR 0.98, 95% CI 0.91 to 1.05; 1203 participants) between the two groups and moderate-certainty evidence of no important difference in quality of life between the two groups (the mean quality-of-life score measured using the National Eye Institute Refractive Error Quality of Life scale 42 was 1.42 better (1.04 worse to 3.90 better) in children with ready-made spectacles (1 study of 188 participants). Although none of the studies reported on costs directly, ready-made spectacles are cheaper and may represent considerable cost-savings for vision screening programmes in lower income settings. There was low-certainty evidence of no important difference in adverse effects between the two groups. Adverse effects were reported in one study and were similar between groups. These included blurred vision, distorted vision, headache, disorientation, dizziness, eyestrain and nausea.

Authors' conclusions

Vision screening plus provision of free spectacles improves the number of children who have and wear the spectacles they need compared with providing a prescription only. This may lead to better educational outcomes. Health education interventions, as currently devised and tested, do not appear to improve spectacle wearing in children. In lower-income settings, ready-made spectacles may provide a useful alternative to expensive custom-made spectacles.

PLAIN LANGUAGE SUMMARY

Screening school-age children and adolescents for reduced vision caused by the need for spectacles

What is the aim of this review?

The aim of this Cochrane Review was to find out if vision screening of school-age children and adolescents reduces the number of children who need spectacles but who either don't have any or who are wearing the wrong prescription.

Key messages

Vision screening and provision of free spectacles improves the number of children who have and wear the spectacles they need. In lower-income settings, ready-made spectacles may provide a useful alternative to expensive custom-made spectacles.

What was studied in the review?

Worldwide, an unmet need for corrective spectacles is the leading cause of reduced vision in children; short-sightedness (unable to see objects in the distance clearly) has become the commonest eye condition. Reduced vision may affect academic performance and therefore choice of occupation and socio-economic status in adult life. It can also be associated with other symptoms such as headaches. Vision screening programmes designed to identify children who need spectacles have therefore been introduced into schools. Such programmes

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improve access to health care for some children who would not otherwise have it, but the value of these screening programmes is debatable. This review was therefore designed to collect and evaluate any evidence regarding how well such programmes are working.

What are the main results of the review?

Cochrane Review authors found seven relevant studies. These studies tested ways of improving the take-up of spectacle prescriptions given as part of a screening programme. Five studies were from China, one from India and one from Tanzania. These studies compared: vision screening with free spectacles with vision screening alone; vision screening with education with vision screening alone; and vision screening and ready-made spectacles with vision screening and custom-made spectacles.

The review shows that:

• There are no studies comparing vision screening with no vision screening (evidence gap).

• Vision screening with provision of free spectacles results in more children wearing spectacles after screening compared with giving the children a prescription on its own (high-certainty evidence). Children in the free-spectacle group had better educational attainment (low-certainty evidence).

• Vision screening with health education designed to increase spectacle uptake did not appear to improve the number of children wearing spectacles after screening compared with no education (moderate-certainty evidence).

• Ready-made and custom-made spectacles appear to give similar visual results and similar spectacle wearing (moderate- and high-certainty evidence).

How up-to-date is this review?

Cochrane Review authors searched for studies that had been published up to 3 May 2017.

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SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Vision screening and provision of free spectacles compared with vision screening and provision of prescription for correctable visual acuity deficits in school-age children and adolescents

Patient or population: school-age children and adolescents
Settings: schools
Intervention: vision screening and provision of free spectacles
Comparison: vision screening and provision of prescription

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk[1]	Corresponding risk				
	prescription	free spectacles				
Uncorrected visual acuity deficit due to refractive error Follow-up: 6 months	-	-	-	-	-	Not reported
Uncorrected visual acuity deficit due to refractive error Follow-up: more than 6 months	-	-	-	-	-	Not reported
Visual acuity deficit due causes other than refractive error Follow-up: 6 months	-	-	-	-	-	Not reported
Spectacle wearing Follow-up: 6 months	**Low uptake of spectacles**		**RR** 1.60 (1.34 to 1.90)	1092 (2 RCTs)	⊕⊕⊕⊕ High	
	250 per 1000	**400 per 1000** (335 to 475)				

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	High uptake of spectacles					
	750 per 1000	**1000 per 1000** (1000 to 1000)				
Quality of life Follow-up: 6 months	-	-	-	2289 (1 RCT)	⊕⊕◯◯ Low[2]	In one study in China, children who received free spectacles had better educational attainment as measured by a standardised mathematics score (adjusted difference 0.11 (95% CI 0.01 to 0.21). This difference is equivalent to approximately half a term (semester) of additional learning
Cost	In one study in Tanzania in 2008 the overall cost of screening and spectacle provision for each screened student was USD 0.87. The overall cost of screening and spectacle provision for each student who used spectacles was USD 46.3 (GBP 23.40) for free spectacles; USD 64.7 (GBP 32.70) for prescribed spectacles. Calculations were based on spectacle use of 47% if spectacles were provided free and 26% if spectacles were only prescribed				⊕⊕◯◯ Low[3]	
Adverse effects Follow-up: any time period	One study investigated the impact of assignment to free spectacles compared with prescription only on uncorrected visual acuity at follow-up. There was a mean difference of -0.02 logMAR (95% CI adjusted for clustering -0.04 to 0.01) between the groups i.e. no evidence of any important impact of free spectacles on uncorrected acuity				⊕⊕⊕◯ Moderate[4]	Not reported

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High-certainty: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different
Low-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different
Very low-certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[1]Spectacle wearing in the comparator groups of studies included in this review varied from 23% to 96%. We have chosen 25% and 75% as illustrative risks.
[2] Downgraded 1 level for imprecision and 1 level for indirectness.
[3] Downgraded 2 levels for indirectness as costs very specific to location (Tanzania) and time period (nearly 10 years ago).
[4] Downgraded 1 level for indirectness because average logMAR acuity may not adequately reflect proportion of children with important changes in uncorrected visual acuity.

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BACKGROUND

Description of the condition

Refractive error (need for spectacles) can be defined as the inability of an eye to bring parallel rays of light into focus on the retina resulting in a blurred image. There are three types of refractive error. Myopia (short-sightedness) compromises distance vision. Hypermetropia (long-sightedness) compromises near vision and, if severe enough, distance vision as well. Astigmatism, caused by a non-spherical cornea, impairs both distance and near vision.

In normal visual development, changes in refractive error occur over the first few years of life. The majority of full-term babies are hypermetropic at birth (Banks 1980) but this decreases with growth so that in adult life the preponderance of refractions are around zero or emmetropia (Sorsby 1964). Most of this change occurs in early childhood (Ehrlich 1997) in a process known as emmetropisation (Jensen 1995). The main risk factors for development of myopia appear to be intensive education and limited time outdoors (Morgan 2017). Myopia can be inherited (Yap 1994), possibly through the genetic determination of the axial length of the eye (Canoll 1982).

Myopia is a common condition. Some authors estimate that 34% of the world population will be affected by myopia in 2020 (uncertainty interval 26% to 43%) (Holden 2016). This corresponds to 2620 million people (1976 to 3366 million people). There is considerable global variation in the prevalence of myopia in children. A recent systematic review and meta-analysis of population-based studies suggested that 70% (95% credible interval (CrI) 61% to 77%) of East Asian children have myopia by the time they are 15 years old (Rudnicka 2016). East Asian was defined as Chinese, Japanese, Mongolian and Taiwanese. This high prevalence contrasts with relatively low prevalence in black children living in Africa (6%, 95% CrI 3% to 9%) and slightly higher prevalence in white children (17%, 95% CrI 11% to 25%). This review also provides evidence that there has been a 23% increase in myopia prevalence per decade in East Asian children (adjusted odds ratio per decade 1.23, 95% CrI 1 to 1.55). In contrast over the same period, the prevalence of myopia in white children has appeared to be stable (adjusted odds ratio per decade 0.85, 95% CrI 0.69 to 1.05). However, a study in the UK published since the review was done, has suggested that there has been an increase in myopia prevalence in white children, albeit to a smaller degree (from 7% in the 1960s to 16% between 2006 to 2008) (McCullough 2016).

Uncorrected refractive error is an important cause of visual impairment in children. Approximately 1% of children (13 million) worldwide are estimated to be visually impaired due to uncorrected refractive error (Resnikoff 2008). There is important global variation in the prevalence of visual impairment due to uncorrected refractive error ranging from 0.034% in the Western Pacific Region (A) to 5.94% in China (Resnikoff 2008). Studies show that children with refractive error often do not have spectacles or are not wearing optimal correction (Sharma 2012).

Uncorrected visual acuity deficit has been shown to have a negative impact on academic performance in some (Goldstand 2005; Maples 2003;) but not all (Dirani 2010) studies. Qualitative studies have described how uncorrected visual deficits may lead to reduced focus, perseverance and class participation, affecting academic performance and leading to psychosocial stress (Dudovitz 2016),

Description of the intervention

Vision screening involves testing the visual acuity of children in schools or communities with the aim of identifying children with reduced vision.

Reduced vision is detected at screening using age-appropriate visual acuity tests; commonly letter, picture, illiterate E or Landolt C optotypes. Although visual impairment and refractive error are correlated, the level at which refractive error becomes significant enough to impact on visual performance varies considerably depending on the individual and measurement-specific variables (WHO 2002). Data from the Sydney Myopia Study suggests that uncorrected visual acuity of 6/9.5 or less has a high sensitivity (97.8%) and specificity (97.1%) for detecting refractive errors in adolescents (Leone 2010). Similar results were seen in the NICER study in Northern Ireland (UK) (O'Donoghue 2012).

Treatment for reduced visual acuity due to refractive error in school age children usually consists of optical correction of the error. Spectacles are a simple and effective means of correcting refractive error and are the most widely used treatment. Contact lenses are used as an alternative to spectacles in specific clinical circumstances (keratoconus, severe anisometropia, high refractive power) mainly in high-income countries but increasingly also in urban centres of low- and middle-income countries.

Provision of optical correction requires measurement of the type and degree of refractive error in each eye. This can be done clinically (by retinoscopy) or by an automated refractometer. The optical centres of the corrective lenses in spectacles must align with the visual axis of each eye. Spectacles without astigmatic correction and where the refractive error is the same in both eyes can be mass produced at low cost. These are known as 'ready-made' spectacles. Optical correction of the refractive error will result in a more or less immediate improvement in visual acuity to a normal level, if spectacles are worn. Whether or not children wear spectacles is an important determinant of a screening programme's success. The availability, affordability and acceptability of spectacles may affect whether any that are prescribed are actually worn. Barriers to spectacle use are likely to be complex and include cultural and economic factors. Over-prescribing, whereby spectacles are prescribed for insignificant refractive error is probably one important factor leading to a low proportion of children wearing prescribed spectacles (Sharma 2012). Other factors may include concerns

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over appearance, teasing from peers, discomfort, negative parental attitudes, cost, and beliefs that spectacles will lead to weaker eyes. There is debate as to whether optical correction can result in persistence of a refractive error that might otherwise have naturally resolved or reduced. Animal experiments suggest that emmetropisation may be affected by optical correction (Hung 1995). Currently available evidence from human populations does not provide support for this hypothesis (Walline 2011).

Visual acuity screening programmes vary with regard to who carries out the testing, for example teachers, nurses, optometrists, parents, other volunteers or computer programs (Sharma 2012). Vision screening programmes can be provided as part of the government healthcare system or can be run by non-governmental organisations, such as charities or the private sector.

Regular screening activities for correctable visual acuity deficits are concentrated in high-income countries. In Ohio USA, for example, children are screened at kindergarten and then bi-annually throughout their school careers (Ohio 2004); in Sweden visual acuity is measured in pre-school age children and again at seven and 10 years of age (Kvarnstrom 2001). In the UK routine vision screening is recommended for four- to five-year-old children only (PHE 2017). Although screening programmes have been introduced in lower-income countries (Limburg 1999) the great majority of children never receive an eye examination and access to health services is often limited, especially in rural areas (Congdon 2008; Ma 2014; Wedner 2000; Wedner 2003).

How the intervention might work

Vision screening for correctable visual acuity deficit is expected to work by identifying children who require spectacles, but who currently do not have them, and enabling access to spectacles for those children. One of the roles of mass vision screening in this context is to improve equity of access to care.

It should be noted that visual acuity screening programmes for undetected, correctable visual acuity deficits will inevitably identify some children with reduced vision due to causes other than refractive error, for example cataract or amblyopia, although these will occur much less commonly than refractive error. Whilst these conditions are not the focus of this review, we will describe any data found regarding the proportions of such conditions detected by screening.

Why it is important to do this review

Given the high prevalence of visual impairment due to uncorrected refractive errors in children, and the simplicity of treatment, the detection and correction of refractive errors has been made one of the priorities of the World Health Organization (WHO) Vision 2020 initiative (Resnikoff 2001). Observed variation in provision of screening programmes worldwide highlights the uncertainty around the effects of such programmes (Hopkins 2013). A review of the evidence for the effectiveness of screening in reducing the proportion of school-age children and adolescents with an uncorrected correctable visual acuity deficit is important to resolve this uncertainty and identify future directions for research.

OBJECTIVES

To evaluate the effectiveness of vision screening programmes carried out in schools to reduce the prevalence of correctable visual acuity deficits due to refractive error in school-age children.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials (parallel or cluster design) of vision screening conducted after the first year at school. We did not have any language or date restrictions.

Types of participants

We considered participants identified by a school vision screening programme to have reduced visual acuity due either to an unidentified refractive error or suboptimal correction of a previously identified refractive error.

Types of interventions

Vision screening carried out by visual acuity assessment using any age-appropriate vision test was the intervention of interest. We included studies applying any threshold for failure and administered by any testing personnel, measuring the following:

- monocular visual acuity, binocular visual acuity or both;
- distance visual acuity only;
- near and distance visual acuity.

Trials of interventions designed to improve the cost-effectiveness of screening were also eligible for inclusion.

We planned the following comparisons:

- screening versus no screening;
- failure threshold of worse than 6/9 (Snellen) (or equivalent) versus failure threshold of 6/9 (Snellen) or better (or equivalent);
- type of testing personnel, that is nurses, teachers, and eye trained personnel;
- interventions to improve spectacle use versus no intervention to improve spectacle use;

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- interventions to reduce cost.

Any studies of visual acuity screening at or before school entry are more likely to have amblyopia as their target condition and are therefore not relevant to this review.

Types of outcome measures

Primary outcomes

- Uncorrected, or suboptimally corrected, visual acuity deficit due to refractive error at six months after screening

Secondary outcomes

- Uncorrected or suboptimally corrected, visual acuity deficits more than six months after screening
- Visual acuity deficit due to causes other than refractive error, for example cataract, amblyopia
- Compliance with spectacles prescribed as a result of vision screening (i.e. spectacle wearing)
- Quality of life: any formal, validated assessment of quality of life undertaken, for example, the National Eye Institute Refractive Error Quality of Life-42 (NEI-RQL-42) (Hays 2003). We included assessment of general confidence, academic achievement, employment, social interaction etc
- Costs: this refers to any comparative information on costs or resources incurred at any time period.

Follow-up: six months unless otherwise specified.

Adverse effects

We extracted data on the following adverse effects.

- Impact of correction of refractive error on the development of refractive error by comparing the prevalence and degree of refractive error in screened versus unscreened populations
- Anxiety (from interviews, self-completion questionnaires, focus groups etc)
- Prevalence of over prescribing
- Any other adverse effect as reported

Search methods for identification of studies

Electronic searches

The Cochrane Eyes and Vision Information Specialist conducted systematic searches in the following databases for randomised controlled trials and controlled clinical trials. There were no language or publication year restrictions. The date of the search was 3 May 2017.

- Cochrane Central Register of Controlled Trials (CENTRAL; 2017, Issue 4) (which contains the Cochrane Eyes and Vision Trials Register) in the Cochrane Library (searched 3 May 2017) (Appendix 1);
- MEDLINE Ovid (1946 to 3 May 2017) (Appendix 2);
- Embase Ovid (1980 to 3 May 2017) (Appendix 3);
- ISRCTN registry (www.isrctn.com/editAdvancedSearch; searched 3 May 2017) (Appendix 4);
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; searched 3 May 2017) (Appendix 5);
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP)(www.who.int/ictrp; searched 3 May 2017) (Appendix 6).

Searching other resources

We did not do any handsearching for the current update (2018). For previous editions of this review we manually searched the *British Orthoptic Journal* from 2003 to publication date (years prior to 2003 had already been searched) and the following conference proceedings:

- European Strabismus Association (ESA);
- International Strabismus Association (ISA);
- American Association of Paediatric Ophthalmology and Strabismus (AAPOS);
- Royal College of Ophthalmologists (RCO).

Data collection and analysis

Selection of studies

For previous editions of this review, one review author checked the search results and selected all reports of studies that made reference to refractive error, myopia and vision screening. Any reports that were clearly not relevant were excluded at first viewing. Two authors then screened the remaining titles and abstracts of the reports to establish if they met the inclusion criteria for this review.

For the current update, two authors independently screened the citations arising from the electronic searches using online review management software (Covidence).

Data extraction and management

For previous versions of this review, two authors independently extracted data from trials that met the inclusion criteria using the Cochrane Eyes and Vision data collection form.

For the current update, two authors independently extracted data and we used a data extraction template in Covidence (available on request). We re-extracted data for all included studies and imported them into Review Manager 5 (Review Manager 2014) from

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Covidence. As two of the review authors were also authors of one of the included studies (Morjaria 2016), an independent assessor extracted data on this trial (Acknowledgements).

Assessment of risk of bias in included studies

We assessed risk of bias using the guidelines in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a).

We assessed the following domains for all studies.

- Selection bias: we considered how the random sequence was generated and whether this allocation was concealed.
- Performance bias: we considered whether the participants and personnel were masked and whether this masking was effective.
- Detection bias: we considered whether the outcome assessors were masked and whether this was likely to be effective.
- Attrition bias: we considered the completeness of the outcome data with particular reference to attrition and exclusions, and handling of any incomplete outcome data.
- Selective reporting: we considered the bias introduced by selective reporting.

We also considered three additional sources of bias for cluster-randomised studies as described in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b).

- Baseline imbalance: this may be an issue in studies with small numbers of clusters.
- Recruitment bias: this can occur when individuals are recruited to the trial after the clusters have been randomised.
- Loss of clusters: this is analogous to incomplete outcome data for individuals.

We graded domains as low risk of bias, high risk of bias or unclear.

Measures of treatment effect

We used the risk ratio as the measure of effect for dichotomous variables. All of our outcomes were dichotomous with the exception of quality of life. For continuous outcomes, such as quality of life, we used the mean difference. We considered whether or not this outcome was skewed using Altman's method (Altman 1996).

Unit of analysis issues

The main unit of analysis issue in this review relates to cluster-randomised trials. The studies included in this review were correctly reported with confidence intervals adjusted for the additional variance introduced by the cluster design. It was not always straightforward to pool the results of different studies, however, because they reported different effect measures. In order to pool the results of studies, we did an approximate analysis following guidelines in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). We extracted the raw data and reduced the sample size to take into account the cluster design by dividing the sample size by the estimated design effect. We calculated an estimated design effect by comparing the variance with and without taking into account the clustering.

Dealing with missing data

We used data as reported by the included studies and did not impute data. We considered the risk of bias introduced by incomplete outcome data (Assessment of risk of bias in included studies). We contacted investigators for clarification as needed.

Assessment of heterogeneity

We assessed heterogeneity by examining the characteristics of the included studies. We also inspected the forest plots to assess variation in direction and size of the effect and poor overlap of confidence intervals. We tested for the statistical significance of heterogeneity using the Chi^2 test, being aware that this test may have low power when there are few trials, or the trials are small, therefore a non-significant result may not be evidence of no heterogeneity. We also calculated the I^2 statistic (Higgins 2003), which describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance) as described in Chapter 9 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011).

Data synthesis

We pooled data using Cochrane's review management software (Review Manager 2014). We used a fixed-effects model as only three studies or fewer were included in any analysis. We did a sensitivity analysis to compare the results of fixed-effect and random-effects models to test how robust our assumptions were as to the most relevant model.

Summary of findings

We prepared a 'Summary of findings' table for the following three comparisons following guidance in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011).

- Vision screening and provision of free spectacles compared with vision screening and provision of prescription
- Vision screening and educational intervention compared with vision screening and no educational intervention
- Vision screening and provision of ready-made spectacles compared with vision screening and provision of custom-made spectacles

The 'Summary of findings' table provides outcome-specific information. We graded the certainty of the evidence for each outcome using the GRADE approach (Schünemann 2011) to assist with the interpretation of the findings. Each outcome was initially assessed

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as high certainty (as data drawn from randomised controlled trials) but we then downgraded it one level for serious (or two levels for very serious) concerns in the following domains: study limitations (risk of bias), indirectness of evidence, inconsistency, imprecision or publication bias.

The following outcomes are included in the 'Summary of findings' tables.

- Uncorrected visual acuity deficit due to refractive error: follow-up six months
- Uncorrected visual acuity deficit due to refractive error: follow-up more than six months
- Visual acuity deficit due to causes other than refractive error: follow-up six months
- Spectacle wearing: follow-up six months
- Adverse effects: follow-up any time period
- Quality of life: follow-up six months
- Cost

RESULTS

Description of studies

Results of the search

The original electronic searches identified a total of 901 reports of studies. Full-text copies were obtained for three papers where no abstract was provided; we excluded all three papers as they were not trials (Cross 1985; Gole 2001; Yamada 2004). An additional 528 reports were identified in the first update of this review; none of these were eligible for inclusion. Updated searches conducted in May 2017 identified 2491 new records (Figure 1). After 715 duplicates were removed the Cochrane Information Specialist (CIS) screened the remaining 1776 records and removed 1547 references that were not relevant to the scope of the review. We screened the remaining 229 records and obtained 16 full-text reports for further assessment. We included nine reports of seven studies (see Characteristics of included studies for details) and one study is currently awaiting classification (Wang 2017). We excluded six studies, see Characteristics of excluded studies for details. We did not identify any ongoing studies from our searches of the clinical trials registries.

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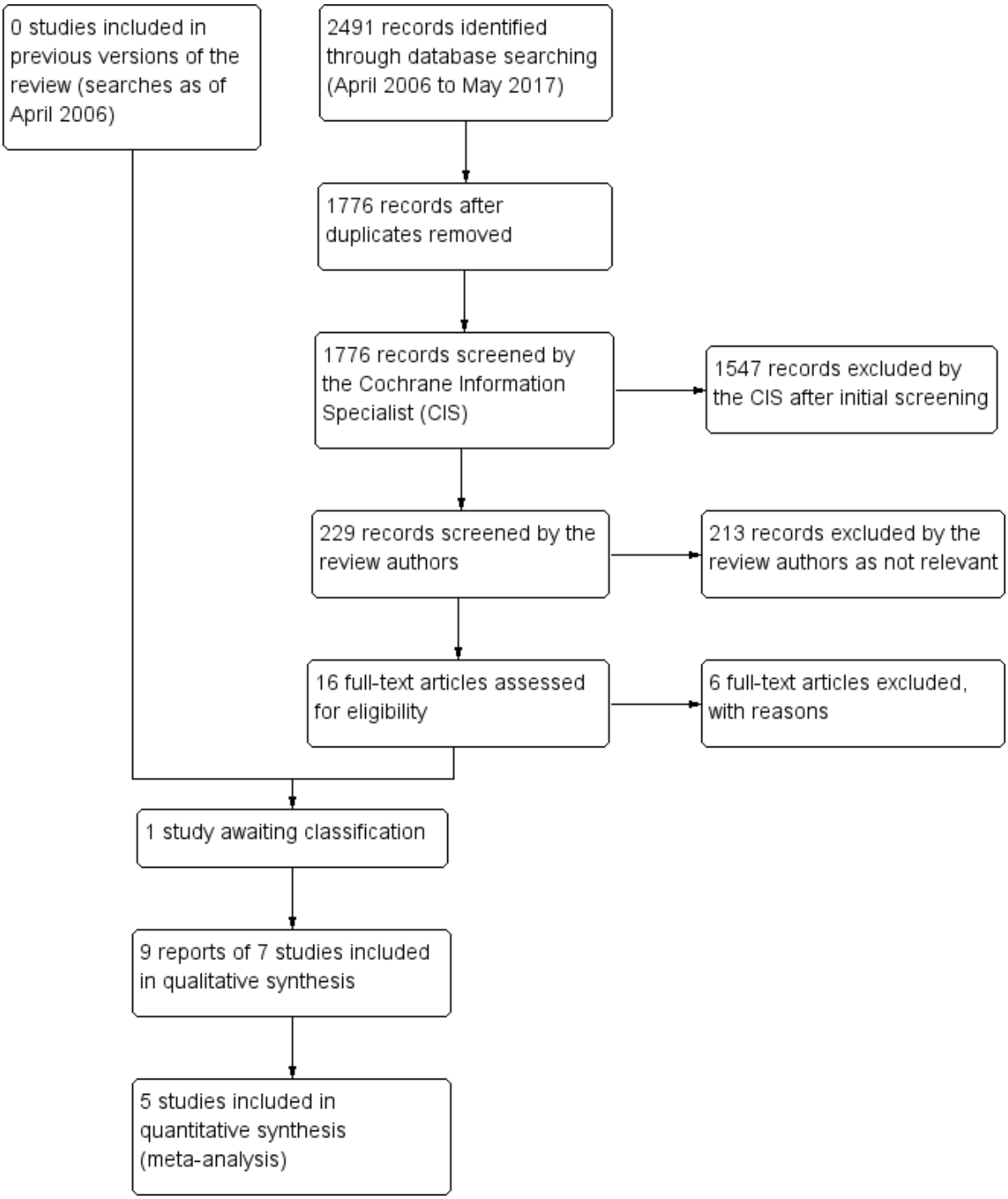
Figure 1. Study flow diagram



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Included studies

We included seven studies in this review (Congdon 2011; Morjaria 2016; RECS 2009; SIL 2014; SIL II 2015; WEAR 2017; Wedner 2008).

Study design and setting

There were four cluster-randomised studies (Congdon 2011; SIL 2014; SIL II 2015; Wedner 2008) and three individually randomised studies (Morjaria 2016; RECS 2009; WEAR 2017). Five studies were conducted in China (Congdon 2011; RECS 2009; SIL 2014; SIL II 2015; WEAR 2017), one in India (Morjaria 2016) and one in Africa (Wedner 2008). All the studies were conducted in schools.

All the cluster-randomised trials were analysed appropriately with standard errors adjusted for clustering by school.

Participants

Participants in these studies were male and female children, between the ages of 10 to 12 years (SIL II 2015), 11 to 15 years (Morjaria 2016), 12 to 15 years (RECS 2009; WEAR 2017), 12 to 17 years (Congdon 2011), 12 to 18 years (Wedner 2008) or an average age of 10.5 years (SIL 2014) (range not reported).

The following table shows the number of children randomised and followed up in the trials.

Study	Number randomised	Number followed up	% followed up	Number of schools (cluster-randomised controlled trials only)
Congdon 2011	4448	3200	72%	20
Morjaria 2016	460	362	79%	
RECS 2009	495	414	84%	
SIL 2014	3177	3054	96%	252
SIL II 2015	728	693	95%	94
WEAR 2017	426	409	96%	
Wedner 2008	125	108	86%	37
Total	**9859**	**8240**	**84%**	

The children recruited to these studies had visual impairment due to refractive error. The inclusion criteria are shown in the following table. Presenting visual acuity means visual acuity with usual spectacles.

Study	Visual acuity	Minimum vision improvement with full correction	Difference between the spherical equivalent of the right and left eyes (anisometropia) D = dioptres	Minimum uncorrected spherical refractive error	Astigmatism D = dioptres

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(*Continued*)

Congdon 2011	6/12 or worse in either eye (presenting)	2 or more lines in either eye			
Morjaria 2016	Worse than 6/9 in better eye (presenting)	2 or more lines in better eye	1 D or less		Spherical equivalent corrects the visual acuity to not more than one line less than best corrected visual acuity with a full prescription in the better eye
RECS 2009	6/12 or worse in better eye (presenting)		Less than 2 D myopic Less than 1 D hyperopic	1 D or more	Less than 2 D
SIL 2014	6/12 or worse in either eye (uncorrected)	Better than 6/12 with spectacles			
SIL II 2015	6/12 or worse in either eye (uncorrected)			"refractive error meeting cutoffs shown to be associated with significantly greater improvement in visual acuity when corrected: myopia <0.75 diopters (D), hyperopia >2.00 D, or astigmatism (nonspherical refractive error) >1.00 D."	
WEAR 2017	6/12 or worse in both eyes (presenting)	Better than 6/7.5 in both eyes	Less than 2 D	-1.00 D or less	Less than 2 D
Wedner 2008	Worse than 6/12 in either eye (presenting)				

There were additional criteria for trials of ready-made versus custom-made spectacles, that is, inter pupillary distance matched that of ready-made spectacle frames available (i.e. 54 mm to 62 mm), and spectacle frames were of acceptable size and fit (Morjaria 2016).

Interventions and comparators

None of these studies addressed the comparison of primary interest to this review, that is, considered the prevalence of correctable, uncorrected visual acuity deficits in school-age children and adolescents in screened populations compared with populations who had no screening.

The included studies considered strategies either to improve the uptake of spectacle wear in school vision screening programmes or to increase the cost-effectiveness of school screening programmes. Some studies considered more than one strategy.

The interventions and comparators are set out in the following table.

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Type of intervention	Intervention	Comparator	Studies
Interventions to improve uptake	Provision of free spectacles	No free spectacles (prescription only)	Wedner 2008; SIL 2014
	Free spectacles combined with a teacher incentive	No free spectacles or teacher incentive	SIL II 2015
	Provision of voucher	No voucher (prescription only)	SIL 2014
	Educational intervention	No educational intervention	Congdon 2011; SIL 2014
Interventions to improve efficiency or cost-effectiveness	Ready-made spectacles	Custom-made spectacles	Morjaria 2016; RECS 2009; WEAR 2017
	Rural refractionist	University optometrist	WEAR 2017
	Self-refraction	University optometrist	WEAR 2017

Outcomes

The studies all followed up at slightly different time periods. Follow-up ranged from one month (RECS 2009), two months (WEAR 2017), three months (Wedner 2008), three to four months (Morjaria 2016), six months (Congdon 2011; SIL II 2015), and eight months (SIL 2014).

There was some variation in outcomes depending on the objective of the trials.

Most of the studies looked at some measure of spectacle wear, either purchase of spectacles (Congdon 2011), observed spectacle wear (Congdon 2011; Morjaria 2016; RECS 2009; SIL 2014; SIL II 2015; Wedner 2008), self-reported spectacle wear (Congdon 2011; SIL 2014; SIL II 2015) or frequency of spectacle wear (Congdon 2011; RECS 2009; SIL II 2015). Reasons for non-wear were also assessed (Congdon 2011; Morjaria 2016) and predictors of wear (Wedner 2008).

Fewer studies looked at visual acuity. Congdon 2011 assessed presenting and uncorrected vision, and also measured refraction along with the power of spectacles and spectacle-corrected vision when spectacles were available. WEAR 2017 assessed the proportion with best-corrected visual acuity better or equal to 6/6 and also considered the vector dioptric difference values between the prescription power and power measured by lensometry in the better-seeing eye falling within 0.25 dioptres, 0.50 dioptres and 1.0 dioptre. Wedner 2008 reported the prevalence of uncorrected significant refractive error.

RECS 2009 looked at other outcomes including:

- previous and planned use
- perceived value
- adaptation time
- spectacle remakes
- symptoms

SIL 2014 reported educational attainment (maths test).

Only one study examined quality of life (WEAR 2017) using the NEI-RQL-42 questionnaire. The study also examined patient satisfaction and self-reported rating of study spectacles.

Excluded studies

We excluded nine studies (Characteristics of excluded studies). For most of these studies this was because, on closer inspection it was obvious that these were not randomised controlled trials. One of these studies was a randomised controlled trial but it was addressing a different hypothesis relating to the progression of myopia (Li 2013).

Risk of bias in included studies

See Figure 2

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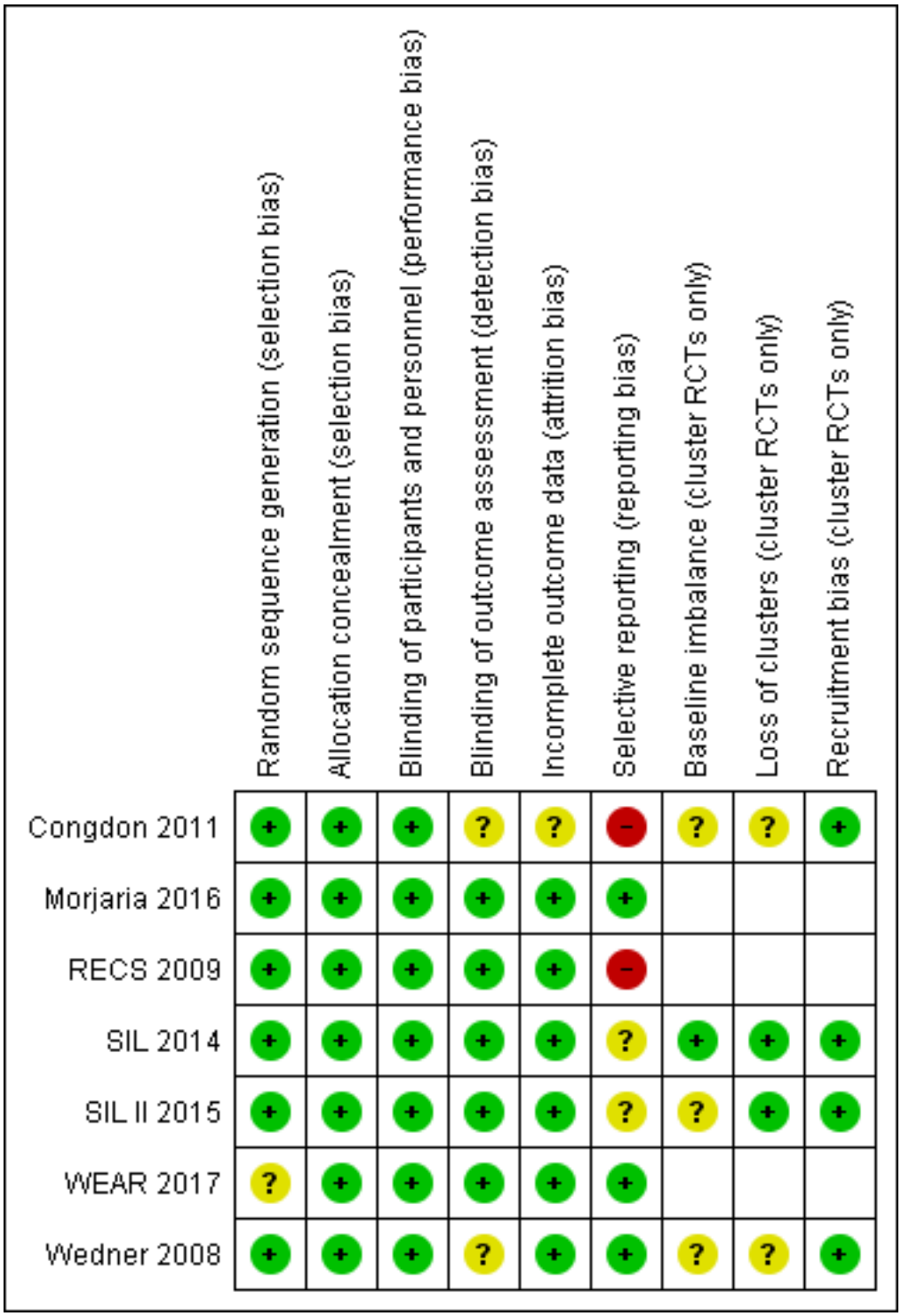
Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study



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Allocation

Random sequence generation

Most of the trials described an adequate method of generating the random sequence. This was either by random number tables (Congdon 2011), computer-generated using Excel (Morjaria 2016), R software (SIL 2014; SIL II 2015) or other computer generated random number (RECS 2009; Wedner 2008). WEAR 2017 did not clearly report random sequence generation.

Allocation concealment

We judged all seven studies as having adequate allocation concealment. Three of the studies were cluster-randomised studies where the allocation of schools was done at the beginning of the study (Congdon 2011; RECS 2009; Wedner 2008).
Two studies had central allocation (SIL 2014; SIL II 2015). One study delivered the allocation in "Sequentially numbered, sealed, stamped opaque envelopes containing labels with unique study identification numbers and random allocation" "prepared by persons not involved in the trial." (Morjaria 2016).
Two studies did not specifically mention allocation concealment but the description of the study procedures suggested that enrolment was likely to have been masked. "Both the participant and those involved in data collection were masked to the type of spectacles ordered. Masking was maintained during follow-up" (RECS 2009). "Subjects and study personnel administering the questionnaires and assessing VA were masked to study group assignment." (WEAR 2017).

Blinding

Performance bias

We judged all the studies to be at low risk of performance bias. Some studies made explicit statements as to masking of participants and carers (Morjaria 2016; RECS 2009; WEAR 2017; Wedner 2008) and certainly this masking was relatively straightforward in trials of ready-made and custom spectacles (Morjaria 2016; RECS 2009). The cluster-randomised trials avoided discussion of interventions in other schools (SIL 2014; SIL II 2015; Wedner 2008). This was not explicitly stated in Congdon 2011 but is likely and the overall negative result of the study suggests that significant bias unlikely.

Detection bias

Five out of the seven studies reported efforts to mask outcome assessment (Morjaria 2016; RECS 2009; SIL 2014; SIL II 2015; WEAR 2017). In Wedner 2008 this was not clearly described. Congdon 2011 did not mask the outcome assessments but any bias would have been expected to favour the intervention (education), which was not the case.

Incomplete outcome data

Follow-up was high and reasonably balanced between groups in most studies (6) and we judged these to be at low risk of attrition bias. In SIL 2014; SIL II 2015 and WEAR 2017 follow-up was over 95% and balanced between groups. In RECS 2009 and Wedner 2008 follow-up was over 80% and again balanced between groups. In Morjaria 2016 follow-up was nearly 80% in each group and balanced between groups and reasons for loss to follow-up were unlikely to be associated with outcome, "All children not followed up in school (n = 98) had changed schools and moved to a different area.". In Congdon 2011 follow-up was lower (72%) but again balanced so we judged it to be unclear whether this would have introduced bias.

Selective reporting

Selective reporting was harder to judge. Two studies reported all pre-planned outcomes (Morjaria 2016; Wedner 2008), other studies did not report all pre-planned outcomes but the missing outcomes were not relevant to the review (SIL 2014; SIL II 2015; WEAR 2017). Two studies did not report some of our pre-specified review outcomes. Congdon 2011 did not report the prevalence of refractive error at six months and RECS 2009 did not report spectacle use at 6 to 12 months.

Other potential sources of bias

For the cluster-randomised controlled trials only (Congdon 2011; SIL 2014; SIL II 2015; Wedner 2008) we considered three additional potential sources of bias.

Baseline imbalance

Baseline data were poorly reported at the cluster level but individual-level data were available that largely suggested no major imbalances in these trials. Only SIL 2014 provided enough information to be confident that there were no baseline imbalances.

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Loss of clusters

Again there was no strong evidence that this was a problem but only two studies provided enough information to judge definitively (SIL 2014; SIL II 2015).

Recruitment bias

Although this was not addressed directly the trials had made efforts to mask treatment assignment and we felt that recruitment bias was unlikely in a school setting.

Effects of interventions

See: **Summary of findings for the main comparison** Free spectacles versus no free spectacles (prescription only); **Summary of findings 2** Educational intervention versus no educational intervention; **Summary of findings 3** Ready-made versus custom-made spectacles

Interventions to improve uptake

Comparison: provision of free spectacles versus no free spectacles (prescription only)

See Summary of findings for the main comparison.

Two studies compared provision of free spectacles versus no free spectacles (prescription only). Both of these studies were cluster-randomised trials. Wedner 2008 randomised 37 schools in Tanzania involving 125 children aged 12 to 18 years (average age 14 years) and followed up for three months, at which point they measured spectacle use. SIL 2014 randomised 252 schools in China, with 2189 children aged on average 10.5 years and followed up for approximately eight months. This study also had a third study arm who received vouchers only.

Outcome: uncorrected visual acuity deficits due to refractive error (primary outcome) within six months of screening

Not reported

Outcome: uncorrected visual acuity deficits due to refractive error more than six months after screening

Not reported

Outcome: proportion of participants with visual acuity deficit due to causes other than refractive error at six months and more than six months

Not reported

Outcome: compliance with spectacles prescribed as a result of vision screening (i.e. spectacle wearing)

Wedner 2008 defined spectacle wearing as either wearing spectacles or had them at school. Children who had received free spectacles were more likely to be wearing spectacles (or have them at school) (27/58, 47%) compared with children who had been given a prescription only (13/50 (26%) three months after screening. Wedner 2008 reports an odds ratio of 2.4 (95% confidence intervals (CI) 1.0 to 6.7) adjusted for clustering.

SIL 2014 defined spectacle wearing as "wearing glasses during an unannounced examination". Children who had received free spectacles were more likely to be wearing spectacles (469/1153, 41%) compared with children given a prescription only (266/1036, 26%) at follow-up (approximately eight months after screening). SIL 2014 reported a risk ratio adjusted for baseline wear and clustering of 1.54 (95% CI 1.28 to 1.85).

It was a little difficult to pool these two different effect measures directly but an approximate analysis is provided in Figure 3. We have used the raw data and reduced the sample size to take into account the cluster design by dividing the sample size by the estimated design effect (calculated by comparing the variance with and without taking into account the clustering). The analysis suggests an approximate 60% increased wearing of spectacles in the free-spectacles group (RR 1.60, 95% CI 1.34 to 1.90; 2 studies; 1092 participants). The results of the two studies were reasonably consistent. We judged this to be high-certainty evidence.

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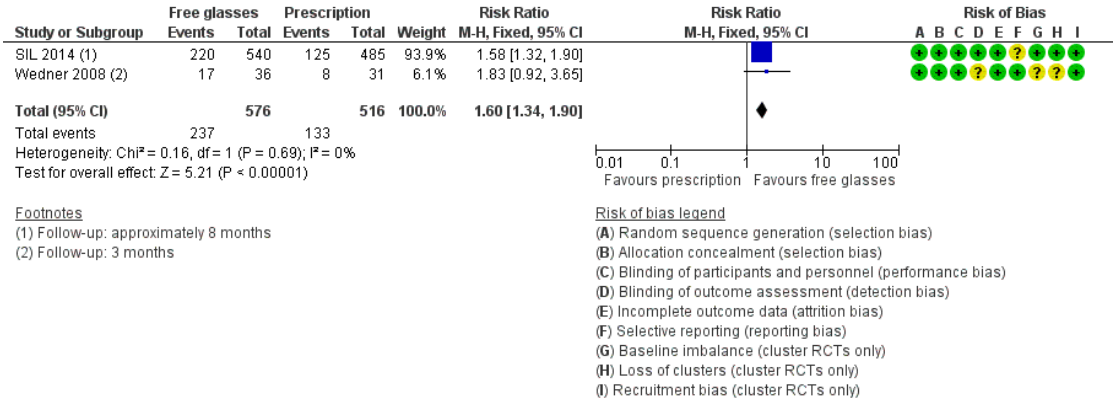
Figure 3. Forest plot of comparison: 1 Free glasses compared with prescription only, outcome: 1.1 Spectacle wearing.



SIL 2014 also reported similar findings with self-reported spectacle wear (RR 1.81, 95% CI 1.61 to 2.04). Wedner 2008 reported spectacle wear with the same definition as above but also including children who self-reported that they had spectacles at home. There was a very high odds ratio of 14.3 (4.6 to 50).

In SIL 2014 children who had received a voucher were also more likely to be wearing spectacles (361/988, 37%) compared with children given a prescription only (266/1036, 26%) at follow-up. SIL 2014 reported a risk ratio adjusted for baseline wear and clustering of 1.42 (95% CI 1.16 to 1.73).

Outcome: quality of life

SIL 2014 found that children who received free spectacles had better educational attainment as measured by a standardised mathematics score (adjusted difference 0.11 (95% CI 0.01 to 0.21). The authors state that this difference is equivalent to approximately half a term (semester) of additional learning.We judged this to be low-certainty evidence, downgrading one level for imprecision and one level for indirectness as this outcome may be specific to location and unclear if it is applicable to other settings. .

Outcome: cost

Wedner 2008 calculated the overall cost of screening and spectacle provision for each screened student was USD 0.87. The overall cost of screening and spectacle provision for each student who used spectacles (definition 1) was USD 46.3 (GBP 23.40) for free spectacles; USD 64.7 (GBP 32.70) for prescribed spectacles. Calculations were based on spectacle use of 47% if spectacles were provided free and 26% if spectacles were only prescribed. We judged this to be low-certainty evidence, downgrading two levels for indirectness as costs are very specific to location (Tanzania) and time period (nearly 10 years ago).

Outcome: adverse effects

Refractive error

SIL 2014 investigated the impact of assignment to free spectacles compared with prescription only on uncorrected visual acuity at follow-up. There was a mean difference of -0.02 logMAR (95% CI adjusted for clustering -0.04 to 0.01) between the groups at follow-up i.e. no evidence of any important impact of free spectacles on uncorrected acuity. We judged this to be moderate-certainty evidence downgrading one level for indirectness average logMAR acuity may not adequately reflect proportion of children with important changes in uncorrected visual acuity.

Other pre-specified outcomes were not reported.

- Anxiety (from interviews, self-completion questionnaires, focus groups etc)
- Over prescribing

Comparison: free spectacles combined with a teacher incentive versus no free spectacles or teacher incentive

Only one study reported the effect of supplying free spectacles alongside a teacher incentive compared with receiving a prescription only in Chinese schools (SIL II 2015). Teachers and children received an educational intervention. The teacher received a tablet computer (approximate value USD 350) if 80% or more of the children who received spectacles were wearing them.

Outcome: uncorrected visual acuity deficits due to refractive error (primary outcome) within six months of screening

Not reported

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Outcome: uncorrected visual acuity deficits due to refractive error more than six months after screening

Not reported

Outcome: proportion of participants with visual acuity deficit due to causes other than refractive error at six months and more than six months

Not reported

Outcome: compliance with spectacles prescribed as a result of vision screening (i.e. spectacle wearing)

Spectacle wear was higher at six months in children who had received free spectacles 233/341 and whose teachers had received an incentive (68.3%) compared with children who did not receive free spectacles and whose teachers did not receive an incentive (84/352 (23.9%)). The following effect estimates were reported by SIL II 2015.

- Odds ratio adjusted for cluster design: 6.88, 95% CI 4.09 to 11.6
- Odds ratio adjusted for cluster design and other predictor variables: 11.5, 95% CI 5.91 to 22.5.

Note that the odds ratio will give exaggerated estimates of effect. For example, the odds ratio of 6.88 will correspond to a risk ratio of 2.86.

Outcome: adverse effects

The following outcomes were not reported.

- Refractive error
- Anxiety (from interviews, self-completion questionnaires, focus groups etc)
- Over prescribing

Outcome: quality of life

Not reported

Comparison: educational intervention versus no educational intervention

See Summary of findings 2.

Two cluster randomised trials, both conducted in China, explored the effect of an educational intervention. In Congdon 2011 children aged between 12 to 17 years in rural China, received a lecture, video and classroom demonstration promoting spectacle purchase or no education intervention. In SIL 2014 children aged between 10 and 12 watched a 10-minute, documentary-style video and were given a booklet of cartoons, followed by a classroom discussion led by study staff. "These materials showed children experiencing the benefits of glasses and teachers explaining that glasses do not harm vision". Teachers and parents also viewed a presentation on the safety and benefits of spectacles. The control group received no educational intervention.

Outcome: uncorrected visual acuity deficits due to refractive error (primary outcome) within six months of screening

Not reported

Outcome: uncorrected visual acuity deficits due to refractive error more than six months after screening

Not reported

Outcome: proportion of participants with visual acuity deficit due to causes other than refractive error at six months and more than six months

Not reported

Outcome: compliance with spectacles prescribed as a result of vision screening (i.e. spectacle wearing)

In SIL 2014 spectacle wearing was defined as "wearing glasses during an unannounced examination". A similar proportion of children in the educational intervention group were wearing spectacles (588/1648, 36%) compared with children in the group with no educational intervention (508/1529, 33%) at follow-up (approximately eight months after screening). SIL 2014 reported a risk ratio adjusted for baseline wear and clustering of 1.11 (95% CI 0.95 to 1.31). We judged this to be moderate-certainty evidence, downgrading one level for imprecision.

Congdon 2011 reported a related outcome measure, that is, whether or not the child obtained spectacles. A smaller proportion of the children in the educational group, reported buying spectacles (417, 25.7%) compared with the control group (537, 34.0%) at approximately six months' follow-up. Congdon 2011 reported the following effect measures.

- Odds ratio 0.84, 95% CI 0.55 to 1.31, adjusted for cluster design
- Odds ratio 0.86, 95% CI 0.66 to 1.11, adjusted for cluster design and other predictors.

Outcome: quality of life

Not reported

Outcome: adverse effects

The following outcomes were not reported.

- Refractive error
- Anxiety (from interviews, self-completion questionnaires, focus groups etc)

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- Over prescribing

Interventions to improve efficiency or cost-effectiveness

Comparison: ready-made spectacles versus custom-made spectacles

See Summary of findings 3.

Ready-made spectacles have the same spherical equivalent in both eyes and are available in a range of powers and interpupillary distances. Custom-made spectacles are tailored to the individual prescription of the child.

Three individually randomised studies explored the use of ready-made versus custom-made spectacles, two studies in China (RECS 2009; WEAR 2017) and one in India (Morjaria 2016).

Outcome: uncorrected visual acuity deficits due to refractive error (primary outcome) within six months of screening

RECS 2009 reported slightly worse visual acuity in children wearing ready-made spectacles compared with children wearing custom-made spectacles. Mean logMAR acuity was 0.11 (standard deviation (SD) 0.09) for children wearing ready-made spectacles and 0.08 (SD 0.07) in children wearing custom-made spectacles (mean difference (MD) 0.03 logMAR score, 95% CI 0.01 to 0.05; 414 participants). However, this difference, of less than 5 letters, is unlikely to represent a meaningful difference between the groups. This analysis was for the eye with the lower amount of spherical refractive error, that is, the better eye. As ready-made spectacles were dispensed on the basis of the less myopic eye the same analysis on the worse eye (eye with higher spherical refractive error) was 0.14 (SD 0.12) logMAR score in the ready-made spectacle group compared with 0.08 (SD 0.08) in the custom-made spectacle group (MD 0.06, 95% CI 0.04 to 0.08). We judged this to be moderate-certainty evidence. Children with astigmatism of 0.75 dioptres or more had approximately 1 line of Snellen acuity worse with ready-made spectacles than with custom-made spectacles.

Outcome: uncorrected visual acuity deficits due to refractive error more than six months after screening

Not reported

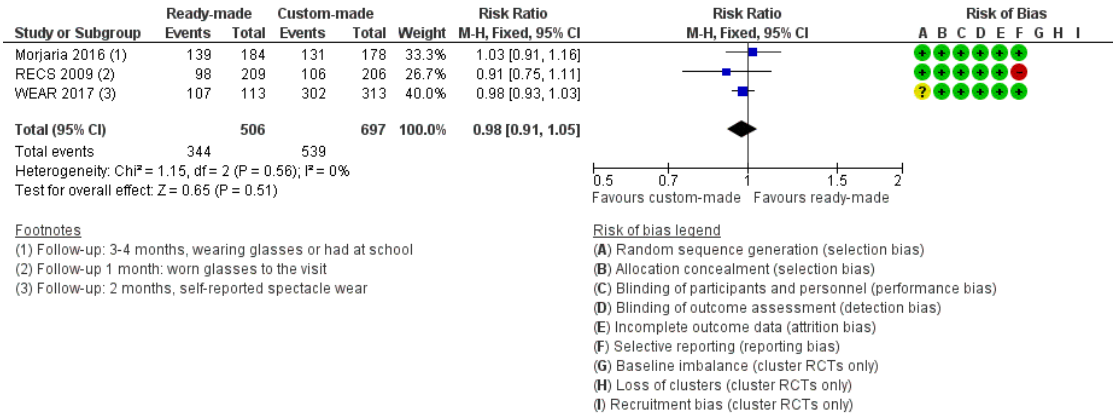
Outcome: proportion of participants with visual acuity deficit due to causes other than refractive error at six months and more than six months

Not reported

Outcome: compliance with spectacles prescribed as a result of vision screening (i.e. spectacle wearing)

All three studies found similar proportions of children in the ready-made versus custom-made spectacles group were wearing spectacles at follow-up, with an overall pooled risk ratio of 0.98 (95% CI 0.91 to 1.05; 1203 participants; I^2 = 0%) Figure 4. This analysis was done using a fixed-effect model. We compared this with a random-effects model with similar results (RR 0.98, 95% CI 0.94 to 1.03).

Figure 4. Forest plot of comparison: 2 Ready-made versus custom-made spectacles, outcome: 2.1 Spectacle wearing.



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Outcome: quality of life

WEAR 2017 measured quality of life using the NEI-RQL-42 questionnaire. There was no evidence of any important difference in quality of life with the two types of spectacles. After wearing ready-made spectacles for two months, the mean NEI-RQL-42 global score had changed from 59.6 (SD 10.6) at baseline to 64.3 (SD 11.8) in children with ready-made spectacles. This is a change of 4.65 (95% CI 2.45 to 6.86). In the custom-made spectacles group, mean NEI-RQL changed to a similar degree (MD 1.43, 95% CI -1.04 to 3.90). We judged this to be moderate-certainty evidence, downgrading one level for indirectness as follow-up was two months (rather than six months specified) and reported in only one location (China).

Outcome: adverse effects

The following outcomes were not reported.

- Refractive error
- Anxiety (from interviews, self-completion questionnaires, focus groups etc)
- Over prescribing

The following symptoms were reported in RECS 2009 at one month's follow-up:

Symptom n (%)	Ready-made spectacles n = 209	Custom-made spectacles n = 205
Blurred vision	44 (21)	40 (19)
Distorted vision	22 (11)	19 (9)
Headache	42 (20)	47 (23)
Disorientation	18 (9)	11 (5)
Dizziness	52 (25)	40 (19)
Eyestrain	110 (53)	91 (44)
Nausea	12 (6)	19 (9)

Comparison: rural refractionist versus university optometrist

One study addressed this comparison. WEAR 2017 was conducted in China. Children aged 12 to 15 years were randomised to subjective cycloplegic retinoscopy by a rural refractionist or by a university optometrist and followed for two months. They were given custom-made spectacles.

Outcome: uncorrected visual acuity deficits due to refractive error (primary outcome) within six months of screening

Children receiving spectacles prescribed after assessment by a rural refractionist were less likely to have uncorrected visual acuity deficits: 25/108 (23%) had best-corrected visual acuity worse than 6/6 compared with 78/103 (76%) of the children receiving spectacles prescribed by a university optometrist (RR 0.31, 95% CI 0.21 to 0.44; 211 participants). All children in both groups had best-corrected visual acuity with study spectacles better than 6/12.

Outcome: uncorrected visual acuity deficits due to refractive error more than six months after screening

Not reported

Outcome: proportion of participants with visual acuity deficit due to causes other than refractive error at six months and more than six months

Not reported

Outcome: compliance with spectacles prescribed as a result of vision screening (i.e. spectacle wearing)

Both groups self-reported high levels of wear: 105/108 (97%) of the rural refractionist groups compared with 99/103 (96%) of the optometrist group (RR 1.01, 95% CI 0.96 to 1.06; 211 participants).

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Outcome: quality of life

There was little evidence of any important differences in quality of life as measured at two months using the NEI-RQL-42 (WEAR 2017). (MD 1.81, 95% CI -1.01 to 4.63; 198 participants).

Outcome: adverse effects

The following outcomes were not reported.

- Refractive error
- Anxiety (from interviews, self-completion questionnaires, focus groups etc)
- Over prescribing

Comparison: self-refraction versus university optometrist

One study addressed this comparison. WEAR 2017 was conducted in China. Children aged 12 to 15 years were randomised to non-cycloplegic self-refraction compared with subjective cycloplegic refraction by a university optometrist and followed for two months. They were given custom-made spectacles. Self-refraction was done using fluid-filled adjustable spectacles.

Outcome: uncorrected visual acuity deficits due to refractive error (primary outcome) within six months of screening

Children receiving spectacles prescribed after self-refraction were less likely to have uncorrected visual acuity deficits: 55/102 (54%) had best-corrected visual acuity worse than 6/6 compared with 78/103 (76%) of the children receiving spectacles prescribed by a university optometrist (RR 0.71, 95% CI 0.58 to 0.88). All children in both groups had visual acuity better than 6/9.

Outcome: uncorrected visual acuity deficits due to refractive error more than six months after screening

Not reported

Outcome: proportion of participants with visual acuity deficit due to causes other than refractive error at six months and more than six months

Not reported

Outcome: compliance with spectacles prescribed as a result of vision screening (i.e. spectacle wearing)

Both groups self-reported high levels of wear: 98/102 (96%) of the self-refraction group compared with 99/103 (96%) of the university optometrist group (RR 1.00, 95% CI 0.95 to 1.06).

Outcome: quality of life

There was little evidence of any important differences in quality of life as measured by change between baseline and two months in the NEI-RQL-42: MD 0.82, 95% CI -2.00 to 3.64; 188 participants).

Outcome: adverse effects

The following outcomes were not reported.

- Refractive error
- Anxiety (from interviews, self-completion questionnaires, focus groups etc)
- Over prescribing

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ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Vision screening and educational intervention compared with vision screening and no educational intervention for school-age children and adolescents

Patient or population: school-age children and adolescents
Settings: schools
Intervention: vision screening and educational intervention
Comparison: vision screening and no educational intervention

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed[1] risk	Corresponding risk				
	Educational intervention	No educational intervention				
Uncorrected visual acuity deficit due to refractive error Follow-up: 6 months	-	-	-	-	-	Not reported
Uncorrected visual acuity deficit due to refractive error Follow-up: more than 6 months	-	-	-	-	-	Not reported
Visual acuity deficit due causes other than refractive error Follow-up: 6 months	-	-	-	-	-	Not reported
Spectacle wearing Follow-up: 6 months	**Low uptake of spectacles**		**RR** 1.11 (0.95 to 1.31)	3177 (1 RCT)	⊕⊕⊕◯ Moderate[2]	Another study of 4448 participants reported odds ratio of 0.84 (0.55 to 1.31) for related outcome spectacle pur-

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						chase
	250 per 1000	**278 per 1000** (238 to 328)				
	High uptake of spectacles					
	750 per 1000	**833 per 1000** (713 to 983)				
Quality of life Follow-up: 6 months	-	-	-	-	-	Not reported
Cost	-	-	-	-	-	Not reported
Adverse effects Follow-up: any time period	-	-	-	-	-	Not reported

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RCT**: randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence
High-certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Low-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Very low-certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[1]Spectacle wearing in the comparator groups of studies included in this review varied from 23% to 96%. We have chosen 25% and 75% as illustrative risks.
[2]Downgraded one level for imprecision.

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Vision screening and provision of ready-made spectacles compared with vision screening and provision of custom-made spectacles for correctable visual acuity deficits in school-age children and adolescents

Patient or population: school-age children and adolescents
Settings: schools
Intervention: vision screening and ready-made spectacles
Comparison: vision screening and custom-made spectacles

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Assumed risk[1]	Corresponding risk				
	custom-made	ready-made				
Uncorrected visual acuity deficit due to refractive error Follow-up: 6 months	-	-	-	414 (1 RCT)	⊕⊕⊕◯ Moderate[2]	In one study, mean logMAR acuity in better and worse eye was similar between groups: MD better eye 0.03 logMAR, 95% CI 0.01 to 0.05; MD worse eye 0.06 logMAR, 95% CI 0.04 to 0.08
Uncorrected visual acuity deficit due to refractive error Follow-up: more than 6 months	-	-	-	-	-	Not reported
Visual acuity deficit due to causes other than refractive error Follow-up: 6 months	-	-	-	-	-	Not reported

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Spectacle wearing Follow-up: 6 months	**Low uptake of spectacles**		**RR** 0.98, (0.91 to 1.05)	1203 (3 RCTs)	⊕⊕⊕⊕ High	
	250 per 1000	**245 per 1000** (228 to 263)				
	High uptake of spectacles					
	750 per 1000	**735 per 1000** (683 to 788)				
Quality of life Measured using the NEI-RQL-42. Higher scores are better quality of life Follow-up: 6 months	The mean change in quality of life score between baseline and follow-up was 4.65 (95% CI 2.45 to 6.86) in children with custom-made spectacles	The mean quality of life score was 1.43 better (1.04 worse to 3.90 better) in children with ready-made spectacles	-	188 (1 RCT)	⊕⊕⊕◯ Moderate[3]	Follow-up was 2 months in this study
Cost	-	-	-	-	-	Not reported
Adverse effects Follow-up: any time period	Adverse effects were reported in one study and were similar between groups. These included: blurred vision, distorted vision, headache, disorientation, dizziness, eyestrain and nausea				⊕⊕◯◯ Low[4]	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **NEI-RQL-42**: National Eye Institute Refractive Error Quality of Life scale 42; **RR:** risk ratio

GRADE Working Group grades of evidence
High-certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Low-certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Very low-certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect

[1]Spectacle wearing in the comparator groups of studies included in this review varied from 23% to 96%. We have chosen 25% and 75% as illustrative risks.

[2]Downgraded 1 level for indirectness because average logMAR acuity may not adequately reflect proportion of children with uncorrected visual acuity deficit .

[3]Downgraded 1 level for indirectness as follow-up was 2 months rather than 6 months, pre-specified and reported in only one location (China).

[4]Downgraded 1 level for imprecision and 1 level for indirectness as only reported in one location (China).

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DISCUSSION

Summary of main results

The primary aim of vision screening of school-age children and adolescents is to identify and address visual acuity deficits due to the development of refractive error, especially myopia. While other causes of reduced vision may also be detected these occur relatively infrequently (Wallace 2017). Vision screening for refractive error in school-age children is not expected to impact on the prevalence of refractive error itself but aims to reduce the prevalence of uncorrected refractive error. To achieve this, vision screening programmes must not only reliably detect the target condition but also ensure that treatment, in whatever form, is available, affordable and can be realistically implemented. The remit of this review was to identify RCTs (including cluster-randomised controlled trials) that evaluated the effectiveness of screening as an intervention.

We identified seven relevant studies. Five of these studies were conducted in China with one study in India and one in Tanzania. Children enrolled in these studies were aged between 10 and 18 years. None of these studies compared vision screening for correctable visual acuity deficits versus not screening.

Two studies compared vision screening with provision of free spectacles versus vision screening with no provision of free spectacles (Summary of findings for the main comparison). These studies provide high-certainty evidence that vision screening with provision of free spectacles results in a higher proportion of children wearing spectacles than if vision screening is accompanied by provision of a prescription only. The studies suggest that if approximately 250 per 1000 children who are given vision screening plus prescription only are wearing spectacles at follow-up (three to six months) then 400 per 1000 (335 to 470) would be expected to be wearing spectacles after vision screening and provision of free spectacles. Costs were reported in one study in Tanzania in 2008 and indicated a relatively low cost of screening and spectacle provision but the extent to which these can be extrapolated to other locations is unclear. One study investigated the effect of combining a teacher incentive with free spectacles and found that this may also improve spectacle wearing. Other pre-specified outcomes of this review were not reported.

Two studies explored the effect of an educational intervention in addition to vision screening on spectacle wear (Summary of findings 2). There was little apparent effect of the education interventions investigated in these studies in addition to vision screening, compared to vision screening alone in terms of spectacle wearing. Other outcomes were not reported.

Three studies compared vision screening with ready-made spectacles versus vision screening with custom-made spectacles (Summary of findings 3). These studies provide moderate-certainty evidence that the two types of spectacles provide similar visual results and quality of life, and high-certainty evidence of no important difference in spectacle wearing. There was low-certainty evidence that the adverse effects or symptoms were similar in the two groups. Although none of the studies reported on costs directly, ready-made spectacles are cheaper and may represent considerable cost savings for vision screening programmes in lower-income settings.

Overall completeness and applicability of evidence

VIsion screening programmes directed to school-age children and adolescents take place in many different contexts throughout the world. They may be affected by the background prevalence of refractive error as well as the organisation and delivery of eye healthcare services in the locality, including access to affordable spectacles. The purpose and impact of vision screening may be different at different ages, for example, screening at school entry (age four to five years) differs from screening at older ages. Evidence provided in this review may not, therefore, be universally applicable and must be interpreted in context.

There are a wide variety of approaches to school-age vision screening throughout the world. Some commentators have observed that the existence of these variations, both between and within countries, is a reflection of the low-certainty evidence base (Rahi 2002). It is not the aim of the current review to provide a summary of current vision screening programmes but for relevant reviews see Sharma 2012 and Hopkins 2013. The studies in the current review were from Asia, the Indian subcontinent and Africa. As such, the results of these studies may be more applicable to low- and middle-income settings. The children included in these trials were aged 10 to 18 years. The results of these studies will not apply to vision screening at school entry (four to five years in many countries).

This review does not provide a direct answer to the question as to what are the benefits and harms of vision screening programmes in school-age children and adolescents. We did not identify any randomised controlled trials addressing that question. However, the included studies that compare provision of free spectacles (SIL 2014; Wedner 2008) demonstrated reasonably large differences in spectacle wearing and these were not associated with any important adverse effects. in particular SIL 2014 provides evidence that spectacle wearing did not lead to an increased progression of myopia and this is supported by other evidence (Walline 2011).

The evidence on the provision of free spectacles is reasonably robust and will be applicable to settings where such provision is not currently available. The review also provides reasonably conclusive evidence that cheaper, ready-made spectacles may be an acceptable alternative to expensive, custom-made spectacles in children without astigmatism or anisometropia. The finding that educational interventions, as tested so far, do not appear to be effective in improving spectacle wear may also be applicable to other higher-income settings. It is notable that the prevalence of spectacle wearing in the comparator group in the included studies varied from 25% to 75% and possibly higher. The reasons for variation in spectacle

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wear are not clearly understood but may include over-prescribing, concerns over appearance, teasing, discomfort and beliefs around spectacle wearing (Sharma 2012).

There may be unanticipated economic effects of provision of free spectacles. A recently published trial has tested out a model for sustainable provision of free spectacles (Wang 2017). Offering an upgrade option (stylish designs and scratch-free coatings) to free spectacles resulted in greater percentage of children purchasing spectacles and increased programme income.

Certainty of the evidence

The certainty of the evidence ranged from high to low, depending on the outcome.

We judged the studies largely to be at low risk of bias and judged the estimates of effect from each individual study as reasonably secure, downgrading only for imprecision as needed for each individual effect estimate. We were concerned with the applicability of the evidence with respect to location and downgraded for indirectness, depending on the comparison and the outcome. The extent to which the findings may be extrapolated to other settings was sometimes unclear.

Potential biases in the review process

Two of the review authors (JE/PM) were involved in one of the trials (Morjaria 2016). We tried to minimise any bias in assessment of this trial by making sure that data extraction for this study was performed by a review author not involved in the trial (CP) and another independent assessor (AS - see Acknowledgements).

Agreements and disagreements with other studies or reviews

The results of this review concur with other relevant reviews (Logan 2004; Mathers 2010; Rahi 2001; Rahi 2002; Wallace 2017). There is consensus that there is insufficient evidence to support the planning and development of vision screening programmes after school entry. The US Preventive Services Task Force identified no randomised controlled trials comparing screening with no screening in children aged six months to five years (Jonas 2017). The authors concluded that they could not establish whether vision screening in preschool children was better than no screening and the evidence of benefit was indirect.

We identified one review of ready-made spectacles (Pearce 2014). Although this review also considered studies in adult populations it came to the same conclusions as the current review, that is, that ready-made spectacles are a potential alternative to custom-made spectacles.

AUTHORS' CONCLUSIONS

Implications for practice

We did not find any randomised controlled trials that compared vision screening versus no vision screening however the results of the trials of vision screening with provision of free glasses compared with prescription alone may provide an indication of the likely benefit of vision screening programmes.

Vision screening plus provision of free spectacles improves the number of children who have and wear the spectacles they need compared with providing a prescription only. This may lead to better educational outcomes. Health education interventions, as currently devised and tested, do not appear to improve spectacle wearing in children. In lower-income settings, ready-made spectacles may provide a useful alternative to expensive custom-made spectacles.

The majority of studies included in this review were conducted in China with one from Tanzania and one from India. The extent to which these findings can be extrapolated to other settings is unclear.

Implications for research

Emerging evidence, from China in particular, suggests that vision screening of school-age children and adolescents for correctable visual acuity deficits may improve spectacle wearing and educational outcomes, if provision of spectacles is free. This finding may be applicable to other parts of the world but currently it is unclear if it is. Such studies could usefully be done in other countries and should be accompanied by formal cost-effectiveness analyses. Where there is the intention to introduce a new screening programme, the opportunity to carry out a randomised controlled trial should not be missed, so that the potential benefits or harms of this intervention can be measured. Outcomes should include both the prevalence of uncorrected visual acuity deficit as well as quality of life and educational outcomes. Further evidence on the progression of myopia is also needed.

There was considerable variation in spectacle wearing in the studies included in this review. Barriers to spectacle wear need to be further explored in different settings before the development of new interventions are tested more formally in randomised controlled trials.

In countries with low school attendance, information is needed on whether screening programmes in schools are sufficient or whether additional efforts have to be made to identify children with correctable visual acuity deficit in the community.

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* *Indicates the major publication for the study*

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Congdon 2011

Methods	**Study design:** cluster-RCT **Study grouping:** parallel group **Unit of analysis:** mixed-effects logistic regression was used to take into account the cluster design
Participants	**Country:** China **Setting:** school **Baseline characteristics:** Educational intervention • Age: mean (range): 14.1 years (12-17) • Gender: percentage female: 60% • Ethnic group: NR No educational intervention • Age: mean (range): 14.3 years (12-17) • Gender: percentage female: 54% • Ethnic group: NR Overall • Age: mean (range): 14.2 years (12-17) • Gender: percentage female: 57% • Ethnic group: NR **Inclusion criteria:** Quote "At each junior and senior high school in the 3 townships of Fuyang, Xichang, and Liangying, Chaoshan region, Guangdong Province, all year 1 and year 2 classes (approximate age, 12-17 years) were enumerated, and 10 classes were selected at random. " Quote "Children meeting the following criteria were given a prescription for spectacles by the examining ophthalmologist, together with a note addressed to their parents recommending that glasses be purchased: all participants with presenting VA of 6/12 or worse in either eye (e.g., with or without spectacles) and whose vision could be improved by 2 lines or more in either eye with refraction, and children already having spectacles improving the vision to better than 6/12, but whose vision could be improved by 2 lines or more in either eye with refraction." **Exclusion criteria:** NR **Pretreatment:** groups well balanced with respect to age, visual acuity, refractive error and spectacle ownership. Slightly more girls in the intervention group (60%) than the comparator group (54%)
Interventions	**Intervention:** Educational intervention • Number randomised: 2236 (10 schools) • Number (%) followed up: 1622 (73%) • Description of intervention: educational intervention delivered within 4 weeks of the initial visit. Trained study personnel for children recommended to receive spectacles and their teachers: (1) presentation of a 10-min cartoon video in Mandarin

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	Chinese explaining refractive error and its correction with spectacles; (2) an interactive lecture in Mandarin and Chaoshan Hua (the local dialect) delivered by young, trained ophthalmologists from the nearby Joint Shantou International Eye Center explaining the benefits of spectacle correction of refractive error and specifically stating that wearing spectacles improves vision and does not harm the eyes; (3) an interactive, classroom-based demonstration carried out by study personnel where children were asked to read typical homework assignments from the classroom blackboard, written to be visible with 6/6 vision, while seated at a distance of 6 m in the usual classroom seating. Children then were given self-refracting spectacles (Adspecs; Adlens, Ltd., Oxford, UK) and were directed to adjust the spectacle power to optimise vision in each eye and then to read the assignments again. The purpose of this demonstration was to make children aware of their poor vision and of the potential impact of corrected visual acuity in the classroom setting. **Comparator:** No educational intervention • Number randomised: 2212 (10 schools) • Number (%) followed up: 1578 (71%) • Description of intervention: no educational intervention **Intervention received by both groups:** Quote "Parents were recommended to obtain glasses at vision centers located within local, government-run hospitals in each of the 3 townships where the study took place. Each of these vision centers had been provided by Project Vision, a Hong Kong-based non governmental organization, with the following: equipment for refraction and dispensing of spectacles, high-quality children's frames, and 3 or 6 months of refraction training by optometrists at a tertiary center in nearby Shantou City. The trained personnel, who had various backgrounds, took part in the study screening examinations in their own townships. Spectacles were available at the vision centers at a cost of USD 10 and up. Vision centers were located within 10 miles of the homes of all children in the study. Other refractive services in this area were offered by unlicensed private shops, staffed by persons without formal refraction training, providing spectacles on the basis of noncycloplegic automated refraction or subjective refraction with loose lenses."
Outcomes	**Primary outcome:** • purchase of spectacles **Secondary outcomes:** • observed use (wear or possession of the spectacles at school) of newly purchased spectacles • frequency of wear • reasons for non-purchase of spectacles (in children who reported not buying spectacles) Presenting and uncorrected vision and refraction also measured along with the power of spectacles and spectacle-corrected vision were measured when spectacles were available **Follow-up:** approximately 6 months
Notes	**Study name:** The See Well to Learn Well Study **Date study conducted:** not reported but trial registry entry suggests start date was November 2007 **Trial registration number:** CUHK_CCT00149 and ChiCTR-TRC-09000710 **Funding:** quote "The See Well to Learn Well Project was supported by a grant to Oxford

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	University from the Li Ka Shing Foundation, Hong Kong SAR." **Declaration of interest:** quote "Financial Disclosure(s): The author(s) have no proprietary or commercial interest in any materials discussed in this article." **Investigators contacted:** no

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A random number table and list of junior and senior high schools in the 3 selected communities was used to assign 10 schools to receive an educational intervention and 10 schools to serve as controls."
Allocation concealment (selection bias)	Low risk	Judgement comment: cluster-RCT with allocation of schools at the beginning of the study
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Judgement comment: not reported but probably this was not an issue as allocation by schools and unlikely that the other intervention arm was explained in the control schools
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Staff were not masked as to the randomization status of schools at the time of follow-up." Judgement comment: it is arguable what effect this would have, especially as the overall results were negative, but ideally masking would have been used to avoid bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Judgement comment: 1622/2236 (72.5%) of children were followed up in the intervention group and 1578/2212 (71.3%) of children were followed up in the control group. Judgement comment: 1 in 3 or 4 children not seen but unclear if this would impact the results as follow-up was reasonably similar between the 2 groups
Selective reporting (reporting bias)	High risk	Judgement comment: the outcomes on registry entry were different to the final published study "A. Vision-related: - at 6 months and 1 year post visit to schools • Prevalence of refractive error and need for spectacles

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		• Proportion of children requiring refractive correction who have obtained it at baseline • Determinants of spectacles wear at baseline • Behaviorial and familial risk factors for myopia • Visual function and healthy behaviour knowledge pre and post-intervention, compared to control schools • Uptake of spectacles among children with refractive error, comparing the control and ocular interventions • Other determinants of spectacle uptake • Impact of spectacle uptake on visual function and school performance outcomes • Barriers to parents in providing spectacles“ B. Outcomes related to other proposed health interventions - at 6 months and 1 year post visit to schools • Changes in attitude/behaviour post-intervention, compared to control schools • Smoking rates and changes in attitude/behaviour post-intervention, compared to control schools • Social marketing approaches will be tested out and assessed for their impact Main outcome measures in trial report: ”Self-reported purchase of spectacles (primary outcome) and observed wear or possession of newly purchased glasses (secondary outcome) at follow-up examinations (mean, 219 +/- 87 days after the baseline visit).“
Baseline imbalance (cluster RCTs only)	Unclear risk	Judgement comment: not reported. Baseline characteristics reported at individual level. Groups well balanced with respect to age, visual acuity, refractive error and spectacle ownership. Slightly more girls in the intervention group (60%) than the comparator group (54%)
Loss of clusters (cluster RCTs only)	Unclear risk	Judgement comment: not reported.
Recruitment bias (cluster RCTs only)	Low risk	Judgement comment: not reported but we judge that this is unlikely to be an issue in the school setting

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Morjaria 2016

Methods	**Study design:** RCT **Study grouping:** parallel group **Unit of analysis:** people were randomly allocated to treatment and the study was analysed at the people level
Participants	**Country:** India **Setting:** school **Baseline characteristics:** Ready-made spectacles • Age: mean (range): 13.4 years (11-15) • Gender: percentage female: 48% • Ethnic group: NR Custom-made spectacles • Age: mean (range): 13.6 years (11-15) • Gender: percentage female: 51% • Ethnic group: NR Overall • Age: mean (range): 13.5 years (11-15) • Gender: percentage female: 49% • Ethnic group: NR **Inclusion criteria:** quote: "Screening was offered to all children aged 11 to 15 years present at school at the time of screening" Quote: "To be eligible for recruitment, the following criteria had to be met: (1) VA with full correction improved in the better seeing eye by 2 or more lines, (2) the SE corrected the VA to not more than 1 line less than best-corrected VA with a full prescription in the better eye, (3) the difference between SE of the right and left eyes was not more than 1.0 diopter (D), (4) inter pupillary distance matched that of ready-made spectacle frames available (ie, 54-62 mm), and (5) spectacle frames were of acceptable size and fit." **Exclusion criteria:** quote: "Exclusion criteria consisted of other causes of visual impairment and lack of parental consent." **Pretreatment:** quote "the range of spherical equivalent in the better eye was wider in the custom-made than ready-made arms."
Interventions	**Intervention:** Ready-made spectacles • Number randomised: 232 • Number (%) followed up: 184 (79%) • Description of intervention: ready-made spectacles had the same spherical correction in each eye **Comparator:** Custom-made spectacles • Number randomised: 228 • Number (%) followed up: 178 (78%) • Description of intervention: custom-made spectacles were dispensed on the basis of a prescription from study optometrists
Outcomes	**Primary outcome:** • proportion of children who were wearing their spectacles at an unannounced visit Categories 1 or 2 were used to define spectacle wearing, and categories 3 or 4 as non-

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	spectacle wearing: 1. wearing the spectacles at the time of the unannounced visit 2. not wearing the spectacles at the time of the visit but have them at school 3. not wearing the spectacles at the time of the visit but said they are at home 4. not wearing the spectacles at the time of the visit as they are broken or lost **Secondary outcomes:** • reasons for not wearing spectacles **Follow-up:** 3-4 months
Notes	**Study name: n**one given **Date study conducted:** January 2015-July 2015 **Trial registration number:** ISRCTN14715120 **Funding:** quote "This study was supported by L'Occitane Foundation and the Vision Impact Institute." **Declaration of interest:** quote "Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported" **Investigators contacted:** not appicable (investigator is author of current review)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "After recruitment, children were randomly assigned 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 one of us who was an epidemiologist (J.E.) away from the study site."
Allocation concealment (selection bias)	Low risk	Quote: "Sequentially numbered, sealed, stamped opaque envelopes containing labels with unique study identification numbers and random allocation were prepared by persons not involved in the trial. At the study site, the optometrist opened the envelopes."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "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."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Children, teachers, and parents were masked to the allocation arm. To maintain masking, a field worker and op-

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Morjaria 2016 (*Continued*)

		tometrist not previously involved in the trial were trained to assess the primary outcome."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: follow-up nearly 80% in each group and balanced between groups. "All children not followed up in school (n = 98) had changed schools and moved to a different area."
Selective reporting (reporting bias)	Low risk	Judgement comment: all outcomes in protocol published

RECS 2009

Methods	**Study design:** RCT **Study grouping:** parallel group **Unit of analysis:** people randomised to intervention and analysis by person
Participants	**Country:** China **Setting:** school (urban) **Baseline characteristics:** Ready-made spectacles • Age: mean (range): 14.1 years (12-15) • Gender: percentage female: 57% • Ethnic group: NR CMS • Age: mean (range): 14.1 years (12-15) • Gender: percentage female: 46% • Ethnic group: NR Overall • Age: mean (range): 14.1 years (12-15) • Gender: percentage female: 52% • Ethnic group: NR **Inclusion criteria:** presenting vision 20/40 or worse in better eye. Minimum uncorrected spherical refractive error of ≥ 1 dioptre. Students already wearing spectacles were eligible if their current spectacles required a change of ≥ 1 dioptre **Exclusion criteria:** best corrected distance acuity 20/25. Cylinder power > -2 dioptre. Anisometropia (for myopia, sphere difference ≥ 2D, for hyperopia, sphere difference = 1 dioptre. Other eye disease affecting vision **Pretreatment:** slightly higher proportion boys in CMS group
Interventions	**Intervention:** Ready-made spectacles • Number randomised: 250 • Number (%) followed up: 208 (83%) • Description of intervention: quote "All study spectacles were made to order, produced by the Zhongshan optical laboratory and their quality verified according to standard parameters. Any spectacles not meeting standards were remade. Because

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	cosmetic acceptability of frames has been reported to influence spectacles compliance in the past, we provided a choice of frames to all participants in metal (5 colors) and plastic (3 colors) in sizes ranging 42-16 to 52-16 mm (eye size) and temple length, 125 to 143 mm. For the RMS group, the smallest frames were made with 55 mm, the medium-sized frames 60 mm, and the largest frames, 65 mm optical center distances. The anticipated spectacle lenses in the RMS group were +1.00 to +4.00 D in 0.50 steps, +5.00 D, +6.00 D, and +8.00 D, −1.00 to −6.00 D in −0.50 steps, −7.00 D, −8.00 D, −9.00 D, and −10.00 D and had the same power in each eye to mimic an inventory of 25 stock keeping units. If there was a difference between the 2 eyes, for RMS, the spectacles were prescribed for the eye with lower refractive error. At the 1-month follow-up visit, children who were intolerant to their spectacles were issued new spectacles." **Comparator:** CMS • Number randomised: 245 • Number (%) followed up: 206 (84%) • Description of intervention: quote "All study spectacles were made to order, produced by the Zhongshan optical laboratory and their quality verified according to standard parameters.Any spectacles not meeting standards were remade. Because cosmetic acceptability of frames has been reported to influence spectacles compliance in the past, we provided a choice of frames to all participants in metal (5 colors) and plastic (3 colors) in sizes ranging 42-16 to 52-16 mm (eye size) and temple length, 125 to 143 mm. The CS used the final, adjusted subjective refraction and the optical center distance was matched to the student's pupillary distance. [...] At the 1-month follow-up visit, children who were intolerant to their spectacles were issued new spectacles."
Outcomes	**Primary outcome:** • proportion of the target population with compliance to spectacle lens wear as measured by having spectacles on hand **Secondary outcomes** • previous and planned use • perceived value • duration or wear (all day, part of day, only for distance or near vision) • adaptation time • spectacle remakes • symptoms **Follow-up:** 1 month
Notes	**Study name:** Evaluation of effectiveness of correcting refractive error with ready-made spectacles (RECS) (from trial registry entry) **Date study conducted:** April 2008-November 2008 (from trials registry entry) May-July 2008 (in paper) **Trial registration number:** NCT00657670 **Funding: q**uote "Support for this project was provided by the Michael and Susan Dell Foundation, by Helen Keller International (YZ, MH, & DF), Australian National Health and Medical Research Council Sidney Sax post doctoral fellowship (LK) and a Knights Templar Eye Foundation Pediatric Ophthalmology Grant (LK & BM). Mingguang He is supported by a grant from the World Bank to test a proprietary spectacle technology." **Declaration of interest:** quote "Financial Disclosure(s): Proprietary or commercial dis-

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	closure may be found after the references." But none were included **Investigators contacted:** no

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization occurred at the study center after completion of the first visit. A randomization grid with 500 possible enrollments generated using a random number generator (available at: http://www.randomization.com; accessed March 21, 2008). Participants were assigned a position on the grid according to enrollment order."
Allocation concealment (selection bias)	Low risk	Quote: "Both the participant and those involved in data collection were masked to the type of spectacles ordered.Masking was maintained during follow-up" Judgement comment: although not clearly stated likely that the enrolment was masked too
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote "Masking was maintained during follow-up assessment because the spectacles were made at the optical facility, which was remote to the testing site and the RMS and CS were not different in appearance."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote "Masking was maintained during follow-up assessment because the spectacles were made at the optical facility, which was remote to the testing site and the RMS and CS were not different in appearance." Quote "Furthermore, those involved in data collection were not equipped to measure refractive power of the spectacles during assessment and thereby remained masked to the treatment allocation during all evaluations"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: follow-up reasonably high and similar between groups. RMS: 208/250 (83%) CMS: 206/245 (84%)

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RECS 2009 (*Continued*)

Selective reporting (reporting bias)	High risk	Judgement comment: not all outcomes on trial register reported and some of the missing outcomes would have been of relevance to this review e.g. continued spectacle use at 6-12 months after dispensing Outcomes on trial registry entry Quote "Primary outcome measures: Wearer retention (% wearing at 1 month) , vision (logMAR), visual function (0-100) , quality of life (0-100) [Time Frame: a 1-month period of spectacle wear] Secondary outcome Measures: Cost-effectiveness [Time Frame: 1-month of spectacle wear] Willingness to pay [Time Frame: 1-month of spectacle wear] Recommendations for those who will benefit from ready made spectacles [Time Frame: 1-month of spectacle wear] Quantify the prismatic effects which has an impact of spectacle compliance, need for adaptation and satisfaction with spectacles [Time Frame: 1-month of spectacle wear] Continued spectacle use 6-12 months after dispensing [Time Frame: 12 months]"

SIL 2014

Methods	**Study design:** cluster-RCT **Study grouping:** parallel group **Unit of analysis:** analyses were adjusted for clustering by school
Participants	**Country:** China **Setting:** school **Baseline characteristics:** Free spectacles • Age: mean (range): 10.5 years (NR) • Gender: percentage female: 51% • Ethnic group: NR Voucher • Age: mean (range): 10.5 years (NR) • Gender: percentage female: 52% • Ethnic group: NR Control (no free spectacles/no voucher) • Age: mean (range): 10.5 years (NR) • Gender: percentage female: 50% • Ethnic group: NR Education

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	• Age: mean (range): 10.5 years (NR) • Gender: percentage female: 52% • Ethnic group: NR No education • Age: mean (range): 10.5 • Gender: percentage female: 50% • Ethnic group: NR Overall • Age: mean (range): 10.5 years (NR) • Gender: percentage female: 51% • Ethnic group: NR **Inclusion criteria:** children with uncorrected visual acuity ≤ 6/12 in either eye **Exclusion criteria:** schools with < 50 students, schools with > 150 students **Pretreatment:** some differences in blackboard use - free spectacles group higher proportion (40%) were in classes with little or no blackboard use. Some differences in family wealth. Greater proportion of free spectacles group in top third (37%) for family wealth
Interventions	**Factorial trial with 3 x 2 interventions/comparators giving 6 groups** **Intervention 1:** Free spectacles • Number randomised: 1153 • Number (%) followed up: 1104 (96%) • Description of intervention: "Free spectacles, based on the child's measured refractive power and dispensed at school by the study optometrist.A letter with information about the free glasses program and including the child's prescription was sent to parents." • Number of schools randomised: 84 • Number of schools wit children with refractive error: 84 **Intervention 2:** Voucher • Number randomised: 988 • Number (%) followed up: 947 (96%) • Description of intervention: "Vouchers bearing the child's name, school, and glasses prescription, exchangeable for free glasses at the local county hospital, at a median distance from children's townships of 30 km (range 1-105 km). Parents were responsible for paying the transportation costs. Voucherscould not be exchanged or sold, and students were required to produce school identification to redeem them. Childrenwhose families did not redeem their vouchers received free glasses at study closeout, though this was not previously announced. " • Number of schools randomised: 84 • Number of schools wit children with refractive error: 83 **Comparator 1:** No free spectacles/no voucher • Number randomised: 1036 • Number (%) followed up: 1003 (97%) • Description of intervention: "A glasses prescription and letter to the parents informing them of the refractive status of their child, with free glasses provided only at closeout, although this was not previously announced." • Number of schools randomised: 84

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	• Number of schools wit children with refractive error: 84 **Intervention 3**: Education • Number randomised: 1648 • Number (%) followed up: 1585 (96%) • Description of intervention: "Children at education group schools watched a 10 minute documentary style video and were given a booklet of cartoons,followed by a classroom discussion led by study staff. Allchildren in the selected classes, regardless of vision status,participated. These materials showed children experiencing the benefits of spectacles and teachers explaining that spectacles do not harm vision. Teachers and parents viewed a presentation at school on the safety and benefits of glasses, accompanied by a brochure with similar information, and posters with similar content were hung in classrooms. All materials delivered to children, teachers, and parents were designed to convey the same set of messages: that myopia is common in China, that glasses provide the safest and most effective treatment of myopia for children, and that wearing glasses does not harm children's eyes. Study staff returned in December 2012 to reinforce these messages, which were based on previous research in ruralChina." • Number of schools randomised: 126 • Number of schools wit children with refractive error: 126 **Comparator 2:** No education • Number randomised: 1529 • Number (%) followed up: 1469 (96%) • Description of intervention: No educational intervention. • Number of schools randomised: 126 • Number of schools with children with refractive error: 125
Outcomes	**Primary outcome:** • educational attainment (maths test) **Secondary outcomes:** • observed spectacle wear • self-reported spectacle wear **Follow-up:** approximately 8 months
Notes	**Study name:** Seeing is learning: providing vision care to rural primary school children in China (name on clinical trials registry entry only) **Date study conducted:** September 2012-June 2013 **Trial registration number:** ISRCTN03252665 (retrospectively registered) **Funding:** quote "This study was funded by OneSight (Mason, OH), Luxottica-China (Shanghai), Essilor-China (Shanghai), CLSA (Asia Pacific Markets; Hong Kong), Charity Aid Foundation (Sydney), and an anonymous donor (Hong Kong). NC is supported by a Thousand Man Plan grant from the Chinese government. The study sponsors had no role in study design; the collection, analysis, and interpretation of data; the writing of the report; or the decision to submit the paper for publication." **Declaration of interest:** quote "All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: the free glasses used in this study were supplied by OneSight, Luxottica-China, and Essilor-China, producers of frames and lenses in China who also provided financial support for the study; the authors have no other financial relationships with any organisations that might have an

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	interest in the submitted work in the previous three years; and no other relationships or activities that could appear to have influenced the submitted work“ **Investigators contacted:** no

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: ”Stratification and random assignment were carried out at a central location (Stanford University, Stanford, CA) using R software (R Foundation for Statistical Computing, Vienna, Austria).“
Allocation concealment (selection bias)	Low risk	Quote: ”Stratification and random assignment were carried out at a central location (Stanford University, Stanford, CA) using R software (R Foundation for Statistical Computing, Vienna, Austria). Participants (students, parents, and teachers) and enumerators were not informed of either the overall design of the study or the explicit treatment arm assignment“
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote ”Participants (students, parents, and teachers) and enumerators were not informed of either the overall design of the study or the explicit treatment arm assignment. Participants were told only that this was a study of vision care among rural, school aged children. Only one school was selected in each township, minimizing the possibility of cross arm communication and contamination.“
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote ”Participants (students, parents, and teachers) and enumerators were not informed of either the overall design of the study or the explicit treatment arm assignment. Participants were told only that this was a study of vision care among rural, school aged children. Only one school was selected in each township, minimizing the possibility of cross arm communication and contamination.“
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: follow-up high and reasonably balanced between groups (range 95.1% to 97.5% in six treatment arms).

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		Multiple imputation used for missing values
Selective reporting (reporting bias)	Unclear risk	Judgement comment: not all outcomes on trials registry entry were reported. The non-reported outcomes include: knowledge of vision care and mental health, such as anxiety, mental health, self-esteem, and enjoyment of school
Baseline imbalance (cluster RCTs only)	Low risk	Clusters were balanced for numbers of children in fourth and fifth grades and uncorrected visual acuity < 6/18. Individual level factors also appeared to be reasonably balanced. Allocation was stratified: quote "Within each group, schools were randomised in October 2012 to receive an educational intervention promoting spectacle wear (education group) or no education. There were six groups of 42 schools in this 3×2 factorial design. Schools were stratified by three variables, information on which was collected during the baseline survey and screening: county; the total number of students in grades 4 and 5; and the number of students failing vision screening in grades 4 and 5. Within each stratum a school was randomly assigned to one of the six treatment arms."
Loss of clusters (cluster RCTs only)	Low risk	One (out of 84) clusters excluded because there were no children that met the inclusion criteria. This is unlikely to affect the results
Recruitment bias (cluster RCTs only)	Low risk	Quote "Participants (students, parents, and teachers) and enumerators were not informed of either the overall design of the study or the explicit treatment arm assignment. Participants were told only that this was a study of vision care among rural, school aged children. Only one school was selected in each township, minimizing the possibility of cross arm communication and contamination."

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SIL II 2015

Methods	**Study design:** cluster-RCT **Study grouping:** parallel group **Unit of analysis:** schools were randomly allocated to intervention and analysis by person, adjusted for cluster design
Participants	**Country:** China **Setting:** school (rural) **Baseline Characteristics:** Free spectacles and teacher incentive • Age: mean (range): 10.9 years (10 to 12) • Gender: percentage female: 50% • Ethnic group: NR Prescription only • Age: mean (range): 11.0 years (10 to 12) • Gender: percentage female: 48% • Ethnic group: NR Overall • Age: mean (range): 11.0 years (10 to 12) • Gender: percentage female: 49% • Ethnic group: NR **Inclusion criteria:** quote "All elementary schools in these cities identified by the local Bureaus of Education as having a primarily migrant population were enumerated and 94 schools were selected at random (66 in Shanghai and 28 in Suzhou/Wuxi). One fifth grade class (children aged 10-12 years) was selected at random in each school, and questionnaires (see below) were administered and visual acuity testing and refraction (see below) carried out. All children in the selected classes meeting both the following visual and refractive criteria were eligible: uncorrected visual acuity <6/12 in either eye; refractive error meeting cutoffs shown to be associated with significantly greater improvement in visual acuity when corrected: myopia <=-0.75 diopters (D), hyperopia >=+2.00 D, or astigmatism (nonspherical refractive error) >1.00 D." **Exclusion criteria:** exclusion criteria unclear but in the results some children were excluded because parents refused, visual acuity was not correctable to ≥ 6/12 in both eyes **Pretreatment:** no obvious imbalance
Interventions	**Intervention 1:** Free spectacles and teacher incentive • Number randomised: 358 • Number (%) followed up: 341 (95.3%) • Description of intervention: quote "Free spectacles based on the child's measured refractive power dispensed at school by the study optometrist. A letter informing the parents about the free glasses program and including the child's prescription was sent to parents, and a previously described educational intervention directed at teachers and children and promoting spectacle wear was carried out. Additionally, teachers (but not children) in eligible classes were informed that if >80% of children given glasses were wearing them at the time of 2 unannounced class visits, the teacher would receive a tablet computer (approximate value US$350; approximate monthly teacher income US$450). This offer was made to Chinese, mathematics, and English teachers (the main academic subjects in Chinese primary schools) (Intervention group, 47 schools); " • Number of schools: 47 **Comparator:**

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	Prescription only • Number randomised: 370 • Number (%) followed up: 352 (95.1%) • Description of intervention: quote "A glasses prescription and letter to the parents informing them of the refractive status of their child, with free glasses provided only at the conclusion of the trial, though this was not previously announced. No teacher incentive was offered. (Control group, 47 schools)." • Number of schools: 47
Outcomes	**Primary outcome:** • observed wear of spectacles **Secondary outcomes:** • self-reported wear • self-reported frequency of wear ("always," "only for studying," or "usually not worn.") **Follow-up:** 6 months
Notes	**Study name:** Seeing is learning: vision care for children in three migrant communities (name on clinical trials registry entry only) **Date study conducted:** September 2013 (baseline) to follow-up at 6 months **Trial registration number:** ISRCTN16720066 (retrospectively registered) **Funding:** Quote "FUNDING/SUPPORT: THIS STUDY WAS FUNDED BY CATERPILLAR INC (PEORIA, IL, USA), ESSILOR-CHINA (SHANGHAI), BRIEN Holden Vision Institute (Sydney, Australia), Leibniz Institute of Agricultural Development in Transition Economies (IAMO, Halle, Germany), National Natural Science Foundation of China (Beijing, China) (Grant: 71373255), the Institute of Geographic Sciences and Natural Resources Research (Beijing, China), CAS (Grant: 2013RC204, 2012RC102). N. Congdon is supported by the Chinese government Thousand Man Plan (Beijing, China) and the Ulverscroft Foundation (Anstey, UK). The free spectacles used in this study were supplied by Essilor-China (Shanghai, China), producers of frames and lenses in China, who also provided financial support for the study." **Declaration of interest:** all authors reported no financial disclosures. **Investigators contacted:** no

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomization was carried out at a central location (Stanford University, Stanford, California, USA) using R software (R Foundation for Statistical Computing, Vienna, Austria)."
Allocation concealment (selection bias)	Low risk	Quote: "Randomization was carried out at a central location (Stanford University, Stanford, California, USA) using R software (R Foundation for Statistical Computing, Vienna, Austria)."

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Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Participants (students, parents, and teachers) and enumerators were not informed of either the overall design of the study or the explicit treatment arm assignment."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "These study personnel were masked to children's group assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: "Follow-up high (>95%) and reasonably equal between groups. 4.7% of the free glasses/teacher incentive group were lost to follow-up and 4.9% of the prescription only group lost to follow-up."
Selective reporting (reporting bias)	Unclear risk	Judgement comment: not all outcomes on the trials registry entry (ISRCTN16720066) were reported. The trials registry entry specified the following outcomes: 1. Number of children wearing spectacles regularly 2. School performance, determined from a standardized test 3. Student interest in school 4. Student mental health 5. Student self confidence Only outcome (1) available in published reports to date.
Baseline imbalance (cluster RCTs only)	Unclear risk	Judgement comment: baseline characteristics of clusters (schools) was not provided. No obvious imbalances on individual level characteristics
Loss of clusters (cluster RCTs only)	Low risk	Judgment comment: no clusters lost
Recruitment bias (cluster RCTs only)	Low risk	Judgement comment: recruitment bias unlikely as participants (students, parents, teachers) not informed of the overall design of the study and treatment assignment

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WEAR 2017

Methods	**Study design:** RCT **Study grouping:** parallel group **Unit of analysis:** person: for ocular measures the better-seeing eye was used
Participants	**Country:** China **Setting:** school **Baseline characteristics:** University optometrist • Age: mean (range): 14.1 years (12-15) • Gender: percentage female: 64% • Ethnic group: NR Ready-made • Age: mean (range): 14.2 years (12-15) • Gender: percentage female: 47% • Ethnic group: NR Rural refractionist • Age: mean (range): 14.1 years (12-15) • Gender: percentage female: 51% • Ethnic group: NR Self-refraction • Age: mean (range): 14.2 years (12-15) • Gender: percentage female: 55% • Ethnic group: NR Overall • Age: mean (range): 14.2 years (12-15) • Gender: percentage female: 54% • Ethnic group: NR **Inclusion criteria:** quote "Children meeting all the following criteria after refraction as described above were eligible for recruitment in the study: 1 Presenting VA (if the child wears glasses, her/his presenting VA is her/his corrected VA with their own spectacles;if the child does not wear spectacles,her/his presenting VA is her/his uncorrectedVA) ≤6/12 in both eyes; 2 Subjective spherical equivalent refractive error (SER) ≤1.00 dioptres (D) in both eyes; 3 Visual acuity (VA) improvable to >6/7.5 in both eyes with refraction as assigned in their group. It was considered unethical to permit children to wear glasses not providing adequate vision, and the goal of the study was to determine whether children achieving good VA with alternative modalities might have ocular discomfort or other issues affecting quality of life **Exclusion criteria:** quote "Children with ocular diseases potentially affecting the vision and those with astigmatism or anisometropia ≥2.00 dioptre were excluded, the latter for ethical reasons, following the example of Brady et al. (2012). Children with visual acuity ≤6/7.5 in either eye after self-refraction, refraction by the rural optometrist or with pseudo-ready-made glasses were referred for refraction by the university optometrist and provision of free spectacles after exclusion from the study. Children whose visual acuity could not be improved by the university optometrist were referred to the local county hospital for further examination." **Pretreatment:** Some imbalances in gender between groups: university optometrist group had more girls (64%) compared with the other groups that had 47% to 55% girls

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Interventions	**Intervention 1:** Ready-made spectacles • Number randomised: 113 • Number (%) followed up: 107 (95%) • Description of intervention: quote "Cycloplegic automated refraction with refinement by a rural refractionist from a local county-level hospital who had received refraction training in an ongoing programme administered by ZOC.the ready-made group, received pseudo ready-made spectacles as previously described (Zeng et al. 2009), with power in both eyes equal to the spherical equivalent of the eye with lower power (absolute value),on subjective refraction by an optometrist from ZOC following cycloplegic automated refraction. Spectacle powers were available in 0.50 D steps between1.00 and 6.00 D, and 1.00D steps between7.00 and 10.00 D, with measured power being rounded down to the nearest step as needed. Available interpupillary distances were 50, 55, 60 and 65 mm. **Intervention 2:** Rural refractionist • Number randomised: 108 • Number (%) followed up: 105 (97%) • Description of intervention: "Cycloplegic automated refraction with refinement by a rural refractionist from a local county-level hospital who had received refraction training in an ongoing programme administered by ZOC" **Intervention 3:** Self-refraction • Number randomised: 102 • Number (%) followed up: 98 (96%) • Description of intervention: Non-cycloplegic self-refraction using fluid-filled adjustable spectacles and a protocol based on that which has previously been reported (He et al. 2011; Zhang et al.2011). **Comparator:** University optometrist • Number randomised: 103 • Number (%) followed up: 99 (96%) • Description of intervention: quote "Cycloplegic automated refraction with refinement by an experienced optometrist from ZOC"
Outcomes	**Primary outcome:** • visual function-related quality of life NEI-RQL-42 **Secondary outcomes:** • proportion of vector dioptric difference (VDD) values between the prescription power and power measured by lensometry in the better-seeing eye falling within 0.25 D, 0.50 Dand 1.0 D • proportion with best-corrected VA $\geq$ 6/6 • proportion reporting being very satisfied or satisfied • rating the study spectacles as their most valued possession, of high value or of moderate value **Follow-up:** 2 months

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Notes	**Study name:** Wearability and Evaluation of Adjustable Refraction (WEAR) trial (Phase II) **Date study conducted:** February 2013-May 2013 **Trial registration number:** NCT01704729 **Funding:** not reported **Declaration of interest:** not reported **Investigators contacted:** no

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote "All provisionally eligible children in each grade and each county (VA <6/12 in both eyes) were randomised individually to one of four groups, stratifying by grade (grade 7 and grade 8) and the two towns" Judgement comment: not reported how the allocation was generated
Allocation concealment (selection bias)	Low risk	Quote "Subjects and study personnel administering the questionnaires and assessing VA were masked to study group assignment."
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote "Subjects and study personnel administering the questionnaires and assessing VA were masked to study group assignment."
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote "Children themselves and investigators assessing study outcomes were masked to group assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: follow-up over 95% and balanced between groups
Selective reporting (reporting bias)	Low risk	Judgement comment: although there were some differences between the trials registry entry and publication, data on outcomes specified on the trials registry entry that were relevant to this review were available

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Wedner 2008

Methods	**Study design:** cluster-RCT **Study grouping:** parallel group **Unit of analysis:** analysis by participant with adjustment for clustering by school
Participants	**Country:** Tanzania **Setting:** school **Baseline characteristics:** Free spectacles • Age: mean (range): 14.1 years (12-18) • Gender: percentage female: 71% • Ethnic group: 95.6% African Prescription only • Age: mean (range): 14.8 years (12-19) • Gender: percentage female: 40% • Ethnic group: 96.5% African Overall • Age: mean (range): 14.4 years (12-19) • Gender: percentage female: 57% • Ethnic group: 96% African **Inclusion criteria:** Quote "All 51 secondary schools within 30 km from the Centre for Community Based Rehabilitation andTreatment (CCBRT), a non-government tertiary eye care facility, were invited to participate in the screening, and all but three agreed. Distance visual acuity testing was offered to all students in the first school year. After an intensive period of training, a team of research assistants collected socio-economic information on participants and tested uncorrected visual acuity (right and left eye separately and both eyes together) with a Snellen's E-chart at 6 m. They also tested presenting visual acuity in students who had their own spectacles with them. All students who were not able to identify at least four of the five optotypes in the 12-line in either eye unaided or wearing their spectacles, were defined as having "poor eyesight" and were referred to CCBRT. At CCBRT, an optometrist retested visual acuity and assessed refractive errors by retinoscopy and subjective refraction. Cycloplegia was only used if hyperopia was suspected. An ophthalmologist performed a detailed eye examination in all students whose visual acuity did not improve to normal (better than 6/12 in both eyes) with best correction. The optometrist also refracted non-attenders in their schools 2-4 weeks after referral." **Exclusion criteria:** none reported **Pretreatment:** more girls in intervention group (71%) compared with comparator (40%) . Other imbalances e.g. residence with family, possession of car, TV and computer but with small numbers e.g. 1 vs 4 participants for non-family residence and 10 versus 5 participants for possessions
Interventions	**Intervention characteristics** Free spectacles • Number randomised: 68 • Number (%) followed up: 58 (85%) • Description of intervention: quote "Students who had refractive errors causing visual impairment of 6/12 or worse whose visual acuity improved with spectacles by at least one line, and students with significant hyperopia (>2D), were provided with free spectacles (arm A) or with a prescription only (arm B)." A choice of fashionable metal frames was available to students in schools allocated to free spectacles. All children

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	received an information leaflet explaining the importance of spectacles and regular eye examinations. • Number of schools: 37 schools in total - unclear number of schools in each group Prescription only • Number randomised: 57 • Number (%) followed up: 50 (88%) • Description of intervention: quote "Students who had refractive errors causing visual impairment of 6/12 or worse whose visual acuity improved with spectacles by at least one line, and students with significant hyperopia (>2D), were provided with free spectacles (arm A) or with a prescription only (arm B)."Students in schools allocated to prescription only were given a prescription and could purchase their spectacles at the Centre for Community Based Rehabilitation and Treatment (30km away) or any optical workshop of their choice. All children received an information leaflet explaining the importance of spectacles and regular eye examinations. • Number of schools: 37 schools in total - unclear number of schools in each group
Outcomes	**Primary outcome:** • spectacle use 2 definitions of spectacle use: all students in categories 1 and 2 and all students in categories 1 to 3 1. were wearing spectacles, 2. were not wearing spectacles but had them at school, 3. were not wearing spectacles and did not have them at school but said that they had them at home or 4. claimed that they did not have any spectacles **Secondary outcome** • prevalence of uncorrected significant refractive error • predictors of spectacle use **Follow-up:** 3 months
Notes	**Study name:** The school eye screening study **Date study conducted:** January 2004-August 2004 **Trial registration number:** NR **Funding:** quote "Funding: British Council for the Prevention of Blindness (BCPB)." **Declaration of interest:** quote "Competing interests: None." **Investigators contacted:** no

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Secondary schools were randomly allocated to one of two intervention arms (A or B) before the screening took place." Judgement comment: method of doing allocation not reported but personal communication "computer generated random numbers"

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Wedner 2008 (*Continued*)

Allocation concealment (selection bias)	Low risk	Quote: "Secondary schools were randomly allocated to one of two intervention arms (A or B) before the screening took place." Judgement comment: cluster-RCT
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The screening team and the optometrist were not aware of the allocation at the time of visual acuity measurement and refraction." Participants in comparator arm were unaware that children in other schools had received spectacles for free
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Judgement comment: not specifically reported whether outcome assessors were masked
Incomplete outcome data (attrition bias) All outcomes	Low risk	Judgement comment: follow-up high and similar between the intervention (85%) and comparator group (88%)
Selective reporting (reporting bias)	Low risk	Judgement comment: personal communication: all outcomes were reported as planned
Baseline imbalance (cluster RCTs only)	Unclear risk	Judgement comment: cluster-level data not reported. At an individual level the groups were well balanced apart from gender - fewer boys in intervention group - but the impact of that is unclear
Loss of clusters (cluster RCTs only)	Unclear risk	Judgement comment: not clearly reported
Recruitment bias (cluster RCTs only)	Low risk	Judgement comment: recruitment bias probably unlikely as the children were unaware of the intervention in the other arm of the study

CS: custom-made spectacles; **NEI-RQL-42**: National Eye Institute Refractive Error Quality of Life questionnaire; **NR**: not reported; **RCT**: randomised controlled trial; **RMS**: ready-made spectacles; **VA**: visual acuity

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Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Cross 1985	Not a RCT
Gole 2001	Not a RCT
Li 2013	This was a RCT but was comparison undercorrection of 0.50 dioptres and full correction on the progression of myopia so not directly assessing vision screening
Priya 2015	Not a RCT
Pärssinen 2014	Not a RCT
Pärssinen 2015	Not a RCT
Terveen 2015	Not a RCT
Wei 2016	Not a RCT
Yamada 2004	Not a RCT

RCT: randomised controlled trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

Wang 2017

Methods	Cluster-randomised trial
Participants	Country: China 882 children with uncorrected visual acuity 6/12 or worse in either eye correctable to better than 6/12 in both eyes 138 randomly-selected primary schools
Interventions	Free spectacles Free spectacles and USD 15 upgrade Free spectacles and USD 30 upgrade No free spectacles (prescription only)
Outcomes	Spectacle purchase Follow-up: 6 months
Notes	Date study conducted: October 2014-June 2015 Trial registration number: NCT02231606

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DATA AND ANALYSES

Comparison 1. Free glasses compared with prescription only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Spectacle wearing	2	1092	Risk Ratio (M-H, Fixed, 95% CI)	1.60 [1.34, 1.90]

Comparison 2. Ready-made versus custom-made spectacles

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Spectacle wearing	3	1203	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.91, 1.05]

Analysis 1.1. Comparison 1 Free glasses compared with prescription only, Outcome 1 Spectacle wearing.

Review: Vision screening for correctable visual acuity deficits in school-age children and adolescents

Comparison: 1 Free glasses compared with prescription only

Outcome: 1 Spectacle wearing

Study or subgroup	Free glasses n/N	Prescription n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
SIL 2014 (1)	220/540	125/485		93.9 %	1.58 [1.32, 1.90]
Wedner 2008 (2)	17/36	8/31		6.1 %	1.83 [0.92, 3.65]
Total (95% CI)	**576**	**516**		**100.0 %**	**1.60 [1.34, 1.90]**
Total events: 237 (Free glasses), 133 (Prescription)					
Heterogeneity: Chi^2 = 0.16, df = 1 (P = 0.69); I^2 =0.0%					
Test for overall effect: Z = 5.21 (P < 0.00001)					
Test for subgroup differences: Not applicable					

(1) Follow-up: approximately 8 months

(2) Follow-up: 3 months

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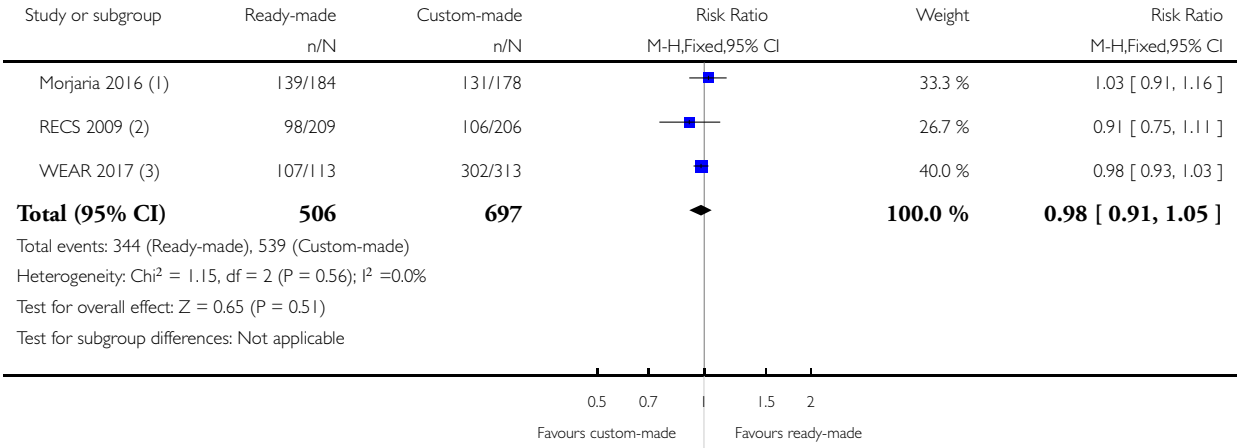
Analysis 2.1. Comparison 2 Ready-made versus custom-made spectacles, Outcome 1 Spectacle wearing.

Review: Vision screening for correctable visual acuity deficits in school-age children and adolescents

Comparison: 2 Ready-made versus custom-made spectacles

Outcome: 1 Spectacle wearing



(1) Follow-up: 3-4 months, wearing glasses or had at school

(2) Follow-up 1 month: worn glasses to the visit

(3) Follow-up: 2 months, self-reported spectacle wear

APPENDICES

Appendix 1. CENTRAL search strategy

#1 MeSH descriptor: [Vision Screening] explode all trees
#2 MeSH descriptor: [Mass Screening] explode all trees
#3 MeSH descriptor: [School Health Services] explode all trees
#4 MeSH descriptor: [Child Health Services] explode all trees
#5 MeSH descriptor: [Vision Disorders] explode all trees
#6 MeSH descriptor: [Vision Tests] explode all trees
#7 vision near/15 (test* or screen* or diagnos* or assess*)
#8 visual near/15 (test* or screen* or diagnos* or assess*)
#9 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10 MeSH descriptor: [Refractive Errors] explode all trees
#11 MeSH descriptor: [Astigmatism] explode all trees
#12 astigmat*
#13 MeSH descriptor: [Myopia] explode all trees
#14 myop*
#15 MeSH descriptor: [Hyperopia] explode all trees

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#16 hyperop* or hypermetrop*
#17 MeSH descriptor: [Anisometropia] explode all trees
#18 anisometrop* or ammetrop*
#19 #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18
#20 MeSH descriptor: [Pediatrics] explode all trees
#21 pediatric* or paediatric*
#22 MeSH descriptor: [Child, Preschool] explode all trees
#23 child:kw
#24 MeSH descriptor: [Adolescent] explode all trees
#25 child* or adolesc* or juvenile* or minor* or kindergarten* or pre school* or preschool* or nurser*
#26 MeSH descriptor: [Schools] explode all trees
#27 MeSH descriptor: [Child Day Care Centers] explode all trees
#28 #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27
#29 #9 and #19 and #28

Appendix 2. MEDLINE Ovid search strategy

1. randomized controlled trial.pt.
2. (randomized or randomised).ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.
8. or/1-7
9. exp animals/
10. exp humans/
11. 9 not (9 and 10)
12. 8 not 11
13. exp vision screening/
14. exp mass screening/
15. exp school health services/
16. exp child health services/
17. exp vision disorders/
18. exp vision tests/
19. (vision adj15 (test$ or screen$ or diagnos$ or assess$)).tw.
20. (visual adj15 (test$ or screen$ or diagnos$ or assess$)).tw.
21. or/13-20
22. exp refractive errors/
23. exp astigmatism/
24. astigmat$.tw.
25. exp myopia/
26. myop$.tw.
27. exp hyperopia/
28. (hyperop$ or hypermetrop$).tw.
29. exp anisometropia/
30. (anisometrop$ or ammetrop$).tw.
31. or/22-30
32. exp pediatrics/
33. (pediatric$ or paediatric$).tw.
34. exp child, preschool/
35. exp child/

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36. exp adolescent/
37. (child$ or adolesc$ or juvenile$ or minor$ or kindergarten$ or pre school$ or preschool$ or nurser$).tw.
38. exp school/
39. exp child day care centers/
40. or/32-39
41. 21 and 31 and 40
42. 12 and 41

The search filter for trials at the beginning of the MEDLINE strategy is from the published paper by Glanville 2006.

Appendix 3. Embase Ovid search strategy

1. exp randomized controlled trial/
2. exp randomization/
3. exp double blind procedure/
4. exp single blind procedure/
5. random$.tw.
6. or/1-5
7. (animal or animal experiment).sh.
8. human.sh.
9. 7 and 8
10. 7 not 9
11. 6 not 10
12. exp clinical trial/
13. (clin$ adj3 trial$).tw.
14. ((singl$ or doubl$ or trebl$ or tripl$) adj3 (blind$ or mask$)).tw.
15. exp placebo/
16. placebo$.tw.
17. random$.tw.
18. exp experimental design/
19. exp crossover procedure/
20. exp control group/
21. exp latin square design/
22. or/12-21
23. 22 not 10
24. 23 not 11
25. exp comparative study/
26. exp evaluation/
27. exp prospective study/
28. (control$ or prospectiv$ or volunteer$).tw.
29. or/25-28
30. 29 not 10
31. 30 not (11 or 23)
32. 11 or 24 or 31
33. exp vision test/
34. exp mass screening/
35. exp school health services/
36. exp child health care/
37. exp vision disorder/
38. (vision adj15 (test$ or screen$ or diagnos$ or assess$)).tw.
39. (visual adj15 (test$ or screen$ or diagnos$ or assess$)).tw.
40. or/33-39
41. exp refractive error/

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42. exp astigmatism/
43. astigmat$.tw.
44. exp myopia/
45. myop$.tw.
46. exp hypermetropia/
47. (hyperop$ or hypermetrop$).tw.
48. exp anisometropia/
49. (anisometrop$ or ammetrop$).tw.
50. or/41-49
51. exp pediatrics/
52. (pediatric$ or paediatric$).tw.
53. exp preschool child/
54. exp child/
55. exp adolescent/
56. (child$ or adolesc$ or juvenile$ or minor$ or kindergarten$ or pre school$ or preschool$ or nurser$).tw.
57. exp school/
58. exp day care/
59. or/51-58
60. 40 and 50 and 59
61. 32 and 60

Appendix 4. ISRCTN search strategy

(vision screening) AND (visual acuity)

Appendix 5. ClinicalTrials.gov search strategy

vision screening AND visual acuity

Appendix 6. WHO ICTRP search strategy

screening AND visual acuity

WHAT'S NEW

Last assessed as up-to-date: 3 May 2017.

Date	Event	Description
20 December 2017	New citation required and conclusions have changed	Issue 2, 2018: Seven studies have been identified that met the inclusion criteria (Congdon 2011; Morjaria 2016; RECS 2009; SIL 2014; SIL II 2015; WEAR 2017; Wedner 2008).
20 December 2017	New search has been performed	Issue 2, 2018: Searches updated.

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HISTORY

Protocol first published: Issue 4, 2004

Review first published: Issue 1, 2005

Date	Event	Description
30 July 2008	Amended	Converted to new review format.
9 May 2006	New search has been performed	In the first update of this review an additional 528 reports of studies were identified; none were eligible for inclusion. Additional detail regarding possible harm from early or inappropriate treatment with glasses has been added into the introductory text and the discussion

CONTRIBUTIONS OF AUTHORS

Co-ordinating the review: JE, CP

Undertaking manual searches: CP

Screening search results: JE, PM, CP

Organising retrieval of papers: JE, CP

Screening retrieved papers against inclusion criteria: JE, PM, CP

Appraising quality of papers: CP, JE

Abstracting data from papers: CP, JE

Writing to authors of papers for additional information: CP, JE

Providing additional data about papers: CP

Obtaining and screening data on unpublished studies: CP

Data management for the review: CP, JE

Entering data into Review Manager 5: JE

Analysis of data: JE, CP

Interpretation of data: JE, CP, PM

Writing the review: JE, CP, PM

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DECLARATIONS OF INTEREST

Jennifer Evans is an investigator of one of the included studies Morjaria 2016.

Priya Morjaria is an investigator of one of the included studies Morjaria 2016.

Christine Powell: none

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- The College of Optometrists, UK.

The College provided funding to Cochrane Eyes and Vision to update this review (2018).

- National Institute for Health Research NIHR), UK.
- Richard Wormald, Co-ordinating Editor for Cochrane Eyes and Vision (CEV) acknowledges financial support for his CEV research sessions from the Department of Health through the award made by the National Institute for Health Research to Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology for a Specialist Biomedical Research Centre for Ophthalmology.
- This protocol was supported by the National Institute for Health Research, via Cochrane Infrastructure funding to the CEV UK editorial base.

The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

Christian Blind Mission, Germany.

Sightsavers International, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Amendments to the objectives

We simplified the objectives, removing additional statements about subgroup analyses and outcomes, as these are described elsewhere in the methods.

Amendments to the criteria for considering studies for this review

Types of studies: we planned to describe other studies if randomised controlled trials (RCTs) were not found but in the event we identified RCTs and have not considered other study types systematically.

Types of participants: we removed the following sentence as it was not a useful criteria for inclusion "Referred participants will have had a fundus and media examination, post screening, to confirm cases where visual acuity deficit is due to refractive error alone."

Type of interventions: we added in the following comparisons

- interventions to improve spectacle use versus no interventions (or other interventions) to improve spectacle use
- interventions to reduce cost versus no intervention (or other intervention) to reduce cost

We excluded studies of visual acuity screening at or before school entry as these are more likely to have amblyopia as their target condition and therefore are not relevant to the scope of the review.

Types of outcomes:

- we included spectacle wearing as a separate outcome - in the protocol it was specified under the primary outcome which was not so clear;

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- we added in cost as an outcome to reflect the additional comparisons aimed at improving the cost-effectiveness of screening

Additional methods

We did an approximate analysis of cluster-randomised studies following guidance in the *Cochrane Handbook for Systematic Reviews of interventions* (Higgins 2011b). This situation had not been predicted at the protocol stage although we had specified that we would follow guidance in the *Cochrane Handbook for Systematic Reviews of Interventions*.

We planned to use a fixed-effect model if there were fewer than three studies measuring an outcome and a random-effects model if there were more than that, but in the event the maximum number of studies was three. We felt that a fixed-effect model was more appropriate but, as this was a judgement call, we added in a sensitivity analysis comparing fixed- and random-effects models.

We prepared 'Summary of findings' tables and did a GRADE assessment, as these are now mandatory Cochrane methods (methods.cochrane.org/mecir).

Methods not used because of lack of data

We specified the standardised mean difference as an effect measure if different instruments had been used to measure the same outcome.

We planned the following subgroup analyses:

- failure thresholds of 6/9 (Snellen) or better; worse than 6/9 (Snellen) (or equivalent)
- different types of personnel for example teachers, school nurses and eye trained professionals

We planned the following sensitivity analyses:

- excluding trials where the judgement on any aspect of methodological quality was high risk of bias;
- excluding trials where the judgement on any aspect of methodological quality was high risk of bias or unclear;
- excluding industry funded studies;
- excluding unpublished studies.

INDEX TERMS

Medical Subject Headings (MeSH)

*Vision Screening; Refractive Errors [complications; *diagnosis]; Vision Disorders [*diagnosis; etiology]

MeSH check words

Adolescent; Child; Humans

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Priya Morjaria
Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	BMJ Global Health
Please list the paper's authors in the intended authorship order:	Priya Morjaria, Ian McCormick, Clare Gilbert
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Screening search results; Screening retreived pages against inclusion criteria; Interpretation of data; Writing the review

Student Signature: [redacted] **Date:** 03 May 2018

Supervisor Signature: [redacted] **Date:** May 3 2018

Compliance and predictors of spectacle wear in schoolchildren and reasons for non-wear: a review of the literature

Priya Morjaria[1], Ian McCormick[1], Clare Gilbert[1]

1. London School of Hygiene & Tropical Medicine, UK

Abstract

Uncorrected refractive errors are the leading cause of visual impairment in children, affecting children in all settings. The majority of refractive errors are not complex and can be corrected with a pair of spectacles. Despite evidence that children with vision impairment from uncorrected refractive errors are adversely affected in terms of academic performance, visual functioning, behavioural development and quality of life, a high proportion of children do not wear their spectacles. These low levels of spectacle compliance are a concern for those delivering school eye health programmes. There is an epidemic of myopia (short-sightedness) globally and by the year 2050, 50% of the population will be myopic. This makes it even more crucial to understand the predictors of spectacle wear in children and reasons for non-wear.

Barriers to spectacle wear from this review can be categorised as biomedical and socio-demographic. Biomedical barriers include UCVA, degree and type of RE, improvement in VA and headaches/eyestrain. Lost or broken spectacles (which programmes may not be able to replace) also fall into this category. Socio-demographic barriers include age, gender, cost and access to spectacles, parental education and disapproval of spectacle wear, and teasing and bullying by peers.

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INTRODUCTION

The World Health Organization (WHO) estimates that there are 19 million children with vision impairment globally, 12 million of whom have uncorrected refractive error (uRE).[1] Refractive errors (REs) affect children of all ethnicities and in all settings i.e. urban and rural and in low, middle and high income countries. The commonest type of RE, myopia, increases with increasing age. Refractive errors cause blurred vision and can vary in severity. The majority of children have uncomplicated REs which can be readily and cost effectively corrected with spectacles.[2-4] There is evidence that children can be adversely affected by vision impairment and that it has an impact on

their academic performance,[5] visual functioning, behavioural development[6] and quality of life.[4]

Despite the benefits of wearing spectacles, there is some evidence that a high proportion of children in many settings do not wear them.[7] Low levels of spectacle compliance is a common problem for a variety of reasons and this is an increasing concern for those delivering and financing school eye health programmes. However, the definition of spectacle compliance, and the length of time from dispensing to assessment of wear, are not standardised.

Purpose and focus of the review

The purpose of this review is to collate the evidence on compliance with spectacle wear, factors which predict spectacle wear and reasons for non-compliance among schoolchildren. This information will be of value to those designing and implementing school eye health programmes.

METHODS

Literature searches were conducted on Medline, Embase, Global Health and the Cochrane Library. (See appendices for search strategies used.) The date range was January 2000 to November 2017 and there were no language restrictions. The search retrieved a total of 1299 references, 522 duplicate records were removed leaving a total of 777 references to assess.

Study selection and assessment

Two reviewers independently assessed 777 references for potential inclusion in the review. In addition, further publications were identified from checking the citations from appropriate studies. Two non-English language articles were excluded as resources were not available for translation. A total of 35 articles were included in this review, and included randomized control trials (RCTs), observational cross sectional studies and qualitative research. Studies were excluded if they were not undertaken in schools, or only included pre-primary or post-secondary school age children. The following information was extracted from included studies, as relevant, and entered into an Excel spreadsheet: study design; setting (country) and participants (age,

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gender, number and comparison groups, if relevant). Main outcomes: how compliance with spectacle wear was defined and assessed, and rates of compliance; predictors of spectacle wear with relevant statistics, and reasons non-wear. Other outcomes were follow-up rates, use of prescribing guidelines, health education and medium of delivery, and whether students could select their preferred spectacle frames,

There was considerable heterogeneity across studies in terms of purpose, design, and the outcomes measured which limited comparisons. However, the wide range of countries and settings in which the studies were undertaken means the findings can be generalizable.

RESULTS

Several of the 35 included studies reported more than one of the outcomes of interest (i.e., compliance, predictors and reasons for non-wear). There were 27 studies on compliance, 19 studies on predictors (cross-sectional studies and RCTs) and 13 studies reported reasons for non-wear; 7 used qualitative methods and 6 used structured questionnaires, or details of the methods were not given.

Spectacle compliance

The 27 studies that investigated spectacle compliance were undertaken in the following countries: China (7), India and the USA (6), and one in each of the following countries, Oman and Nepal (Asia), Brazil, Mexico and Chile (South America), Saudi Arabia (Middle East), and South Africa and Tanzania (Africa). The majority of studies were observational with three RCTs.

Spectacle wear was either assessed by direct observation during unannounced visits (n=15 studies) or during planned visits (n=2), or was self-reported by interviewing children (n=5) or children and teachers (n=1), or was not clearly stated (n=4). In a trial in China, there was significant difference in the control and intervention arms between self-reported (41% and 26%) and observed wear (68% and 37%) respectively.[5] Compliance was defined as either wearing spectacles (n=16), or wearing or carrying spectacles (n=7) or was not clearly stated (n=4).

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Using all definitions, compliance levels ranged from as low as 13.4% (wearing) in Mexico[8] to 87.4% (wearing) in the USA. Spectacle wear in studies which defined compliance as wearing spectacles assessed by direct observation ranged from 28% to 73%. Self-reported wear ranged from 58% to 82%.

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Table 1: Spectacle compliance proportions from different studies

Author	Year	Country	Age (yrs)	Follow up (mn)	Sample size	Choice of frames	Definition of compliance	How wear assessed?	Compliance
Khandekar[9]	2002	Oman	6 -17	12	571	Not stated	Wearing	Observation, school health staff informed of follow-up visit	73%
Castanon Holguin[8]	2006	Mexico	5 - 18	4-18	493	No	Wearing or carrying	Unannounced observation	13.4% wearing; 34% carrying
Congdon[10]	2008	South Africa	6 -19	4-11	483	Not stated	Wearing or carrying	Unannounced observation	31%
Li[11]	2008	Rural China	ND	3	597	Bought by parents	Self-reported wear among children who bought specs	Self-reported	63.9% (134/210 who bought)
Congdon[12]	2008	Rural China	11 - 17	Not relevant	948	Children's own	Self-reported wear among existing spec owners	Self-reported	82.1%
Khandekar[13]	2008	Central India	ND	3-4	77	Not stated	Not clearly stated	Not stated	80.5%
Wedner[14]	2008	Tanzania	11 - 19	3	Free spectacles: 58 Prescription only: 50	Yes in free spectacles arm	Wearing or carrying	Unannounced observation	Free spectacles 47%; prescription only 26%
Yabumoto[15]	2009	Brazil	ND	10	95	Not stated	Not stated	Self-reported	73.7% Self-reported
Zeng[16]	2009	China	12 -15	1	Ready-made:243 Custom-made: 245	5 metal frame colours, 3 plastic frame colours	Wearing or carrying	Unannounced observation	Ready-made arm 46.9%, custom arm 51.5% (P=0.23)
Keay[17]	2010	China	12 - 15	1	415	5 metal frame colours, 3 plastic frame colours	Wearing or carrying	Unannounced observation outside the classroom	49.2% (46.5% wearing, 2.7% carrying)
Ethan[18]	2010	US (low income urban)	Grades 1 & 2	Not stated	Free spectacles: 102 Screening only:127	Yes in free spectacles arm	Wearing	Unannounced observation (6 times; 2 pre- & 4 post-intervention)	baseline: free specs group 22%, control 19% follow-up: free specs

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									group 47%, control 19%
Congdon[19]	2011	Rural China	12 - 17	6	Health education: 2236 Control: 2212	Bought by parents	Purchased spectacles (primary outcome), Wearing or carrying (secondary outcome)	Self-reported	Education intervention 21%; Control 30%
Messer[20]	2012	USA (Native American)	8 - 14	10-14	247	Yes, over 30 options	Presented with spectacles (not in class)	Unannounced observation with vision testing	33.2%
Manny[21]	2012	USA	6 - 16	12	798	Not stated	Presented with correction that improves VA >6/12+2 ("adequate correction")	Observation. Location, and whether unannounced, not stated.	28%
Gogate[22]	2013	North India	8 - 16	6-12	1018	No	Wearing	Unannounced observation	29.5%
Aldebasi[23]	2013	Saudi Arabia	7 - 13	6	631	Not stated	Wearing	Observation at announced visit	66.8%
Pavithra[24]	2014	South India	7 -15	3	83	Not stated	Wearing	Unannounced observation	58%
von-Bischhoffshausen[25]	2014	Chile	4 - 19	12	204	Not stated	Wearing (at interview)	Student and teacher interviews (no direct examination)	Self-report: 58% Teacher reported: 55%
Ma[5]	2014	China	9 - 12	7-8	3054	Not stated	Wearing	Unannounced observation	Free glasses: 41% Voucher: 37% Prescription only: 26%
Kodjebacheva[26]	2014	USA	6 - 8	6	15	Yes	Wearing	Unannounced observation	73.30%
Alvi[27]	2015	USA	6 - 18	1 & 12	565	Not stated	Not stated	School nurse observation/student self-report; teacher input, knowledge of use of spare specs	At 1/12: school mean 85.9%; at 12/12: school mean 70.8% (28 schools)

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Yi[28]	2015	Urban China	10 - 12	6	Intervention arm (free specs & HE & teacher incentive) 341, control arm (prescription only) 352	Not stated	Wearing	Unannounced observation	Intervention arm; 68.3% Control arm: 23.9%
Bhandari[29]	2016	Nepal	7 - 16	12	170	Not stated	Wearing	Unannounced observation; not assessed in class	28%
Morjaria[30]	2017	India	11 - 15	3 - 4	Ready-made arm 232 Custom-made arm 228	Yes in both arms	Wearing spectacles or had them at school	Unannounced observation	Ready-made arm: 75.5% Custom-made arm: 73.6%
Huang[31]	2017	USA	Grades 2 and 3	Not stated	Not stated	Not stated	Wearing	Not stated	87.4%
Bhatt[32]	2017	India	6 - 15	3	200	Not stated	Wearing	Unannounced observation	39%

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Predictors of spectacle compliance

Age

Age was described as a continuous variable (per year increase in age) and as a binary or ordinal variable – comparing children above and below a certain age or those of different school grades. The included studies encompass a range of different age groups and direct comparison of age as a factor for non-compliance of spectacle wear is, therefore limited.

Amongst the quantitative studies, increasing age was associated with lower spectacle wear in four studies [8, 24, 25, 27] whereas in two studies, in India and the USA, younger children were less compliant.[9, 21] A study in China of school children who reported already owning spectacles, also reported compliance to be lower in younger children [adjusted OR=1.39 (95% CI 1.04-1.86) per year increase in age].[12]

Lower compliance with increasing age was significant in three observational studies with similar age ranges: in Mexico [OR 1.19 (95% CI 1.05-1.33) per year decrease in age (range 5-18)][8] and in Chile OR 0.83 (95% CI 0.76-0.92) per year increase in age (range 4-19)[25]. A study in the USA compared children younger and older than 12 years (range 6-18)[27]; at one month follow-up younger children were more than twice as likely to be wearing their spectacles [OR 2.26 (95% CI 1.08-4.73)] which had declined by 4 months [OR 1.74 (95% CI 1.11-2.74)]. At one year the differences were no longer significant [OR 1.14 (95% CI 0.42-2.50)]. A further study in India reported compliance to be highest in the youngest of three age groups but did not report complete statistics to support this.[24]

Eleven studies found no significant difference in the level of spectacle wear between younger and older children.[10, 11, 13-15, 17, 19, 22, 23, 28, 32]

Three qualitative studies [33-35] with parents and teachers reported that spectacles were for adults or that they should not be worn by children. However, these studies did not explore reasons for differing compliance by age.

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Gender

Boys were less likely to wear spectacles than girls in eight studies.[10, 12, 17, 19, 22, 23] One study did not provide statistics to support this,[29] while another reported a p-value that was not significant.[9]

Odds ratios for greater compliance in girls were reported in an observational study, a cluster RCT in China and in an observational study in the USA [OR 1.72 (95% CI 1.10-2.68) and OR 1.78 (95% CI 1.21-2.62); OR 1.8 (95% CI 1.1-3.2)] respectively. In another study in China, of children who already owned spectacles, girls were almost three times more likely to wear spectacles than boys [OR 2.82 (95% CI 1.77-4.51)][12]

Nine studies found no significant difference in compliance by gender, [8, 13-15, 21, 24, 25, 28, 32] and no quantitative studies reported lower spectacle wear amongst girls.

In the qualitative studies, barriers to spectacle wear were identified for boys and girls, but more frequently for girls. Amongst students in Tanzania,[36] spectacles were considered feminine and less acceptable for boys. In India, three studies all identified girls as facing additional societal and psychological barriers to spectacle wear.[35, 37, 38] These included concerns about getting married [37] and being 'singled out' over boys for wearing spectacles [35] which led to some parents preventing their daughters using their spectacles.[38] Greater apprehension was also expressed by girls about long-term spectacle wear.[35] Focus group discussions with children, parents and teachers in Nigeria, the USA and China did not address gender-related barriers.[33, 34, 39]

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Table 2: Studies reporting age and/or gender as barriers to spectacle wear

Author	Year	Country	Age	Gender
Khandekar[9]	2002	Oman	6-7 years: 65.5%; 12-13 years: 64.4%; 16-17 years: 79.3%. p=0.0004	Girls more compliant: girls 78.4% vs boys 65.2%, p=0.21
Castanon Holguin[8]	2006	Mexico	OR 1.19 (1.05-1.33) per year less in age	No significant difference
Congdon[10]	2008	South Africa	No significant difference between 3 age groups	Girls more compliant; p=0.0004
Congdon[12]	2008	China	Not reported	Girls more compliant: Adjusted OR 2.82 (1.77-4.51)
Khandekar[13]	2008	India	No significant difference: <10 years vs ≥10 years	No significant difference
Li[11]	2008	China	Not reported	Not reported
Wedner[14]	2008	Tanzania	Not significant	Not significant
Yabumoto[15]	2008	Brazil	Not significant	Not significant
Keay[17]	2010	China	Not significant	Girls more compliant: OR 1.72 (1.1-2.68)
Congdon[19]	2011	China	Not significant	Girls more compliant: OR 1.78 (1.21-2.62) P=0.003
Manny[21]	2012	USA	OR 1.12 (1.03-1.22) per year increase in age	Not significant
Messer[20]	2012	USA	Not reported: compared school levels but no stats	Girls more compliant: OR 1.8 (1.1-3.2)
Aldebasi[23]	2013	Saudi Arabia	Older age (7-9 years vs 10-13years) p=0.052 chi square test	Boys more compliant: p=0.032 chi squared test
Gogate[22]	2013	India	8-10 years: 56.3%; 11-13 years: 29.2%; 14-16 years: 27.6%. p=0.058	All: boys compliance 26.3% vs girls 32.5%.p=0.029. Myopes only, girls more compliant: OR 1.3 (0.8-1.9)
Pavithra[24]	2014	India	7-9 years higher compliance than 10-12 years and 13-15 years. No stats	Not reported
von-Bischh-offshausen[25]	2014	Chile	Per year increase: 0.83 (0.76-0.92)	No significant difference
Alvi[27]	2015	USA	<12 vs >12 years at 1/12: OR 2.26 (1.08-4.73), at 4/12 OR 1.74 (1.11-2.74), at 12/12 OR 1.14 (0.42-2.50)	Not reported
Yi[28]	2015	China	Not significant	No significant difference
Bhandari[29]	2016	Nepal	Not reported	Boys more compliant, but no data
Bhatt[32]	2017	India	6-9 years 46.2%; 10-12 years 42.7%; 13-15 years 27.1%; p=0.077	Not reported

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Type and degree of refractive error

Only a few quantitative studies have investigated whether the type of RE (i.e. myopia, hyperopia or astigmatism) effect spectacle wear. There was no significant difference between RE types in Chile, Oman and Brazil.[9, 15, 25] However, in Tanzania, compliance was zero amongst hyperopes and astigmats compared with 43% in myopes.[14] Another study in India reported differences between myopes, hyperopes and emmetropes (better than -0.50D) but did not provide statistical analysis.[22]

The severity of RE is reported more frequently as a predictor of spectacle wear, but the definition of ammetropia differed between studies.

In Oman, the proportion of compliant children was significantly higher in myopes of -2.50D or more compared with myopes of less than -2.50D.[9] In India, a significant trend of increasing compliance was reported across four categories of myopia of increasing severity.[22] Another Indian study reported significantly better compliance in myopes of -1.00D or more compared with lower levels of myopia but did not show statistics to support this.[24] In one Chinese study, children's self-reported wear was categorised as 'usually', 'sometimes' or 'seldom'. The proportion of children with myopia higher than -2.00D in both eyes reported significantly higher spectacle wear. [11]

In Mexico, the odds of compliance for myopia higher than -1.25D were 3.97 (95% CI 1.98-7.94) times greater than that for myopia of -1.25D or less and the odds for hyperopia higher than +0.50D were 3.63 (95% CI 1.02-12.9) times greater than for hyperopia of +0.50D or less.[8] In Chile, the same analysis was carried out using a cut-off of -0.75D and +0.75D. For myopes, the odds ratio was 4.93 (95% CI 2.28-10.67) and 2.37 (95% CI 1.06-5.31) for hyperopes. [25]

Two studies in the USA treated RE as a continuous variable in 1.00D units. In one study the odds ratio for increasing myopia in the better eye was 2.5 (95% CI 1.7-3.7) per 1.00D increase in myopia, and astigmatism in non-myopes had an odds ratio of 1.4 (95% CI 1.1-2.0) per 1.00D increase in cylinder.[20] The second study investigated spectacle compliance at one month and one year, for better and worse eyes. At one month, higher better and worse eye hyperopia had higher odds of compliance of 1.69

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(95% CI 1.05-2.71) and 1.57 (95% CI 1.02-2.42) respectively. Better eye myopia also gave a significant odds ratio at one month of 1.35 (95% CI 1.07-1.72). At one year only higher myopia was significantly associated with greater compliance, with a better eye odds ratio of 1.49 (95% CI 1.09-2.08) and worse eye odds ratio of 1.75 (95% CI 1.27-2.44).[27]

Studies in South Africa and Brazil found no significant difference in compliance with differing levels of RE, [10, 15] and a study in China reported no significant difference between the mean spherical equivalent RE of right and left eyes of children with and without spectacles at school.[12]

A qualitative study in China found that children, parents and teachers were not in favour of spectacle wear for low amounts of myopia for practical reasons as well as concerns that wear would increase myopic progression.[34]

Uncorrected visual acuity and lines improvement in visual acuity

Seven studies reported higher compliance with lower levels of uncorrected visual acuity (UCVA).[11, 12, 19-22, 28] An eighth study reported compliance to be better with 'poor VA' compared to 'better VA', but no analyses were reported.[29] Two studies found no significant difference in compliance according to UCVA.[15, 27] No studies contradicted this trend.

UCVA was reported as a continuous variable, per line change in VA, in four studies.[12, 19-21] In two USA studies, the odds of compliance increased by 1.13 (95% CI 1.06-1.20) and 1.6 (95% CI 1.4-1.8) per line (0.1 logMAR) worse UCVA in the better eye.[20, 21] An observational study in China also reported an odds ratio per line logMAR increase [OR=1.46 (95% CI 1.26-1.69)] although the authors used the mean UCVA score of right and left eyes.[12] In a cluster RCT in China the odds of compliance was lower with worse UCVA in the better eye [OR=0.287 (95% CI 0.106-0.774)], however, the unit of change was not reported.[19]

Multiple categories of UCVA were compared in a study in India which showed a significant trend of increasing compliance across five categories of decreasing UCVA.[22] A cluster RCT in China compared two categories of UCVA where the odds of compliance were 1.70 (95% CI 1.14-2.53) times greater amongst children with

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UCVA less than 6/18 in both eyes compared with those with 6/18 or better.[28] A Chinese observational study compared the mean UCVA scores of children (mean UCVA of right and left eyes) who self-reported that they wore spectacles 'usually', 'sometimes' or 'never'. As in the other studies, there was a statistically significant inverse trend between UCVA and self-reported spectacle wear.[11]

A study in South Africa investigating compliance and various prescribing protocols also reported on lines improvement in VA. There was no significant difference in spectacle wear between children with 0, 1-2 or 3 or more lines of improvement.[10] An RCT in India, which compared ready-made and custom-made spectacles, used two or more lines of improvement in the better-seeing eye as the indication for prescribing. Spectacle wear in both arms of the trial (76% and 74% respectively, 75% overall) was higher than most other Indian studies.[30]

Cost and accessibility of spectacles

The majority of studies examining predictors of spectacle wear provided free spectacles or did not report if costs were borne by the child's family. In a cluster RCT in Tanzania children given free spectacles were almost two and half times more likely to wear their spectacles than children given a prescription only.[14]

Another cluster RCT in China compared the effect of three post-vision screening options on mathematics test scores: free spectacles, a voucher for free spectacles and a prescription only. The effect on compliance with spectacle wear (a secondary outcome) showed that children issued a voucher for spectacles had an adjusted relative risk of spectacle wear at follow-up 1.44 (95% CI 1.19-1.76) times greater than those issued a prescription only, while the adjusted relative risk increased to 1.55 (95% CI 1.30-1.85) for those given free spectacles at school.[5]

A cluster RCT in the USA to compare free spectacles with referral only found significantly higher compliance among children in schools randomized to free spectacles [18] A second study in the USA also investigated the effect of providing free eye examination and spectacles versus referral only: in this study there was no significant difference in compliance with spectacle wear, but children were not randomly allocated.[21]

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Qualitative studies revealed cost and accessibility to be barriers to spectacle wear when spectacles (or replacement spectacles) were not supplied free of cost at schools.

Cost was reported to be a concern amongst most parents in Nigeria, India and minority groups in the USA. Issues such as frequent replacement and lack of use were highlighted in India, while spectacles were considered a luxury in Nigeria, especially for large families.[33, 37, 39] Parents in rural China did not frequently report cost to be a barrier to spectacle wear – instead they were more likely to be too busy to buy them; this was also the main reason given by parents for not attending the optometrist in higher socioeconomic groups in Nigeria.[33]

One group of children in China discussed cost as a barrier whereas their parents did not,[5] and a study with Indian children reported cost as barrier in almost one fifth of participants.[37] Children in Tanzania also felt spectacles were often not affordable and should be freely available to those who could not purchase them.[14]

Access to quality, trustworthy local optical services was raised as a concern by students in Tanzania where distance to the local hospital was a barrier.[14] Parents in the USA reported several issues with accessibility; a lack of services in minority communities with resulting lengthy and costly trips to appointments and difficulty in taking time off work to attend.[39]

Less than half (12/26) of the studies on compliance indicated whether children were offered a choice of spectacle frames. Compliance ranged from 22% to 75% when there was a choice (7 studies), from 21% to 30% when parents bought the spectacles or children used existing frames (3 studies), and from 13.4% to 30% when no choice was offered.

Parental level of education

Two studies reported that lower levels of spectacle wear were associated with lower levels of parental education.[29, 32] However, in Nepal this was not supported by any data while the results from India were not accurately presented or described. A

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second Indian study reported significantly lower compliance with lower education levels of fathers but not mothers. However, while compliance differed with parental education level, there did not appear to be a trend towards lower compliance with lower levels of father's education.[22] Four studies found no significant difference in spectacle wear by parental education level.[20, 21, 24, 28]

Qualitative studies have highlighted a perceived lack of understanding of RE and spectacles by parents in Nigeria and China, [33, 34] while parents in minority groups in the USA recognised the short-term and long-term benefits of spectacle wear.[39] Studies have not sought to investigate barriers by carrying out separate focus group discussions with parents of different education levels.

Child-reported barriers to spectacle wear

Thirteen quantitative and six qualitative studies sought children's perspectives on spectacle wear.

The main reasons why children did not wear their spectacles include being teased and/or bullied,[8, 11, 16, 37, 40, 41] they did not like their spectacles,[22] or they were lost or broken, [8, 15, 18, 42] or they forget to wear them,[12, 16, 18, 42] parental disapproval, [16, 37] and misconceptions that using spectacles would make their vision worse[11, 12, 14]

The proportion of children reporting the four most commonly encountered reasons for non-wear are summarized in Table 3. 'Lost or broken spectacles' was usually the commonest child-reported reason for non-wear, but there was considerable variation in the findings (5.3% to 80.2%). Parental disapproval was the least frequently reported reason for non-wear and did not appear to constitute an important concern for children except in Saudi Arabia, where 30% of non-compliant children gave this reason.

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Table 3: Four most common reported reasons for spectacle non-wear in children

Study	Country	Sample size	% children reporting a reason for non-wear			
			Lost/Broken	Bullying/ Teasing	Headaches/ Eyestrain	Parental Disapproval
Castanon Holguin[8]	Mexico	493	14.0	16.6	6.1	1.6
Congdon[12]	China	376	5.3	3.2	6.4	Not reported
Khandekar[13]	India	15	20.0	Not reported	20.0	6.7
Yabumoto[a15]	Brazil	25	40.0	Not reported	64.0	Not reported
Messer[20]	USA	165	80.2	Not reported	Not reported	Not reported
Gogate[22]	India	718	26.7	19.8	7.4	2.2
Aldebasi[23]	Saudi Arabia	422	11.1	4.0	3.6	30.3
Dhoble[43]	India	242	Not reported	Pretest 36%, post-test 22% (p=<0.001)[b]	Not reported	Not reported
Pavithra[24]	India	35	25.7	5.7	8.5	11.4
Von-Bischhoffshausen[25]	Chile	83	27.7*	2.4	6.0	Not reported
Bhandari[29]	Nepal	122	46.7	6.5	8.2	3.2
Huang[a 31]	USA	Not reported	Not reported	20.2	Not reported	Not reported
Bhatt[32]	India	122	16.4	31.1	5.7	0.0

[a]Abstract only [b]Before and after a one group health education intervention *Calculated by the authors

Concerns about lost or broken spectacles were not raised by children in qualitative studies and headaches or eyestrain were also not mentioned. However, in China all focus group discussions with children rated an accurate prescription as the most important requirement for spectacles.[34]

In a mixed-methods study in Tanzania less than 10% of students reported being teased in a survey, but most students described negative experiences and some degree of bullying in focus group discussions.[36]

One study in Nigeria did not report on bullying/teasing[33] while a study from China did not encounter it as a barrier reported by children.[34] The other three qualitative studies with child participants in India all reported teasing to be an important reason why children did not wear their spectacles.[35, 37, 38] In contrast, children in the

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USA who did not need spectacles did not have negative opinions of their spectacle wearing peers but perceived them to be more intelligent.[44]

Parental disapproval was voiced as a barrier to spectacle wear by children in Nigeria and Tanzania.[33, 36] In two studies in India, children reported that parents did not believe that they had vision problems or needed spectacles and preferred to ignore the problem.[35, 38]

DISCUSSION

There was considerable variation between studies in how spectacle compliance was defined (wearing and/or carrying), the time interval between dispensing the spectacles and assessment (1-12 months), and how compliance was assessed (observed or self-reported). There is a need to standardize all aspects of the assessment of compliance so that the effectiveness of interventions can be compared across settings. To avoid response bias, which is likely to be a particular problem in children, we would recommend direct observation at unannounced visits several months after the spectacles are dispensed, with compliance being defined as spectacles being worn or the child having them at school.

Barriers to spectacle wear from this review can be categorized as biomedical and socio-demographic. Biomedical barriers include UCVA, degree and type of RE, improvement in VA and headaches/eyestrain. Lost or broken spectacles (which programmes may not be able to replace) also fall into this category. Socio-demographic barriers include age, gender, cost and access to spectacles, parental education and disapproval of spectacle wear, and teasing and bullying by peers.

The evidence suggests that increasing severity of uRE and decreasing levels of UCVA are associated with higher levels of spectacle wear, which is to be expected as these factors are highly correlated. However, there was variability in how the degree of RE and the level of UCVA were reported in studies e.g., as a continuous variable or using different cut-off values. A factor likely to lead to behaviour change - the degree of improvement in VA with correction in the better eye - was rarely reported. Several studies suggest an improvement of two or more lines of VA in the better

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seeing eye to define children in need of refractive correction,[12, 30, 45] and there seems to be an emerging consensus that prescribing should be based on improvement of VA rather than the degree of RE.[46] Prescribing guidelines have the potential to reduce over-prescribing which would improve the cost effectiveness of programmes and reduce out of pocket expenditure for parents.

Addressing the socio-demographic reasons for non-compliance is more complex as they are context specific and require interventions for children who require spectacles, their classmates who do not, as well as teachers, parents, other family members and the community. The engagement of all these groups is important to ensure behavior change.

The evidence that children become less compliant with spectacle wear with increasing age is not consistent in all settings, but suggests that younger and older children have different motivations for wearing their spectacles, requiring different strategies by age and context.

Quantitative data indicate that girls are more likely to be compliant with spectacles wear than boys, but qualitative studies highlight the challenges faced by girls who need to wear spectacles. This apparent paradox may be explained by parental concerns on one hand, and the evidence that girls tend to be more compliant on the other, particularly in how they respond to authority figures. [47, 48]

Creating behavior change is challenging and requires a deep understanding of the cultural context. An RCT of educational interventions to promote spectacle wear among children in rural China did not demonstrate any effect, highlighting the difficulty of creating behavior change. It is not enough to embed generic health education within school eye health programmes, as health education interventions need to be developed bearing in mind local cultural and gender norms, and the concerns of parents.

There is some evidence that the lower the level of parental education the lower the compliance, but this is not consistent. Parental disapproval and misconceptions were also identified in some studies, as were teasing and bullying of children by their peers. However, these are sensitive issues which may not have been expressed

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if reasons for non-compliance were elicited by inadequately trained interviewers, and may not have been included in questionnaire-based assessments. Qualitative methods are recommended to better understand the social and cultural reasons for non-compliance, and the findings used to design health education strategies. Ideally health education should include parents, children who do and who do not need spectacles, and teachers.

There is limited evidence that giving children a choice of spectacle frames increases compliance, as no studies have investigated this as a specific intervention. However, one study which did not offer a choice of frame, to facilitate easier distribution, reported particularly poor spectacle wear.[8] It could be hypothesised that allowing children to choose their own frame from a cosmetically acceptable range may encourage a greater sense of ownership and improve compliance.

The provision of good quality, acceptable spectacles at an affordable price is, therefore, essential and the most appropriate options should be determined by preliminary qualitative research. Provision of free spectacles may not be appropriate for every setting and this should be determined before implementing a programme. If a child loses or breaks their spectacles mechanisms for replacement must be put in place to ensure access to spectacles.

In response to estimates that myopia is projected to affect 50% of the world's population by 2050,[49] eye health activities in schools are increasing in all regions of the world, with several large scale initiatives established in recent years.[50-52] Spectacles are the most cost-effective way to treat children with uREs, but there is evidence that spectacle compliance is low in many settings, particularly amongst boys, older children and those with mild RE and better UCVA. There is a need to assess and address the biomedical and socio-demographic factors which affect compliance with spectacle wear, using standard definitions, prescribing protocols and reporting mechanisms to ensure that the next generation can maximize their potential for learning.

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RESEARCH PAPER COVER SHEET

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SECTION A – Student Details

Student	Priya Morjaria
Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Community Eye Health Journal		
When was the work published?	August 2017		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Drafting of the manuscript; Contributed to final write up and confirming data.

Student Signature: [redacted] **Date:** 03 May 2018

Supervisor Signature: [redacted] **Date:** May 3 2018

Improving spectacle wear in school children

Spectacle compliance is low in many school eye health programmes. There are various reasons for this, including that children do not perceive a beneficial improvement in their vision. Accurate visual acuity (VA) measurement, refraction and prescribing based on the degree of improvement in VA can also help.

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VER BIEN PARA APRENDER MEJOR PROGRAMME MEXICO

Inserting corrective trial lenses into a trial frame suitable for children. MEXICO

Measurement of visual acuity

Children who fail visual acuity screening must undergo thorough and detailed visual acuity measurement. This is the first step in identifying those who may benefit from spectacle correction.

Ideally, visual acuity measurement is done in the school immediately or very soon after vision screening. This should be done by an optometrist or a trained refractionist experienced in measuring visual acuity in children. Visual acuity measurements carried out in schools should be of the same standard as at an eye unit.

The distance between the screener and the student (usually 6 metres) should be measured and marked appropriately. The student's chair may move around, so make a mark on the floor where the front legs of the chair should be. Check that the chair is in the right place before assessing each child. If using a standard, unlit visual acuity chart, the room should be well lit, taking care to avoid reflections off the chart. Backlit charts can be used in a darkened room. Students should not be distracted by strong external sources of light. Before starting to measure visual acuity, the optometrist/ refractionist should check that the environment is correctly set up by sitting where the student will sit.

The following equipment is required:

- Tape measure
- Full tumbling E chart (or multi-letter Snellen). Ideally, this should be the logMAR version
- Eye occluder or a piece of card to place over one eye
- Student record sheet.

Procedure

- Explain the test to the child. If an E chart is being used, ensure that they understand what they are being asked to do before starting to measure their visual acuity.
- Measure the acuity one eye at a time, usually the right eye first, then the left.
- If a child already wears spectacles, measure their acuity without spectacles first.
- Ensure that the chart is at the student's eye level.
- Cover the left eye with the eye occluder or a piece of card. It is advisable that they do not use their hand as they may be able to see between their fingers.
- If using a tumbling E chart, point first to the 6/60 size E and ask the student to indicate which way the bars of the E point. Proceed down the chart, pointing out each E in turn, taking care not to cover any part of the E with the pointer.
- Follow the same procedure if using a standard letter Snellen chart.
- To see any particular line of the chart, the child must be able to see at least three of the five Es or letters.
- The smallest line accurately read is expressed as a fraction, e.g. 6/18. The upper number refers to the distance between the chart and the person being tested (6 metres), and the lower number is the line on the E or Snellen chart that the child can see.
- Record the VA for each eye immediately after measuring the acuity, stating whether this was tested with or without spectacle correction.
- If the child cannot read the 6/60 E or letter this is recorded as <6/60.

Refraction

Refraction should be undertaken by a competent practitioner experienced in refracting children.

NOTE: Children whose visual acuity does not improve to normal with refraction must be referred for examination to determine the cause so that appropriate action can be taken.

Retinoscopy, or preliminary assessment using an autorefractor appropriate for children, should be followed by comprehensive subjective refraction. Children should be referred for cycloplegic refraction if they are uncooperative, if there is a variable or inconsistent end-point to refraction, in the presence of strabismus or suspected amblyopia and if they are difficult to refract because of media opacities or irregular corneas.

Continues overleaf ➤

Before describing how to prescribe spectacles for children, it is important to understand why children may not wear their spectacles.

Why children do not wear their spectacles

A key issue in school eye health programmes is that children do not always wear the spectacles provided, which means they do not benefit when they have the potential to. Studies in all income settings show that spectacle wear is often less than 50%. Reasons include:

1 Parents do not buy the spectacles
2 Parents are concerned about their child's appearance
3 Parents are concerned that spectacles will weaken their child's eyes
4 Teachers do not encourage children to wear their spectacles
5 The child is teased or bullied for wearing spectacles
6 The child does not like the spectacles or they are uncomfortable
7 The child does not notice any improvement in vision

There are simple solutions for many of these reasons.

- Reasons 1–5 can be addressed by health education which should include teachers, parents and all children whether they need spectacles or not.
- Reason 6 can be addressed by ensuring that children select the frames they prefer from a range of colours and designs which school children in the programme area say they like, and by checking that the frames are a good fit.
- Reason 7 relates to prescribing.

A recent randomised clinical trial compared rates of spectacle wear in children based on the type of spectacles used. In the trial, children received spectacles only if doing so improved their visual acuity by two or more lines. When followed up after 3–4 months, 75% of all the children were still wearing their spectacles or had them at school.[1]

This is much higher than in other studies, conducted among children of similar ages, in which prescribing was based on the degree of refractive error found at retinoscopy. This meant that spectacles were prescribed even when some children already had good VA in one eye. These children would not notice an improvement in their vision and would be less likely to wear their spectacles.

Prescribing guidance

The prescribing guidelines given here are based on those followed in the clinical trial[1], in modified form. We hope that the guidelines will help to avoid unnecessary prescribing of spectacles – which will not be worn – in settings with limited resources. However, this must not override the needs of an individual child.
Note: The guidelines apply to children with VA <6/9.

Correction for myopia is indicated if:

- Minus powered lenses improve the VA by 2 or more logMAR (or Snellen) VA lines in the better eye or with both eyes tested together.

Correction for hypermetropia is indicated if:

- Plus powered lenses improve the acuity by 2 or more logMAR (or Snellen) VA lines in the better eye or with both eyes tested together, and/or noticeably improve eye comfort when reading
- There is amblyopia (and the child's age suggests that the amblyopia is potentially treatable)
- There is esotropia or a large esophoria (and the child has some potential for normal binocular vision).

Correction of astigmatism is indicated if:

- Cylindrical lenses improve the acuity by 2 or more logMAR (or Snellen) VA lines in the better eye or with both eyes tested together; and/or noticeably improve eye comfort
- There is amblyopia (and the child's age suggests that the amblyopia is potentially treatable).

Correction for anisometropia is indicated if:

- There is significant anisometropia (i.e. 1D or more), **and** one or more of the following apply:
  - correctly balanced lenses improve the acuity of the most affected eye by 2 or more logMAR VA lines
  - eye comfort is notably improved.
- There is amblyopia (and the child's age suggests that the amblyopia is potentially treatable).

Conclusion

There is increasing evidence that, if most children see better with spectacles than without, a higher proportion will wear them. Ideally, a sample of children who do not their wear spectacles should be interviewed to find out why they are not wearing them so that corrective measures can be put in place. An important measure of success for any school eye health programme is the proportion of children given spectacles who subsequently wear them – it is not enough just to measure and report the number of spectacles that are dispensed.

PRIYA MORJARIA

Children are more likely to wear their spectacles if they are happy with their appearance.
INDIA

Reference

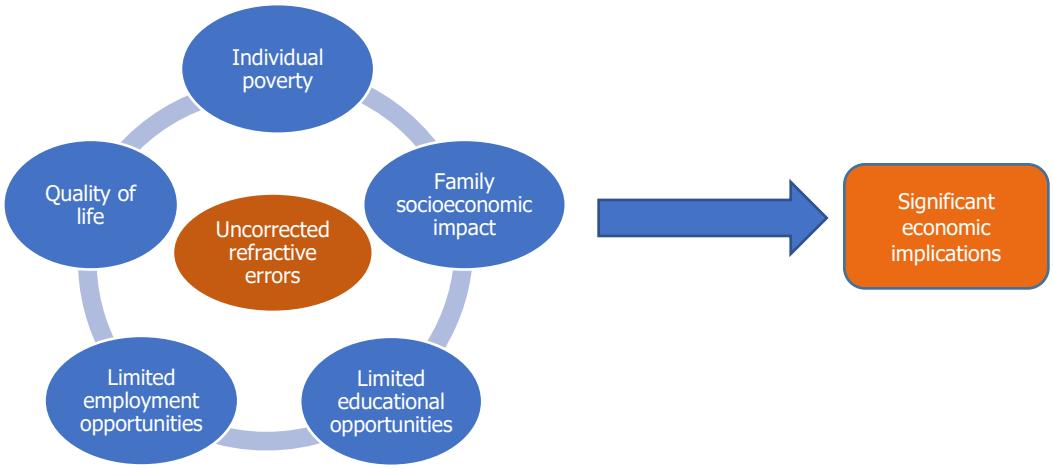
1 Morjaria P, Evans J, Murali K, Gilbert C. Spectacle Wear Among Children in a School-Based Program for Ready-Made vs Custom-Made Spectacles in India: A Randomized Clinical Trial. JAMA Ophthalmol. 2017 Jun 1;135(6):527-533. doi: 10.1001/jamaophthalmol.2017.0641.

Chapter 3: Rationale and objectives

The previous chapters describe the evidence and the scale of visual impairment in children due to uREs. It is evident that uREs among school going children need to be addressed in an appropriate manner, which allow children to continue their academic and social development.

The health of school children is recognised by international health experts, policy makers, governments and international agencies as contributing to child development and learning, and hence to socio-economic development (Figure 24). There is compelling evidence on the loss in global gross domestic product due to uRE in all age groups which is estimated to be USD 202,000 million annually.[1] The cost of establishing a comprehensive system for managing the increasing incidence of REs is a small proportion of this loss, ranging from USD 20,000 million in some countries to USD 28, 000 million in others.[2]

Figure 23: The long term impact of uncorrected refractive errors on socio-economic development



Refractive errors are prevalent in Indian children and they are being addressed by the Government of India's National Programme for Control of Blindness (NPCB) and RBSK (described in chapter 2). However, the NPCB guidelines do not include recommendations on how to assess the effectiveness of programmes nor approaches that could be used to improve efficiency. The available evidence as discussed in chapter 2, suggests that effectiveness can be low in India as not all children dispensed spectacles actually wear them.

The overall aim of this research is to provide evidence that can be used to improve the efficiency and effectiveness of school health programs for uREs. The research entails two randomized clinical trials, each of which focus on a specific research question, based on reported reasons why children do not wear their spectacles: one trial addressed the cost of spectacles and the other addressed negative attitudes towards spectacle wear by parents and peers.

Another important barrier to non-wear is no perceived benefit, and this is addressed in both trials by only recruiting children who have significant uREs. Another barrier is that children do not like the appearance of their spectacles and the frames are not comfortable. These issues are also addressed in both trials by allowing children to select the frames they prefer, giving careful attention during dispensing to frames size and IPDs.

4.1 Trial 1

Currently all SEH programs in India dispense custom-made spectacles regardless of the severity or type of RE. These spectacles are more expensive to make up than ready-made spectacles, requiring the time of dispensing opticians, and as they that cannot be dispensed immediately in schools, they have to be delivered which also increases costs. The costs are, therefore higher for parents and for providers.

In trial 1, we compared spectacle wear at 3 to 4 months in school children aged 11-15 years with significant, simple uRE randomized to ready-made or custom-made spectacles and to evaluate the potential cost saving to programs.

4.1.1. <u>The trial design</u>
Non-inferiority, individual randomized trial.

4.1.2 <u>Trial registration</u>
ISRCTN14715120 (Controlled-Trials.com)

4.1.3 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.

4.1.4 Objectives

1. To estimate the proportion of schoolchildren aged 11 to 15 years with uRE who might benefit from ready-made spectacles.
2. To compare the proportion of children wearing spectacles among those randomised to ready-made or to 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 savings to programs of using ready-made spectacles.

4.2 Trial 2

As described in the chapter 2, many studies report that children do not wear their spectacles because of negative reactions from their peers (teasing and bullying), and parental misconceptions (e.g., that spectacles make their vision worse) or parents' concerns that wearing spectacles is stigmatising. Only two published trials have addressed whether health education improves spectacle wear, both undertaken in China. In the first trial all children in selected classes were randomised to a health education intervention using short 10 minute documentary style video, a booklet of cartoons, and classroom discussion led by teachers. In this trial spectacle wear was actually lower in the intervention arm than in the standard explanation arm.[3] In the second trial, health education was delivered to children classroom teachers and children but not parents.[4] To date no trials have been undertaken that we are aware of that have included health education for parents. As parents often purchase spectacles and are concerned about their child's well-being and academic performance, this evidence gap is addressed in our second trial.

In trial 2, we evaluated whether a health education package for teachers, parents and children aged 11-15 years old, delivered using an innovative mobile phone technology (Peek) increases spectacle wear at 3 to 4 months.

4.2.1 The trial design

Superiority clustered randomized trial.

4.2.2 Trial registration

ISRCTN78134921 (Controlled-Trials.com)

4.2.3 Main Hypothesis

The proportion of children wearing spectacles 3 to 4 months after they were given their spectacles is higher in schools allocated to the innovative educational package for children, teachers and parents than in schools randomised to the standard program.

4.2.4 Objectives

1. To assess spectacle wear during unannounced visits 3-4 months after children receive their spectacles and to compare spectacle wear between the two arms of the trial.
2. To identify reasons why children do, or do not wear their spectacles.
3. To compare the uptake of referrals in both arms of the trial.

Chapter 4 and 5 describe trial 1 and 2 respectively with detailed protocols and the primary outcome of both trials.

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Chapter 4. Trial 1: Spectacle wearing amongst children randomized to ready-made spectacles or prescription spectacles, and cost savings to programmes

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Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Trials		
When was the work published?	January 2016		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Conception and design; data collection; manuscript writing and final approval of the manuscript.

Student Signature: [redacted] **Date:** 03 May 2018

Supervisor Signature: [redacted] **Date:** May 3 2018

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Trials

STUDY PROTOCOL Open Access

Spectacle wearing in children randomised to ready-made or custom spectacles, and potential cost savings to programmes: study protocol for a randomised controlled trial

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Abstract

Background: Uncorrected refractive errors are the commonest cause of visual impairment in children, with myopia being the most frequent type. Myopia usually starts around 9 years of age and progresses throughout adolescence. Hyperopia usually affects younger children, and astigmatism affects all age groups. Many children have a combination of myopia and astigmatism. To correct refractive errors, the type and degree of refractive error are measured and appropriate corrective lenses prescribed and dispensed in the spectacle frame of choice. Custom spectacles (that is, with the correction specifically required for that individual) are required if astigmatism is present, and/or the refractive error differs between eyes. Spectacles without astigmatic correction and where the refractive error is the same in both eyes are straightforward to dispense. These are known as 'ready-made' spectacles. High-quality spectacles of this type can be produced in high volume at an extremely low cost. Although spectacle correction improves visual function, a high proportion of children do not wear their spectacles for a variety of reasons. The aim of this study is to compare spectacle wear at 3–4 months amongst school children aged 11 to 15 years who have significant, simple uncorrected refractive error randomised to ready-made or custom spectacles of equivalent quality, and to evaluate cost savings to programmes. The study will take place in urban and semi-urban government schools in Bangalore, India. The hypothesis is that similar proportions of children randomised to ready-made or custom spectacles will be wearing their spectacles at 3–4 months.

Methods/design: The trial is a randomised, non-inferiority, double masked clinical trial of children with simple uncorrected refractive errors. After screening, children will be randomised to ready-made or custom spectacles. Children will choose their preferred frame design. After 3–4 months the children will be followed up to assess spectacle wear.

Discussion: Ready-made spectacles have benefits for providers as well as parents and children, as a wide range of prescriptions and frame types can be taken to schools and dispensed immediately. In contrast, custom spectacles have to be individually made up in optical laboratories, and taken back to the school and given to the correct child.

Trial registration: ISRCTN14715120 (Controlled-Trials.com)
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Keywords: Uncorrected refractive errors, Children, School eye health, India, Spectacle wearing rate, Ready-made spectacles, Randomised clinical trial

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Background

Uncorrected refractive errors are the commonest cause of visual loss in children [1]. Myopia (short-sightedness) is the commonest form; it usually starts around the age of 9 to 10 years, progressing in severity throughout adolescence. Hypermetropia (long-sightedness), which is more common in younger children, usually resolves by around the age of 10 years. Astigmatism (distorted vision, measured in cylinders) affects all age groups and does not change over time. Myopia is far more common in Asian children, particularly in Southeast Asia. Many children with myopia also have some degree of astigmatism, and one of the standard ways of reporting refractive error is to use the 'spherical equivalent', which is calculated as the sphere plus 0.5 x the cylinder, in dioptres (D). Refractive errors can also differ between eyes (anisometropia).

Correcting refractive errors requires the following steps: measuring visual acuity in each eye without any form of correction, followed by measurement of the type and degree of refractive errors in each eye, which can be done clinically (by retinoscopy) or by an automated refractometer. The next step is to use the findings to assess which corrective lenses give the best visual acuity in each eye, which are then prescribed. The next step is to dispense the spectacles, which entails ensuring that the optical centres of the lenses required align with the visual axis of each eye when mounted in the spectacle frames of choice. If an individual has astigmatism, the axis of the cylinder in the lens must align accurately with that of the eye. Custom spectacles are needed if astigmatism is present and/or the refractive error differs between eyes. Spectacles without astigmatic correction and where the refractive error is the same in both eyes

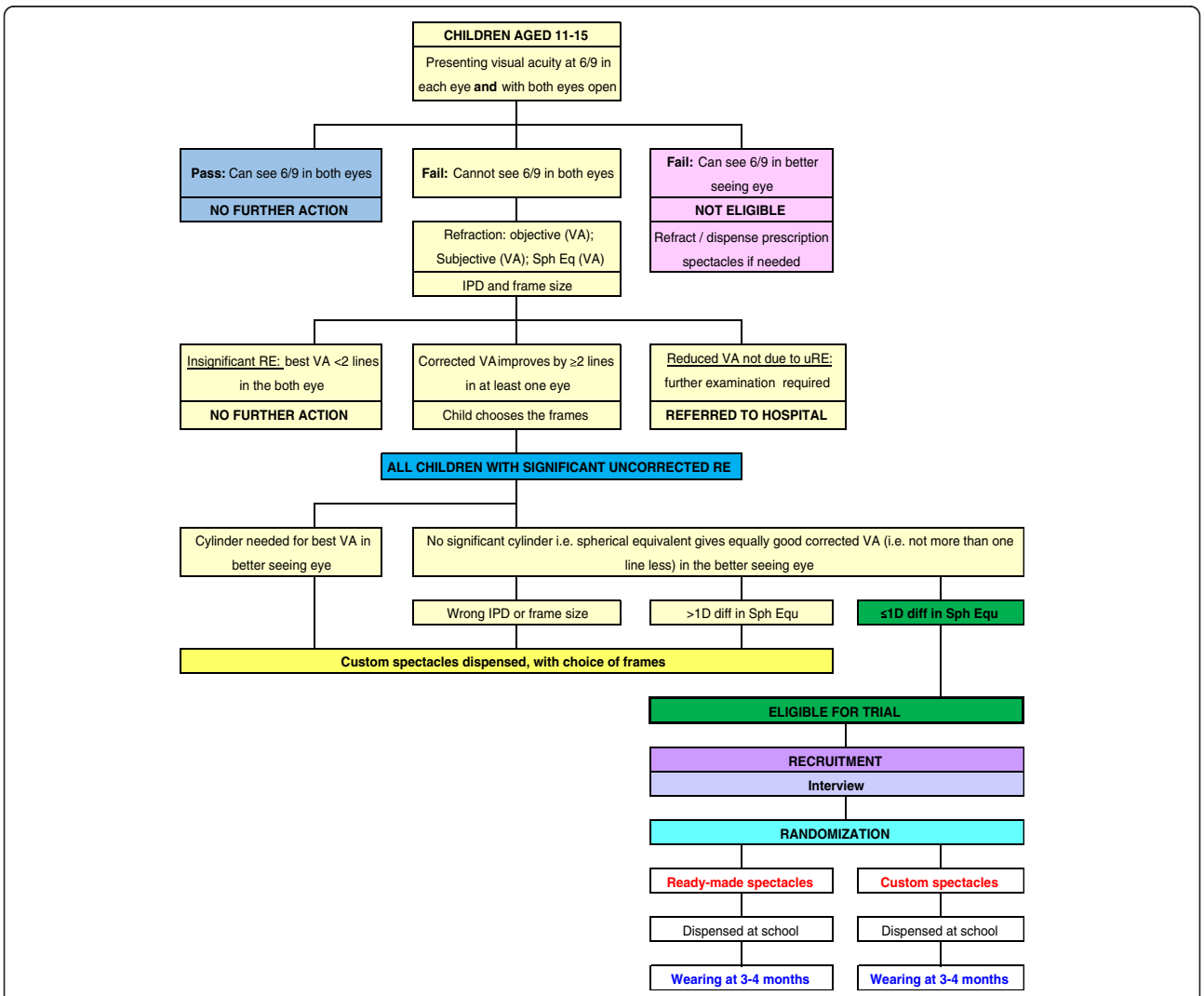

Fig. 1 Randomisation flow chart of activities. Flow chart shows a child's journey and the activities involved from screening to deciding whether they are eligible for recruitment, then randomisation and follow-up

(simple refractive error) are much more straightforward to dispense. Indeed, high-quality spectacles without astigmatic correction with a range of spherical powers (the same in each eye) are being mass produced at extremely low cost (0.5US$). Several different frame sizes are also available, allowing for variation in the distance between the visual axis in different age groups, gender and populations. These spectacles are called 'ready-made' or 'off-the-shelf' spectacles. 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 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 prevalence of uncorrected refractive errors in children varies by country and by urban/rural location, for example, in India [2–4]. In one study in rural India, 4.1 % of children aged 7–15 years were myopic, and 61 % of visual impairment was due to uncorrected refractive errors [2]. In an urban Indian setting 7.4 % of children aged 5–15 years were myopic and 82 % of visual impairment was due to uncorrected refractive errors. In both studies older children had a higher prevalence of uncorrected refractive error than younger children [4]. Global estimates indicate that 13 million children have visual impairment due to uncorrected refractive errors [5]. A recent study in China provides evidence of what might be anticipated, that academic performance improves with correction of refractive error in children [6]. Studies have also highlighted that correcting refractive error is highly cost effective [7] and improves visual function and quality of life. These findings add impetus to the need for the inclusion of eye health into school health initiatives, which are being supported and scaled up by Ministries of Health and Education, the World Bank, WHO, UNESCO, UNICEF and the Partnership for Child Development. India has had a programme to detect and treat uncorrected refractive errors in school children since 1994 [8].

Approaches being used to detect and correct uncorrected refractive errors in children are not standardised, and spectacle wearing rates can be very low in all settings [5]. For example, in Native American students in the USA, only 32 % of children given two pairs of free spectacles wore their spectacles [9]. Similar findings have been reported from rural areas near Delhi where only 29.4 % of children wore their spectacles [10]. Spectacle wear is higher in children with more severe uncorrected refractive errors [9] and in girls [11]. In another study in India only 30 % of children dispensed spectacles were wearing them at 6–12 months. Spectacle wearing was higher amongst girls, those with higher refractive errors and poor uncorrected visual acuity, and those whose fathers were better educated [12].

Only four trials have assessed the impact of interventions to increase spectacle wear in children, three being in low/middle income countries. One compared spectacle wear at 3–6 months in school children in Tanzania who were randomised to free spectacles or a prescription. Spectacle wear was significantly higher amongst those given free spectacles (47 % versus 26 % respectively, $p = 0.05$) [13]. In a trial in China, children were randomised to attend or not attend a health education session. Children in the health education group actually had lower rates of spectacle wear at follow-up than the controls [14]. In another study in China, a health education DVD shown to parents, teachers and children increased self-reported wear but not observed wear [6].

One study has addressed the utility of ready-made spectacles in Chinese school children. In this study children with high degrees of astigmatism, anisometropia or eye disease (8 %) were excluded and the remainder were randomised to ready-made spectacles or custom spectacles regardless of the extent to which correction improved their visual acuity. The study was powered to detect at 15 % difference in spectacle wear, but at follow-up one month later spectacle wear was similar in both groups (47 % in the ready-made spectacles group and 52 % in the custom spectacles group ($p = 0.23$) [15].

Despite spectacle correction improving visual function [16], children do not wear their spectacles for a variety of reasons, such as no perceived benefit [17], loss or breakage [18–21], misconceptions that spectacles will make their vision worse [11, 13, 22], parental disapproval [10, 15], being teased [13, 15, 18, 21–23] and forgetfulness [14, 15, 19, 21]. In a recent Indian study [12], reasons for not wearing spectacles included being teased (19.8 %), the spectacles were broken (17.4 %) or lost (9.3 %), and the child did not like their spectacles (12 %). There is also evidence that the degree of visual impairment also influences spectacle wear. For example, in the Tanzanian trial outlined above, increasing myopia was an independent predictor of spectacle wear. In a recent study in Bangalore, designed to assess different visual acuity screening cut-offs, children wearing their spectacles at 3–4 months also had higher degrees of myopia than those who were not (mean spherical equivalent in the better seeing eye −3.50 D, range −1.75 to −9.00 D versus mean −2.50 D range −0.75 to −2.25 D respectively) ($p = 0.001$) (unpublished data).

Purpose

The purpose of this trial is to compare spectacle wear at 3 to 4 months in school children aged 11 to 15 years

with significant simple uncorrected refractive errors who are randomised to ready-made spectacles or custom spectacles, and to evaluate the potential cost savings to programmes.

The hypothesis is that similar proportions of children randomised to ready-made spectacles or custom spectacles will be wearing their spectacles at 3–4 months.

Pilot study December 2014

A pilot study was undertaken in non-trial schools to test all aspects of the trial and to provide data for the sample size calculation, including the proportion of children with uncorrected refractive errors who would be eligible for ready-made spectacles.

Methods/design

The trial is a randomised, non-inferiority, double masked clinical trial of children with simple uncorrected refractive errors. A non-inferiority design was chosen, as the benefits of ready-made spectacles are the considerably lower cost and ease of dispensing, both of which have the potential to increase the efficiency and cost effectiveness of programmes. As millions of children are affected by uncorrected refractive errors, the lower cost of ready-made spectacles also has the potential to increase coverage of school-based programmes. Under these circumstances a slightly lower acceptance of ready-made 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. The allocation ratio is approximately 1:1.

Study setting

The trial is being undertaken in government middle and secondary schools in urban and peri-urban areas in and around Bangalore, Karnataka state, India. The trial is coordinated by Sankara Eye Hospital, Bangalore. The field team consists of optometrists, dispensing opticians, field workers and ophthalmologists, all of who are members of staff at the Sankara Eye Hospital. Training, quality assurance and oversight of data collection are being provided by staff at the International Centre for Eye Health, London School of Hygiene & Tropical Medicine.

Participant eligibility

Inclusion criteria

For a student to be eligible for recruitment, he/she must be aged 11–15 years, be present at school at the time of screening, and meet all the following criteria: a) presenting visual acuity (with spectacles if usually worn) of less than 6/9 in both eyes, b) visual acuity with full correction improves in the better seeing eye by two or more lines, c) the spherical equivalent corrects the visual acuity to not more than one line less than best corrected visual acuity with a full prescription in the better eye, d) the difference between the spherical equivalent of the right and left eyes is not more than 1 D, e) the interpupillary distance (IPD) matches that of ready-made spectacle frames available (54 to 62 mm) and f) spectacle frames are of acceptable size and fit. Parents must consent for their child to take part in the study.

Exclusion criteria

The following children are not being recruited: those with other causes of visual loss or whose visual acuity does not improve by two lines or more with spherical equivalent lenses; there is more than 1 D of anisometropia or parents do not consent. All these children are being dispensed custom spectacles and are not recruited to the trial.

Eligibility of those performing interventions

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

Identification of potential participants and recruitment

In the schools selected for the trial, trained field workers measure visual acuity at the 6/9 level in each eye and with both eyes open, with spectacles if the child usually wears them. A LogMAR visual acuity chart in an illuminated cabinet is being used at the recommended test distance of 6 metres to overcome variable illumination in the classrooms. Children who pass the screening test are given a green card and sent to another field worker who registers their age and gender.

All children who fail screening undergo objective and subjective refraction by an optometrist. The following information is being recorded: objective refractive error and corrected visual acuity in each eye; subjective refractive error and best corrected visual acuity in each eye. The spherical equivalent is calculated for each eye, and visual acuities are measured and recorded for each eye using the spherical equivalent. An optometrist then decides whether the child is eligible for recruitment. All children requiring spectacles, whether eligible for the trial or not, are allowed to select the frames they prefer from a range of coloured plastic or metallic frames. The type of frame and the frame size needed are recorded.

All eligible children are given an information sheet and consent form for their parents to sign which they return to the school. A trained field worker goes through an assent form with each child. Each child is allocated a unique study number and randomised to ready-made spectacles or custom spectacles. All those recruited are given a red ID card that contains their name, their father's name, a mobile telephone number and study ID. Children are asked to give the card to their class teacher

so they can be identified when the trial spectacles are delivered a few weeks later, to ensure that each child receives the correct spectacles.

Children not eligible are either given a green card, if spectacles are not required, or a red card if they need custom spectacles or referral to Sankara Eye Hospital for assessment of other eye conditions. These findings are recorded by a field worker.

In both arms of the trial the same procedures are followed, including the day on which spectacles are delivered to the school. Before giving each child their spectacles, their identity is confirmed by a field worker using the red card issued at the time of recruitment. Corrected visual acuity with the new spectacles is also measured in each eye. Children not eligible for the trial who require custom spectacles also receive their spectacles at the same time.

Children, parents/carers, and teachers are not aware which type of spectacles (ready-made spectacles or custom spectacles) each child receives (Fig. 1).

Sample size calculation

Parameters used in the sample size calculation include a significance level of 0.05, 95 % confidence interval, 90 % power and 1:1 allocation. The trial is powered to detect a non-inferiority margin (Δ) of 10 %. No increase has been added for loss to follow-up, as all eligible children present on the day of the visit are being recruited, and high response rates are anticipated based on previous experience. Calculations, which were one sided, were performed using a web-based sample size calculation programme (Sealed Envelope, https://www.sealedenvelope.com/power/binary-noninferior/, accessed 31 October 2014). A sample of 240–260 eligible children will be required in each arm of the trial. The prevalence of uncorrected refractive errors in the earlier study in Bangalore was 4 %. Assuming approximately a third would not be eligible for ready-made spectacles, the effective prevalence would be 2.6 %; therefore, 20,000 children in 200 schools would need to be screened.

Randomisation

The random allocation has been stratified by school. An epidemiologist away from the study site generated the allocation schedule in Excel using the *rand between* function, using block randomisation with variable block sizes. Two pre-printed adhesive labels were placed in opaque envelopes, which were sealed and stamped in London and Bangalore by persons not involved in the trial. For each child recruited, the optometrist opens the next envelope in sequence to see to which arm of the trial the child has been allocated. One label has the unique study ID number and code for ready-made spectacles or custom spectacles which is adhered to the child's data collection form. The other label, which only has the unique study ID, is adhered to the red card issued to the child.

Primary outcome

The primary outcome is the proportion of children who are wearing their spectacles at an unannounced visit to the school 3 to 4 months after delivery of the spectacles. A field worker, masked to the allocation arm, assesses spectacle wear using categories described by Wedner [13]. Categories 1 or 2 below are used to define spectacle wearing, and categories 3 or 4 as non-spectacle wearing:

1. wearing the spectacles at the time of the unannounced visit
2. not wearing the spectacles at the time of the visit but have them at school
3. not wearing the spectacles at the time of the visit but said they are at home
4. not wearing the spectacles at the time of the visit as they are broken or lost

Children categorised as non-spectacle wearing are given an opportunity to give two reasons. The field worker asks the child the reason and this is coded and recorded on the follow-up data collection form.

Fieldwork has been planned such that the initial assessment, delivery of spectacles and follow-up 3 to 4 months later do not coincide with school examination periods, long school holidays, or the end of the school year when children may leave school.

Data management

All field staff have undergone rigorous training, including inter-observer agreement studies for visual acuity measurement and refraction, and instruction on how to record data.

Two password protected databases have been created in Epidata and Excel, one for the primary outcome data and the other for all other data. Consistency and range checks have been built in. Data are double entered by the lead investigator as soon as possible after recruitment to monitor recruitment. During the trial all data recording forms are kept in a locked cupboard or filing cabinet in Sankara Eye Hospital and photocopies made and transferred to London for data cleaning, where they are again stored in a locked filing cabinet.

Data analyses

Analysis will be in the groups to which the children were randomly allocated. We expect all children will have been given the correct spectacles. The randomisation code will only be broken once the analysis has been completed. We do not plan any subgroup analysis.

Comparability of the intervention and comparator groups

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

Primary analysis

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 difference with 95 % confidence intervals.

We will also calculate and present the risk ratio with 95 % confidence intervals.

Cost savings to programmes

Analysis of cost savings to programmes of ready-made spectacles will only be undertaken if analysis of the primary outcome demonstrates non-inferiority. The unit cost of ready-made spectacles ($Cost_{Ready\text{-}made\ spectacles}$) and custom spectacles ($Cost_{custom\ spectacles}$) will be calculated. The cost of dispensing spectacles to the two groups of children in the study will be determined as follows:

A = not eligible for the trial and dispensed custom spectacles
B = eligible for randomisation, that is, suitable for ready-made spectacles
The cost of programmes without ready-made spectacles

$$\mathrm{Cost}^{\text{Custom only}} = \mathrm{A} * \mathrm{Cost}^{\text{Custom}} + \mathrm{B} * \mathrm{Cost}^{\text{Custom}}$$

The cost of programmes with ready-made spectacles

$$\mathrm{Cost}^{\text{Ready-made used}} = \mathrm{A} * \mathrm{Cost}^{\text{Custom}} + \mathrm{B} * \mathrm{Cost}^{\text{Ready-made}}$$

The cost savings to programmes

$$\mathrm{Cost}^{\text{Custom only}} - \mathrm{Cost}^{\text{Ready-made used}}$$

Additional analyses

(i) *Reasons for non-spectacle wear*
Reasons for non-wear will be compared in children who were not wearing ready-made spectacles or custom spectacles.
(ii) *Predictors for spectacle wear*
We will investigate factors that may affect spectacle wear in this cohort such as gender, age, degree of uncorrected refractive error in the better seeing eye, previously wore spectacles, and parental spectacle wear using multivariable logistic regression analysis.

Data monitoring

A data monitoring committee will not be required, as 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.

Harm

Inaccurate prescribing or fitting of spectacles can cause blurred vision and/or symptoms of eyestrain or headache whilst the spectacles are worn. 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 ready-made spectacles will not be eligible for the trial, thus reducing the risk of symptoms arising through under/over 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 follow-up 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

Ethical approval has been obtained from the Interventions Research Ethics Committee, LSHTM and the Institutional Review Board of Sankara Eye Institute. 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.

Protocol amendment

No important protocol modifications, such as changes to eligibility criteria, were required.

Consent

Written informed approval has been obtained in the local language by the lead collaborator in India from each school authority, head teacher and/or the school administrator to allow the school to participate in the study. Written informed consent is being obtained from parents of children recruited to the trial. Parents of the children are being sent an information sheet which

explains the study procedure along with the consent form in the local language.

Guidelines are being followed for school screening in India and by the collaborating institute which state that before starting screening at each school, children should be given verbal information about the study and an explanation of the procedures by trained field workers, which allows children to ask questions.

Confidentiality

Data are kept confidential and no identifiers are entered into the databases. Data are anonymised by allocating a unique study ID for each participant. The unique study ID will be used to merge the two study datasets.

Paper records are being stored in a locked filing cabinet at LSHTM, and the data will be made readily available in a public domain after the initial analyses and results are published. At the end of the study, the data will be archived at LSHTM.

Access to data

A memorandum of understanding has been drawn up between the two institutions highlighting intellectual property issues, which include data sharing and making the database available online.

Post-trial care

It is recommended that school vision testing be repeated every two years, to identify children whose spectacles need to be replaced as well as to screen children aged 11–12 years for the first time. This will be discussed with head teachers, who may want to consider training teachers to measure visual acuity, with support from Sankara Eye Hospital. This is the process adopted in other schools in the locality.

Discussion

This trial is designed to investigate whether low-cost, high-quality, ready-made spectacles result in comparable rates of spectacle wear at 3 to 4 months as more expensive custom spectacles and how much cost savings there would be to programmes.

The dissemination strategy will include a summary of the findings for head teachers, a report for the websites of both institutions, publications in peer-reviewed journals and presentations at national (UK and India) and international conferences. In India the findings will be shared with the State Ministry of Health, State Ministry of Education and specifically the Government of India's 'Rashtriya Bal Swasthya Karyakram' (RBSK) programme, which includes refractive error, technically called the 'Child Health Screening and Early Intervention Services'.

Trial status

At the time of submission recruitment was ongoing. Recruitment started on 12 January 2015 and ended on 31 July 2015. A total of 23,345 children were screened and 460 recruited.

Abbreviation

D: dioptres.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

PM: Conception and design; data collection; manuscript writing and final approval of the manuscript. 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. All authors read and approved the final manuscript.

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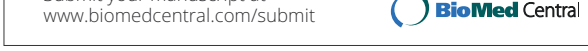
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SECTION A – Student Details

Student	Priya Morjaria
Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

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Student Signature: [redacted] **Date:** 03 May 2018

Supervisor Signature: [redacted] **Date:** May 3 2018

JAMA Ophthalmology | Original Investigation | CLINICAL TRIAL

Spectacle Wear Among Children in a School-Based Program for Ready-Made vs Custom-Made Spectacles in India
A Randomized Clinical Trial

Priya Morjaria, MSc; Jenifer Evans, PhD; Kaushik Murali, DNB(Ophth); Clare Gilbert, MD

IMPORTANCE Uncorrected refractive errors are the most common cause of visual impairment in children despite correction being highly cost-effective.

OBJECTIVE To determine whether less expensive ready-made spectacles produce rates of spectacle wear at 3 to 4 months comparable to those of more expensive custom-made spectacles among eligible school-aged children.

DESIGN, SETTING, AND PARTICIPANTS This noninferiority, double-masked, randomized clinical trial recruited children aged 11 to 15 years from January 12 through July 31, 2015, from government schools in urban and periurban areas surrounding Bangalore, India. Follow-up occurred from August 1 through September 31, 2015. Participants met the following eligibility criteria for ready-made spectacles: failed vision screening at the 6/9 level in each eye; refraction was indicated; acuity improved with correction by 2 or more lines in the better-seeing eye; the corrected acuity with the spherical equivalent was not more than 1 line less than with full correction; anisometropia measured less than 1.0 diopter; and an appropriate frame was available.

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

MAIN OUTCOMES AND MEASURES Proportion of children wearing their spectacles at unannounced visits 3 to 4 months after the intervention.

RESULTS Of 23 345 children aged 11 to 15 years who underwent screening, 694 had visual acuity of less than 6/9 in both eyes, and 535 underwent assessment for eligibility. A total of 460 children (227 female [49.3%] and 233 male [50.7%]; mean [SD] age, 13.4 [1.3] years) were eligible for ready-made spectacles (2.0% undergoing screening and 86.0% undergoing assessment) and were randomized to ready-made (n = 232) or custom-made (n = 228) spectacles. Follow-up rates at 3 to 4 months were similar (184 [79.3%] in the ready-made group and 178 [78.1%] in the custom-made group). Rates of spectacle wear in the 2 arms were similar among 139 of 184 children (75.5%) in the ready-made arm and 131 of 178 children (73.6%) in the custom-made arm (risk difference, 1.8%; 95% CI, −7.1% to 10.8%).

CONCLUSIONS AND RELEVANCE Most 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 to 4 months. These findings suggest that ready-made spectacles could substantially reduce costs for school-based eye health programs in India without compromising spectacle wear, at least in the short term.

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The proportion of visual impairment due to uncorrected refractive errors (REs) in children aged 3 to 15 years varies from 72.6% in Australia[1] to 82% in India[2] and 97.1% in China.[3] Uncorrected REs are the most common cause of visual impairment in children in all regions, affecting an estimated 12.4 million children,[4] despite correction of 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 the United States.[8] In Singapore, China, Taiwan, Hong Kong, Japan, and Korea, 80% to 90% of children completing high school have myopia.[8,9] Variation in the prevalence of uncorrected RE in children by age and urban or rural location is also evident in India.[2,10,11] In a 2002 study in urban India,[12] 7.4% of children aged 5 to 15 years had myopia, and 82% of visual impairment was attributable to uncorrected RE. In a similar study in rural India,[10] 4.1% of children aged 7 to 15 years had myopia, and 61% of visual impairment was due to uncorrected RE. In both studies, older children had a higher prevalence of uncorrected RE than younger children.

Complex refractions require spherical and astigmatic correction, and in clinical practice, these are usually fully corrected. In this trial, these corrections used custom-made spectacles. Simple REs with low or no astigmatism and minimal difference in spherical correction between the 2 eyes can be corrected using low-cost spectacles that have the same spherical equivalent (SE) in both eyes (ie, ready-made spectacles). Two broad criteria need to be fulfilled before dispensing ready-made spectacles: the prescription is suitable, and the available frames are of the correct size and fit.

The high levels of visual impairment due to uncorrected RE 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; furthermore, spectacle wear is not usually monitored.[14] Available evidence suggests that the rate of spectacle wear among children with RE is low in many settings, including 13% in Mexico,[15] 29.4% in rural areas near Delhi,[16] and 33.2% among Native American students.[17] Spectacle wear rates are higher among children with more severe uncorrected RE[18] and among girls,[19] but associations between socioeconomic status or parental education are inconclusive.[14,17,20] In a recent study in India, only 30% of children dispensed spectacles were wearing them at 6 to 12 months, with higher rates among girls, those with higher REs and poor uncorrected visual acuity (VA), and those whose fathers were better educated.[21]

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, require the time of dispensing opticians, and cannot be dispensed immediately in schools. The spectacles must be delivered, which increases costs. Costs are therefore likely to be higher for parents and clinicians if custom-made spectacles are used rather than ready-made.

We have identified 2 trials that compared ready-made with custom-made spectacles for children with uncorrected RE, both undertaken in China.[22] The trial by Zeng et al[22] 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 rates of spectacle wear.[17-19,21,23] Subsequent spectacle wear was defined as observation of children wearing their spectacles at an unannounced visit. At 1 month, similar proportions of children were wearing their spectacles (46.9% ready-made vs 51.5% custom-made spectacles, a difference of 5.4%; $P = .23$). The purpose of the other trial by Zhou et al,[24] which had a noninferiority design, was to assess the effect of spectacle correction on quality of life. The rate of self-reported spectacle wear was high (>94.7%) in all groups, including those dispensed ready-made spectacles.

In our trial, a noninferiority design was used with the null hypothesis that the proportion of children wearing their ready-made spectacles (intervention group) at 3 to 4 months would not be inferior to the proportion wearing custom-made spectacles (standard care group). A noninferiority design was chosen because benefits of ready-made spectacles are the considerably lower cost and the 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 noninferiority margin of 10% was chosen based on the trial by Zeng et al[22] 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 as clinically inferior.[25] The trial protocol was published in January 2016.[26]

This prospective, randomized clinical trial was undertaken in government schools in and around Bangalore, India. Reporting follows the CONSORT 2010 Checklist for noninferiority and equivalence trials.[27]

Key Points

Question What proportions of children given ready-made vs custom-made spectacles are still wearing the spectacles at 3 to 4 months after testing?

Findings In this randomized clinical trial of a school-based eye health program in India that included 460 children, the proportion of children wearing spectacles at follow-up included 139 of 184 (75.5%) in the ready-made arm vs 131 of 178 (73.6%) in the custom-made arm.

Meaning In school-based eye health programs, use of ready-made spectacles may be no different from use of more expensive custom-made spectacles.

Methods

The trial protocol is available in the Supplement. The study adhered to the Declaration of Helsinki.[28] Children requiring further examination or spectacles for complex REs were not recruited and were referred to Sankara Eye Hospital, Bangalore,

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India, for free examination and spectacles, if required. The trial was approved by the Interventions and Research Ethics Committee of the London School of Hygiene and Tropical Medicine and the institutional review board of Sankara Eye Hospital. All parents of children eligible to be recruited to the trial provided written informed consent, and the children provided assent.

A list of government secondary schools in urban and periurban areas surrounding Bangalore in Karnataka State was obtained from the district education officer. Schools were excluded if eye screening had taken place within 2 years. Schools were stratified by location (urban or rural) and size (≥200 or <200 children aged 11-15 years) and 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 to 15 years to take home for parents to sign if they did not want their child to undergo screening and receive spectacles, if required. Field workers who were part of an earlier study were recruited and underwent further training in VA screening, including assessment of interobserver agreement.

Participants and Eligibility

Recruitment took place from January 12 through July 31, 2015. Screening was offered to all children aged 11 to 15 years present at school at the time of screening using the 6/9 row of 5 tumbling Es on an illuminated, distance acuity logMAR chart. Each eye was tested separately. To pass, children had to correctly identify 4 or 5 Es. Children who failed screening (ie, presenting VA<6/9 in each eye) were referred to study optometrists who retested their VA using a full logMAR chart. If a child's VA was 6/9 in both eyes at the second testing, no further action was taken. Children confirmed with a VA of less than 6/9 in both eyes underwent objective and subjective refraction and assessment for frame size to ascertain whether they fulfilled eligibility criteria for the trial. Because 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: (1) VA with full correction improved in the better-seeing eye by 2 or more lines, (2) the SE corrected the VA to not more than 1 line less than best-corrected VA with a full prescription in the better eye, (3) the difference between SE of the right and left eyes was not more than 1.0 diopter (D), (4) interpupillary distance matched that of ready-made spectacle frames available (ie, 54-62 mm), and (5) spectacle frames were of acceptable size and fit. Exclusion criteria consisted of other causes of visual impairment and lack of parental consent. Ineligible children were prescribed custom-made spectacles or referred to Sankara Eye Hospital. Eligible children were recruited by optometrists and given a unique identifier and a red card with the child's name and identification, class, and father's name.

Interventions

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

Children recruited to the trial selected the frames they preferred from a range of 6 different colors of 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 2 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 categorized as follows: children were (1) wearing their spectacles at the time of the unannounced visit, (2) not wearing their spectacles but had them at school, (3) not wearing their spectacles but said they were at home, and (4) no longer had the spectacles because they were broken or lost.[14] Categories 1 and 2 were defined as wearing and categories 3 and 4 as nonwearing.

Field workers made unannounced visits to study schools 3 to 4 months after spectacles were delivered to assess the proportion of children wearing their spectacles (August 1 through September 31, 2015). They were given a list of children dispensed spectacles and went to the relevant classrooms, where teachers identified each child. Whether the child was wearing spectacles was noted. Children not wearing their spectacles were interviewed in another room to explore whether they had their spectacles with them and, if they did, were asked to show them to field workers.

Sample Size Calculation

Sample size was calculated using the Sealed Envelope program,[29] assuming a noninferiority margin (Δ) of 10% and considering a difference of 10% or less in spectacle wear to be acceptable. Other parameters included 95% CI, 80% power, and 1:1 allocation. Sample size was not increased to allow for loss to follow-up, and high follow-up at 3 to 4 months was anticipated because the communities were stable and few study children were expected to leave school during the academic year.

Randomization and Masking

After recruitment, children were randomly assigned 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 one of us who was an epidemiologist (J.E.) away from the study site. Sequentially numbered, sealed, stamped opaque envelopes containing labels with unique study identification 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.

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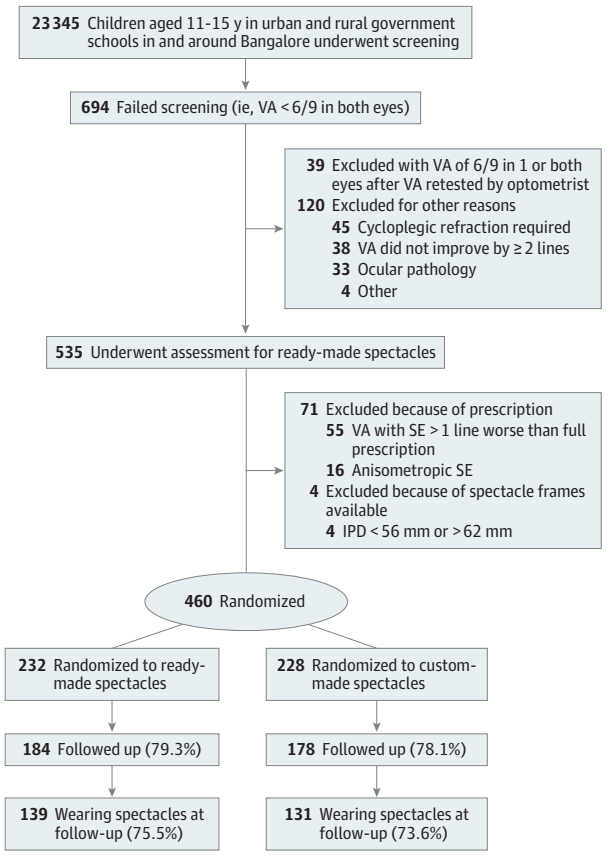
Figure. Study Flowchart



IPD indicates interpupillary distance; SE, spherical equivalent; and VA, visual acuity.

Table 1. Baseline Characteristics of Children Randomized to Ready-Made or Custom-Made Spectacles

Characteristic	Study Group, No. (%)[a]	
	Ready-Made Spectacles (n = 232)	Custom-Made Spectacles (n = 228)
Sociodemographic		
Age, mean (SD) [range], y	13.4 (1.28) [11 to 15]	13.6 (1.28) [11 to 15]
Female	111 (47.8)	116 (50.9)
Rural location	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 (28.4)	49 (21.5)
Spectacle wear		
Father only	25 (10.8)	29 (12.7)
Mother only	18 (7.8)	19 (8.3)
Both parents	6 (2.6)	3 (1.3)
Neither parent	183 (78.9)	177 (77.6)
Clinical		
Presenting VA in better eye		
<6/9 to 6/12	62 (26.7)	63 (27.6)
<6/12 to 6/18	75 (32.3)	72 (31.6)
<6/18 to 6/60	91 (39.2)	85 (37.3)
<6/60	4 (1.7)	8 (3.5)
SE (better eye), mean (SD) [range]	−1.51 (0.92) [0.50 to −5.50]	−1.42 (1.20) [2.25 to −9.50]

Abbreviations: SE, spherical equivalent; VA, visual acuity.

[a] Percentages have been rounded and may not total 100.

Statistical Analysis

Data were double entered by the lead investigator at regular intervals to monitor recruitment. After data cleaning and 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% CI of the difference. Analyses were prespecified.[26] All analyses were performed using STATA software (version 14.1; StataCorp).

Results

All school principals approached agreed that their school would participate in the trial, and no parent or child refused consent. A total of 23 345 children underwent screening at 112 government schools (**Figure**), 694 (3.0%) of whom had a presenting VA of less than 6/9 in each eye. Thirty-nine children were excluded because their VA was 6/9 or better in 1 or both eyes at a second test. An additional 120 were excluded after refraction and basic eye examination. Of these, 45 required specialist refraction, 38 did not show improvement of VA by 2 or more lines, 33 had pathologic findings that required specialist examination, 1 wanted contact lenses, 1 refused spectacles, and 2 had learning disabilities. Among the 535 children undergoing assessment for eligibility for ready-made spectacles, 75 (14.0%) were excluded because they did not meet all requirements for ready-made spectacles, mainly that their VA with SE was more than 1 line worse than with a full prescription (55 children). Therefore, 460 (86.0%) of the children undergoing assessment were eligible for ready-made spectacles.

A total of 460 children eligible for ready-made spectacles were recruited from January 12 through July 31, 2015, of whom 227 (49.3%) were female and 233 (50.7%) were male (mean [SD] age, 13.4 [1.3] years). Two hundred thirty-two 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 2 weeks later. The mean SE was similar in both arms of the trial (ready-made: −1.51 D; custom-made: −1.42 D), but the range of SE in the better eye was wider in the custom-made than ready-made arms (**Table 1**). All other baseline variables were similar in both arms.

Overall, 362 of 460 children (78.7%) were identified in their schools at follow-up (**Table 2**). Follow-up was similar in both arms, with 184 of 232 (79.3%) in the ready-made and 178 of 228

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Table 2. Characteristics of Children in Both Arms of the Trial by Follow-up Status

Characteristic	Study Group, No. (%)[a]			
	Ready-Made Spectacles (n = 232)		Custom-Made Spectacles (n = 228)	
	Followed Up (n = 184)	Lost to Follow-up (n = 48)	Followed Up (n = 178)	Lost to Follow-up (n = 50)
Sociodemographic				
Age, mean (SD) [range]	13.3 (1.3) [11 to 15]	13.8 (1.2) [11 to 15]	13.6 (1.3) [11 to 15]	13.7 (1.1) [11 to 15]
Female	93 (50.5)	18 (37.5)	87 (48.9)	29 (58.0)
Rural school	56 (30.4)	17 (35.4)	56 (31.5)	17 (34.0)
Parental				
Literacy				
Father only	31 (16.8)	7 (14.6)	41 (23.0)	16 (32.0)
Mother only	31 (16.8)	7 (14.6)	33 (18.5)	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)
Spectacle wear				
Father only	21 (11.4)	4 (8.3)	21 (11.8)	8 (16.0)
Mother only	17 (9.2)	1 (2.1)	15 (8.4)	4 (8.0)
Both parents	6 (3.3)	0	2 (1.1)	1 (2.0)
Neither parent	140 (76.1)	43 (89.6)	140 (78.7)	37 (74.0)
Clinical				
Presenting VA in better eye				
<6/9 to 6/12	47 (25.5)	15 (31.3)	46 (25.8)	17 (34.0)
<6/12 to 6/18	61 (33.2)	14 (29.2)	57 (32.0)	15 (30.0)
<6/18 to 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)
SE (better eye), mean (SD) [range]	−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]

Abbreviations: SE, spherical equivalent; VA, visual acuity.

[a] Percentages have been rounded and may not total 100.

(78.1%) in the custom-made arms. All children not followed up in school (n = 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 (30 of 48 [62.5%] vs 21 of 50 [42.0%]) and to have parents who did not wear spectacles (43 of 48 [89.6%] vs 37 of 50 [74.0%]). Children not followed up in the custom-made arm were more likely to have a literate father (33 of 50 [66.0%] vs 27 of 48 [56.3%]) and better presenting VA (32 of 50 [64.0%] vs 29 of 48 [60.4%]).

Overall, 270 of 362 children (74.6%) were wearing their spectacles or had them at school, including 139 of 184 (75.5%) in the ready-made arm and 131 of 178 (73.6%) in the custom-made arm. The risk difference between the 2 arms was 1.8% (95% CI, −7.1% to 10.8%). The proportion of children given spectacles and wearing them were 126 (68.5%) in the ready-made arm and 112 (62.9%) in the custom-made arm. Other children had their spectacles with them (13 [7.1%] in the ready-made and 19 [10.7%] in the custom-made arms).

Discussion

In our trial, most of the children undergoing assessment were eligible for ready-made spectacles, as reported in the 2 previous studies.[22,24] At the 3- to 4-month follow-up, spectacle wear was similar in both arms. These important findings suggest that ready-made spectacles, which can be purchased in bulk at very low cost, would be suitable for most children with uncorrected REs in this setting without compromising spectacle wear. In addition to the lower purchase cost, ready-made spectacles can be dispensed on site at the time of refraction, which reduces the cost of dispensing the optician's time and visits to schools by clinicians. In some programs, children are given a prescription for spectacles that parents collect from the opticians or the 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, colors, and shapes) with a range of powers. A recent innovation, termed *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.

Strengths

The rate of spectacle wear in our trial was much higher than in other studies of children of similar ages.[12,15,16,18,21,23] Several explanations may exist. First, in our trial, only children with significant uncorrected RE who had improvement of 2 or more lines in VA in the better-seeing eye were prescribed spectacles, unlike the trial by Zeng at al.[22] Second, children underwent refraction only if both eyes had a presenting VA of less

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than 6/9. Most other studies define screening failure as a reduced VA in 1 or both eyes, and in the absence of prescribing guidelines, many children are prescribed spectacles when they already have good VA in 1 eye. This practice decreases spectacle wear because 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 that 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.[15,23,30] Comparison with other studies is difficult because definitions of spectacle wear and intervals from dispensing to follow-up vary among studies. The trial by Zeng et al[22] had a superiority design and was powered to detect a 15% difference in spectacle wear; the study had a short follow-up, and the definition of significant RE was not based on improvement in VA with correction. In our trial, significant RE was clearly defined, follow-up was 3 to 4 months, and we used more established ways of assessing spectacle wear.[14,15,18,21,23,30,31]

Other strengths of our study include the noninferiority design; the large sample size, which was representative of the school-going population in the study area; and the primary outcome assessed by direct observation, as in other studies,[14,15,23] instead of self-report, which may induce response bias, particularly because the trial involved children. The findings can, therefore, be extrapolated to other children aged 11 to 15 years attending school in this part of India. However, the proportion of children eligible for ready-made spectacles is likely to vary across India because the type and degree of REs vary.[10,16]

Limitations

A limitation of this study was loss to follow-up of children who had left school 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 assessment of spectacle wear at 3 to 4 months rather than a longer period. Although longer follow-up would be desirable, children often move schools at the end of the academic year, making follow-up difficult.

Conclusions

Our study is the first, to our knowledge, to use clearly defined prescribing guidelines, which may explain the high rates of spectacle wear at follow-up. However, because this approach was used in both arms, other factors may also have been important. Additional studies may be of value to address the effect of prescribing guidelines on spectacle wear among children.

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Study concept and design: All authors.
Acquisition, analysis, or interpretation of data: Evans, Murali, Gilbert.
Drafting of the manuscript: Morjaria, Evans, Gilbert.
Critical revision of the manuscript for important intellectual content: Evans, Murali, Gilbert.
Statistical analysis: Morjaria, Evans.
Obtained funding: Morjaria.
Administrative, technical, or material support: Morjaria, Murali.
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Student	Priya Morjaria
Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

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Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Study concept and design; Acquisition, analysis and interpretation of data; Drafting of manuscript; Critical revision of manuscript; Statistical analysis;

Student Signature: [redacted] **Date:** 03 May 2018

Supervisor Signature: [redacted] **Date:** May 3 2018

Predictors of spectacle wear and reasons for non-wear in children randomized to ready-made or custom-made spectacles

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ABSTRACT

Importance

Globally there are 12.8 million children visually impaired from uncorrected refractive errors. Spectacles are a simple and cost-effective way to correct refractive errors but low spectacle compliance in children is a significant issue in all income settings.

Objective

To determine the predictors of spectacle wear and reasons for non-wear in children randomized to ready-made or custom-made spectacles.

Design setting and participants

Children aged 11 to 15 years were recruited from government schools in Bangalore, India to take part in a randomised controlled trial comparing ready-made and custom-made spectacles. Spectacle wear and reasons for non-wear were assessed at unannounced visits to schools 3-4 months after children were given their spectacles. Children not wearing their spectacles were asked an open-ended question to elicit reasons for non-wear.

Main outcomes and measures

Predictors of spectacle wear collected at baseline and the reasons for non-wear elicited at follow-up.

Results

At follow-up, 79% (362/460) children were traced, and 92 children (25.4%) were not wearing their spectacles (no difference between trial arms). Two variables were associated with spectacle wear: poorer presenting VA and improvement in VA with correction

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Children presenting with an uncorrected VA <6/18 in the better eye were nearly three times more likely to be wearing their spectacles at follow-up than children with a VA of <6/9-6/12 adjusted odds ratio 2.84 (95% CI 1.52-5.27). Improvement of 3-6 lines of acuity with correction had an adjusted odds ratio of 2.31 (95% CI, 1.19, 4.50), compared with an improvement of up to three lines, and an improvement of six or more lines had an adjusted odds ratio of 2.75 (95% CI 1.42-5.29). The main reason children gave for non-wear was 'teasing or bullying by peers' (48.9%). Girls reported parental disapproval as a reason for non-wear more frequently than boys (11.4% and 4.2%, respectively).

Conclusions and relevance

The predictors of spectacle wear poorer presenting VA and greater improvement in acuity with correction support the use of prescribing guidelines. Only children likely to perceive a benefit should be prescribed spectacles, reducing costs for programmes and parents. Interventions to reduce teasing and bullying must be gender appropriate.

Trial registration: ISRCTN14715120

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INTRODUCTION

Refractive errors (RE) affect people of all ages, both genders and in all settings i.e. high, middle and low income regions, urban and rural locations. Uncorrected refractive error is the most common cause of avoidable visual impairment and the second leading cause of blindness.[1, 2] Data from the Global Burden of Disease Study estimates there are 6.6 million people who are blind (presenting visual acuity (VA) worse than 3/60 in the better eye) and 101.2 million are visually impaired (presenting VA worse than 6/18 in the better eye), simply because they do not have a pair of spectacles.[3] In the United States, half the population over the age of 20 years has a RE.[4] Some regions and countries are disproportionately affected by visual impairment due to REs because of the increasing prevalence of myopia in Asia.[5]

Despite correcting REs being highly cost effective[6-8], uncorrected REs (uRE) are the most common cause of visual impairment in children. Global estimates from 2004

indicate that there are 12.8 million children visually impaired from uREs[2], i.e., 1% of all children, and this is set to rise, with the increasing incidence of myopia in what is now an 'epidemic' in East Asia, Europe and the United States.[5, 9, 10] Although the prevalence of REs varies by region, uREs are the leading cause of visual impairment in school aged children in all regions.[2]

Visual impairment can negatively impact on children's academic performance,[11] visual functioning, behavioural development[12] and quality of life.[8] For example, in a study in Mexico self-reported visual function improved with spectacle wear.[13] An Australian study found that children who failed vision screening had significantly lower academic achievement than their peers who passed screening.[14] There is also evidence from an American study where providing children with spectacles demonstrated a positive impact on academic performance and psychosocial wellbeing.[15]

The high prevalence of visual impairment due to uRE and the benefits of spectacle wear have led to large scale school eye health screening programs in many countries, including India. However, the delivery of these programs is not standardized and many do not monitor whether children actually use their spectacles.[16] Where studies have reported spectacle wear, it is difficult to compare the findings as different methods have been used (i.e., observed wear or self-reported wear), different time intervals have been used and definitions vary (i.e., some define wear as spectacles were being used at the time of assessment whereas other studies include children who had their spectacles at school). The available evidence suggests that low rates of spectacle wear are a significant issue in all income settings. For example, only 33.2% of native American students in the United States were wearing their spectacles[17] and 29.4% in rural areas near Delhi, India.[18]

Several studies have investigated reasons why children do not wear their spectacles which include loss/breakage,[19-22] misconceptions that using spectacles will make their vision worse,[16, 23,24] parental disapproval,[18,25] being teased[16,19,20,24-26] and forgetfulness.[20,21,23,25,27,28] In a recent Indian study,[29] reasons for not wearing spectacles included being teased (19.9%), the spectacles were broken (17.4%) or lost (9.3%) and the child did not like their spectacles (12%). Children with more severe uRE[17] and

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girls[23] are more likely to wear their spectacles. The evidence of associations between socioeconomic status and parental education and spectacle wear is inconclusive.[16,24,30,31]

The results presented in this paper are the secondary objectives of a non-inferiority randomized controlled trial undertaken in Bangalore, India the purpose of which was to compare spectacle wear in school children randomized to ready-made or custom-made spectacles.[32] Spectacle wear in both arms of the trial were similar,139/184 children (75.5%) in the ready-made arm and 131/178 (73.6%) in the custom-made arm (risk difference, 1.8%; 95% CI, -7.1% to 10.8%).[33] In this paper we report reasons for non-wear and predictors of wear amongst children recruited to this trial.

METHODS

The protocol for the trial was published in January 2016.[32] Primary outcome data i.e. spectacle wear at unannounced follow up visits, were published in June 2017.[33]

Recruitment took place between 12 January and 15 July 2015 from government schools in urban and peri-urban areas surrounding Bangalore, India. An information sheet in the local language was sent to the parents of each child aged 11-15 years prior to screening. If parents did not want their child to be screened they were requested to complete and return the form. Children were screened in the schools. Those who failed screening (i.e. presenting visual acuity (VA) <6/9 in one or both eyes) were referred to the study optometrist for complete objective and subjective refraction and to assess their eligibility for recruitment. To be eligible, all the following criteria had to be met: a) presenting VA of <6/9 in the better eye; b) VA with full correction improved by two or more lines in the better seeing eye, c) the spherical equivalent (sphere + ½ astigmatic correction dioptre (D)) corrected the VA to not more than 1 line less than best-corrected VA with a full prescription in the better eye, d) the difference between the spherical equivalent of right and left eyes was not more than 1.0D, e) inter-pupillary distance matched that of ready-made spectacle frames available (i.e., 54-62 mm), and f) spectacle frames were of acceptable size and fit. 86% of those who failed screening were eligible for recruitment. Children selected

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the spectacle frame they preferred from a range of six different colours of metal and plastic frames. The spectacles (ready-made and custom-made) were provided free and were delivered to children in schools at the same time. Children not meeting the strict eligibility criteria were dispensed spectacles but were not included in the trial. This included children with reduced VA in only one eye. Data on the following socio-demographic variables were collected from children recruited to the trial: parental literacy, parental spectacle wear, ownership of a mobile phone and the assets owned.

Spectacle wear and reasons for non-wear were assessed at the time of unannounced visits to the schools 3-4 months after children were given their spectacles. Spectacle wear was assessed by field workers who were masked to which arm of the trial the children were allocated to, who observed spectacle wear. Spectacle wear was categorised as follows: children were a) wearing their spectacles at the time of the visit; b) not wearing their spectacles but had them at school; c) were not wearing their spectacles but said they were at home; or d) children said they no longer had the spectacles as they were broken or lost.[16] Categories 1 or 2 were defined as wearing and categories 3 and 4 as non-wearing. At this visit, children in categories 3 and 4 i.e. were asked an open-ended question to elicit reasons for non-wear. A list of themes were developed based on a review of the literature, with the addition of further themes as required. All responses were coded accordingly.

Data for spectacle compliance and reasons for non-wear were double entered by the lead investigator throughout the trial. For the analysis of predictors of wear, descriptive analyses were used, tabulating the proportion of children wearing spectacles against the following predictors: age, gender, presenting VA in the better eye, improvement in VA with correction, parental literacy, parental spectacle wear, ownership of mobile phone and number of assets owned. We analysed all these variables in a multivariable logistic regression model. Presenting VA in the better eye and improvement in VA with correction were collinear so we included them in separate models. Data were analysed using STATA software (version 15.1; StataCorp).

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RESULTS

A total of 460 children eligible for ready-made spectacles were recruited and randomized: 232 to ready-made and 228 to custom-made spectacles. At follow-up, 79% (362/460) children were traced: 184/232 (79.3%) in the ready-made arm and 178/228 (78.1%) in the custom-made arm. 92 children (25.4%) were not wearing their spectacles, with no difference between arms of the trial. 48 (52.2%) were male, and 46 children were aged 11-12 years and 13-15 years in each arm.

Table 1 shows the association between predictors of wear (age, gender, presenting vision (better eye), improvement in VA with correction, parental literacy, parental spectacle wear, ownership of mobile phone, assets owned and allocation to the trial arm) and wearing spectacles at 3 to 4 months after they were prescribed. Only presenting vision (better eye) and improvement in VA with correction were strongly associated with spectacle wear, and this association remained after adjusting for all the variables in the table. These variables were collinear and were not included in the same multivariable model. Children who presented with a VA <6/18 in the better eye were nearly three times more likely to be wearing their spectacles than children with a VA of <6/9-6/12 adjusted odds ratio 2.84 (95% confidence interval (CI) 1.52-5.27). The odds of spectacle wear also increased with increasing improvement in VA with correction. Improvement of 3-6 lines of acuity had an adjusted odds ratio of 2.31 (95% CI, 1.19, 4.50) compared with an improvement of up to three lines, and an improvement of six of more lines had an adjusted odds ratio of 2.75, 95% CI 1.42-5.29).

The two most frequent reasons for non-wear in this cohort were 'teasing or bullying by peers' (48.9%), and 'lost/forgot/stolen spectacles' (26.1%)(Table 2). These two reasons accounted for three quarters of non-wear. Headaches or the spectacles were uncomfortable were uncommon reasons and did not differ according to whether the child had ready-made or custom-made spectacles. Reasons for non-wear were explored by gender and age (Table 3), using the age groups 11-12 years (pre-adolescent) and 13-14 years (adolescent). In both age groups 'teasing/bullying by peers' was the main reason for non-compliance, followed by 'lost/forgot/stolen spectacles'. Girls reported parental disapproval as a reason for non-wear more

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frequently than boys (11.4% and 4.2%, respectively), and boys reported headaches or discomfort more often than girls (10.4% and 4.5%, respectively). Younger children were more likely to report that their spectacles were broken than older children (8.7% and 2.2%, respectively). There were no significant differences in the proportion of boys or girls or younger or older children for any of the reasons for non-wear (two-sample test of proportions). Only two children reported 'no perceived benefit' and one disliked the appearance of the spectacles as a reason for non-wear.

DISCUSSION

In multivariable analysis, the two statistically significant predictors of spectacle wear were poorer presenting VA and a greater improvement in acuity with correction. These findings reflect the reasons reported by children, as only one child reported no perceived benefit as the reason for non-wear. Our findings support the use of prescribing guidelines, which means that only children likely to perceive a benefit are prescribed spectacles. Prescribing guidelines will also reduce over prescribing, so increasing the cost effectiveness and reputation of school eye health programmes. Two studies report the use of prescribing protocols, one in Australia and a group of studies in China. The Australian study was population based, where children were considered 'in need of refractive correction' if the VA improved in the better eye by at least two lines.[31] The authors highlighted the need for evidence-based prescribing of spectacles as children seldom wear low prescription spectacles. In the Xichang Paediatric Refractive Error Study, a school-based study of spectacle wear among 1,900 children in China, a referral protocol was used. Spectacles were recommended for children whose VA improved by two or more lines with refraction.[24]

As in other studies, the main reason children gave for not wearing their spectacles was teasing or bullying by their peers.[26,29,34,35] It would have been useful to explore this in more depth through interviews with the children given spectacles as well as among a group of children not requiring spectacles. Teasing and bullying reason may also have been under reported, as children may not have felt they could express these views, instead reporting that the spectacles were lost or broken or that their parents disapproved.

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The second reason for non-compliance in both age groups and in boys and girls was that the spectacles were lost, they had forgotten to bring them to school or they had been stolen. This has also been cited in studies from Saudi Arabia,[36] Chile,[35] USA[17] and Mexico[19] and other studies in India.[29,34,37] One way to address this would be for class teachers to be given a spare pair of spectacles. Two studies to our knowledge have used this strategy, both in the USA.[17, 20] The first actively involved teachers by giving them a list of the children in their class prescribed spectacles and which activities the children needed to wear them for. The teacher was responsible for monitoring and encouraging children to use their spectacles.[20] In the second study teachers were also given a spare pairs of spectacles but had no other responsibility with regards to spectacle wear.[17] In the first study, at follow up 11.2% of children reported that their spectacles were broken and 2.7% that they were lost. In the second study 80% of children reported that their spectacles were broken or lost. This suggests that supplying a spare pair of spectacles via teachers can help to address non-wear but the engagement of teachers is also important.

In our study girls were more likely to express parental disapproval as a reason than boys, which has been reported in other studies, including two in India.[19,23,29,34,36,38,39] In the Indian studies parents were concerned that wearing spectacles would adversely affect the marriage prospects of their daughters[18] and that girls would be 'singled out' for wearing spectacles.[40] Unpublished data from another study we have undertaken in India,[42] provides an explanation for these views, as parents considered that spectacle wear implied a disability. Indian parents are, therefore, more likely to stop girls from wearing spectacles and have greater anxiety about them wearing spectacles.[41]

Seven children reported non-wear because of 'headaches or the spectacles were uncomfortable. All the children reporting headaches were refracted again, and only one required a modified prescription. The other children had their spectacle frame adjusted and were satisfied. Only one child reported that they did not wear their spectacles because they gave no improvement in vision, which is likely to reflect the stringent prescribing guidelines used in the trial. Several studies from different regions of the world have also reported no perceived benefit as a reason for non-wear

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varying from 2.4% in the United States,[17] to 8.7% in Mexico[19] and 25.6% in Saudi Arabia.[36]

In our study, no child reported the appearance of their spectacles as a reason for non-wear, which is in contrast to many other studies undertaken in a range of high, middle and low-income settings, including India.[16,17,19,29,34-36] In our study, we offered a range of different plastic and metal coloured frames for children to choose from. This highlights the importance of giving children the opportunity to decide what they want to wear.

A limitation of this study was that we did not ask children who were wearing their spectacles why this was the case. This would be of benefit, providing insights which could be used in health education. Another limitation was that we were not able to have in-depth discussions with the children about the reasons they gave for non-wear. For further studies, it would be beneficial to explore the attitudes of parents and the role they could play in influencing spectacle wear, particularly amongst girls. This will ensure that relevant and appropriate messages are sent to parents of children who require spectacles. Our study highlights the importance of building culturally relevant and gender norms within any intervention. There are examples of this from other interventions in India from HIV research,[43] where the authors recommended preliminary qualitative research, to influence and guide the intervention strategies.

Implications for programmes

Only two other studies have reported the use of prescribing guidelines in school programs. This is an important guideline to adopt as only children who are likely to perceive a benefit are prescribed spectacles. This approach also can reduce costs to programs and parents. We also used a stringent prescribing guideline of VA improvement binocularly, which better reflects how a child is likely to function visually. Again, this can influence compliance, as children will be able to recognise the improvement in their vision when wearing their spectacles.

Programs for the correction of RE in school children should address the most important reasons for non-compliance with spectacle wear. In our study compliance

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might have improved by increasing awareness of the benefits of spectacle wear amongst teachers and parents, and by giving a spare pair of spectacles to classroom teachers and asking them to encourage spectacle wear. Interventions to reduce teasing and bullying is more challenging as it would require interventions which address societal norms and attitudes.

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Table 1: Univariate and multivariable analysis of factors associated with spectacle wear

	Wear (n=270)		Non-wear (n=92)		Crude odds ratio (95% CI)	Adjusted odds ratio*	p
Age group							
11 to 13	125	46%	44	48%	1	1	Reference
14 to 15	145	54%	48	52%	1.06 (0.66, 1.71)	1.02 (0.62, 1.67)	0.95
Gender							
Male	134	50%	48	52%	1	1	Reference
Female	136	50%	44	48%	1.11 (0.69, 1.78)	1.12 (0.68, 1.84)	0.65
****Presenting vision (better eye)**							
<6/9 to 6/12	60	22%	33	36%	1	1	Reference
<6/12 to 6/18	83	31%	35	38%	1.30 (0.73, 2.34)	1.28 (0.71, 2.32)	0.42
<6/18	127	47%	24	26%	2.91 (1.56, 5.44)	2.84 (1.52, 5.27)	<0.00
****Improvement in VA with correction**							
≤3 lines of improvement	82	30%	38	41%	1	1	Reference
>3 to 6 lines of improvement	93	34%	38	41%	1.13 (0.66, 1.94)	2.31 (1.19, 4.50)	0.01
>6 lines of improvement	95	35%	16	17%	2.75 (1.42, 5.29)	2.57 (1.32, 5.01)	<0.00
Parental literacy							
Father							
Cannot read	97	36%	36	39%	1	1	Reference
Can read	156	58%	49	53%	1.18 (0.73, 1.95)	1.23 (0.73, 2.10)	0.42
No father	17	6%	7	8%	0.90 (0.34, 2.36)	1.01 (0.37, 2.77)	0.98
Mother							
Cannot read	124	46%	36	39%	1	1	Reference
Can read	144	53%	53	58%	0.79 (0.48, 1.28)	0.73 (0.44, 1.24)	0.25
No mother	2	1%	3	7%	0.19 (0.03, 1.24)	0.21 (0.33, 1.37)	0.1
Parental spectacle wear							
Neither parent	206		74	80%	1	1	Reference
One or both parents	64	24%	18	20%	1.28 (0.71, 2.30)	0.78 (0.42, 1.47)	0.45
Ownership of mobile phone							
Both	133	49%	50	54%	1	1	Reference
Mother only	37	14%	13	14%	1.07 (0.52, 2.18)	0.85 (0.34, 2.09)	0.72
Father only	86	32%	23	25%	1.41 (0.80, 2.48)	0.67 (0.36, 1.23)	0.19
Neither parent	14	5%	6	7%	0.88 (0.32, 2.42)	0.87 (0.30, 2.60)	0.81
Assets owned							
None or one	119	44%	45	49%	1	1	Reference
Two	117	43%	37	40%	1.20 (0.72, 1.98)	1.19 (0.70, 2.01)	0.51
Three or four	34	13%	10	11%	1.29 (0.59, 2.82)	1.28 (0.57, 2.90)	0.54
Trial arm							
Ready-made	139	51%	45	49%	1	1	Reference
Custom-made	131	49%	47	51%	1.11 (0.69, 1.78)	1.10 (0.67, 1.80)	0.69

*Adjusted for all variable in the model ****** Included in separate models because of collinearity

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Table 2: Reasons for not wearing spectacles by allocation group

	Ready-made		Custom-made		Total	
	N	**%**	**N**	**%**	**N**	**%**
Teasing or bullying by peers	24	53.3 %	21	44.7 %	45	48.9
Lost/forgot/stolen spectacles	14	31.1 %	10	21.3 %	24	26.1
Parental disapproval	2	4.4%	5	10.6 %	7	7.6
Headache/spectacles feel uncomfortable	3	6.7%	4	8.5%	7	7.6
Broken spectacles	2	4.4%	3	6.4%	5	5.4
Does not wear for sports	0	0.0%	1	2.1%	1	1.1
No perceived benefit of spectacles	0	0.0%	1	2.1%	1	1.1
Does not like appearance of spectacles	0	0.0%	1	2.1%	1	1.1
Moved to the front of the class	0	0.0%	1	2.1%	1	1.1
Total	**45**	**100**	**47**	**100**	**92**	**100**

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Table 3: Reasons for not wearing spectacles by age and gender

Reasons for non-compliance	Age group (years)				Gender				Total	
	11-12		13-15		Male		Female			
	N	%	N	%	N	%	N	%	N	%
Teasing or bullying by peers	20	43.5%	25	54.3%	24	50.0%	21	47.7%	45	48.9%
Lost/forgot/stolen spectacles	15	32.6%	9	19.6%	10	20.8%	14	31.8%	24	26.1%
Parental disapproval	3	6.5%	4	8.7%	2	4.2%	5	11.4%	7	7.6%
Headaches or discomfort	2	4.3%	5	10.9%	5	10.4%	2	4.5%	7	7.6%
Broken spectacles	4	8.7%	1	2.2%	4	8.3%	1	2.3%	5	5.4%
No perceived benefit	1	2.2%	0	0.0%	0	0.0%	1	2.3%	1	1.1%
Does not wear for sports	1	2.2%	0	0.0%	1	2.1%	0	0.0%	1	1.1%
Dislike appearance of spectacles	0	0.0%	1	2.2%	1	2.1%	0	0.0%	1	1.1%
Moved to the front of the class	0	0.0%	1	2.2%	1	2.1%	0	0.0%	1	1.1%
Total	**46**	**100%**	**46**	**100%**	**48**	**100%**	**44**	**100%**	**92**	**100%**

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SECTION A – Student Details

Student	Priya Morjaria
Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Ophthalmic Epidemiology
Please list the paper's authors in the intended authorship order:	Neda Minakaran, Kevin Frick, Priya Morjaria, Clare Gilbert
Stage of publication	**Not yet submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Study concept and design; Acquisition of data; Drafting of manuscript;

Student Signature: [redacted] **Date:** 03 May 2018

Supervisor Signature: [redacted] **Date:** May 3 2018

Cost-minimization analysis from a non-inferiority trial of Ready-Made versus Custom-Made Spectacles in schools in India

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INTRODUCTION

Uncorrected refractive error is the leading cause of visual impairment in children, affecting an estimated 1%, or 13 million children worldwide (1). Correcting refractive error has been shown to be highly cost-effective (2), improving visual function and quality of life. Many countries, including India, have introduced school-based programmes to address these high levels of correctable visual impairment (3), and such school-based screening and fitting of spectacles has also been shown to be cost-effective (4). A recent Cochrane Review concluded that vision screening plus provision of free spectacles improves the number of children who have and wear the spectacles they need compared with providing a prescription only (5).

The provision of free spectacles to children in school eye health programmes has great cost implications for the organisations involved, although this strategy reduces costs for parents. In some low-resource settings, ready-made spectacles have been used for spectacle delivery programmes to reduce cost-restraints (6-10). These are low cost spectacles that can be used to correct simple refractive errors with no astigmatism and minimal difference in spherical correction between the two eyes. An inventory of such spectacles in commonly prescribed powers can be stored to be dispensed immediately to those requiring them. Complex refractions and those including astigmatic or anisometric correction are not suitable however, and still require custom-made spectacles to be dispensed. These are not only more expensive to manufacture, but require extra resources such as dispensing optometrist and technician time, and added cost of delivering the spectacles to schools.

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Whilst several studies have demonstrated equivalent effectiveness of ready-made versus custom-made spectacles in the school-aged population (11, 12), there have been no cost-analyses to demonstrate whether such programmes are potentially cost-saving. There has been one cost-effectiveness analysis of ready-made versus custom-made spectacles in the adult population, which was conducted alongside a randomised controlled trial in an urban hospital in Delhi, India. (13) This study concluded that ready-made spectacles were highly cost-effective, with an estimated incremental cost per quality-adjusted life year gained of between US$0.44 and US$23.74.

To our knowledge, school-based eye-screening programmes in India currently dispense custom-made spectacles only, regardless of severity or type of refractive error. This study reports an economic evaluation conducted alongside a randomised clinical trial comparing provision of ready-made versus custom-made spectacles for children aged 11-15 years in a schools in urban and peri-urban areas surrounding Bangalore in Karnataka State. The trial had a non-inferiority design, with a non-inferiority margin of 10%. This margin was chosen to balance considerations of efficacy and secondary benefits i.e., the lower cost of ready-made spectacles, and the maximum difference we were prepared to tolerate if ready-made spectacles were not to be considered clinically inferior. The primary outcome of the trial was the proportion of children wearing their spectacles at unannounced visits 3-4 months after the spectacles were delivered to schools. (14). At follow up the difference in spectacle wear between the two arms of the trial was 1.8% (95% confidence interval -7.1% to 10.8%; 75.5% in the ready-made arm and 73.6% in the cust-made arm), so justifying a cost minimization analysis.

The objective of this study was to describe the costs incurred if custom-made spectacles only had been available in this trial and costs if ready-made spectacles were also available. By calculating cost-differences per child needing spectacles, it is possible to estimate cost-savings from providing ready-made spectacles in school-based screening programmes. Key cost drivers are examined to inform a discussion of factors to consider in implementing ready-made spectacle provision in school-based programmes at a national or international level.

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The randomised controlled trial

Full details of the trial are published elsewhere (14,15). Briefly, government schools surrounding Bangalore were stratified by location and size, and selected for inclusion by block randomisation. Children aged 11-15 years at these schools were offered vision screening by trained field workers. Those who failed screening (visual acuity <6/9 in each eye) were referred to study optometrists for further assessment. Children confirmed with a VA of less than 6/9 in both eyes underwent objective and subjective refraction with assessment for frame size to ascertain whether they fulfilled eligibility criteria for the trial. To be eligible for recruitment, the following criteria had to be met: (1) VA with full correction improved in the better- seeing eye by 2 or more lines, (2) the SE corrected the VA to not more than 1 line less than best-corrected VA with a full prescription in the better eye, (3) the difference between SE of the right and left eyes was not more than 1.0 diopter (D), (4) interpupillary distance matched that of ready-made spectacle frames available (ie, 54-62 mm), and (5) spectacle frames were of acceptable size and fit. Exclusion criteria consisted of other causes of visual impairment and lack of parental consent. Ineligible children were prescribed custom-made spectacles or referred to Sankara Eye Hospital.

After recruitment, children were randomly assigned to ready-made or custom-made spectacles. All children had the same choices of frames. The custom-made spectacles were made at Sankara Eye Hospital by an optical technician, and all spectacles were delivered to the school at the same time, within 2 weeks of refraction, to maintain masking. Children, teachers, and parents were masked to the allocation arm, as were the field workers and optometrist assessing the primary outcome. The primary outcome of the trial was proportion of children wearing their spectacles at unannounced visits 3-4 months after the intervention.

The trial was a non-inferiority trial, powered to detect a non-inferiority margin of 10%. In the trial, of 23 345 children who underwent screening at 112 government schools, 535 underwent assessment for ready-made spectacles, and 460 (86%) were eligible for inclusion in the trial and randomised to ready-made or custom-made spectacles. Overall, 362 of 460 children (78.7%) were identified in their schools at follow-up. 139 of 184 (75.5%) children in the ready-made arm and 131 of 178 (73.6%) in the custom-made arm were wearing their spectacles or had them at school at follow-

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up, with a risk difference between the 2 arms was 1.8% (95% CI, –7.1% to 10.8%). The results demonstrated that, at the 3- to 4-month follow-up, spectacle wear was SIMILAR IN BOTH ARMS.

METHODS

Cost-analysis

Given the non-inferiority demonstrated of ready-made versus custom-made spectacles, the economic evaluation method used for this study was a cost-minimisation approach. Although this technique is not often used as a tool for cost comparisons in the health economics field, where the benefits or utility of alternative approaches may differ (16, 17), it is valid where the effects of alternative programs are demonstrably similar (18), as in this case.

The analysis has been conducted from a service provider perspective. We used real costs where available, determined in Indian Rupees and converted into US dollars using the exchange rate in 2015 of (1USD = 65 Indian Rupees). Data taken directly from the trial were used for many of the parameters required in the cost calculations. This included the proportion of the 535 children (of the 23345 screened) requiring spectacles who were eligible for ready-made spectacles (460 children) and proportion requiring custom-made spectacles whichever programme was employed, as they were not eligible for ready-mades (75 children). It also included the number of schools (112) and proportion of schools with children who required spectacles and were eligible for ready-mades (79).

Where real data was not available regarding resource use, assumptions were made based on expert opinion, and these have been outlined below. The costs of the initial vision screening were not included in the analysis, as these would be the same regardless of the type of spectacles dispensed. The costs of the trial (project) management were also excluded. For calculating personnel costs, it was assumed that there were 225 school days in a year (19), and 240 working days in a year (20).

Cost of refraction

The cost of refraction for each child requiring spectacles was calculated based on inclusion of personnel and equipment costs.

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For personnel costs, monthly salaries of the optometrists performing the refractions were identified, and converted into a daily cost per optometrist performing school refractions based on there being 225 school days available for refraction per year. In a custom-made only programme of delivery of spectacles, it was estimated that each optometrist could refract 20 children per day. In a programme where ready-made spectacles were available, as in the trial, each optometrist could refract only 15 children per day. The reason for the lower number is the extra thinking/processing time required for the optometrist to deem whether or not the child's refraction would be suitable for ready-made spectacles, or whether custom-made spectacles would be required. Also extra time is required to fit the ready-made spectacles at the time of prescribing.

For equipment costs, the unit costs of a LogMAR chart, retinoscope, trial set and trial frame were identified, as required per refracting optometrist. It was estimated that the LogMAR chart, retinoscope and trial frame would have a workable longevity of 3 years, and the trial set of 2 years. The equipment cost per child refracted in the two groups was calculated based on numbers of children the optometrists could refract over the usable life-time of the pieces of equipment, again based on 20 children being refracted per day in a custom-made spectacles only programme and 15 in a ready-made spectacles programme.

Cost of dispensing custom-made spectacles

Only personnel costs were included in the cost of dispensing custom-made spectacles. Buildings and other overhead costs such as utilities, insurance, land rental, and general supplies for Sankara Eye Hospital, where the spectacles were manufactured, were not included due to the limited scope of this study. Manufacturing costs were also not included, as it was assumed that these were captured by the unit costs of the spectacles themselves.

Monthly salaries of the dispensing optometrists were identified, and converted into a daily cost, based on there being 240 working days available for dispensing per year. It was estimated that the dispensing optometrist could manufacture 10 pairs of custom-made spectacles per day, and from these data the dispensing optometrist's cost per pair of custom-made spectacles was calculated. The number of custom-made spectacles dispensed in either programme from the RCT data (535 in custom-made

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only programme; 75 in ready-made programme) was used to calculate the cost of dispensing custom-made spectacles per child needing them..

Cost of spectacles

The unit costs of ready-made spectacles, low-prescription custom-made, astigmatic custom-made and high myopic custom-made spectacles were identified. The RCT data were used to determine the proportions of each type of spectacle that would be required in a custom-made only and in a ready-made spectacles programme. From this the total cost of spectacles and the cost of spectacles per child needing them could be calculated.

Cost of transport/delivery of custom-made spectacles

Transport costs to deliver the custom-made spectacles (from Sanakara Eye Hospital where they were manufactured to the schools) comprised vehicle rental and fuel, and personnel costs (driver salary). RCT data were used regarding number of schools to be visited, and mean number of spectacles requiring delivery per school. Estimates were made regarding the number of schools that the cars could visit per day, based on the number of spectacles that were being delivered to each school. The vehicle would have to wait at the school whilst the delivered spectacles were fitted to the children, so the more spectacles delivered per school, the fewer schools the cars could deliver to per day within the restricted opening hours of the school. It was estimated that for delivery of 1-2 pairs of spectacles per school, 4 schools could be visited per day, for 3-4 pairs this was 3 schools, for 5-6 pairs this was 2 schools and for 7 or more pairs only 1 school. These parameters were used to calculate total transport costs per child needing spectacles.

Cost of fitting custom-made spectacles

Personnel costs included the cost to fit the custom-made spectacles after delivery to the schools. Monthly salaries of the optometrists were identified, and converted into a daily cost per optometrist fitting spectacles based on there being 225 school days available for this activity per year. It was estimated that an optometrist could fit 30 children with spectacles per school day. These parameters, along with proportion of children requiring custom-made spectacles in the custom-made only and ready-made

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programmes (from RCT data) were used to calculate cost of fitting custom-made spectacles per child requiring spectacles.

Cost of training

Training of the optometrists (as well as the screeners) in school-based programmes is necessary whether ready-made spectacles are available or not. Personnel costs of the trainer only were included for the cost of training in this analysis, and not building/other overhead costs or opportunity costs with respect to time forfeited for the delegates, due to the scope of the study. Daily salary of the trainer was identified, and an assumption made that in the first year of a programme, 3 full days of training are required, and then for the following 3 years, 2 days of training per year are required. A further assumption was made that in 5th year, again 3 days of training would be required to refresh knowledge, and that this training cycle would continue. In the trial, each training session could accommodate 7 optometrists and this figure was used in the analysis. The cost of the trainer was applied to the total number of children that could be refracted by all optometrists trained in each training cycle (for each programme based on 15 per day in the ready-made programme and 20 per day in the custom-made only programme), to give the training cost per child needing spectacles.

<u>Cost-saving to programmes</u>

The total cost per child needing spectacles in a custom-made only programme and a ready-made spectacles programme was calculated by summation of the above components for each group. The cost-difference between the groups was calculated to give the cost-savings to programmes, in terms of cost-savings per child needing spectacles, and cost-savings per 100 children needing spectacles. Furthermore, these costs were applied to the proportion of children with uncorrected refractive error in the population studied (based on the numbers screened in the RCT), to give the cost-saving per 1000 children screened.

<u>Sensitivity Analysis</u>

To test the robustness of the results, sensitivity analyses were conducted to assess the impact of variation of input parameters on the cost-minimisation results. Univariate

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deterministic sensitivity analyses were conducted, varying personnel salaries, equipment costs, vehicle/fuel costs and spectacles costs by +/- 10%, and the number of school and working days per year by +/-10. Resource use parameters including number of children optometrists could refract per day and could fit custom-made spectacles to per day, number of custom-made spectacles dispensing optometrists could manufacture per day, life expectancy of equipment and days needed for training, duration of training cycle and number of optometrists trained per training day were varied by +/-25%. The number of schools that custom-made spectacles could be delivered to per day based on the average number of spectacles per school were varied by +/- 1 school for each category previously described.

A Tornado diagram was created to examine which of the above parameters the results and model was most sensitive to. These parameters were then used to perform multivariate deterministic sensitivity analyses to give 'best-case' and 'worst-case' results. Of particular importance was to determine whether the ready-made programme was still cost-saving using the 'worst-case' parameters.

Scenario analyses were also conducted to examine results when varying the prevalence of uncorrected refractive error by a larger range: 1% - 70%; and varying the proportion of children eligible for ready-made spectacles by a larger range: 70%-90%.

RESULTS

Base-case analysis

Table 1 shows the breakdown of the component costs per child needing spectacles for the custom-made only and ready-made programmes, and the overall cost-saving results. The cost per child needing spectacles in a custom-made only programme was USD$26.91, and in a programme with ready-made spectacles available was $11.15, giving a cost-saving per 100 children needing spectacles of $1575.97. This equated to a cost-saving per 1000 children screened of $361.17 (Table 1).

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Table 1: Base-case analysis results

Cost	Custom-made only programme	Ready-made programme	
Refraction	$1.09	$1.46	
Dispensing custom-made spectacles	$1.13	$0.16	
Spectacles	$10.85	$6.55	
Transport/delivery of custom-made spectacles	$13.21	$2.88	
Fitting custom-made spectacles	$0.62	$0.09	
Training	$0.01	$0.02	
Total cost per child needing spectacles	$26.91	$11.15	
Cost-saving per 100 children needing spectacles			**$1575.97**
Cost-saving per 1000 children screened			**$361.17**

Sensitivity Analysis

Univariate deterministic sensitivity analysis was conducted, varying one parameter at a time. The results are shown in table 2, and the resultant Tornado diagram in figure 1. The results were most sensitive to the parameter relating to the number of schools the cars were able to visit per day for delivery of the custom-made spectacles (this being related to the relatively high cost of vehicle rental and fuel). If the vehicles were able to deliver the custom-made spectacles to more schools per day, the cost-saving was more conservative, and vice-versa. In the base-case analysis it was assumed that for delivery of between 4 and 6 pairs of custom-made spectacles to each school, the cars were able to visit 2 schools per day. Reducing this to 1 school per day increased to the cost-saving per 100 children needing spectacles to $2609.12, and increasing it to 3 schools per day reduced the cost-saving to $1231.59.

The second most influential parameter was the proportion of children eligible for ready-made spectacles. The higher proportion of children were eligible for ready-made spectacles, the more substantial the cost-saving. In the base-case analysis, 460 of the 535 children (86%) who required spectacles were eligible for ready-mades, a figure taken directly from the RCT. Reducing this by 10% to 414 children (77%) reduced the cost-saving per 100 children needing spectacles to $1517.96, and increasing by 10% to 506 children (95%) increased the cost-saving to $2667.14.

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The cost of vehicle rental and fuel, of the low-prescription custom-made spectacles and of the ready-made spectacles also changed the overall cost-saving result more significantly than the other parameters, but within about +/-$100 per 100 children needing spectacles, which compared to the two parameters described above is still fairly modest.

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Table 2: Univariate deterministic sensitivity analysis

Parameter	Baseline value (USD)	Low value (USD)	High value USD)	Cost-saving per 100 children needing spectacles: low value (USD)	Cost-saving per 100 children needing spectacles: high value (USD)
Personnel salaries					
Optometrist (monthly)	350	315	385	1573.73	1578.21
Dispensing optician (monthly)	225	202.5	247.5	1566.3	1585.64
Driver (monthly)	280	252	308	1564.95	1587
Trainer (daily)	169.1	152.2	186	1576.01	1575.93
Transport					
Vehicle rental and fuel (daily)	125	112.5	137.5	1483.68	1668.26
Equipment					
LogMAR chart	1340	1206	1474	1576.30	1575.64
Retinoscope	505	454.4	555.5	1576.10	1575.85
Trial set	150	135	165	1576.03	1575.92
Trial frame	70	63	77	1576.04	1532.90
Spectacles					
Low prescription custom-made	10	9	11	1489.99	1661.95
High myopia custom-made	15	13.5	16.5	1575.97	1575.97
Astigmatism custom-made	20	18	22	1575.97	1575.97
Ready-made	5	4.5	5.5	1618.96	1532.98
RESOURCE USE					
Refraction: number of children optometrist can refract per day					
Custom-made only	20	15	25	1612.60	1554.00
Ready-made	15	11.25	18.75	1526.91	1605.41
Life expectancy of equipment (yr)					
LogMAR chart	3	2.25	3.75	1574.87	1576.63
Retinoscope	3	2.25	3.75	1575.56	1576.22
Trial set	2	1.5	2.5	1575.79	1576.08
Trial frame	3	2.25	3.75	1575.74	1576.11
Training					
No. of days in yr 1 of each cycle	3	2.25	3.75	1576.00	1575.94
No. of days in yrs 2,3,4 of each cycle	2	1.5	2.5	1576.04	1575.90
No. of yrs in each training cycle	4	3	5	1575.96	1575.98
No. of optometrists in each session	7	5.25	8.75	1575.84	1576.05
Dispensing of custom-made spectacles					
No. of spectacles dispensing optometrist can make per day	10	7.5	12.5	1608.21	1556.63
Delivery of spectacles: no. of schools driver/vehicle can visit per day					
>6 pairs of spectacles per school	1	1	2	1575.97	1575.97
4 to ≤6 pairs of spectacles per school	2	1	3	2609.12	1231.59
2 to ≤4 pairs of spectacles per school	3	2	4	1575.97	1575.97
≤2 pairs of spectacles per school	4	3	5	1575.97	1575.97
Fitting of custom made spectacles					
Children optometrist can fit per day	30	22.5	37.5	1593.80	1565.27
Number of children eligible for ready-made spectacles	460	414	506	1517.96	2667.14
Other					
No. of school days per year	225	215	235	1581.85	1570.59
No. of working days per year	240	230	250	1580.18	1572.10

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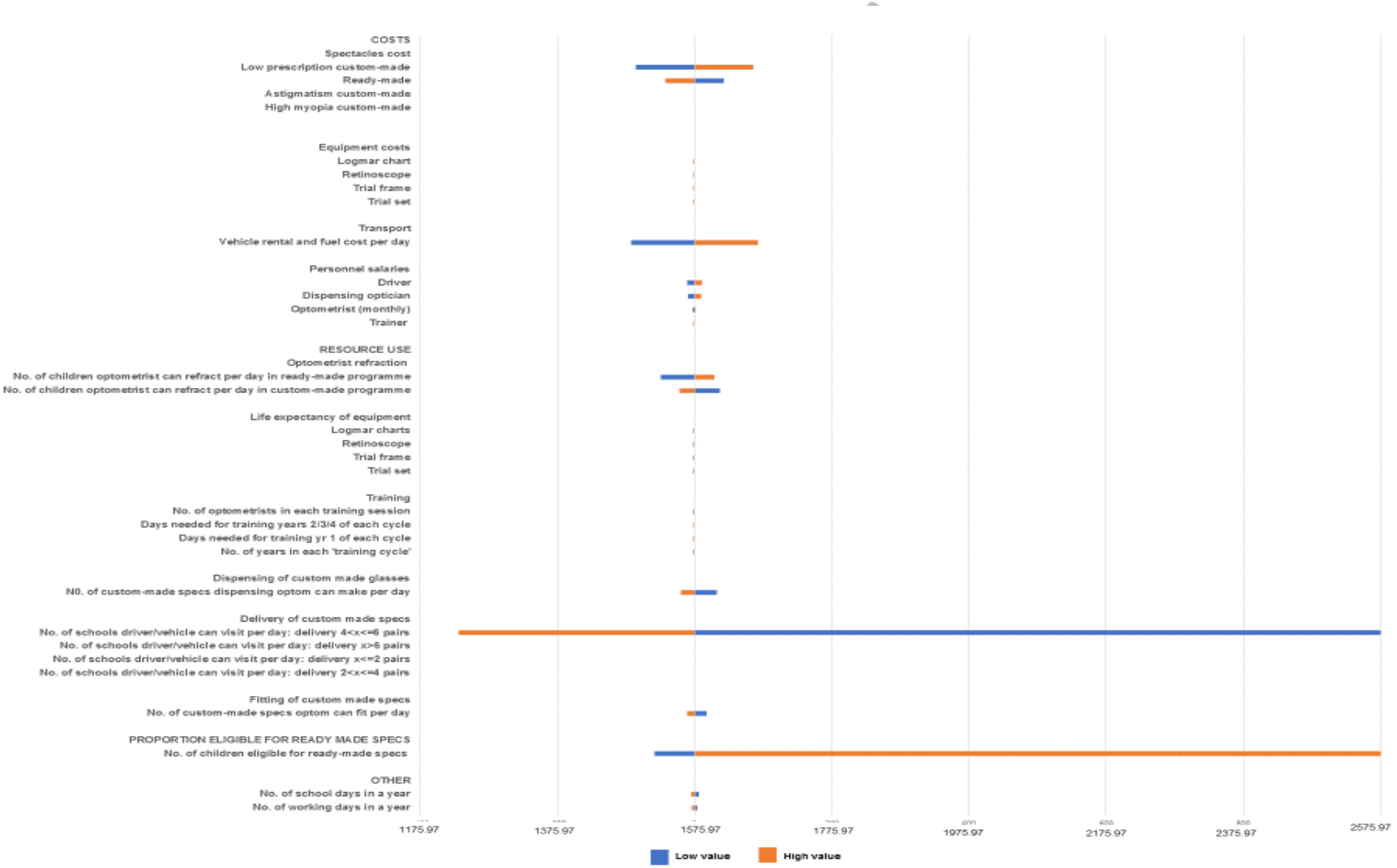
Figure 1: Tornado Diagram showing Univariate Deterministic Sensitivity Analysis: cost saving per 100 children needing spectacles



Multivariate sensitivity analysis was conducted, varying the five most influential parameters described above at the same time, to give 'worst-case' and 'best-case' scenarios. The results are shown in table 3. In the 'worst-case' scenario, the programme with ready-made spectacles is still cost-saving, at $995.97 per 100 children needing spectacles, or $228.25 per 1000 children screened. In the 'best-case' scenario, the cost-saving is $2993.59 per 100 children needing spectacles, or $686.04 per 1000 children screened.

Table 3: Multivariate deterministic sensitivity analysis

Parameter varied	**"Worst-case"**	**"Best-case"**
No. of schools driver/vehicle can visit per day to deliver delivery 4 to ≤6 pairs of custom-made spectacles	High	Low
No. of children eligible for ready-made spectacles	Low	High
Cost of vehicle rental and fuel per day	Low	High
Cost of low prescription custom-made spectacles	Low	High
Cost of ready-made spectacles	High	Low
Cost-saving per 100 children needing spectacles (USD)	**$995.97**	**$2993.59**
Cost-saving per 1000 children screened (USD)	**$228.25**	**$686.04**

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Scenario 1: Varying the proportion of children eligible for ready-made spectacles

In the RCT, the percentage of children requiring spectacles who were eligible for ready-made spectacles was 86%. Whilst in the sensitivity analyses this was varied by +/-10% (relative, not absolute), a more informative range, deemed from expert opinion, would have been to look at 70-90% eligibility. Results are shown in table 4. The cost-saving using this range would be from $1468.14 to $2636.24 per 100 children needing spectacles.

Table 4: Results when varying the proportion of children needing spectacles who are eligible for ready-made spectacles

Percentage eligible for ready-made spectacles	Cost (USD) per child needing spectacles: Custom-made only programme	Cost per child needing spectacles: Ready-made programme	Cost-saving per 100 children needing spectacles	Cost- saving per 1000 children screened
Base-case 86%	**$26.91**	**$11.15**	**$1575.97**	**$361.17**
70%	$29.31	$14.63	$1468.14	$336.46
90%	$36.27	$9.91	$2636.24	$604.15

Scenario 2: Varying the prevalence of uncorrected refractive error

In the RCT, the prevalence of uncorrected refractive error was 2.3%. Given the large variation in prevalence of refractive error globally, the variation in prevalence of uncorrected refractive error is also large. Using the range of 1-70% prevalence of uncorrected refractive error, the cost-saving per 100 children needing spectacles does not change, but the cost-saving per 1000 children screened changes substantially. Results are shown in table 5. The cost-saving per 1000 children screened would range from $157.60 to $11,031.80.

Table 5: Results when varying the prevalence of uncorrected refractive error in children aged 11-15 years

Prevalence of uncorrected refractive error	Cost per child needing spectacles: Custom-made only programme (USD)	Cost per child needing spectacles: Ready-made programme (USD)	Cost-saving per 100 children needing spectacles (USD)	Cost- saving per 1000 children screened (USD)
Base-case 2.23%	$26.91	$11.15	$1575.97	$361.17
1%	$26.91	$11.15	$1575.97	$157.60
70%	$26.91	$11.15	$1575.97	$11,031.80

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DISCUSSION

This analysis demonstrates that school-screening programmes for refractive error in children aged 11-15 years that utilize ready-made spectacles are significantly cost-saving compared to programmes where custom-made spectacles only are available. Using data from our RCT in India, the cost-saving is $1575.97 per 100 children needing spectacles, or $361.17 per 1000 children screened at a prevalence of uncorrected refractive error of 2.23%. Even when varying parameters to give a "worst-case" scenario, the ready-made programme is still more cost-effective, demonstrating the robustness of this conclusion.

Whilst the primary RCT did not look at quality adjusted life years (QALYs), and as such cost per QALY and incremental cost-effectiveness ratios were not calculated in this economic analysis, our results do support those of the only other economic analysis of ready-made spectacles, albeit in an adult population in India (13).

Given the magnitude of the problem of uncorrected refractive error in both India and globally, using ready-made spectacles in school-based screening programmes offers a highly cost-saving strategy for governments and organisations involved in setting up these programmes. Global trends appear to suggest that the incidence of myopia is increasing, with some authors estimating that 34% of the global population will be myopic in 2020 (21). The highest prevalence is seen in East Asia, where there has been an increase in myopia prevalence of 23% per decade, and where about 70% of children have myopia by age 15 years (22). School-based screening programmes for uncorrected refractive error will increasingly play a role in addressing this increase in prevalence, and as such it is important to have a strategy for minimising cost, with ready-made spectacles playing a part in this strategy.

The largest determinants of cost in the custom-made only programmes is both the cost of the spectacles themselves versus ready-made spectacles, and the cost of transporting and delivering them from the site of manufacture to the schools. Whilst transport costs and distances within this trial were specific to the location, it would be sound to assume that similar costs, distances and time constraints would be present in other semi-urban locations in India at least, if not also in other middle and

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low income countries. With more rural destinations it is likely that the transport and delivery cost of custom-made spectacles would be even higher, and as such having an inventory of ready-made spectacles available for immediate dispensing at the schools would significantly increase the cost-savings.

The study does have some limitations. Firstly, we did not include many itemised costs related to manufacture and dispensing of the custom-made spectacles, such as the hospital buildings, utilities and overhead costs. Inclusion of these, if anything, would have increased the cost per child needing spectacles in the custom-made only programme relative to the ready-made programme, and as such increased the overall cost-saving result. We also performed a financial rather than fully economic analysis, as we did not include opportunity costs. For example, we did not account for the time that the optometrists who were attending training sessions effectively 'lost' with respect to refracting and fitting spectacles. However, given that these personnel costs were not the main drivers in the difference in overall costs between the two programmes, it is unlikely that much change would have been seen in the cost-saving result. In a study where quality of life measures were employed, we may have seen inclusion of the opportunity cost from delay in children receiving their spectacles in a custom-made only programme versus a ready-made programme would have in fact also increased the cost-saving or cost-effectivenesss result in favour of ready-made spectacles.

A further limitation is that we did not include cost of maintaining an inventory of ready-made spectacles which would include the opportunity cost of investing the cost of spectacles up front and the cost of storing the spectacles before they are issued. This may have reduced the overall cost-saving figure. However, it is important to note that a recent innovation, termed '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. Availability of such ready-made spectacles would likely also increase the proportion of children eligible for ready-made spectacles, as anisometropic non-astigmatic prescriptions could also be issued as ready-made spectacles rather than having to be custom-made, as lenses of different powers for each eye could be clipped in.

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Conclusions

Our study is the first, to our knowledge, to demonstrate the significant cost-saving potential for using ready-made spectacles in school-based screening programmes for uncorrected refractive error, versus using custom-made spectacles alone. This can have substantial economic benefits for large, national and international programmes. Ready-made spectacles are currently not commonly used or available, and anecdotally there has been some resistance amongst clinicians to use them. However, with these results demonstrating the clear economic benefit of such spectacles, this may be a step towards supporting and creating behaviour change amongst clinicians.

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Use of ready-made spectacles in school eye health programmes

Priya Morjaria
Research Fellow and Public Health Optometrist: International Centre for Eye Health, London, UK.

Ready-made spectacles are suitable for a high proportion of children with refractive errors – but not everyone can benefit.

The most common means of correcting refractive errors is with spectacles. Spectacles are prescribed and dispensed with corrective lenses that give the best visual acuity and are comfortable. Custom-made spectacles (i.e., made up for each individual) are more expensive, but they are essential in some cases, i.e., when a person requires astigmatic correction or needs different power lenses in each eye (anisometropia).

A standard way to report refractive error is to use the 'spherical equivalent', which is calculated as the sphere plus half the cylinder, in dioptres (for example, the spherical equivalent for a refractive error of +2.0D with a -1.0D cylinder is 2 + (-1.0/2) = 1.5D). In children who have no or low astigmatism, and only a small difference between the left and right eyes, their refractive error can be corrected using a pair of ready-made spectacles: low cost, high quality spectacles that have been pre-fitted with pairs of lenses of the same spherical equivalent.

Advantages and disadvantages

The advantage of ready-made spectacles is that they are less expensive, can be dispensed immediately in schools or clinics, and require less time to dispense.

The drawback to ready-made spectacles is that it requires a large inventory of frames in different sizes, colours and shapes, each with a range of power lenses. They are only suitable if the prescription in both eyes is the same and lenses are seldom available in powers of over +/-3.5 D. That said, evidence from studies in Cambodia, China and India indicate that 70–90% of children with uncorrected refractive errors could benefit from ready-made spectacles.[1, 2, 3]

2.5 New Vision Generation, an Essilor Group initiative, has produced a range of spectacles called 'Ready-to-Clip' that allows on-the-spot delivery. The lenses, which are interchangeable between right and left, are clipped into the person's chosen frame according to their individual prescription. Lenses of different powers can be used in each eye, which means that some children with anisometropia can also benefit. Inventory is also reduced.

PRIYA MORJARIA

Figure 1 Lens being clipped into a 'clip-and-go' spectacle frame.

Conclusion

Despite the many advantages of ready-made spectacles, it is important to identify which children have refractive error needs that cannot be met by ready-made spectacles; these children need custom-made spectacles made up by a dispensing optician (Table 1). Those who prescribe and dispense spectacles must be trained to be able to distinguish which type of spectacles would be suitable for each child.

Custom-made spectacles and ready-made spectacles should only be dispensed by a trained person, based on appropriate refractive technique, e.g., retinoscopy undertaken by a competent practitioner. All children who require spectacles must have their inter-pupillary distance measured to ensure the correct size spectacles are fitted (Figure 2).

Figure 2
Measuring the inter-pupillary distance

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Table 1 Indications for ready-made and custom-made spectacles

	Ready-made spectacles	Custom-made spectacles
Improvement in vision with spherical equivalent lenses	The same or only one line less than with full correction	Visual acuity with full correction is more than one line better than with the spherical equivalent
Difference in the spherical equivalent in right and left eyes	Not more than 1.00D	More than 1.00D
Astigmatism	Maximum of 0.75D cylinder in both eyes	More than 0.75D cylinder in one or both eyes
Maximum spherical equivalent	+ or -3.50D	No limit
Inter-pupillary distance between the eyes and the frames available	Not more than +/- 2 mm	This may be more than +/- 2 mm
Comfort of spectacle frames	As comfortable as custom made spectacles	

Chapter 5. Trial 2: Effectiveness of a novel mobile health education intervention (Peek) on spectacle wear among children in India

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Trials

STUDY PROTOCOL Open Access

Effectiveness of a novel mobile health education intervention (Peek) on spectacle wear among children in India: study protocol for a randomized controlled trial

Priya Morjaria[1*], Andrew Bastawrous[1], Gudlavalleti Venkata Satyanarayana Murthy[2], Jennifer Evans[1] and Clare Gilbert[1]

Abstract

Background: Uncorrected refractive errors are the commonest cause of visual loss in children despite spectacle correction being highly cost-effective. Many affected children do not benefit from correction as a high proportion do not wear their spectacles. Reasons for non-wear include parental attitudes, overprescribing and children being teased/bullied. Most school programmes do not provide health education for affected children, their peers, teachers or parents.
The Portable Eye Examination Kit (Peek) will be used in this study. Peek has applications for measuring visual acuity with software for data entry and sending automated messages to inform providers and parents. Peek also has an application which simulates the visual blur of uncorrected refractive error (SightSim).
The hypothesis is that higher proportion of children with uncorrected refractive errors in schools allocated to the Peek educational package will wear their spectacles 3–4 months after they are dispensed, and a higher proportion of children identified with other eye conditions will access services, compared with schools receiving standard school screening.

Methods/Design: Cluster randomized, double-masked trial of children with and without uncorrected refractive errors or other eye conditions. Government schools in Hyderabad, India will be allocated to intervention (Peek) or comparator (standard programme) arms before vision screening. In the intervention arm Peek will be used for vision screening, SightSim images will be used in classroom teaching and will be taken home by children, and voice messages will be sent to parents of children requiring spectacles or referral.
In both arms the same criteria for recruitment, prescribing and dispensing spectacles will be used. After 3–4 months children dispensed spectacles will be followed up to assess spectacle wear, and uptake of referrals will be ascertained. The cost of developing and delivering the Peek package will be assessed. The cost per child wearing their spectacles or accessing services will be compared.

Discussion: Educating parents, teachers and children about refractive errors and the importance of wearing spectacles has the potential to increase spectacle wear amongst children. Innovative, potentially scalable mobile technology (Peek) will be used to screen, provide health education, track spectacle wear and adherence to follow-up amongst children referred.

Trial registration: Controlled-Trials.com, ISRCTN78134921. Registered on 29 June 2016.

Keywords: Uncorrected refractive errors, Children, School eye health, India, Spectacle wearing rate, Health education, Portable eye examination kit, Peek, Randomized clinical trial

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Background

Uncorrected refractive errors (uRE) are the commonest cause of visual loss in children.

The proportion of visual impairment due to uREs, defined as ≤6/12 in the better eye, in a group of standardized studies of children aged 5 to 15 years was 56.0% in Nepal [1], 56.3% in Chile [2], 61.0% in rural India [3], 63.6% in South Africa [4], 81.7% in urban India [5], 87.0% in Malaysia [6], 89.5% in rural China [7] and 94.9% in urban China [8]. Correcting refractive errors (RE) is highly cost-effective [9–11]. It is estimated that 12.8 million children worldwide are visually impaired from uRE [12].

Refractive errors can result from the axial length of the eye being too long or too short, and from abnormalities in the curvature of the cornea. The three most common types of REs are myopia (short-sightedness), hypermetropia (long-sightedness) and astigmatism (distorted vision at distance and near). Myopia is the commonest type of RE [13]. The onset is usually around the age of 8 years and increases in severity throughout adolescence [13]. Myopia is far more common in Southeast Asian children, where the age of onset is earlier and progression more rapid [13]. There is increasing evidence of the impact of correcting RE in children, with improvement in social development, quality of life, visual functioning and academic performance [14].

In India, there are approximately 140 million children aged 11–15 years, 5.6 million (4%) of whom have uRE and would benefit from spectacles. Correction of REs is a priority of the Government of India [15]. However, a high proportion of children who could benefit from RE correction do not wear their spectacles [16], reported as only 30% in a recent study in India [17]. There are many reasons for non-wear, including parents not purchasing spectacles, overprescribing and children being teased and bullied or not liking their spectacles [16]. Some parents fear that spectacles will weaken their child's eyes, are expensive and are stigmatizing, or indicate that their child has a disability [18]. In India, some programmes have trained teachers to screen vision, but teachers are not usually otherwise engaged in the process and they usually do not promote or monitor spectacle wear. It is not standard practice in India to send explanatory pamphlets to parents of children requiring spectacles and parents are not typically made aware of the benefits of spectacle wear.

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 [19]. Another recent trial in China had a factorial design with six subgroups. Children in half the schools were randomized to a health education intervention, which involved showing children a 10-minute documentary-style video, a booklet of cartoons, and classroom discussion led by teachers. The same schools were randomized 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 subgroups randomized to the health education intervention (RR 1.46 to 1.74) [14]. The other trial was of free versus low-cost spectacles in Tanzania, in which free spectacles almost doubled wearing rates [18].

A recent trial by the investigators in Bangalore, India showed that 2.6% of children aged 11–15 years had significant uRE, defined as a level of visual loss due to RE which improved by two or more lines of Snellen visual acuity (VA) in one or both eyes with spectacle correction. In this study, children could select the spectacle frames they preferred and almost 75% were wearing their spectacles at unannounced visits 3–4 months later [20].

Mobile phone technology is a rapidly expanding area in health care [21], including eye care [22]. A recent development, the Portable Eye Examination Kit (Peek) [23] has a suite of applications (apps), including for measuring VA [24] which has been found to be an acceptable tool for patients, examiners and stakeholders in a recent study in Kenya [25]. The Peek School Screening system enables automated text and voice messaging to parents/guardians and contact teachers as well as real-time notifications to refractive or hospital services of screened positive children who require further assessment or follow-up. Peek also has an app which generates images that simulate the visual blur associated with uRE (SightSim). (See Additional file 1: Figure S1.) A recent trial in schools in Kenya using the system demonstrated that teachers could be taught to screen VA reliably using the Peek app, and SightSim images (Polaroid photographs) and text messages were sent to parents. Uptake of referrals to eye care providers was two and a half times higher in the Peek intervention arm of the trial (unpublished data).

Research on why children with significant refractive errors do not wear their spectacles is limited, but the available evidence highlights the importance of environmental factors, particularly the negative attitudes of others i.e., peers, parents, the wider family and teachers, as well as community norms and attitudes [26, 27]. There are multiple theories and constructs which can be used to describe behavior or to bring about behavior change, and the Social Ecological Model (SEM), which describes five nested, hierarchical levels which influence behavior i.e., individual, interpersonal, organizational, community and public policy, has been adopted in this study as it encapsulates the main factors which influence spectacle wear among children [28]. The SEM emphasizes that it is easier to adopt healthier behaviors by bringing about change in the environment, by using the example of role models, and by reinforcement. In the trial being planned, SightSim images of relevance to

Indian children aged 11–15 years will be used, including images of role models such as sports personalities, and used in classroom teaching so that all children as well as teachers learn about the impact of uRE and the impact of correction. Children identified who need spectacles will also take home a SightSim image of their choice to show their parents, which demonstrates how much clearer their child's world would be if they wore their spectacles. Messages will be reinforced to parents through voice messages send to their mobile phones.

Purpose

The purpose of this cluster randomized trial is to evaluate whether a health education package for teachers, parents and children (aged 11–15 years), delivered using Peek increases spectacle wear at 3 to 4 months and uptake of referral of children identified with other eye conditions.

The trial will also assess the cost of developing and delivering the Peek health education intervention and the cost of dispensing and delivering the spectacles in both arms of the trial. The cost per child wearing their spectacles at follow-up will be compared between the two arms of the trial.

The hypothesis is that the proportion of children wearing spectacles 3–4 months after they were given their spectacles is higher in schools allocated to the innovative Peek educational package than in schools randomized to the standard programme. The uptake of referrals is also anticipated to be higher in the schools allocated to the Peek educational package than those randomized to the standard programme.

Formative research and pilot study November 2016

Formative research including a pilot study will be undertaken in non-trial schools to test all aspects of the trial, including which SightSim images to use and the content of voice messages to parents to remind them to encourage their children to wear their spectacles, or to access services. The formative research will use mixed methods, including focus group discussions separately with head teachers, parents of both boys and girls of different ages and also boys and girls of different ages. Focus group discussions with head teachers will gather their views of spectacle wear by children, views on using SightSim images to increase awareness among parents, and which images they consider the most suitable for parents.

Based on data from the focus group discussions, images will be selected for classroom teaching. These classroom education materials will be shown to children and they will be asked to give their opinion on activities that children with uncorrected refractive error might like to do but cannot do because they do not have clear enough vision. Children will be shown SightSim images of the visual blur experienced by children with uRE and they will be asked to express their reactions. Classroom teachers will also be asked to comment on the images suggested.

A short questionnaire to assess children's knowledge of and attitudes towards spectacle wear will be assessed immediately before and after a session of classroom teaching using SightSim images. In each school, two classes of different ages will be administered the questions before and after classroom teaching, a total of approximately 200 children aged 11–15 years.

Methods/design

The trial is designed as a cluster randomized, double-masked clinical trial of children with and without uRE in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [29]. Children will be masked to the allocation as they will not be told that other schools will have a different intervention, and field workers who collect the data for the primary outcome will also be masked to the hypothesis and intervention arm.

Study setting

The trial is being undertaken in government middle and secondary schools in urban and rural areas in and around Hyderabad, Telangana State, India. The trial is being coordinated by the Public Health Foundation of India (PHFI), Hyderabad. The team consists of a programme manager, administrator, optometrists, dispensing opticians, field workers and ophthalmologists. Training, quality assurance and oversight of data collection are being provided by staff at the International Centre for Eye Health, London School of Hygiene & Tropical Medicine (LSHTM).

Participant eligibility

Selection of schools

A list of government secondary schools will be obtained from the District Block Education Officer. The precise location of each school will be determined using Google Maps. Schools will be excluded if they already have school eye health programmes where screening took place within the previous 2 years, or are single-gender schools. If two schools are less than 10 km apart one will be excluded at random. Schools will be stratified by location (urban/rural) and size (more or less than 200 children aged 11–15 years).

The head teacher of each selected school will be visited by a field worker to obtain written informed consent for the school to participate. An information sheet in the local language with an opt-out option will be given to each child aged 11–15 years for them to take home. Parents will be given the option to opt out entirely i.e., that their child is not screened, or to opt out from being recruited to the trial.

Inclusion criteria

There are two mutually exclusive eligibility criteria in this study i.e. for spectacle correction and for referral. Common criteria for both are that children are aged 11–15 years inclusive, parents' consent for their child to take part in the study and the child proves assent, and they have a presenting VA (i.e. with spectacles if usually worn) of less than 6/9.5 in one or both eyes. Children will be eligible for immediate spectacle correction if their binocular VA with full correction improves by two or more lines. Children will be eligible for referral if they require cycloplegic refraction, if their presenting VA is 6/60 or less in one or both eyes regardless of the cause, if their best-corrected visual acuity does not improve by two or more lines in both eyes or they require further investigation for any other non-refractive eye conditions.

Exclusion criteria

Children will not be recruited if parents do not consent or the child does not assent. Children whose parents agree that they can be screened will be assessed and spectacles dispensed if required, or they will be referred, but will not be recruited to the trial. Children whose parents opt out entirely, but where the teacher suspects a problem will be given a letter to take home.

Eligibility of those performing interventions

All refractions, prescribing and dispensing are being undertaken by fully qualified optometrists, with training and quality checks by the lead investigator. All screening, delivery of spectacles and follow-up at 3–4 months will be conducted by trained field workers.

Identification of potential participants and recruitment

In the intervention arm, field investigators in the school identified by the head teacher will first undertake classroom teaching using the SightSim images for all children aged 11–15 years, after training. A training manual will be developed to standardize the delivery. Field workers will be trained in each school to screen VA using the Peek vision screener app at the Snellen equivalent 6/9.5 level of VA, and children aged 11–15 years will be screened. To pass vision screening a child needs to correctly see four or five of five consecutive E optotypes. Once screening has been completed, all those who fail will be automatically referred to a visiting optometrist and will be refracted on the same day. Attendance will be checked against the data in the Peek software. After identifying children requiring spectacles each child will select a SightSim image of their choice from a range of images, which they will be asked to take it home to show their parents.

In the schools allocated to the comparator arm, trained field workers will screen VA using a standard card-based E optotype at the 6/9.5 level at 6 meters. To pass at the 6/9.5 level children need to correctly indicate the orientation of the E in at least four out of five optotypes. No health education materials or voice messages will be sent to the parents (Fig. 1).

To standardize data recording, data will be entered using dedicated Peek software in both arms of the trial. The software will have range and consistency checks built in. Field workers and optometrists working in schools in both arms of the trial will be given tablets for data entry, and data will be regularly backed up onto a cloud server. In both arms of the trial the head teacher will be given a list of all the children in their school who require spectacles or referral. Classroom teachers will also be given a list of children in their class who require spectacles or referral.

The following information will be collected by trained field workers by interviewing all eligible children in both arms of the trial: name, age, gender, class and date of birth; parents' mobile phone number, language used in the home; parental education; occupation of parents; whether one or both parents wear spectacles for distance vision and limited information on household assets taken from National Household Survey questionnaires. Data on subjective refraction and best-corrected VA in each eye will be recorded as well as the prescription of the spectacles required and the frame the child selected from a selection of thirteen plastic frames of different colours. In the intervention arm, the SightSim image the child selects to take home will be recorded.

In both groups of schools, only children with significant REs will be prescribed spectacles i.e., where after correction, the acuity improves by two or more lines binocularly. Children will select the frames they prefer from a range of coloured plastic frames. Each pair of spectacles will have a unique code. Spectacles will be delivered to the schools by field workers at no cost as soon as possible and all children in each school will receive their spectacles on the same day. At the school, field workers will double-check the name of each child against the lists given to classroom teachers, to ensure that each child receives the correct spectacles. The field workers will measure children's VA with their new spectacles.

In both arms of the trial, children with other eye conditions will be referred using a referral slip indicating their study ID, name and school, indicating that assessment and treatment will be provided at no cost at Pushpagiri Eye Institute on presentation of the referral slip. An administrator will be appointed at Pushpagiri Eye Institute who will access lists generated by Peek software of all children referred. The administrator will enter the date of attendance of children who attend Pushpagiri Eye Institute into Peek software for children referred from the intervention and comparator arms of the trial.

In the intervention arm of the trial, voice messages will be sent to parents of children requiring spectacles in the

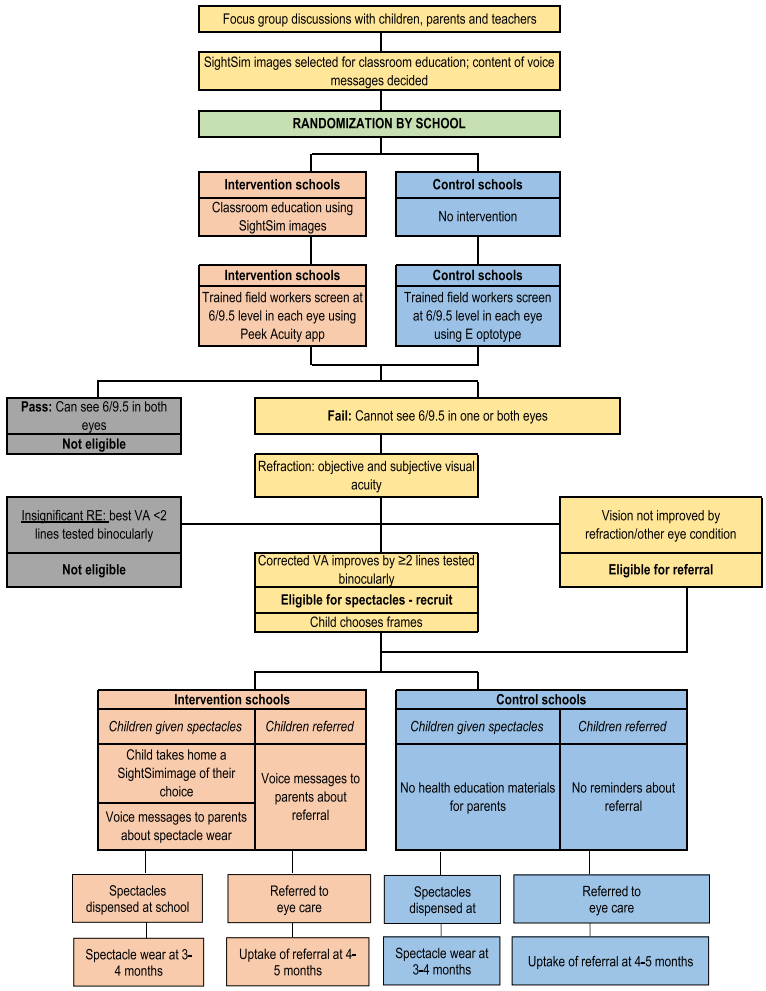

Fig. 1 Study flowchart

local languages within 1 week of their child being given their spectacles and again every 2 weeks for 3 months. Reminder messages will also be sent to parents of children referred within 1 week of referral and again every 2 weeks for 3 months if their child has not attended.

Fieldwork has been planned such that the initial assessment, delivery of spectacles and follow-up 3–4 months later do not coincide with school examination periods, long school holidays, nor the end of the school year when children may leave or change schools.

If the Peek education package is found to be superior to the control schools, the same package will be delivered after the 3–4 month follow-up.

Participant timeline and study flowchart

The study flowchart and participant timeline are presented in Figs. 1 and 2, respectively. A filled Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist is available (see Additional file 2).

Intervention and comparator arm

The intervention will be the Peek Acuity health education package. The comparator will be a standard school screening programme where no health education materials or messages are sent to parents (standard care) (Table 1).

Sample size calculation

A superiority margin of 20% was chosen to balance the anticipated higher costs of developing and delivering the Peek package. We estimate that we will need a study size of 450 children (225 in each arm) to detect a difference of 20% in spectacle wear between the intervention and comparator arm, assuming approximately 60% of children in the control arm will be wearing spectacles at follow-up, with a 95%

		STUDY PERIOD					
	Enrolment		Allocation	Post-allocation			Close-out
TIMEPOINT	$-t_2$	$-t_1$	0	t_1	t_2	t_3	t_4
ENROLMENT:							
Approvals: district education officer and head teachers	X						
Informed consent: parents		X					
Qualitative tools development		X					
Eligibility screen		X					
Allocation			X				
INTERVENTIONS:							
Peek package: Sightsim images & voice messages to parents				←	—	→	
Standard care				X			X
ASSESSMENTS:							
Spectacle wear Uptake of referrals						X	X

Fig. 2 SPIRIT timeline

confidence interval and 90% power. We have adjusted the sample size calculations for clustering using data from our previous study (unpublished) to estimate a design effect of 1.5. We have increased the sample size by 20% to allow for loss to follow-up. A total of 17,300 children will need to be screened to recruit 450 children for this trial. The communities are stable and few study children are expected to leave the school during the school year.

This will detect a 20% difference in spectacle wearing, determined using the sampsi command in Stata Statistical Software version 14 (StataCorp, College Station, TX, USA).

Randomization

A list of schools where the head teachers has given permission will be prepared in India (PM) and each school will be allocated a unique ID. All clusters will be randomized at once so allocation concealment will not be an issue. The schools will be randomized using a web-based randomization service (Sealed Envelope Ltd. 2016. Simple randomisation service [Online]). Available from: https://www.sealedenvelope.com/simple-randomiser/v1/ [Accessed 3 Jan 2017])

The schools will be randomly allocated to intervention or comparator arm, stratified by size, i.e. the number of children enrolled at the school between the age 11–15 years. To reduce contamination, schools will be allocated to the intervention and control arm and not individual children, and study schools will not be closer than 10 km to minimize contact between children in the different arms of the trial. Recruitment bias will be unlikely because all children who fail screening i.e. who have a VA of less than 6/9.5, will have similar procedures thereafter, i.e. refraction, dispensing spectacles or referral, apart from the health education intervention, which will be applied after recruitment. Figure 1 is a flowchart showing a child's journey and the activities involved from screening, to deciding whether they are eligible for recruitment, then randomization and follow-up.

Primary outcome

The primary outcome is defined as the proportion of children who are wearing their spectacles at an unannounced visit to the school 3 to 4 months after delivery of the spectacles. A new field worker will be recruited and trained to collect the primary outcome data who will be masked to the hypothesis and intervention arm. Spectacle wear will be ascertained using the four categories defined by Wedner [18] where categories 1 or 2 below define spectacle wearing, and categories 3 or 4 as non-spectacle wearing: (1) wearing the spectacles at the time of the unannounced visit, (2) not wearing the spectacles at the time of the visit but have them at school, (3) not wearing the spectacles at the time of the visit but said they are at home, and (4) not wearing the spectacles at the time of the visit as they are broken or lost.

Secondary outcome

Uptake of referral to Pushpagiri Eye Institute, which will be assessed 4–5 months after screening.

Table 1 An overview of the two arms of the trial

	Intervention arm	Comparator arm
Age group	11–15 years	11–15 years
Screening VA level	<6/9.5 in one or both eyes	<6/9.5 in one or both eyes
Method of screening	Peek E Acuity by field workers	E card optotype by field workers
Health education	• SightSim images for classroom teaching by field workers, after orientation i.e. for all children • Eligible children will select a SightSim image of their choice from a range of pre-tested images to take home to show their parents with wording in the relevant local language • Personalized voice messages for parents in the relevant local language	None
Refraction	Trained optometrist	Trained optometrist
Definition of significant RE	Same in both arms of the trial	Same in both arms of the trial
Dispensing criteria	Same in both arms of the trial	Same in both arms of the trial
Frame types	Same in both arms of the trial	Same in both arms of the trial
Delivery of spectacles	Same in both arms of the trial	Same in both arms of the trial
Assessment of primary outcome	Same in both arms of the trial	Same in both arms of the trial

VA visual acuity, *Peek* Portable Eye Examination Kit, *RE* refractive errors

Other outcomes

At follow-up, each child not wearing their spectacles will be asked why they are not wearing them. Children wearing spectacles will be asked why they are wearing them. They will be asked if there is a second reason. Their response will be written down verbatim by field workers and coded afterwards, with reasons for non-wear likely to fall into the following categories: (1) never received them, (2) lost, (3) broken or scratched, do not like wearing them because (4) they were teased, or (5) appearance, or (6) headache or eye strain; (7) parents do not like the child to wear them, (8) did not notice an improvement in vision i.e. no benefit and (9) other, which will be specified.

The costs of developing the Peek education package, and for delivering both arms of the trial, will be determined using standard costing methods and data from Peek software developers. The cost per child wearing their spectacles at follow-up will be calculated and compared between arms.

Data management

All data from both arms of the trial will be entered and stored in the Peek database. Data will be transferred into Stata for analysis.

All field staff will undergo rigorous training in using Peek for screening and entering and recording data. Inter-observer agreement studies will be done for VA screening and refraction.

The Peek Acuity database will be password protected. At the end of the study, the data will be archived at LSHTM.

Data analyses

Analysis will be in the groups to which children were randomly allocated. We expect all children will be given the spectacles required.

Primary outcome

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 standard arms using the risk difference with 95% confidence intervals adjusted for cluster (school).

A separate analysis will also be undertaken to adjust for factors that may affect spectacle wear such as gender, age (linear term), degree of refractive error in the better seeing eye (linear term), previously wore spectacles (binary data), parental spectacle wear (binary data) and educational level (categorical data) if there are imbalances between the two arms of the trial. There will be no subgroup analysis.

In the Peek software the name of the school will never be entered, only the school study ID and the allocation code. The same applies to schools in the comparator arm. Schools will, therefore, only be identified by ID number while the data are being analysed.

Masked analysis of the primary outcome will be difficult as the database for schools allocated to the intervention arm will a larger number of fields than the comparator arm e.g., the SightSim image the child took home; the number and date of voice messages sent to parents.

Secondary outcomes

The proportion of children who access eye care after referral to Pushpagiri Eye Institute will be compared between arms, using the risk difference with 95% confidence intervals adjusted for cluster (school).

Other outcomes

Reasons for non-spectacle and spectacle wear will be compared between the two arms of the trial, after categorizing their responses.

Data on the cost per child wearing their spectacles at follow-up will only be analysed should the difference in spectacle wear be 20% or greater in the intervention arm.

Data monitoring

A data monitoring committee will not be required. There is no reason to expect significant adverse effects. Interim analyses are not planned.

Harms

Neither arm of the trial has any anticipated harms. If spectacles are prescribed inaccurately, or fitted incorrectly, they can cause blurred vision and/or eyestrain or headaches whilst using the spectacles. In this trial all refractions and spectacle fittings will be undertaken by highly experienced optometrists to ensure inaccurate prescribing is unlikely. When children are followed up at 3–4 months, they will be asked whether these symptoms were the reason they did not wear their spectacles. If a child reports any of these symptoms, they will be refracted again and given new spectacles if required.

Dissemination

Findings will be reported using CONSORT guidelines for cluster randomized trials. All investigators will contribute to the dissemination strategy, which is likely to include a summary of the findings for the local Steering Committee, head teachers, a report for the website of participating institutions, publications in peer-reviewed journals, presentation at national (UK and India) and international conferences.

Protocol amendment

Important protocol modifications, such as eligibility criteria, will be reported to the Interventions Research Ethics Committee, LSHTM, the Institutional Ethics Committee at Public Health Foundation of India, the Indian Council of Medical Research and Controlled-Trials.com.

Consent

Approval for the trial will be sought from the relevant school authorities, including the District Education Officer and by the lead collaborator in India. Written informed consent will be obtained from head teachers, who will be given copies of the information sheet and signed consent forms.

Parents of all children to be screened will be sent an information sheet via the children explaining that their child's vision will be tested, and they will be given spectacles, if required. Parents will be allowed to opt out. If on the day of screening children whose parents have opted out still want to be screened, the child will be given an assent form to sign which will be countersigned by the head teacher. The child will be given a copy to take home. They will then be screened and given spectacles, if required, but will not be recruited to the trial. The school ID of these children will be entered into the Peek software and they will be given a child ID of 00.

All children recruited to the trial will be given verbal information in the local language about the study and an explanation of the procedures by trained field workers. They will also be given an opportunity to ask questions at the time.

All the information sheets and consent forms will be translated into local languages (Hindi and Telugu).

Confidentiality

Data will be kept confidential as no identifiers will be entered into the Peek database. Data will be anonymized by allocating a unique study ID for each school and each participant. The Peek database will be password protected. At the end of the study, the data will be archived at LSHTM.

All data will be made readily available in a public domain after the initial analyses and results are published.

Access to data

Only investigators at LSHTM and the lead investigator at PHFI 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 availability of the data at the end of the study.

Post-trial care

Given that myopia can progress during adolescence it is recommended that school vision screening be repeated every 2 years for this age group. This ensures that children whose spectacles require replacing are identified and children entering the school system for the first time are screened. This process can be put into place with support from Pushpagiri Eye Hospital and the local education authorities.

Discussion

This trial is designed to evaluate whether a health education package for teachers, parents and children delivered using innovative mobile phone technology (Peek) increases spectacle wear at 3 to 4 months, as well as the uptake of referral of children identified during vision screening with other eye conditions. We will also assess the cost of developing and delivering the health education intervention in the intervention arm of the trial, and the cost of dispensing and delivering the spectacles in both arms of the trial. We will compare the cost per child wearing their spectacles at follow-up in both arms.

The Government of India recognizes the importance of correcting RE in children as they are included in the national programme for child health, called Rashtriya Bal Swasthya Karyakram (RBSK), and the National Program for the Control of Blindness. The health of schoolchildren is also recognized by international health experts, policy makers, governments and international agencies as contributing to child development, learning

and socio-economic development. This includes FRESH (Focus Resources on Effective School Health) whose partners include Education International; Partnership for Child Development; UNESCO; UNICEF; the World Food Programme; the World Health Organization and the World Bank. Results of this project will, therefore, be of relevance to FRESH and local, national and international agencies.

Trial status

At the time of submission, the formative research has been completed and recruitment was ongoing. Recruitment started on 4 January 2017.

Additional files

Additional file 1: Example of a SightSim image generated by Peek simulating the visual blur caused by uncorrected refractive error. (DOCX 1760 kb)

Additional file 2: SPIRIT checklist. (PDF 36 kb)

Abbreviations

App: Application; Peek: Portable Eye Examination Kit; RE: Refractive error; uRE: Uncorrected refractive error; VA: Visual acuity

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Availability of data and materials

Not applicable

Authors' contributions

PM contributed to study conception and design, data collection, manuscript writing and final approval of the manuscript. AB contributed to study design, revising the draft for important intellectual content and final approval of the manuscript. GVM contributed to study design, revising the draft for important intellectual content and final approval of the manuscript. JE contributed to study design, revising the draft for important intellectual content and final approval of the manuscript. CG contributed to study conception and design, revising the draft for important intellectual content and final approval of the manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Written informed consent was obtained from the parents for publication of the schoolgirls' group image in this manuscript. (Additional file 1: Figure S1).

Ethics approval and consent to participate

Ethics approval has been obtained from the Interventions Research Ethics Committee (10798-01), LSHTM and from the Institutional Ethics Committee at Public Health Foundation of India (IIPHH/TRCIEC/068/2016). Approval is being sought from the Indian Council of Medical Research.

The consent process is described in the "Methods" section. All parents will provide consent for their child to participate in the study, and assent will be obtained from the children.

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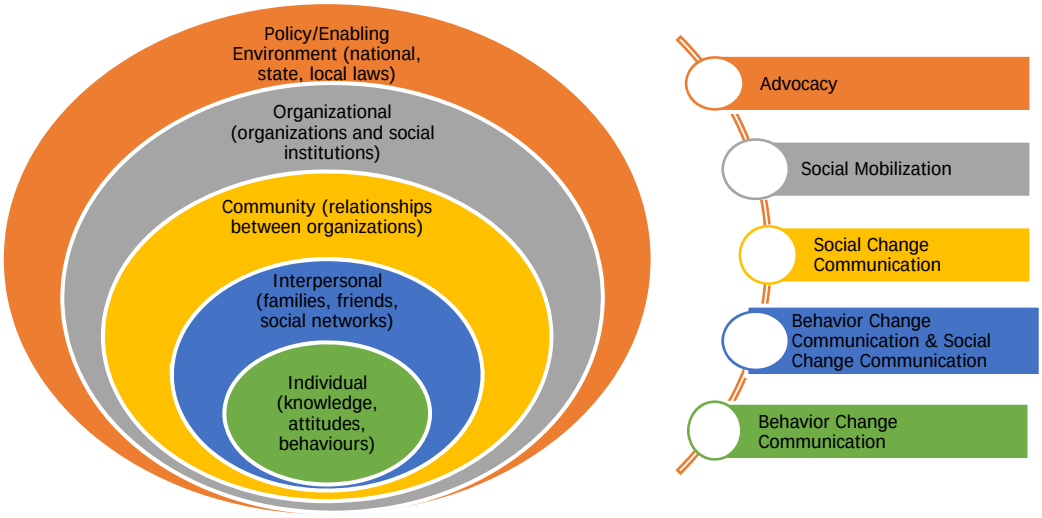
5.1 Development of PeekSim images and voice messages for parents

The intervention in this trial was a complex intervention with components for screening and health education using Peek Solutions i.e., classroom education and health education for parents, using PeekSim images, and voice messages sent to parents of children who require spectacles or specialist examination. This was described in detail in the preceding section which is the protocol for the trial. This section describes how the intervention (PeekSim images and voice messages) was developed.

Evidence on why children do not wear their spectacles highlights the importance of environmental factors, especially the negative attitudes of others e.g. parents, teachers, peers the wider family and even community norms and attitudes.

The framework for the intervention was based on the Social Ecological Model (SEM) which is a theory-based framework for understanding the multidimensional effects of individual and environmental factors that determine behaviours. The framework explains the multiple levels of a social system and interactions between individuals and the environment that can influence behavioural change. The SEM highlights the importance of recognising and incorporating social norms into any behaviour change. There are five nested, hierarchical levels which influence behaviour i.e., individual, interpersonal, organizational, community and public policy (Figure 24).

Figure 24: The Social Ecological Model corresponding with communication approaches



Some of the factors describe in the SEM were adopted in this trial as they capture the main factors that influence spectacle wear among children. For each level in the SEM there are corresponding communication approaches. The SEM emphasizes that it is easier to adopt healthier behaviours by bringing about change in the environment, by using the example of role models, and by reinforcement.[1]

The development of the PeekSim images and the content of voice messages for parents was part of the formative research undertaken before the trial started. Theory of Change was developed (Figure 25), and the formative research was undertaken in non-study schools to assess the barriers and assumptions (Table 5) identified from the Theory of Change.

Figure 25: Theory of change

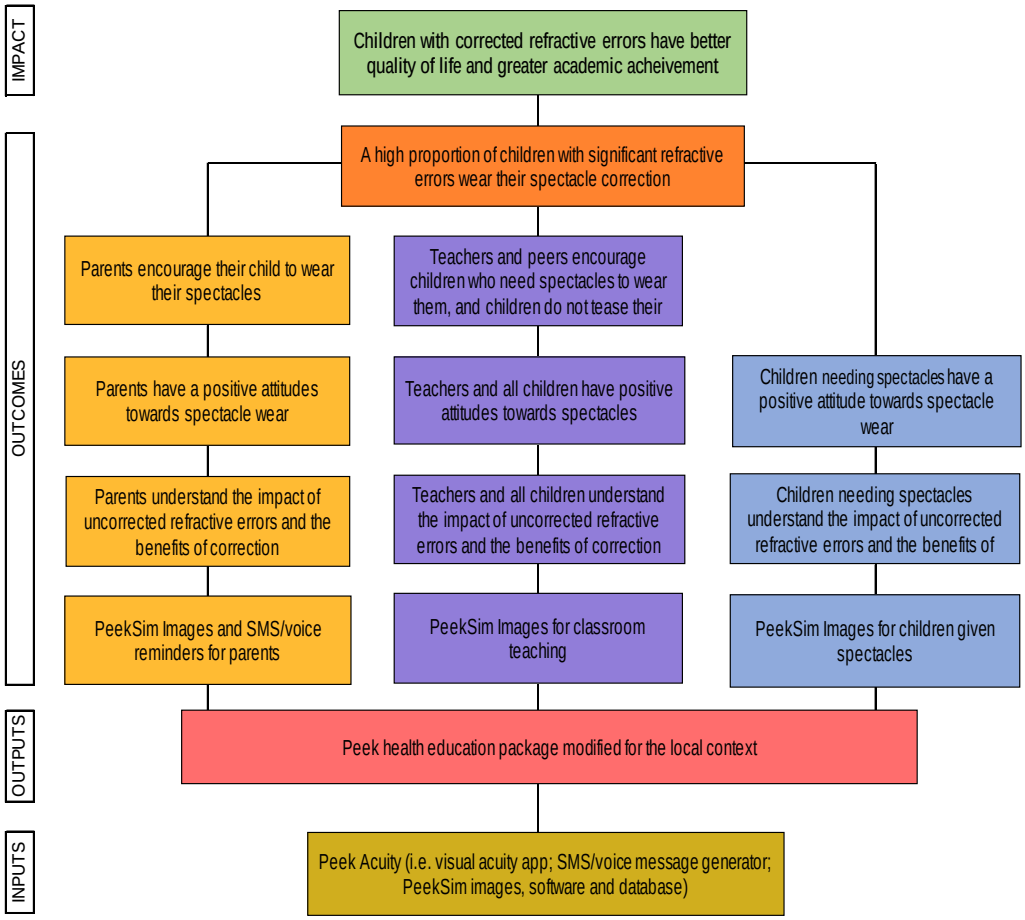


Table 5: Barriers and assumptions arising from the Theory of Change

Participant group	Barrier (B) / Assumption (A)	Methods
Head Teachers	(A) Head teachers willing for study to take place in their school i.e. that teachers can be trained in Peek Acuity, deliver classroom teaching, and screen children in their school and in other schools nearby	Before trial: Interviews
Parents	(A) High proportion of parents are literate (A) High proportion of parents have mobile phones and are willing to share the number with project staff (A) Parents will be more likely to encourage their children to wear spectacles after seeing PeekSim images	Data from earlier trial in India. Before trial: Focus group discussions Data analysis: Reasons why children do wear their spectacles
Children without uRE	(A) Children exposed to classroom teaching using PeekSim images have greater knowledge and more positive attitudes about spectacle wearing (A) Children without RE do not tease their peers who have uRE after exposure to PeekSim images	Before trial: Pre- and post-assessment of knowledge and attitudes Data analysis: Analysis of reasons for non-wear in two arms of the trial
Children with uRE	(A) Children more likely to wear their spectacles after exposure to PeekSim images	Data analysis: Analysis of reasons why children do wear their spectacles

Interviews with head teachers showed that teachers could not undertake screening and health education in the classrooms as this would be distracted from their day-to-day responsibilities and it would take up too much of their time. And teachers would not be able to travel to schools nearby to conduct screening, especially if they are female teachers. The head teachers instead suggested that field workers from the trial team should do the screening and health education. They emphasised that the field workers should be young, the classroom health education should be done in pairs (male and female) and if possible one of the field workers should be a spectacle wearer, to increase the chances of the children being able to relate to them.

From trial 1, we had data on mobile phone ownership by parents: 94.0% of the 460 children recruited, confirmed that at least one parent owned a mobile phone.[2] In 2016, 'Livemint' (an Indian daily business newspaper) reported that 88% of households in India have a mobile phone and while 77% of the bottom quintile own a mobile phone only 18% of them have access to tap water.[3] Most recently in April 2018, the 'Indian Express' (an Indian national newspaper) reported that India is now set to

have the highest number of smartphone users at 580 million, second after 1.3 billion in China.[4]

We attempted to assess the impact of classroom education prior to the trial, using PeekSim images to increase knowledge about uREs and develop positive attitudes towards children wearing spectacles. A visual analogue scale was used before and after the session for 150 children, but this was not successful as the children thought they were being tested and either copied answers from their classmates, memorised what they had answered prior to the health education and wrote the same answers or they would turn the sheet over and copy the previous answers. Appendix 1 is the template that was used pre and post classroom health education to assess knowledge and attitudes.

5.1.1 Developing content for the PeekSim images and voice messages

To develop the PeekSim images and the voice messages, focus group discussion (FGDs) and in-depth interviews were undertaken in eight non-study schools randomly identified from a list supplied by the District Education Officer (DEO). Participants in the formative research were head teachers, teachers, parents and children (a sample of age and gender). (Table 6)

Table 6: Participants in the formative research

		Number	Percentage
Students (n=44)			
Gender	Male	22	50%
	Female	22	50%
Class	6-8th	21	48%
	9-10th	23	52%
Spectacle status	Wearing	7	16%
	Prescribed but not wearing	6	14%
	No spectacles required	31	70%
Do their parents wear spectacles for distance vision?	Father	4	9%
	Mother	4	9%
	Both	1	2.3%
	Neither	33	75%
Does a sibling wear spectacles?	Sister	1	2.3%
	Brother	1	2.3%
Parents (n=16)			
Gender	Male	7	44%
	Female	9	56%
Spectacles status	Reading spectacles	3	19%
	Vision spectacles	3	19%
	No spectacles	10	62.5%
Does their child wear spectacles?	Yes	3	19%
	No	13	81%
Teachers (n=12)			
Gender	Male	2	17%
	Female	10	83%
Spectacles status	Near vision spectacles	8	67%
	Distance vision spectacles	4	33%
Does their child wear spectacles?	Yes	7	58%
	No	5	42%
Head teachers (n=3)			
Gender	Male	1	33%
	Female	2	67%
Spectacles status	Near vision spectacles	3	100%
Does their child wear spectacles?	Yes	3	100%

During the in-depth interviews and FGDs, all participants were shown a demonstration of PeekSim images and asked to express their reactions to the visual blur experienced by children with uRE. They were also asked to identify three to four activities that children with uRE might like to do but cannot because they do not have clear vision. Head teachers and classroom teachers were asked to comment on the images suggested for use in classroom education and to send home to parents of children who require spectacles.

Appendix 2 are the topic guides that were used for head teachers, classroom teachers, parents and children. We also asked head teachers, teachers and parents about the use of voice messages and the content, frequency and appropriateness of using them to send to parents of those children that received spectacles and those children referred to the hospital.

Thematic analysis was conducted to analyse the data from the FGDs and in-depth interviews. Initial themes and codes were developed based on a review of the literature and previously conducted research on the major reasons for spectacle non-wear.

5.1.2 Results from the focus group discussions and in-depth interviews

Below is a summary of some of the main results for the different topics that were discussed with the head teachers, classroom teachers and children.

- Topic: When will a child need to wear spectacles?

Reasons:

- When the child complains of headaches
- When they sit too close to the television
- When the child is not able to see in the distance clearly
- When the child looks at a mobile phone or computer excessively

- Topic: What do you think of children who wear spectacles?

Answers:

- They are studious and not fun

- They were watching television and using the computer for too long
- They are blind
- They have some problem/defect with their vision

  - Topic: Why do children chose to wear and not wear their spectacles although they need to?

Answers:

Reasons for wearing spectacles

- The child has a severe vision problem and is not able to see without their spectacles
- They like their spectacle frames
- Their friends are wearing them and so they want to wear them
- Spectacles are stylish as famous personalities are wearing them

Reasons for not wearing spectacles

- Old fashioned frames
- Classmates tease them
- The size of the spectacle frame is bigger than the face of the child
- Parents think that their child is not old enough to wear spectacles
- List of colloquial phrases used in the local dialect to tease children spectacles
  - Double battery eyes
  - Blind fellow
  - Four eyes
  - Spectacle fellow

The PeekSim images were created after the FGDs with head teachers, classroom teachers and children. Below is a list of the images that were finalised:-

1. PeekSim 1: A market stall selling flowers (Figure 26)
2. PeekSim 2: A clean village setting (Figure 27)
3. PeekSim 3: A classroom with a blackboard (Figure 28)
4. PeekSim 4: A famous South Indian movie star (Figue 29)
5. PeekSim 5: Children playing the local game 'kho-kho' (Figure 30)

6. PeekSim 6: The Indian national cricket team taking a selfie (Figure 31)
7. PeekSim 7: P. V. Sindhu: first female Indian badminton player to win a silver Olympic medal (Figure 32)

Figure 26: A market stall selling flowers

Figure 27 : A clean village setting

Figure 28: A classroom with a blackboard

Figure 29: A famous South Indian movie star

Figure 30: Children playing the local game 'kho-kho'

Figure 31: The Indian national cricket team taking a selfie

Figure 32: P. V. Sindhu: first Indian female professional badminton player to win an Olympic medal

Figure 33: A child choosing a PeekSim image to take home to her parents

- Topic: Voice messages

Answers:

- Parents felt that weekly voice messages are not appropriate, it would annoy parents
- An appropriate frequency is every fortnight and in the evening
- Some suggested a monthly message but were also not sure if that might mean they forget about it
- All parents were comfortable with receiving a voice message as long as it was in the local dialect
- All parents stated that the message should contain a positive and negative detail about spectacle wear or the referral message. For example, if a child did not wear their spectacles it could affect their visual function and by wearing their spectacles, it could improve their quality of life. In addition, for hospital referrals, it was important to state that the both the consultation and the treatment would be free of charge.

The voice messages were recorded in the two local dialects and sent to parents once a fortnight. Below is the wording in English for the two messages recorded:-

<u>Parents whose children who require spectacles</u>

Hello, this is a call from Indian Institute of Public Health in Hyderabad.

We checked your child's eyes at their school and found that they require spectacles to see clearly. We have given them spectacles, please encourage them to wear them at school and while watching TV. By wearing their spectacles your child has the potential to improve their quality of life. Thank you.

<u>Parents whose children were referred to the hospital for further examination</u>

Hello, this is a call from Indian Institute of Public Health in Hyderabad.

We checked your child's eyes at their school and found there is a problem with their eyes. You need to bring your child to Pushpagiri Eye Hospital in Secundarabad, opposite St. Ann's High School for further check-up. You do not pay for the check-up or any treatment if it is required. It is important you bring your child to the hospital to prevent further problems. Thank you.

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SECTION A – Student Details

Student	Priya Morjaria
Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?			
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If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Lancet Global Health
Please list the paper's authors in the intended authorship order:	Priya Morjaria, Andrew Bastawrous, GVS Murthy, Jennifer Evans, Clare Gilbert
Stage of publication	**Not yet submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Study cocnept &design; Acquistioin & Analysis of data; Drafting manuscript; Statistical analysis

Student Signature: Priya Morjaria [redacted] **Date:** 03 May 2018

Supervisor Signature: [redacted] **Date:** May 3 2018

Spectacle wearing in children randomized to a novel mobile health intervention (Peek) or standard care: results from a randomized superiority trial in India

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ABSTRACT

Background

Uncorrected refractive errors can be corrected by spectacles which improve academic performance, visual functioning and quality of life. However, spectacle wear can be low due to teasing/bullying, parental disapproval and no perceived benefit.

Hypothesis: an innovative m-health education intervention, delivered using Peek Solutions to children with uncorrected refractive errors, their peers and parents, improves spectacle wear.

Methods

A superiority, cluster randomised controlled trial was undertaken in 49 government schools in Hyderabad, India using a superiority margin of 20%. Schools were the unit of randomization. Schools were randomized to the Peek intervention or a standard school programme. The same clinical procedures were followed in both arms and free spectacles were delivered to schools. Children 11-15 years with a presenting Snellen visual acuity of <6/9.5 in one or both eyes whose binocular acuity improved by ≥2 lines were recruited. Children requiring further investigation were referred and not recruited.

In the Peek arm, classroom health education was delivered before vision screening using a set of printed images generated by the PeekSim app which mimic the visual

blur of uncorrected refractive error. Children requiring spectacles selected one image to give their parents who were also sent automated voice messages in the local language. The primary outcome was spectacle wear at 3-4 months, assessed by masked field workers at unannounced visits. At 4-6 months parents in the Peek arm were contacted to ask if they had received the PeekSim image and voice messages, and whether they understood the message.

Findings

701 children were prescribed spectacles (Peek arm: 376, control arm: 325). 535/701 (80%) were assessed at 3-4 months: Peek arm: 291/352 (82.7%); standard arm: 244/314 (77.7%). Spectacle wear was 156/291 (53.6%) in the Peek arm and 129/244 (52.9%) in the standard arm, a difference of 0.7% (95% CI, -0.08, 0.09). Among the 292 (78%) parents contacted, only 13.9% had received the PeekSim image from their children, 70.3% received the voice message and 97.2% understood it.

Interpretation

Spectacle wear was similar in both arms of the trial, one explanation being that health education of parents was not delivered as intended. Health education messages to create behaviour change need to be appropriate and use an acceptable and accessible medium.

INTRODUCTION

Uncorrected refractive errors (uREs) are the commonest cause of visual loss in children. Myopia (short-sightedness), the commonest form, usually starts manifesting around the age of eight years, progressing in severity throughout adolescence.[1, 2] 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 South East Asia where it has an earlier age of onset. All types of RE are less common in African children. Urban children are at greater risk of myopia and there is increasing evidence that time spent outdoors is protective although the biological mechanisms are not clear.[3-7] Correcting RE in children can lead to improvement in academic performance,[8] social development, visual functioning[9] and quality of life.[10]

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Approximately 12.8 million children worldwide are visually impaired from uREs,[11] which is increasing, largely due to the increasing incidence of myopia in children in what is described as an 'epidemic' in East Asia, Europe and United States.[12, 13] In Singapore, China, Taiwan, Hong Kong, Japan and Korea, 80-90% of children completing high school are now myopic.[12, 14] This increase is attributed to environmental factors associated with urbanisation, particularly prolonged near work and lack of time spent outdoors.[14]

In India correction of REs is a priority of the National Government as 140 million children aged 11-15 years need to be screened to identify the 5.6 million children who need spectacles.[15] However, many children with uRE do not gain the benefits of correction, and coverage of RE programs can be low, including in India. In addition, a high proportion of children do not wear their spectacles,[16] which was recently reported to be only 30% in a study in India.[17] There are many reasons why children do not wear spectacles such as: being teased or bullied, concerns by parents that spectacles will weaken their child's eyes and are stigmatizing.[18,19-22] Some of are amenable to health education. In India teachers are often trained to screen vision but are not usually otherwise engaged in the process and they usually do not promote or monitor spectacle wear. It is not standard practice in India to send explanatory pamphlets to parents of children requiring spectacles and parents are not typically made aware of the benefits of spectacle wear.

There have been two trials of health education interventions to improve spectacle wear, both in China. In one trial health education was delivered to students, and had negative results, suggesting that educating children alone is not effective.[23] The other trial had a factorial design with six subgroups. Children in half the schools were randomised to a health education intervention in which children were 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).[8]

A recent trial in Bangalore, India showed that 2.6% of children in this aged 11-15 years had significant uRE, defined as a level of visual loss due to uRE which improved by two or more lines of visual acuity (VA) in one or both eyes with spectacle correction. In this

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study children could select the spectacle frames they preferred and almost 75% were wearing their spectacles at unannounced visits 3-4 months later.[24]

Mobile phone technology is a rapidly expanding area in health care, including eye care and school eye health programmes.[25] A recent development is Peek Solutions which consists of mobile phone applications and software which has been specifically designed for eye health programmes in low resource settings. Peek Solutions includes smartphone-based applications for vision screening (Peek Acuity),[26] and a vision simulator application which mimics the visual blur of uRE (PeekSim). PeekSim images can be printed. Data are entered into a smartphone or tablet in the field which allows real time data reporting and eye health service analytics. The Peek School Eye Health system has a platform for data entry to track children through the system, and to collect the mobile phone numbers or carers. The latter can be used to send automated text or voice messages to eye care providers to generate lists of children referred, for example, and parents/carers can be sent referral notifications and health education messages. A recent trial in Kenyan schools demonstrated that teachers could be taught to screen VA using Peek Acuity, and PeekSim images (polaroid photographs) and automated text messages were sent to parents. The uptake of referrals to the eye care providers was two and a half times higher in the Peek intervention arm than in the control arm (unpublished results).

In our trial a superiority design was used with the null hypothesis being that the proportion of children wearing spectacles in the Peek (intervention) arm at 3 to 4 months would be higher than in the standard care (control) arm. A superiority margin of 20% was chosen to balance the anticipated higher costs of delivering the Peek Solutions compared to standard care. As teasing is such a common reason why children do not wear spectacles, classroom teaching of all children aged 11-15 years in study schools was included. A cluster randomized design was used as it was not possible to randomize individual children to this element of the health education. The trial protocol was published in March 2017.[27]

This randomised controlled superiority trial was undertaken in government and public-funded schools in and around Hyderabad, India. The rationale for our study was that greater awareness of the benefits of spectacles amongst all children and the parents of affected children would increase wear. Reporting follows the CONSORT 2010

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Checklist for randomized controlled trials.[28]

METHODS

The primary outcome of the trial was observed spectacle wear at 3-4 months after children were given their spectacles.

A list of government and public-funded secondary schools in the area was obtained from the District Education Officer with the number of children enrolled in each classroom. If a school had been visited for eye health screening within the previous two years, the school was excluded. Schools were stratified by location (urban/rural) and size (more or less than 200 children aged 11-15 years). Schools were randomly selected (further details below) after stratifying by the number of students enrolled. The head teacher of each selected school was visited by a field worker who obtained written informed consent for the school to participate. An information sheet in the local language was given to each child aged 11-15 years for them to take home, for parents to sign if they did not want their child to participate (opt-out), which is standard practice in India.

Participants

Recruitment took place between 05 January 2017 and 14 February 2017. All children aged 11-15 years who were present at the school at the time of screening were offered screening which was undertaken by trained field workers using either Peek Acuity (intervention) or a standard logMAR chart (control). To pass, a child had to correctly identify the orientation 4 out of the 5 optotypes (Es in one of 4 orientations). Children who failed screening i.e. presenting VA of less than Snellen 6/9.5 (logMAR 0.2) in one or both eyes, were referred for triage to the next room. The study optometrist retested their VA using a full logMAR acuity chart. If a child could see 6/9.5 in both eyes on repeat testing no further action was taken. Children confirmed with a VA of less than 6/9.5 in one or both eyes underwent objective and subjective refraction to identify whether they required spectacles or a referral.

Interventions

The intervention was a complex intervention delivered using Peek Solutions. In this trial, PeekSim images relevant to Indian children aged 11-15 years were used. Images were selected after formative research which entailed focus group discussions (FGD) with head teachers, parents, and boys and girls in different age groups between ages 11-15 years. The

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FDGs explored participants views of spectacle wear by children and to seek their opinions on the PeekSim images to use in the trial. Parents and teachers gave input to the content of the voice messages, when they should be sent and how often. Based on the findings the following images were selected: a classroom with a blackboard, a famous South Indian movie celebrity, children playing the local game 'khokho', (Figure 1) the Indian national cricket team, a market stall selling flowers, a clean village setting, and finally P.V. Sindhu (the first female Indian badminton player to win a silver Olympic medal). These images were printed A3 size for classroom teaching by members of the study team for all children in the classroom prior to screening. Children who required spectacles took an A6 image of their choice home to show their parents, to demonstrate how much clearer their child's world would be if they wore their spectacles. The Peek software also sent voice messages in the local language to mobile phones of parents of children who required spectacles or who were referred for specialist eye care.

Figure 1: Example of a PeekSim image – children playing 'kho-kho'

In the comparator arm, the 6/60 row followed by the 6/9.5 row of a standard ETDRS chart was used for vision screening, and no health education was sent home to the parents. In both arms the same clinical procedures were followed for refraction and prescribing (Table 1).

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Table 1: An overview of the two arms of the trial

	Intervention arm	Comparator arm
Age group	11-15 years	11-15 years
Screening VA level	<6/9.5 in one or both eyes	<6/9.5 in one or both eyes
Health education	• PeekSim images for classroom teaching by field workers, after sensitization and orientation i.e. for all children • Eligible children selected a PeekSim image of their choice from a range of pre-tested images to take home to show their parents, with wording in the relevant local language • Personalized voice messages for parents in the relevant local language	None
Refraction	Trained optometrist	
Prescribing criteria	VA improves by 2 or more lines tested binocularly	
Frame types	A range of different coloured plastic frames	
Selection of frames by children	Children selected their preferred frame	
Delivery of spectacles	Delivery of free spectacles to schools within 2 weeks, and VA re-tested with correction	
Assessment of primary outcome	Observation during unannounced visits 3-4 months after spectacles were delivered	

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Sample size calculation

The sample size was calculated with a superiority margin of 20%, using the sampsi command in Stata Statistical Software version 14 (StataCorp, College Station, TX, USA).This margin was chosen to balance the anticipated higher cost of developing and delivering the Peek package. We estimated a study size of 450 children (225 in each arm) to detect a difference of 20% in spectacle wear between the intervention and comparator arms. The assumption was that approximately 60% of children in the control arm would

be wearing spectacles at follow-up, with a 95% confidence interval and 90% power. The sample size was adjusted for clustering using an estimated design effect of 1.5 from our previous study. We increased the sample size by 20% to allow for loss to follow-up. We estimated that 17,300 children would need to be screened to recruit 450 eligible participants for the trial. After screening 7,432 we recruited 701 children. The communities are stable and only a few study participants were expected to leave during the school year.

Eligibility criteria

Eligibility criteria for the trial were a) children aged 11–15 years b) parents do not refuse participation, and c) presenting VA (i.e. with spectacles if usually worn) of less than 6/9.5 in one or both eyes. The following children were not recruited: cycloplegic refraction was required, the presenting VA was ≤6/60 in one or both eyes regardless of the cause, if their best-corrected VA did not improve by two or more lines in both eyes, or they required further investigation for other eye conditions. These children were dispensed spectacles if required.

Children were eligible for immediate spectacle correction if their binocular VA with full correction improved by two or more lines. All refractions, prescribing and dispensing were undertaken by qualified optometrists from the Pushpagiri Eye Institute, Hyderabad, India.

Randomisation and masking

Head teachers were visited and those giving permission were allocated a unique ID. All the schools were randomised at once, so allocation concealment was not an issue. Randomization was done using a web-based randomisation service Sealed Envelope Ltd. 2016 simple randomisation service [Online]). Available from: https://www.sealedenvelope.com/simple-randomiser/v1/ [Accessed 3 Jan 2017]). Schools were randomised to intervention or comparator arm stratified by size, i.e. the number of children enrolled at the school aged between 11-15 years. Schools were allocated to the intervention or control arm and not individual children to avoid contamination.

Recruitment bias was not likely as all children who failed screening had similar procedures thereafter which took place after recruitment. Parents, teachers and eligible children were effectively masked as the health education used in Peek arm of the trial

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was not described in detail in the information sheets. At the end of the trial health education using the PeekSim images was conducted in all the control schools. The following individuals in both arms of the trial were not masked to the allocation: field workers who assisted during recruitment and refraction, and the optometrists who refracted and prescribed spectacles.

Dispensing and delivery of spectacles

Children were allowed to select the frames they preferred from a range of different coloured plastic frames. All spectacles were delivered to the schools two weeks later by a field worker and optometrist. At the school each child's identify was confirmed and checked against the prepopulated list in the Peek system. The spectacle fit was assessed and the corrected distance VA was measured in each eye. Two attempts were made to deliver spectacles to children who were absent on the day of the delivery. After this, the spectacles were left with the teacher but these children were excluded.

Ascertainment of the primary outcome

The field workers were trained to deliver the spectacles to the schools and new field workers were trained to assess the primary outcome at unannounced visits 3-4 months after spectacles were delivered. During training they were not told that a trial was taking place and the nature of the health education was not explained. An average of three fieldworkers visited each school, depending on the number of children that needed to be assessed for spectacle wear. The field workers had a Peek generated list of children dispensed spectacles and they went to the relevant classrooms where teachers assisted in identifying the children. Whether each child was wearing their spectacles or not was noted. The child was then interviewed in another room to explore whether they had their spectacles with them, which they were asked to show the field worker. Spectacle wear was categorised as follows: children were a) wearing their spectacles at the time of the unannounced visit; b) not wearing their spectacles but had them at school (observed); 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.[18] Categories a) and b) were defined as wearing and categories c) and d) as non-wearing. All children were asked an open-ended question to elicit reasons for wear non-wear.

Statistical analysis

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Data in the intervention arm were entered on the tablet device and did not require double entry, as entries were monitored by the lead investigator at regular intervals. In the comparator arm, data were double entered by the lead investigator. After data cleaning and range and consistency checks, the primary analysis was undertaken. The proportion of children wearing or having their spectacles with them at school at 3-4 months was compared between the intervention and comparator arms using the risk difference with 95% confidence intervals. Clustering effects were controlled for by calculating robust standard errors.

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 the 95% confidence interval of the difference. No interim or subgroup analyses were performed. Analyses were pre-specified,[27] and were done using STATA 14.1 (StataCorp, Texas, USA).

Ethics

The trial was approved by the Interventions and Research Ethics Committee, London School of Hygiene & Tropical Medicine and the Institutional Review Board of Public Health Foundation India, Hyderabad. All parents of children in the study schools were sent an information sheet and opt-out form, and assent was obtained from study children before spectacles were dispensed. Children requiring further examination or spectacles for complex REs were referred to Pushapagiri Eye Hospital, Hyderabad for free examination, and all spectacles were provided at no cost.

Role of the funding source

The study was designed by the principal investigator (PM) and CG in collaboration with the other authors. The funders had no role in the design, data analysis, data interpretation, or writing the report. The corresponding author had full access to the data and had final responsibility for the decision to submit for publication.

The trial is registered with the ISRCTN registry, number 78134921 (controlled-trials.com).

RESULTS

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All school head teachers approached agreed that their school take part in the trial and no parent or child refused consent. 7,432 children were screened in 50 public-funded schools (4,374 control, 3,058 Peek), 1,352 (18.2%) of whom failed the screening test i.e. they had presenting VA <6/9.5 in one or both eyes. 277 children (3.7%) were excluded as their VA was 6/9.5 in both eyes on retesting (174 control, 103 Peek). A further 79 (1.1%) were excluded after refraction and basic eye examination (63 control, 16 Peek). 299 children (4.0%) required specialist examination and were referred (see participant flow chart, Figure 2).

Of the 1,352 who screened positive, 701 children (51.8%) were recruited and prescribed spectacles: 325 control, 376 Peek. There was no difference in the gender and age of children between the two arms of the trial (Table 1). Parents in the Peek arm were less well educated and only 2.9% of mothers and/or fathers in the Peek arm did not own a mobile phone. A higher proportion of children in the control arm had a binocular presenting VA of <6/18 than in the Peek arm (52.0% and 40.7%, respectively).

In the control arm 11 children did not receive spectacles and 24 in the Peek arm as they were absent. All the children received the correct spectacles and all had a corrected VA of at least 6/9.5 in each eye with their new spectacles at the time of delivery.

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Figure 2. Participant flow chart

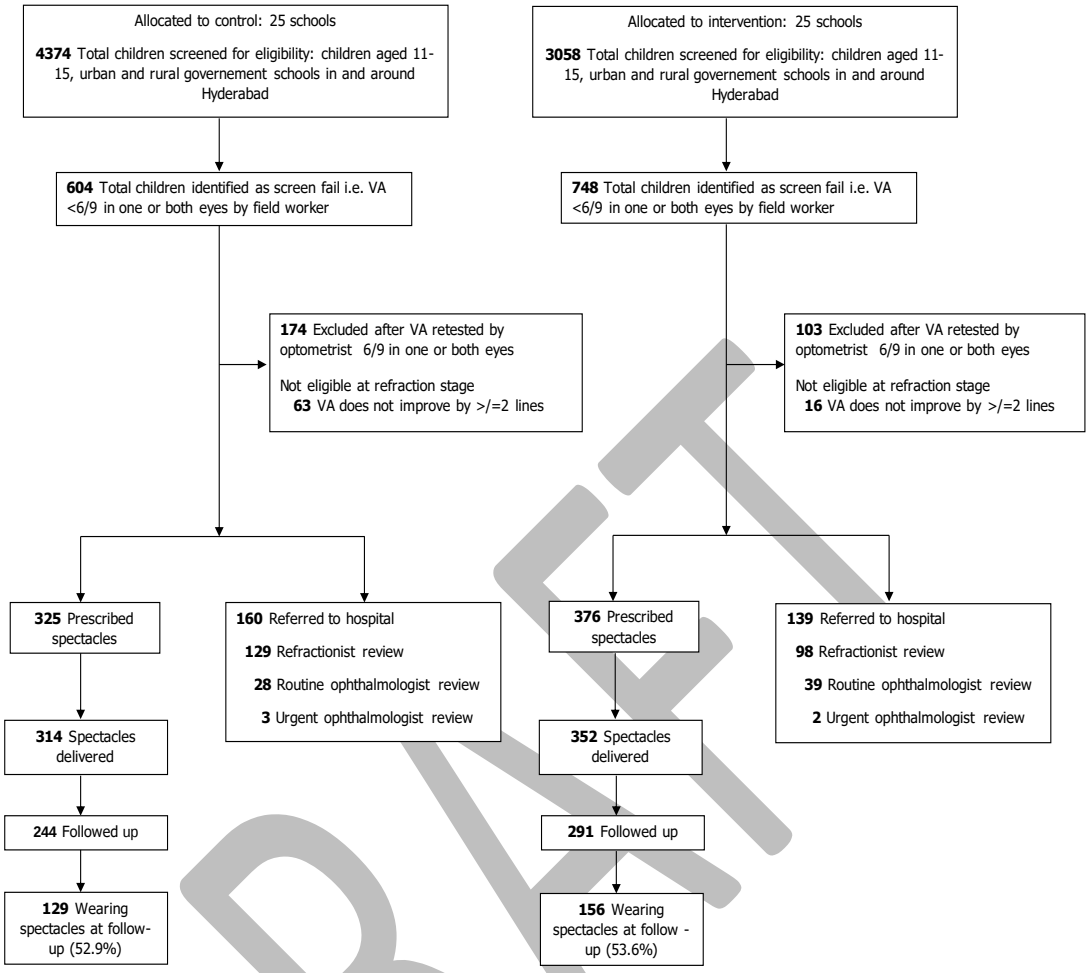

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Table 1: Baseline characteristics of study children, by trial arm

	Socio-demographic variables	Control arm Spectacles prescribed (n=325)		Peek arm Spectacles prescribed (n=376)	
		Mean (SD)	Range	Mean (SD)	Range
	Age	13.5 (1.30)	11 to 15	13.4 (1.30)	11 to 15
Gender	Female	180	56.0	191	50.8
		N	%	N	%
Parental literacy*	Father only	43	14.1	70	21.3
	Mother only	25	8.2	35	10.7
	Both parents	201	66.1	135	41.2
	Neither parent	35	11.5	88	26.8
Parental spectacle wear	Father only	42	12.9	35	9.3
	Mother only	38	11.7	55	14.6
	Both parents	38	11.7	33	8.8
	Neither parent	207	63.7	253	67.3
Mobile phone ownership	Father only	54	16.6	88	23.4
	Mother only	27	8.3	44	11.7
	Both parents	238	73.2	233	62.0
	Neither parent	6	1.8	11	2.9
Presenting binocular vision	<6/9.5 - 6/12	133	40.9	172	45.7
	<6/12 - 6/18	23	7.1	51	13.6
	<6/18 - 6/60	167	51.4	150	39.9
	<6/60	2	0.6	3	0.8

*deceased parents are not included

At follow up, 76% (535/701) children were present: 244/314 (77.7%) in the control arm and 291/352 (82.7%) in the Peek arm. All 166 children (23.7%) not present had changed schools or moved to a different area and could not be traced. Overall 53.3% (285/535) of children were wearing their spectacles or had them at school, being 52.9% (129/244) in the control arm and 53.6% (156/291) in the Peek arm, a difference of 0.7% (95% CI, -0.08, 0.09).

Due to the similar spectacle wearing rates, parents of children given spectacles in both arms of the trial were contacted by telephone by a field worker, to explore whether they knew that their child had been given spectacles. In the Peek arm parents were also asked whether they had seen the PeekSim image and received the voice messages and whether they understood them.

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Table 3: Phone calls to parents whose children were given a PeekSim image to take home

	Peek arm (n=376)		Control arm (n=325)	
	N	5	N	%
Parents called*	292	77.7%	244	75.1%
Calls answered	202	69.2%	151	61.9%
Aware their child had undergone an eye test and were given spectacles at school	195	96.5%	141	93.4%
Parents received image	28	13.9%	NA	NA
Parents understood image	20	71.4%	NA	NA
Parents received the voice message	142	70.3%	NA	NA
Parents understood the voice message	138	97.2%	NA	NA

*some mobile phone numbers were incorrect or unreachable

The majority of children (86.1%) In the Peek arm had not shown their parents the PeekSim image (Table 3). A high proportion of parents (71.4%) who did receive the image correctly understood what the image conveyed, and said they encouraged their children to wear their spectacles. The voice message reached a higher proportion of parents (70.3%) and the vast majority understood the message. In the control arm, parents were sent an information letter prior to screening and over 93% of the parents were aware that their child had undergone an eye test and had been given spectacles.

DISCUSSION

At the 3-4 month follow-up, spectacle wear was almost identical in both arms of the trial, suggesting that the health education intervention had not brought about behaviour change. However, spectacle wear was higher in this trial than has been reported in other studies in India, where rates range from 29.4%[29] to 58.0%,[30] but lower than in our earlier trial of ready-made vs custom-made spectacles (overall 74.6%).[24] There are several possible explanations for the difference between this trial and other studies in India, as we used prescribing guidelines and children chose the frames they preferred. Explaining the difference between the two trials is more conjectural, and may reflect cultural or socio-economic differences.

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One explanation for the findings in the current trial is a Type 2 error, which refers to the statistical probability that a trial would not show a statistically significant difference between the intervention arms even if in reality one intervention is better than the other. Due to the way the sample size is calculated in trials, there is a 2.5% chance that a Type 2 error can occur. This applies to all clinical trials and does not reflect the quality or implementation of the trial.

Having said this, it is important to explore why trials might have negative findings, as highlighted by Pocock et al[31] who states: "An unreasonable yet widespread practice is the labelling of all randomized trials as either positive or negative on the basis of whether the p value for the primary outcome is less than 0.05. This view is overly simplistic. P values should be interpreted as a continuum wherein the smaller the p value, the greater the strength of the evidence for a real treatment effect." Pocock et all recommend that the following questions be addressed:

1. Is there some indication of potential benefit?
There was no evidence of potential benefit as spectacle wear in the two arms of the trial was almost identical.

2. Was the trial underpowered?
The trial was not under-powered as the number of children with primary outcome data (535) was 85 more than the calculated sample size.

3. Was the primary outcome appropriate (or accurately defined)?
The primary outcome was appropriate and accurately defined, i.e. whether children were wearing their spectacles or had them at school at unannounced visits. The outcome was directly observed.

4. Was the population appropriate?
The population recruited was appropriate – school children aged 11-15 years with significant uRE in urban and rural government schools in and around Hyderabad, India.

5. Was the treatment regimen/intervention appropriate?

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The intervention was based on some of the elements of the Social Ecological framework[32] which describes the multifaceted and interactive effects of personal and environmental factors that determine behaviours. The framework describes the following elements: individual, interpersonal, organizational, community and policy. The intention of our intervention was to address some aspects of the individual, interpersonal and organization elements. We planned to use teachers to deliver the classroom health education (organization level) but this was not possible as they were too busy.

The intervention was a complex mHealth education intervention for parents and children using innovative mobile phone technology i.e. health education messages using PeekSim images, voice messages and classroom teaching. A similar intervention in Kenyan schools, in which the primary outcome was adherence to hospital referral, gave positive results, and in India, voice messages were used for the election campaign, which was acceptable by the community. We also engaged parents, children and teachers in the selection of PeekSim images and parents and teachers gave input to the content of the voice messages.

One possible explanation for the negative findings is the assumption that children would give or show their parents the PeekSim images, but the majority did not. In this trial children selected the image they preferred, whereas it may have been preferable to limit the images to those more likely to resonate with parents, such as classroom settings or children engaging in sport, which children might be more willing to part with. A high proportion of parents received and understanding the voice messages, and reported that they encouraged their child to wear their spectacles, despite this it did not bring about measurable behaviour change in schools. We did not assess spectacle wear at home.

An increasingly available means of delivering health education is the messaging service WhatsApp, which is a widely used in India. WhatsApp could be used to transmit voice messages and multiple images (depending on the gender of the child) simultaneously. WhatsApp could be also be used as children are recruited so that parents are aware that their child will be given spectacles, with follow-up

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communication to encourage spectacle wear. In addition, children could be given several PeekSim images, explaining that they can keep only one.

6. Were there deficiencies in trial conduct? A true treatment effect may be diluted, or disappear entirely, if there is poor adherence to the study protocol.

The trial was conducted according to the study protocol and there were no protocol deviations. Contamination was very unlikely as schools were the unit of randomisation. New field workers were recruited for the follow-up assessments who did not know that a trial was taking place.

7. Is a claim of non-inferiority of value?
Not applicable to this trial.

8. Do subgroup findings elicit positive signals?
Subgroup analyses were not planned or carried out.

9. Do secondary outcomes reveal positive findings?
Data on the secondary outcome i.e., uptake of referral, are not presented in this paper.

10. Can alternative analyses help?
Multivariate analyses of some of the baseline variables strongly related to the primary outcome were undertaken but these did not change the general results.

11. Does more positive external evidence exist?
There are a number of studies on the effectiveness of health education using mobile phone technology and for a range of conditions, but there is no evidence that this method of delivering health education improves adherence to spectacle wear.

12. Is there a strong biologic rationale that favours the treatment?

Not applicable to this trial.

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A recent Cochrane review on vision screening that found that health education initiatives (as currently formulated and tested) had little impact on spectacle wear.[8, 23] Future trials of health education to increase spectacle wear among children could benefit from the findings of this trial, and of other trials of mHealth interventions, in terms of the design and implementation. For example, WhatsApp has been successfully used in health education in different settings.[33-35] In India, WhatsApp was used during an influenza outbreak in Gujarat, providing an easy and simple to use medium to transfer information between practitioners and patients.[36] Other school eye health studies have engaged teachers (who represent the organization level of the Social Ecological framework) not only in vision screening, but also to encourage spectacle wear and in some studies teachers have been given a spare pair of spectacles. Interventions which include teachers is recommended for future studies, if possible. More qualitative studies of determinants of spectacle wear in children with a view to designing effective health education interventions?

Peek Solutions provides a unique opportunity to test interventions, as data can be monitored in real time throughout the whole process of school eye health, from screening through to adherence to uptake of referral, and spectacle wear. Embedding different interventions or a change in processes or the personnel involved, for example, can be evaluated quickly and efficiently. Peek Solutions therefore, provides an opportunity to test some of the limitations identified in this trial.

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Priya Morjaria
Principal Supervisor	Clare Gilbert
Thesis Title	Evidence to improve the Efficiency and Effectiveness of School Eye Health Programmes

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Community Eye Health Journal		
When was the work published?	August 2017		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	N/A		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

**If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.*

SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Drafting of the manuscript; Research for references.Contributed to final write up and confirming data.

Student Signature: Priya Morjaria **Date:** 03 May 2018

Supervisor Signature: C Gilbert **Date:** May 3 2018

Helpful developments and technologies for school eye health programmes

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Assistant Professor in International Eye Health: International Centre for Eye Health, London, UK. Co-Founder & CEO of The Peek Vision Foundation and its trading subsidiary, Peek Vision Ltd.

School eye health programmes provide a unique opportunity to positively influence the health of 700 million children globally. The impact of school eye health (SEH) goes far beyond good vision—it encompasses education, social development and economic productivity.

ANDREW BASTAWROUS

Figure 1 *Top:* Teachers screening children using Peek Acuity in a school in Trans Nzoia County, Kenya. *Above:* the Peek Visual Acuity app on a smartphone.

In all school eye health programmes, there are usually a number of factors which limit implementation, which can include a lack of trained personnel for screening, accurate diagnosis and acceptable treatment. The availabiliy of appropriate and affordable spectacle frames and lenses for children with refractive error, and access to specialist treatment for diagnosis and management of other eye conditions, are important resources that need to be accessible. New technology and innovative medical devices and software can be used at many stages in school eye health programmes. These innovations can make the programme more efficient and effective and can offer benefits to those running the programme as well as the children receiving care.

The following are essential to ensure that all children receive appropriate care:

- Visual acuity screening
- Simple eye examination
- Refractive error assessment
- Spectacle dispensing
- Identification of other eye conditions and referral
- Health education for children, parents and teachers.

Each task in a school eye health programme can affect the quality of care provided. Below, and in Table 1, we summarise some of the challenges and outline new developments that could assist in improving the quality and delivery of comprehensive school eye health. The list is not exhaustive and only gives a few examples of what is currently available.

Screening

During screening, there are several challenges from the provider's perspective. The screening needs to be standardised in terms of the type of vision chart used, the training of the personnel who will screen, and the criteria for referral. We recommend using a single line optotype (see Figure 1, p. 30). Peek Acuity is a smartphone-based application which helps to standardise testing and referral and reduce the time taken to screen. It can be used to screen at a test distance of 2 m or 3 m, and the definition of pass or fail visual acuity screening (i.e. less than 6/9 or less than 6/12) is automated and can be adapted to the local programme (Figure 1). See more here: **https://www.youtube.com/watch?v=2l8RD-xsT30**

Eye examination and refractive error assessment

These are crucial elements of a school eye health programme. Depending on the skills and qualifications of personnel available, these can be either two separate stages or be combined. To assist in an eye examination, low cost ophthalmoscopes are now available, including Optyse and ArcLight. These can also be used as torches to examine the anterior segment. ArcLight (Figure 2) has a solar panel to recharge the battery. Read more: **http://arclightscope.com/features/.** Initial assessment of the refractive error using an autorefractor (such as SmartVision or EyeNetra) can help to speed up refraction, but it is essential that this is followed by comprehensive refraction by a skilled practitioner.

Spectacle dispensing

Dispensing and delivering spectacles pose further challenges, particularly when it comes to the availability of high-quality spectacle frames that are affordable,

Table 1 **Challenges in school eye health programmes and new developments**

Challenges	New development
Vision screening	
1 Standardising the type of chart, distance of chart and definition of pass/fail acuity 2 Minimising the subjectivity of the test 3 Reducing the time taken 4 Minimising false positives	Peek Acuity smartphone vision test
Simple eye examination and refraction	
1 Identification of false positive referrals 2 Time taken to identify those that require refraction 3 Skills required for refraction 4 Equipment required for refraction 5 Fundus examination 6 Data entry and management	1 Refraction • SmartVision – smartphone based autorefractor • EyeNetra – Refraction and Electronic Medical Records • SPOT – autorefractor • SureSight Autorefractor 2 Fundus examination • ArcLight (low-cost ophthalmoscope) • Optyse (low-cost ophthalmoscope) • Smartphone ophthalmoscopes (Ophthalmic Docs Fundus) 3 Management information systems (end-to-end systems) • Peek School Screening – patient tracking and data entry • Orbis REACH
Dispensing and health education	
1 Over-prescribing 2 Lack of frame choices 3 No health education/information given to child or parent 4 Time taken to receive spectacles 5 Cost of spectacles 6 Quality of spectacles: lenses and frames 7 Data entry and management	• Ready-made spectacles • Ready-to-clip spectacles • PeekSim images • Voice messages • SMS to carers
Other eye conditions	
1 Skills required to identify eye conditions 2 Equipment required	• Arclight (anterior segment loupe also) • Smartphone ophthalmoscopes (multiple)
Specialist referral and health education	
1 Referral pathway 2 Clear referral criteria 3 Access to service 4 Awareness of importance of referral by parents/carers	• Voice messages • SMS • Peek simulation images • Peek School Screening System

acceptable and appropriate for children (see article on page 33 for innovations in spectacles for children).

Treatment of other eye conditions and specialist referral

The following children need to have a detailed eye examination, including examination of the posterior segment: those with strabismus, corneal opacities, or high degrees of refractive error, and those for whom visual acuity does not improve to normal with refraction. Low-cost ophthalmoscopes, such as ArcLight or Optyse, can also be used for this purpose. After identification, these children need to be referred for further examination as appropriate, e.g., for routine/urgent ophthalmologist review or cycloplegic refraction.

Health education

The final stage in the process is health education of parents/carers, as it is vital that they know about the results of the screening and eye examination of their child, and the action required. This is usually done by giving the child an information sheet or pamphlet to take home for their parents, but this can be challenging where many adults are not literate or where multiple languages are used. Software, such as the Peek School Screening System, can address this by sending SMS or pre-recorded voice messages to parents/carers. Peek can also generate photographs which show how the world appears to a child with uncorrected refractive error (simulation images), which can also be sent to parents.

Figure 2
The ArcLight ophthalmoscope

Continues overleaf ➤

Management information system (MIS) software

Management information system (MIS) software, such as Orbis' REACHSoft, capture data for planning, implementation, and monitoring of field activities. The data generated can then be analysed and used to better understand local service delivery challenges.

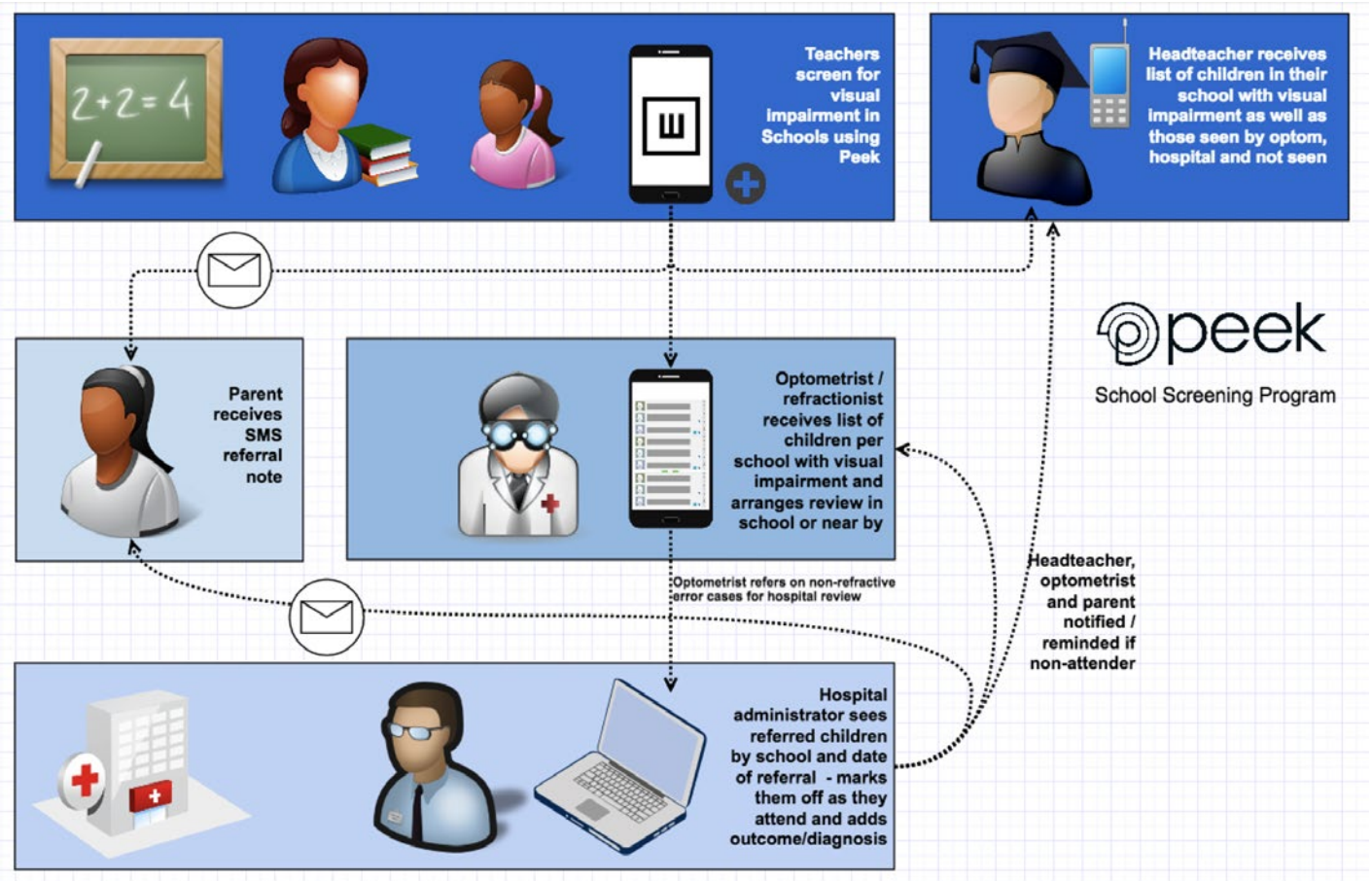
Another example of a MIS system is the Peek School Screening System (Figure 3), which works in tandem with the Peek Acuity App. It is integrated with software that tracks children as they move through each stage in the comprehensive school eye health programme (Figure 3). It can, for example, automatically create a referral for children who have failed screening or have been identified as needing more specialist care, and communicate this to staff at the base hospital or vision centre. The system is also able to capture parents' mobile numbers so they can be kept informed and also receive reminders of follow-up appointments, etc. The software allows children to be tracked at each stage in the process, and generates data that can be used to monitor the programme in real-time, identifying bottlenecks early in the process.

Table 2 summarises how management information system software can be of benefit to programme managers as well as children and their families.

Table 2 The benefits of management information software to programme managers, children and parents

Who benefits	Benefits
Programme managers	• Visual acuity screening is quicker and easier with standardised optotypes or Peek Visual Acuity App • Potential to reduce the burden on specialist eye services • Better accountability as bottlenecks in the system can be detected early and resolved in a timely manner • Provides a system that enables continuous improvement • Alignment of different partners around standardised outcomes • Easier reporting systems and greater accountability
Children and their parents	• Reduced waiting for screening, eye examination/refraction and spectacle dispensing • Empathy from teachers, parents and peers with increased awareness and knowledge about ocular conditions • Better communication with decision makers with an opportunity to have concerns addressed • Less travel for further review/treatment • Less stigma about the use of spectacles or eye treatments • Better vision

Figure 3 The Peek School Screening System and how it can be used to track children through the system and for health education of parents/carers



Chapter 6. Implications of the findings for programmes, policy and future research

The aim of this thesis was to gather evidence to improve the efficiency and effectiveness of school eye health programs for uRE, by undertaking two randomized clinical trials in India – in Bangalore and Hyderabad. The results and main strengths and limitations of both trials are discussed in the individual papers. This chapter is a broader discussion of the implication of the findings for programmes, policy and future research given the findings from both trials.

The majority of children do not know that they are not able to see clearly, until they undergo screening. Poor vision in childhood has negative consequences, such as decreased academic performance and less social interactions with their peers. However, many children are not aware of their debilitating visual needs and tend to find ways in which to compensate. They sit closer to the blackboard, hold their books closer, and partially close their eyes to create a pinhole effect. In some cases, children choose not to do tasks that require visual concentration, further diminishing their academic performance. Although there are limited rigorous research studies, it is recognised that there is correlation between good vision and improved educational outcomes for children. Uncorrected refractive errors are the leading cause of vision impairment in children and can have a significant impact on a child's life and wellbeing. Thus, the detection of eye health issues in children is very important. School based eye health programmes are a platform to align with other school health programmes and can reach the majority of children on a regular basis. (Figure 34)

Figure 34: The use of schools as a platform for delivery of health initiatives

There is evidence that school-based programmes for health and nutrition can be a cost-effective and low-cost solution. Examples from deworming and vitamin A supplementation initiatives in schools have provided positive results.[1, 2] A milestone was reached in April 2000 when there was international consensus and a framework to "Focus Resources on Effective School Health (FRESH)" was developed jointly by UNESCSO, UNICEF, WHO and the World Bank.[3] More recently UNESCO (2015) launched "Education 2030 Framework for Action, the Incheon Declaration, towards inclusive and equitable quality education and lifelong learning for all." The framework includes ensuring a healthy environment, the detection of disability and disease, with multisector policies and strategies involving a range of ministries responsible for nutrition, health, water and sanitation and child protection for example.[4] These documents provide an opportunity for scaling up school eye health initiatives. Indeed, in response to the realization that uRE are increasing in children, particularly myopia, several large scale programs have been launched, such as Our Children's Vision (the Brien Holden Vision Institute),[5] REACH (ORBIS International),[6] SHIP (The World Bank and Sightsavers),[7] and the programmes such as PRICE in China[8] based on evidence from the REAP (Rural Education Action Program.[9] In addition, Peek Solutions is being rolled out in a large number of countries, including a national programme in Botswana.[10] Together these programs will reach millions of school children.

Schools can be used an effective platform to deliver services for a range of eye conditions in children, including uRE, and to create awareness. In chapter 2, we identified a number of questions that affect the delivery of SEH programmes. Some are specific clinical and technical questions that require research to ensure that delivery of programmes is evidence based. An important element of a SEH programme is to ensure that children who are prescribed spectacles actually use them after they are dispensed to receive the benefits. Nevertheless, this is one of the elements that is not usually incorporated in programmes and spectacle wear is rarely monitored.

The first trial on spectacle compliance in ready-made spectacles vs. custom-made spectacles defined screen failure, used prescribing guidelines and children could choose their spectacle frames in both arms. The results provide evidence that a high proportion of children are eligible for ready-made spectacles, and the spectacle

wearing rates were higher than most studies. Although we are not able to disentangle which of these two factors increased spectacle wearing rates, it is a valuable study as to our knowledge it was the first to use clearly defined prescribing guidelines. Additional studies would be of value to address the effect of prescribing guidelines on spectacle wear among children in different settings.

The secondary objective of this trial were predictors of spectacle wear and reasons for non-wear. The results from this trial highlight the importance of prescribing spectacles that children will perceive a benefit from. For a programme this can substantially decrease the cost, is unnecessary spectacles and not dispensed, and it will mean children are more likely to wear their spectacles. The two main reasons for children not to wear their spectacles was teasing or bullying by their peers and parental disapproval. This was not unlike other global studies but it highlighted the issue of appropriate health education and how important it is to include parents, teacher and other children in the classroom. None of the children reported spectacle appearance as a reason for not wearing their spectacles, while many other studies have reported that the appearance of their spectacles is as reason for not wearing them. Giving children a choice to decide what they want to wear is important.

Given the low difference in spectacle wear between the two arms of the trial, a cost minimisation analysis was undertaken. This showed considerable cost savings per hundred children needing spectacles. For example, if 100,000 children are screened and 4% require spectacles (4,000) the cost saving if ready-made spectacles for those eligible would be approximately 85,000 (range 33,600-122,160) USD.

A limitation of this study was that we did not ask children who were wearing their spectacles why they are wearing them.

Lessons learnt from the first trial influenced the design of the second, using novel mobile phone technology (Peek) to deliver health education to increase spectacle compliance. In an attempt to increase spectacle wear and address the teasing and bullying and create awareness amongst parents we used culturally appropriate images (PeekSim) for classroom education and to send home to parents, along with voice messages in the local language to increase awareness amongst parents. Although spectacle compliance was higher than in other studies in India and globally, there was no statistically significant difference between the Peek arm and standard care arm of

the trial.

There are many possible reasons why the health education did not have the desired effect. Firstly, the health education may not have been delivered or accepted as intended. We investigated this by calling parents of children who selected PeekSim images and who were sent voice messages. Through this process, we were able to find out that the majority of parents did not received the images from their children. This finding was extremely important as it helped us understand the complexities of delivering health education and creating behavioural change. We were able to contact 90% of the parents whose children were dispensed spectacles and only 14% had actually received the PeekSim image from their child. What was very positive is that among those who did receive the PeekSim image, 71% understood the message and stated they encourage their child to wear their spectacles. A limitation is that we were not able to contact the children who did not take the PeekSim images home to their parents to understand the reasoning behind this. One assumption is that children chose images they liked i.e. their favourite movie star, the Indian cricket team etc. and so they might have kept them for themselves.

The field workers who delivered the classroom health education may not have had adequate training or skills, although we trained the field workers as part of the training programme. Prior to beginning the trial we attempted to assess the attitudes to spectacle wear before and after classroom education sessions, using a visual analogue scale, but this was challenging and the responses were not reliable. Children in the classroom viewed it as a test of their knowledge. Had teachers able to deliver classroom education, as we intended, the findings may have been different.

6.1 Implications for programmes

The use of ready-made spectacles in programmes would be very beneficial from a provider and a beneficiary perspective. The cost savings to a programmes and the ease of a child receiving their spectacles on the same day as screening would be very efficient for a programme and make it accessible. For parents/guardians the resources required to arrange for transport to take a child to the services and the time they would have to take off from their daily activities is an equally important benefit.

The use of Peek Solutions and technology has the potential to change how programmes are implemented, monitored and evaluated. The availability and easy

access to real-time data can have very positive implications. The Peek SEH system is able to track the child at every point in the patient pathway. Appendix 4 is a visualisation of the patient journey for a child developed for Peek Solutions, identifying at which stage data can be collected and tracked. This allows a programme to identify exactly where there is a 'leakage' and work on solutions that can address this. This allows for a system to continuously improve and work efficiently. The ability to contact individual parents and give them information in a way that is acceptable and easily understood means that parents are included in the decision making process of their child's health and are kept informed at every point. For example, a parent can be notified on the day their child will be screened, their spectacles are ordered and when the spectacles will arrive. Programme managers can use the web based 'Admin' dashboard to view reports and live statistics, including numbers screened, referred and treated. Necessary data can also be sent to other stakeholders, for example, after a child has been refracted, their prescription details including frame number can be generated and sent to an optical laboratory for spectacles to be glazed.

An aspect that was common in both trials was the use of prescribing guidelines which can have two benefits (i) cost savings to programmes and parents and (ii) higher spectacle wear, as as only children with a significant uRE were dispensed spectacles who are more likely to perceive a benefit and hence use their spectacles.

6.2 Implications for research

The use of ready-made spectacles needs to be further explored in other regions of India and globally where SEH programmes are implemented. There are increasing number of programmes where the use of low-cost, good quality ready-made spectacles can bring about significant cost-savings. At Our Children's Vision partners meeting in February 2018, Essilor (a global company that produces ophthalmic lenses and optical equipment) committed to donating ready-made spectacles for SEH until the year 2050 (a generation of children).

The research should focus not just on the proportion of children eligible for ready-made spectacles, but also take account of the perspectives of clinicians. Anecdotal evidence suggests that refractionists and optometrists are resistant to prescribing and

dispensing ready-made spectacles. One of the reasons is the lack of understanding on how to decide which children are suitable for ready-mades. Secondly, some clinicians have expressed that prescribing ready-mades feels like a 'disservice' to their patients. This brings about the importance of creating behaviour change not just within children, parents and teachers but also within clinicians. Further work needs to be done around the acceptability of ready-mades amongst refractionists and optometrists to ensure that they are comfortable and understand the benefits and limitations of dispensing ready-made spectacles.

As discussed, the use of Peek as a novel health education intervention was a complex intervention. Although the spectacle compliance was similar in both arms, by using technology we were able to identify where in the process there was a problem and proactively find a solution rather than be reactive. Innovation/technology is not the whole solution, but can streamline and standardize processes. We were attempting to create behaviour change but in order to do that effectively, further research needs to be done on the social aspects of spectacle wear, such as acceptability, who makes household decisions, is there any gender bias to which children wear spectacles.

Multiple theories and constructs can be used to describe behavior or to bring about behavior change, including the Social Ecological Model (SEM) which describes five nested, hierarchical levels which influence behavior i.e., individual, interpersonal, organizational, community and public policy. However, to tease out at which level the change needs to happen and how much change is complex. The SEM emphasizes that it is easier to adopt healthier behaviours by bringing about change in the environment, by using the example of role models, and by reinforcement.[11] Thus, for stakeholders who implement SEH programmes, addressing the reason for non-compliance of spectacles in their settings and developing relevant and appropriate interventions should be a priority to address before commencing screening activities.

The focus of this thesis is on the uREs component of a comprehensive SEH programme. When planning and implement a comprehensive SEH programme the eye health needs of teachers need to be considered too, such as the management and treatment of presbyopia, diabetic retinopathy and glaucoma. Children will also present with other conditions such as congenital cataract, amblyopia, allergies etc.

the management and treatment of these should also be part of a comprehensive SEH programme.

6.3 Dissemination of findings

In February 2016 staff at the International Centre for Eye Health were invited by the Brien Holden Vision Institute to be part of a working group to draft guidelines for school eye health programs in low resource settings.[12] We were able to include some of the main findings from the two trials in the guidelines, such as the benefits of prescribing guidelines and the use of ready-made spectacles. After feedback from members of IAPB's School Eye Health Working Group, the guidelines were endorsed by the IAPB on 17 April 2018, and were presented at a meeting of Our Children's Vision, which has 72 partners across the world. The guidelines are also being used in several of the other initiatives outlined above.

Already included in this thesis are articles from the August 2017 issue of the Community Eye Health Journal (CEHJ), which had 'School Eye Health' as the theme.[13-15] The CEHJ is distributed at no cost to health care providers in low and middle-income countries. In January 2016, paper copies of the journal were sent directly to 22,500 subscribers, majority of which are in Sub-Saharan Africa. Furthermore, nearly 230,000 users from 220 countries visited the website and made over 421,000 downloads of the content. Thus, the reach of the journal is vast and with the development of a mobile phone based app of the journal, this is set to increase.

Over the last four years, I have had the opportunity to speak at a range of conferences and meetings about the findings of this research and more broadly the importance of SEH guidelines incorporating the use of ready-made spectacles, prescribing guidelines and the use of health education that involves teachers, parents and children. (Table 7)

Table 7: Dissemination of findings over the past four years

	Date	Location	Meeting	Title	Type
1	September 2014	London, UK	International Society of Geographical & Epidemiological Ophthalmology (ISGEO)	Impact of visual acuity screening cut-off and spectacle wearing rates in India	Oral presentation
2	August 2015	Medellin, Colombia	1st World Congress of Optometry (WCO)	Public Health approaches to School Eye Health	Oral presentation
3	May 2016	LSHTM, UK	3-minute thesis competition winner of People's Choice Award	To see or not to see - why is it a question?	Oral presentation
4	October, 2016	Aravind Eye Hospital, Madurai, India	Priorities in Paediatric Eye Care Delivery, Intervention Models and Research. USAID partners meeting	Refractive errors in children: Challenges in approaches and gaps	Oral presentation
5	October, 2016	Aravind Eye Hospital, Madurai, India	Priorities in Paediatric Eye Care Delivery, Intervention Models and Research. USAID partners meeting	Research: interventions for refractive errors	Oral presentation
6	November, 2016	Durban, South Africa	IAPB 10th General Assembly	Predictors of spectacle wear among children randomized to conventional ready-made or custom-spectacles in Bangalore, India	Poster presentation
7	November, 2016	Durban, South Africa	IAPB 10th General Assembly	Spectacle wearing and reasons for non-wear in children randomized to conventional ready-made or custom-made spectacles	Poster presentation
8	November, 2016	Durban, South Africa	International Society of Geographical & Epidemiological Ophthalmology (ISGEO)	Spectacle wearing and reasons for non-wear in children randomised to conventional ready-made or custom made spectacles in Bangalore, India	Oral presentation
9	September 2017	Hyderabad, India	2nd World Congress of Optometry (WCO)	Spectacle wearing and reasons for nonwear in children randomized to conventional ready-made or custom made spectacles in Bangalore, India	Oral presentation

10	August 2017	Taiyuan, China	1st China Eye Health Conference	Peek: Evidence for Implementation in School Eye Health	Oral presentation
11	September 2017	Hyderabad, India	2nd World Congress of Optometry (WCO)	Predictors for spectacle wear in children randomized to conventional ready-mades or custom-made spectacles in Bangalore, India	Oral presentation
12	September 2017	Hyderabad, India	2nd World Congress of Optometry (WCO)	A standardized approach to comprehensive school eye health programs: guidelines	Workshop
13	September 2017	Hyderabad, India	2nd World Congress of Optometry (WCO)	Effectiveness of a novel mobile health education (Peek) on spectacle wear among children: study protocol for an RCT	Oral presentation
14	September 2017	Hyderabad, India	2nd World Congress of Optometry (WCO)	Standard guidelines for comprehensive school eye health programs: the evidence base	Plenary session
15	September 2017	Hyderabad, India	2nd World Congress of Optometry (WCO)	World Council of Optometry: The Paul Berman Young Leader Award	Award
16	September 2017	Hyderabad, India	Wellcome Collection: Packed Lunch event	Packed Lunch: Global Eye Health	Invited speaker
17	October 2017	Cape Town, South Africa	USAID: Child Blindness Program, Partners Meeting	Evaluation of the effectiveness of a novel mobile phone health education intervention (Peek) on spectacle wear among children	Oral presentation
18	April 2018	Belfast, Ireland	Global Health Symposium, Queens University Belfast	A comprehensive mobile phone-based system for School Eye Health	Invited speaker
19	December 2015, 2016, 2017	Paris, France	Vision Impact Institute board meetings	Results of both trials: ready-made spectacles and Peek	Invited speaker
Upcoming					
20	May 2018	Liverpool, UK	Royal College of Ophthalmologists Annual Congress	Evidence-based practice vs Practice-based evidence	Invited speaker
21	June 2018	London, UK	Global Ophthalmology Seminar “How to get involved – as a Team”	Uncorrected refractive errors: the global perspective	Invited speaker
22	June 2018	Barcelona, Spain	World Ophthalmology Congress, 2018	Results of clinical trials to assess ready-made spectacles and health education on compliance with spectacle wear in India	Invited speaker

In September 2017, I was invited by the World Council of Optometry, to speak at a plenary session on evidence based SEH at the 2nd World Congress of Optometry, Hyderabad, India. At the same meeting, I was awarded the Paul Berman Young Leader in Optometry based on my work in the field of Public Health Optometry. This is a great honour and has given me a platform to continue to talk about standardised methods to deliver SEH programmes. Based on this award, I have been invited to the World Ophthalmology Congress in June 2018 to speak at a session on SEH and share the results from the two clinical trials.

Going forward, with the increasing global trend in the prevalence of myopia and the use of technology and mobile phone coverage rapidly increasing globally, it is important to ensure that any implementation of programmes takes all these factors into account. There is a need to collaborate not just within the public health for eye care sector, Ministries of Education, but also with other organisations that implement school health programmes, and with other sectors that have evidence for the use of mHealth and eHealth interventions.

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APPENDICES

Appendix 1: Visual analogue scale used pre and post classroom health education

1 Some children wear spectacles. The reason why they do this is because

- ☐ Their parents have told them to wear them
- ☐ They want to look clever
- ☐ They can only see clearly by wearing spectacles

2 If my best friend was told they needed spectacles, I would

- ☐ Say they should not wear them as they do not look good
- ☐ Say that they should only wear them sometimes
- ☐ Say they should wear them when they need to see clearly

3 If my friend was told they needed to wear spectacles, how would I feel?

Tick the box under the image which shows how I would feel

☐ ☐ ☐ ☐ ☐

4 If I was told I needed spectacles, this is how I would feel

Tick the box under the image which shows how I would feel

☐ ☐ ☐ ☐ ☐

Appendix 2: Topic guides for formative research: interviews and focus group discussions for development of PeekSim images and voice messages

Topic guide for interviews with Head Teachers

Name of school _____

Name of Head teacher _____

Length of time as Head Teacher _____ years

Demonstrate Peek Acuity SightSim images

What are your views on using SightSim images to increase awareness about uncorrected refractive errors in children?

- Which images do you think would be suitable?
- Should there be different images for boys and girls?
- Should there be different images for children aged 11-13 years and those aged 14-15 years?

Would you be willing for older children in your school deliver a short education session on refractive errors using SightSim images, after a short period of training?

Demonstrate Peek Acuity screener

We plan to send voice message reminders to parents of children who are given spectacles.

Do you think parents would be willing to share their mobile phone numbers?

Do you have any comments about Peek Acuity and the SightSim apps?

Thank you for your time and for the discussion

Topic guide for interviews with classroom teachers

Name of school _____

Name of teacher _____

Length of time as teacher _____ years

Demonstrate Peek Acuity SightSim images

What are your views on using SightSim images to increase awareness about uncorrected refractive errors in children?

- Which images do you think would be suitable?
- Should there be different images for boys and girls?
- Should there be different images for children aged 11-13 years and those aged 14-15 years?

What do you think parents of children who need spectacles might think about the SightSim images?

We plan to send voice message reminders to parents of children who are given spectacles.

Do you think parents would be willing to share their mobile phone numbers?

Do you have any comments about Peek Acuity and the SightSim apps?

Thank you for your time and for the discussion

Topic guide for interviews with parents

Name of school _____

Name and gender of participants

Initials	Gender	Gender of child(ren) aged 11-15	Age of child(ren) aged 11-15	Unique ID

Parents without spectacles

Additional questions for parents who wear spectacles themselves

Please can you tell me what you know about refractive errors i.e. the need to wear spectacles?

Do you know why refractive errors occur?

Do you know why refractive errors occur in children?

What are your views about children wearing spectacles?

- Does wearing spectacles cause any harm to the eyes?
- When should children wear their spectacles?
- When do children not need to wear their spectacles?

Do any of your children wear spectacles?

If so, did you encounter any difficulties in encouraging them to wear their spectacles?

Do you any of you have examples of how you were able to ensure your children wore their spectacles?

We are planning a study in which we will use “simulation” images to explain what the world looks like to children who need spectacles but who do not yet have them.

Demonstrate Peek Acuity SightSim images

What kind of activities do you think children who see the world like this might find difficult?

Are there any other things such as leisure time, spending time with friends or playing sport that children with refractive errors may find difficult?

What are your views on using SightSim images to increase awareness about uncorrected refractive errors among the *children* who need them?

- Which images do you think would be suitable to show children??
- Should there be different images for boys and girls?
- Should there be different images for children aged 11-13 years and those aged 14-15 years?

What are your views on using SightSim images to increase awareness about uncorrected refractive errors among the *parents of children* who need them?

- Which images do you think would be suitable to show children??
- Should there be different images for boys and girls?
- Should there be different images for children aged 11-13 years and those aged 14-15 years?

In this study we also plan to send voice messages to parents of children who are given spectacles, to let them know, and to request parents to encourage their child to wear their spectacles.

- What are your views on this idea?
- If you were a parent of a child given spectacles, what SMS message would you find the most useful?
- Do most parents have a mobile phone?
- Do you think parents would be willing to give their mobile phone number to the project team for this purpose? The mobile phone numbers will all be destroyed at the end of the study
- Would it be best to send the SMS message to mothers or to fathers?

Thank you for your time and for the discussion

Topic guide for interviews with children

Participant group

Group	Boys aged 11-13 years	Boys aged 14-15 years	Girls aged 11-13 years	Girls aged 14-15 years
Number				
Group ID	B1	B2	G1	G2

[Warm up exercise]

Some children wear spectacles – why do you think they wear spectacles?

What do you think about children who wear spectacles?

Do any of you know any children who were given spectacles but who do not wear them?

Do you know why they do not wear them?

[Give children +3 dioptre with 2D cylinder spectacles to put on. Say this is what the world can look like for children who need spectacles but do not have any. This is called a refractive error]

What does the world look like while you are wearing these spectacles?

If you were like this all the time, what might you have difficulty doing?

- Could you still see the blackboard, for example?
- What about at home?
- What about sports?
- What about hanging out with friends?

Does this make you feel any differently about children who need to wear spectacles to see clearly?

[Demonstrate Peek Acuity SightSim images. Explain that images like this will be used to make children and parents aware of what the world looks like with a refractive error, and what it could look like with a pair of spectacles]

What do you think about these images which are meant to show what the world looks like if you have a refractive error?

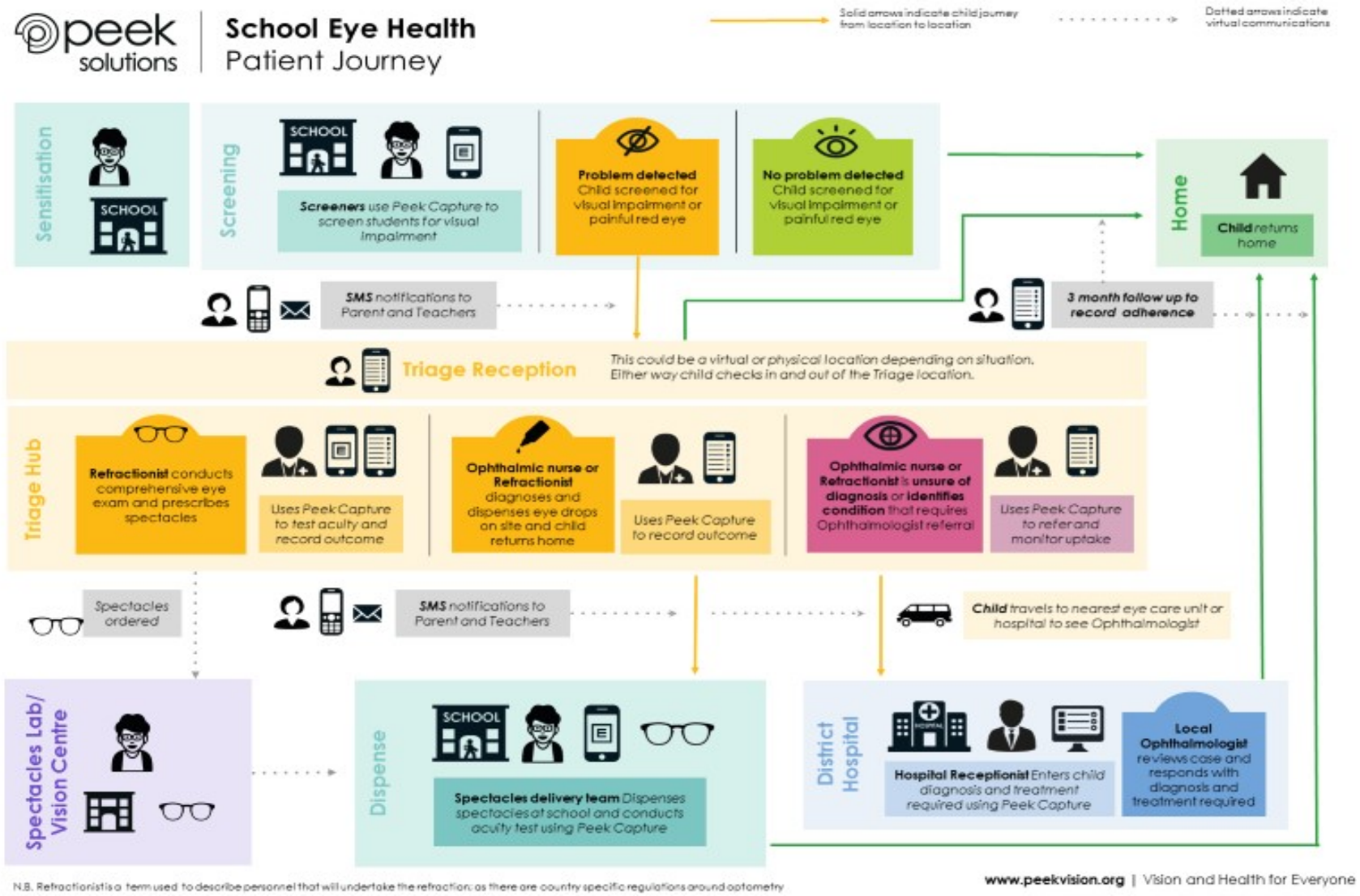
Are there any other activities which it would be good to include?

Should boys and girls be shown different images?

Do have any other comments or questions?

Thank you helping with the project

Appendix 3: Visualisation of the patient journey for a child developed for Peek Solutions



Appendix 4: Ethics approvals

Trial 1: London School of Hygiene & Tropical Medicine ethics approval

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Miss Priya Morjaria
LSHTM

9 January 2015

Dear Miss Morjaria

Study Title: *Spectacle wearing amongst children randomised to ready-made spectacles or prescription spectacles, and cost savings to programmes

LSHTM Ethics Ref: 8827

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Investigator CV	CV Full Clare Gilbert Oct 2014.pdf	01/12/2014	1
Investigator CV	CV_Priya_10_2014.pdf	01/12/2014	1
Protocol / Proposal	Teachers proposal 2 Dec 2014 PM.pdf	02/12/2014	1
Information Sheet	Info and consent forms Dec 2 2014 - v2 PM.doc	02/12/2014	1
Protocol / Proposal	LO India protocol 2Dec 2014.docx	02/12/2014	3
Sponsor Letter	Insurance letter.docx	02/12/2014	1
Covering Letter	LEO reponse to provisional approval 03 Jan 2015	03/01/2015	1
Protocol / Proposal	L'Occitane RE India protocol revised Dec 23 2014	03/01/2015	2
Information Sheet	L'Occitane RE info and consent forms revised Dec 23 2014	03/01/2015	2

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John Dil Porter

Trial 1: Sankara Eye Hospital, Bangalore, India Institutional Review Board approval

ACTION TAKEN REPORT
DATE OF MEETING : 27/12/2014

ETHICS COMMITTEE INSTITUTIONAL REVIEW BOARD
SANKARA EYE HOSPITAL, BANGALORE

Sr. No	Action Item	Action Taken	Owner
1	Welcome address	-	Dr Vikram Chaudhuri
2	Presentation on study 'Spectacle wearing amongst children randomized to ready-made spectacles or prescription spectacles, and cost savings to programs.'	Study approved	Ms Priya

Trial 1: London School of Hygiene & Tropical Medicine sponsorship and insurance

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Our ref: QA653

Professor Clare Gilbert
LSHTM

2nd December 2014

Dear Professor Gilbert,

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

As the authorised representative for the London School of Hygiene & Tropical Medicine (LSHTM), I can confirm that LSHTM will act as the identified Research Sponsor, the organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial, for the above titled project. I can confirm that the research proposal has been reviewed, assessed and registered by the Clinical Trials Sub-Committee.

It is the Chief Investigator's responsibility to ensure that members of the research team comply with all local regulations applicable to the performance of the project, including, but not limited to: the Declaration of Helsinki (2008), ICH Good Clinical Practice Guidelines (1996), and for projects conducted in the UK: the Medicines for Human Use (Clinical Trials) Regulations (2004), the Research Governance Framework for Health and Social Care (2005), the Data Protection Act (1998) and the Human Tissue Act (2004).

LSHTM carries Clinical Trial/Non Negligent Harm Insurance and Professional Negligence Insurance applicable to this study:

	Clinical Trials/Non Negligent Compensation	Medical Malpractice
Insurer	Lloyds (MarketForm)	Lloyds (MarketForm)
Certification No.	2014/00073264	2014/00073265
Finance Cover	£5 million pounds sterling	£10 million pounds sterling

The Non-Negligent harm policy is worldwide, with the exception of the United States and Canada. The policy is subject to terms, conditions and exceptions.

LSHTM Sponsorship is conditional on the project receiving applicable ethical and regulatory approval, complying with LSHTM policies and procedures, as well as successful contract and agreement negotiations from the Research Operations Office, where relevant, before the study commences.

A copy of the ethics and regulatory approval letters must be sent to the Quality & Governance Manager prior to the study commencing. Sponsorship is dependent on obtaining local approval for all sites where the research is being conducted. It is recommended that all members of the study team attend Good Clinical Practice (GCP) training every two years.

Yours sincerely,

[redacted]

Patricia Henley
Quality & Governance Manager
On behalf of the Clinical Trials Sub-Committee
T: 020 7927 2626
E: patricia.henley@lshtm.ac.uk

Trial 2: London School of Hygiene & Tropical Medicine ethics approval

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Miss Priya Morjaria
LSHTM

24 June 2016

Dear Priya

Study Title: Effectiveness of a novel mobile health education intervention on spectacle wear among children in India: a cluster randomized trial

LSHTM Ethics Ref: 10798-01

Thank you for your application for the above amendment to the existing ethically approved study and submitting revised documentation. The amendment application has been considered by the Interventions Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above amendment to research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval for the amendment having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Other	SighSim India protocol April 18 2016 PM amended	19/04/2016	2
Other	SightSim ethics amendment request 19 April 2016 PM	19/04/2016	1

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

[redacted]

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/

Improving health worldwide

Page 1 of 1

Trial 2: Indian Institute of Public Health, Hyderabad Institutional Ethics Committee approval

Institutional Ethics Committee

Indian Institute of Public Health-Hyderabad /
Public Health Foundation of India

ANV Arcade, Plot No.1, Amar Cooperative Society, Kavuri Hills, Madhapur, Hyderabad - 500081, A.P., INDIA

Communication of Decision of the IEC[1]

Form II

TRC-IEC No Application No:	IIPHH/TRCIEC/068/2016	**Date:**		20-07-2016	
Project Title:	Effectiveness of a novel mobile health education intervention on spectacle wear among children in India: a cluster randomized trial				
Principal Investigator:	Prof. Clare Gilbert				
Review	**Full Review**	☒		**Expedited Review**	☐
Date of review:	14th July 2016				
Date of previous review:	*(in case of re-submitted applications)*				
Decision of the IEC:	**Approval**	☒		**Resubmission**	☐
	Conditional Approval	**Study can begin**	☐	**Study cannot begin**	☐
Requirements to be fulfilled in case of conditional approval:					
Suggested alterations in case of resubmission:					
In case of approval, ***recommended for a period of :***	**Approval is valid for a period of one year from the date of issue**				
Comments:					

Please note: Beginning of the research based on this approval implies acceptance of the following conditions:

1. *PI will inform the Secretariat of the start date of the study.*
2. *The PI will inform the IEC in case of any adverse events.*
3. *The PI will inform the TRC (Technical Review Committee) and IEC in case of any change of study procedure (including- changes in the informed consent form, recruitment procedure, potential research participant information), site and investigator.*
4. *The PI will inform the TRC - IEC Secretariat on termination of the study and submit a final report within 3 months of completion of the study.*
5. *Members of the IEC have the right to monitor the study with prior intimation.*
6. *Progress report to be submitted to the TRC-IEC Secretariat every 6 months from the date of start of study.*
7. *This permission is only for the period mentioned above.*

[redacted]

Name and signature of Member Secretary
Dr. Nanada Kishore K

[redacted]

Chairperson, IEC, IIPH
Dr. Shamanna

[1] Adapted from the ICMR form: available at http://www.icmr.nic.in/bioethics/Communication%20of%20Decision%20of%20the%20IEC.doc

Page **1** of **1** FORM II PHFI IEC/Ver3/09

Trial 2: London School of Hygiene & Tropical Medicine sponsorship and insurance

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636
www.lshtm.ac.uk

Our ref: QA817

Professor Clare Gilbert
LSHTM

18th February 2016

Dear Prof Gilbert,

Re: Effectiveness of a novel mobile health education intervention on spectacle wear among children in India: a cluster randomised trial

As the authorised representative for the London School of Hygiene & Tropical Medicine (LSHTM), I can confirm that LSHTM will act as the identified Research Sponsor, the organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial, for the above titled project. I can confirm that the research proposal has been reviewed, assessed and registered by the Research Governance and Integrity Office.

It is the Chief Investigator's responsibility to ensure that members of the research team comply with all local regulations applicable to the performance of the project, including, but not limited to: the Declaration of Helsinki (2008), ICH Good Clinical Practice Guidelines (1996), and for projects conducted in the UK: the Medicines for Human Use (Clinical Trials) Regulations (2004), the Research Governance Framework for Health and Social Care (2005), the Data Protection Act (1998) and the Human Tissue Act (2004).

LSHTM carries Clinical Trial/Non Negligent Harm Insurance and Medical Malpractice Insurance applicable to this study:

Insurer	Newline
Certification No.	FI0816115
Finance Cover	£10 million pounds sterling

The Non-Negligent harm policy is worldwide, with the exception of the United States and Canada. The policy is subject to terms, conditions and exceptions.

LSHTM Sponsorship is conditional on the project receiving applicable ethical and regulatory approval, complying with LSHTM policies and procedures, as well as successful contract and agreement negotiations from the Research Operations Office, where relevant, before the study commences.

A copy of the ethics and regulatory approval letters **must** be sent to the Quality & Governance Manager prior to the study commencing. Sponsorship is dependent on obtaining local approval for all sites where the research is being conducted. It is recommended that all members of the study team attend Good Clinical Practice (GCP) training every two years.

Yours sincerely,

[redacted]

Patricia Henley
Quality & Governance Manager
T: 020 7927 2626
E: patricia.henley@lshtm.ac.uk

Appendix 5: Patient information and consent sheets

Trial 1: English and Kannada

1. Information sheet: For head teachers in study schools
2. Consent sheet: For head teachers in study schools
3. Information sheet: For parents of study children i.e. those eligible to be randomized
4. Consent sheet: For parents of study children i.e. those eligible to be randomized
5. Assent form: For study children i.e. those eligible to be randomized

Trial 2: English, Hindi and Telugu

1. Information sheet: Head teacher and teacher (formative research)
2. Consent sheet: Head teacher and teacher (formative research)
3. Information sheet: Parents focus group discussions (formative research)
4. Consent sheet: Parents focus group discussions (formative research)
4. Information sheet: Children focus group discussions (formative research)
5. Consent sheet: Children focus group discussions (formative research)
6. Information sheet: Children in pre and post-assessment (formative research
7. Assent sheet: Children in pre and post-assessment (formative research
8. Information sheet: Parents of children in focus group discussion (formative research)
9. Consent sheet: Parents of children in focus group discussion (formative research)
10. Information sheet: Parents of children in pre and post-assessment (formative research)
11. Consent sheet: Parents of children in pre and post-assessment (formative research)
12. Information sheet: Field workers taking part in validity
13. Consent sheet: Field workers taking part in validity
14. Information sheet: Parents of children in pre and post-assessment (formative research)
15. Consent sheet: Parents of children in pre and post-assessment (formative research)
16. Information sheet: Head teacher for school participation (main study)
17. Consent sheet: Head teacher for school participation (main study)
18. Information sheet: Parents of children recruited and opt-out (main study)
19. Information sheet: Children recruited (main study)
20. Assent sheet: Children recruited (main study)

#

Trial 1: Information sheet for head teachers

#

Project:	Comparison of two different types of spectacles for children with refractive errors and the eye health needs of teachers
Researchers:	Dr. KaushikMurali blr.nannakannu@sankaraeye.com Sankara Eye Care Institutes, Bangalore Tel: +91 97 39 777726 Miss. Priya Morjaria priya.morjaria@lshtm.ac.uk

We would like certain 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 of school screening programs.

Why was this school chosen?

We are inviting 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 will include children from government schools in and around Bangalore, and 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 by a trained field worker from Sankara Eye Hospital. Children who fail the screening test will then be examined in detail by a fully qualified optometrist who will decide which type of spectacles are suitable for each child. Children with uncomplicated refractive errors, which we anticipate will be approximately two thirds of children, 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 (“prescription” spectacles). Both groups of children will be able to select the spectacle frames they prefer.

Approximately a third of children will have more complicated refractive errors and so will not be suitable for the study. They will be given a pair of prescription glasses.

#

All children in the study who fail the vision screening test 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 spectacles 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 screen approximately 500 children. We anticipate that 20-30 will fail the screening test and will need to be examined by the optometrist. We are very aware that this can be disruptive to teachers as well as children. If you agree that children in your school can take part we will discuss with you when might be the best time for the 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 team will be using standard methods and all children will be given high quality spectacles. Children can occasionally take a little while to become accustomed to new spectacles, but eye strain and headache are uncommon.

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 instil 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 at minimum cost.

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. The name of your school will not be mentioned in any publications.

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.

#

Trial 1: Consent sheet for head teachers

#

Project: A comparison of two different types of spectacles for children with refractive errors and the eye health needs of teachers

Researchers: Dr. KaushikMurali
blr.nannakannu@sankaraeye.com
Sankara Eye Care Institutes, Bangalore
Tel: +91 97 39 777726

Miss. Priya Morjaria
priya.morjaria@lshtm.ac.uk

To confirm that you would like the students in the school to participate in this study, please 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 . The punishment's to do so if this is what they wish.	☐	☐

_____ _____
Head teacher's name (in block capitals) School ID No.

_____ _____
Signature of Head teacher Date (dd/mm/yy)

_____
Name of researcher

_____ _____
Signature of researcher Date (dd/mm/yy)

#

Trial 1: Information sheet for parents

#

Project: Comparison of two different types of spectacles for children with refractive errors and the eye health needs of teachers

Researchers: Dr. KaushikMurali
blr.nannakannu@sankaraeye.com
Sankara Eye Care Institutes, Bangalore
Tel: +91 97 39 777726

Miss. Priya Morjaria
priya.morjaria@lshtm.ac.uk

We would like certain students in your child's school to participate in a research project. Before you decide whether your child 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 your child 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 of school screening programs.

Why was this school chosen?

We are inviting 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 will include children from government schools in and around Bangalore, and your child's 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 by a trained field worker from Sankara Eye Hospital. Children who fail the screening test will then be examined in detail by a fully qualified optometrist who will decide which type of spectacles are suitable for each child. Children with uncomplicated refractive errors, which we anticipate will be approximately two thirds of children, 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 ("prescription" spectacles). Both groups of children will be able to select the spectacle frames they prefer.
We are doing this randomisation to understand the differences between the two types of spectacles and improve efficiency of the school screening programs.

#

Approximately a third of children will have more complicated refractive errors and so will not be suitable for the study. They will be given a pair of prescription glasses. All children needing glasses will receive them free of charge from the project 2 to 3 weeks after our initial visit, as the spectacles 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 screen approximately 500 children. We anticipate that 20-30 will fail the screening test and will need to be examined by the optometrist. This will all be done during the time that your child is at school and will not require any additional time from you or your child.
None of the procedures that will be used in the study will cause any distress or harm to the pupils as the team will be using standard methods and all children will be given high quality spectacles. Children can occasionally take a little while to become accustomed to new spectacles, but eye strain and headache are uncommon.

What happens when the research study stops?
It is recommended that school vision testing be repeated every two years, to indentify children whose spectacles need to be replaced as well as to screen children aged 11-12 years for the first time. This will be discussed with head teachers who may want to consider training teachers to measure visual acuity, with back-up support from Sankara Eye Hospital. This is the process adopted in other schools in the locality.

Does your child have to take part?
No, this is entirely your own decision. You are under no obligation to allow your child 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 child a code so that individual children cannot be identified in any reports. The name of your child will not be mentioned in any publications.

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 ready-made spectacles are shown not to be inferior in this trial, then Sankara Eye Hospital could use this approach in the future, so reducing their costs and allowing other schools to be included in their outreach programme. We also plan to present the findings at meetings and conferences, and to write them up for publication.

What if there is a problem?
If you have any questions or concerns we would be happy to discuss them with you. And you can contact the research co-ordinator at Sankara Eye Hospital (Dr. KaushikMurali on +91 97 39 777726).
Who is organising the research?
The research is being organised by Sankara Eye Hospital and London School of Hygiene and Tropical Medicine. It is being funded by the L'OccitaneFondation and Vision Impact Institute.

You will be given a copy of the information sheet and a signed consent form to keep.
Thank you very much for your attention today.

#

Trial 1: Consent sheet for parents

#

Child study number: |__|__|__|__|__|__| _____(Printed name of parent)

☐ I have read the written information OR

☐ I have had the information explained to me by study personnel in a language that I understand

and I

- confirm that the choice for my child to participate is entirely voluntarily,
- confirm that I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided,
- understand that I grant access to data about my child to authorised persons described in the information sheet,
- have received time to consider whether my child should take part in this study,
- agreefor my child to take part in this study.

Parent's signature/ thumbprint* _____ _____
Date (dd/mmm/yyyy) Time (24hr)

Printed name of impartial witness* _____

Signature of impartial witness* _____ _____
Date (dd/mmm/yyyy) Time (24hr)

Printed name of person obtaining consent _____

I attest that I have explained the study information accurately in _____ to, and was understood to the best of my knowledge by, the participant and that he/she has freely given consent to participate *in the presence of the above named impartial witness (where applicable).

Signature of person obtaining consent _____ _____
Date (dd/mmm/yyyy) Time (24hr)

** Only required if the participant is unable to read or write.*

A copy of this informed consent document has been provided to the parent.

#

Trial 1: Information sheet for children who are eligible

#

Child's Study ID number _____

Study co-ordinators: Dr. KaushikMurali
blr.nannakannu@sankaraeye.com
Sankara Eye Care Institutes, Bangalore
Tel: +91 97 39 777726

Miss. Priya Morjaria
priya.morjaria@lshtm.ac.uk

Dear Student,

When we visited your school a few days ago we tested your vision and found that you have some blurring of your vision. When we examined you today we found that a pair of spectacles will help you to see more clearly, and we will give you a pair of spectacles. You will be able to choose which style and type of frame you would prefer, and the spectacles will be delivered to the school in about two weeks. You will not need to wear the spectacles all the time, but only when you need to see more clearly, such we while at school or to watch television or sports.

We plan to give each child one of two different types of spectacles, in a study. You will not be able to tell the difference as both types will give equally good vision. One type of spectacles will have the same strength lenses in both eyes whereas the other type may have different strength lenses in the right and left eye. Both types of spectacles will be of very high quality. It may take you a little while to get used to wearing spectacles if you have not worn them before.

We will come back to the school in two the three months to find out how you are getting on with the spectacles and may ask you a couple of questions. We will analyse all the information we collect but your name will not be used in the analysis and only the study team will have access to all the information.

You do not have to take part in the study. If you decide you do not want to take part you will still be given a pair of high quality spectacles. If you agree to take part please write you name below.

Your name: _____
Father's name: _____

Class: _____
School:_____

#

Trial 1: Assent form for children who are eligible

#

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

ASSENT FORM FOR CHILDREN
(To be completed by the child and their parent/guardian)

Child (or if unable, parent on their behalf) /young person to circle all they agree with:

Have you read (or had read to you) about this project?	Yes / No
Has somebody else explained this project to you?	Yes / No
Do you understand what this project is about?	Yes / No
Have you asked all the questions you want?	Yes / No
Have you had your questions answered in a way you understand?	Yes / No
Do you understand it's OK to stop taking part at any time?	Yes / No
Are you happy to take part?	Yes / No
If any answers are 'no' or you don't want to take part, don't sign your name	

If you do want to take part, please write your name and today's date

Your name _____ Age _____ Date _____

Your parent or guardian must write their name here too if they are happy for you to do the project
Print Name _____

Sign _____ Date _____

The researcher who explained this project to you needs to sign too:
Print Name _____

Sign _____ Date _____

Thank you for your help.

#

Trial 2: Information sheet 1: Head Teachers and teachers (Formative research)

School refractive error study, Hyderabad

Information sheet and consent form for Head Teachers and classroom teachers

Dear Sir / Madam,

We are conducting a study on refractive errors among children aged 11-15 years in schools in and around Hyderabad. The study is a collaboration between the Public Health Foundation of India, the Pushpagiri Eye Institute, Hyderabad, and the London School of Hygiene & Tropical Medicine (LSHTM). A Steering Committee has been convened, which includes State representatives from the Ministry of Education, the Ministry of Health, the Program for the Control of Blindness and RBSK. We would be grateful if you would consider and agree to take part in this study, which is explained below.

In India approximately one in 25 school students aged 11-15 years have refractive errors but do not have spectacles which would enable them to see clearly. The Government of India recognizes that uncorrected refractive errors are a problem, as they impact on children's ability to learn and their social development, and has allocated resources for refractive errors. The study has ethical approval from The Public Health Foundation of India, The Indian Council of Medical Research and LSHTM.

What is the purpose of the study?
In this study we want to compare two different ways of screening for vision problems, one of which will entail field workers measuring vision using a mobile phone application. We will also assess the impact of different approaches to health education, to assess whether this influences the proportion of children who subsequently wear their spectacles. In some schools we would like older school children to hold a short classroom session to explain refractive errors using images generated on a mobile phone application, and the benefits of wearing spectacles. We will also give children an image to take home as well. An example is shown below.

How a child who needs spectacles sees the

How the same child sees the world

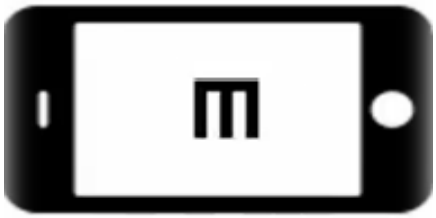
#

world *wearing their spectacles*

What will I be asked to do?
If you agree to take part we would like hold a short discussion with you, to seek your views on refractive errors in children. We would also value your input into the images we might use in classroom teaching, and to give to students to take home.

We anticipate that the interview will take approximately 20 minutes, and will be conducted at a time and location of your choice.

We would also like to train you to screen vision in students using the mobile phone application (see below), and show you how to enter the findings into the phone's software. Which may take place at another time. We anticipate that this training will take up to half a day.



Confidentiality
Everything you say will be kept strictly confidential, as we will not use your name or the name of the school on any documents, and what you say will not be divulged to anyone outside the project.

Do I have to take part?
No, your participation is purely voluntary. Any travel expenses will be reimbursed, and we will provide refreshments.

If you agree to take part we can offer a free eye examination, and can provide free reading spectacles, if required.

If you would like additional information please contact the Project Manager

Name Ms. Jayanthi Sagar
Mobile phone number 093913 86548

#

Trial 2: Consent sheet 1: Head Teachers and teachers (Formative research)

School refractive error study, Hyderabad

Consent form for Head Teachers and classroom teachers

I confirm that I have read and understood the information sheet about the study, and any questions I have about the study have been answered.

	Yes	No
I agree that to take part in the study	☐	☐

Name of Head Teacher / teacher _____

Signature of Head Teacher / teacher _____

Name of Researcher _____

Signature of Researcher _____

Date ---------- / ---------- / ----------
Day *Month* *Year*

#

Trial 2: Information sheet 2: Parents in FGDs (Formative research)

School spectacle project, Hyderabad

Information sheet for parents taking part in focus group discussions

Dear parent,
In India about one in 25 children aged 11 to 15 years cannot see clearly because they need a pair of spectacles. However, we know from other projects that children given spectacles often do not wear their spectacles and so do not benefit.

We are undertaking a project in schools in and around Hyderabad and would like to ask you about your views on children wearing spectacles. In some schools we plan to use images to increase awareness among children, teachers and parents about the benefits of wearing spectacles and we would value your opinions on which images would be the best to use. An example is shown below.

How a child who needs spectacles sees the world

How the same child sees the world wearing their spectacles

In some schools we also plan to send voice messages to the parents of children who need spectacles, and we would value your opinion on which messages might be the most helpful.

What will happen if I take part?
If you agree to take part, you will be invited to join a group of other parents in the school your child attends, and a member of the project team will lead the discussion. This will take about an hour.
If you agree to take part any travel costs will be reimbursed and you will be given refreshments. We will also offer you an eye examination, and will give you a pair of reading spectacles, if required.

Do I have to take part?
No, this is entirely voluntary.

Confidentiality
Everything you say will be kept entirely private and will not be shared with anyone outside the project team. We will not use your name in any reports etc.

If you would like additional information please contact the Project Manager.

Name Ms. Jayanthi Sagar Mobile phone number 093913 86548

#

Trial 2: Consent sheet 2: Parents taking part in FGDs (Formative research)

School spectacle project, Hyderabad

Consent form for parents taking part in focus group discussions

I confirm that I have read and understood the information sheet about the study, and any questions I have about the study have been answered.

	Yes	No
I agree that to take part in the study	☐	☐

Name of parent _____

Signature of parent _____

Name of Researcher _____

Signature of Researcher _____

Date ---------- / ---------- / ----------
Day *Month* *Year*

#

Trial 2: Information sheet 3: Children taking part in FGDs (Formative research)

Information sheet for children taking part in focus group discussions

Dear Student

In India about one in 25 children aged 11 to 15 years cannot see clearly because they need a pair of spectacles. However, we know from other projects that children given spectacles often do not wear their spectacles and so do not benefit.

We are undertaking a project in schools in and around Hyderabad and would like to ask you what you think about children wearing spectacles. In some schools we plan to use images to increase awareness among children, teachers and parents about the benefits of wearing spectacles and we would value your opinions on which images would be the best to use. An example is shown below.

How a child who needs spectacles sees the world

How the same child sees the world wearing their spectacles

#

What will happen if I take part?
If you agree to take part, you will be invited to join a group of other children in your school and a member of the project team will lead the discussion. This will take about half an hour.

Do I have to take part?
No, this is entirely voluntary.

Confidentiality
Everything you say will be kept entirely private and will not be shared with anyone outside the project team. We will not use your name in any reports etc.

If you would like additional information please contact the Project Manager

Name Ms. Jayanthi Sagar
Mobile phone number 093913 86548

#

Trial 2: Assent sheet 3: Children taking part in FGDs (Formative research)

School spectacle project, Hyderabad

ASSENT FORM FOR STUDENTS

To be completed by the child with a researcher

Student to tick all they agree with:

	Yes		No
Have you read (or had read to you) about this project?			
Has somebody else explained this project to you?			
Do you understand what this project is about?			
Have you asked all the questions you want?			
Have you had your questions answered in a way you understand?			
Do you understand it's OK to stop taking part at any time?			
Are you happy to take part?			

If any answers are 'no' or you **don't** want to take part, **don't** sign your name

If you do want to take part, please write your name and today's date

Your name _____ Age_____

Date _____

The researcher who explained this project to you needs to sign too:

Print Name _____

Sign _____

Date _____

Thank you for your help

#

Trial 2: Information sheet 4: Children taking part in pre and post-assessment of classroom teaching (Formative research)

Information sheet for children taking part in pre- and post-assessment of classroom teaching

Dear Student

In India about one in 25 children aged 11 to 15 years cannot see clearly because they need a pair of spectacles. However, we know from other projects that children given spectacles often do not wear their spectacles and so do not benefit.

We are undertaking a project in schools in and around Hyderabad and would like to ask you what you think about children wearing spectacles. We will do this twice, once before an older child in your school tells you a bit about refractive errors, and again immediately afterwards. There are no right or wrong answers - we just want to know what you think.

What will happen if I take part?
If you agree to take part, you will be given a piece of paper with some questions written on it, which we would like you to complete. You will then listen to the older child, and you will then be given questions to answer again. This will take about half an hour.

Do I have to take part?
No, this is entirely voluntary.

Confidentiality
We will ask you to write your name on the pieces of paper, but we will not use your name when we look at what all the students have written. We will not use your name in any reports etc.

If you would like additional information please contact the Project Manager

Name Ms. Jayanthi Sagar
Mobile phone number 093913 86548

#

Trial 2: Assent sheet 4: Children taking part in FGDs (Formative research)

School spectacle project, Hyderabad

ASSENT FORM FOR STUDENTS

To be completed by the child with a researcher

Student to tick all they agree with:

	Yes		No
Have you read (or had read to you) about this project?			
Has somebody else explained this project to you?			
Do you understand what this project is about?			
Have you asked all the questions you want?			
Have you had your questions answered in a way you understand?			
Do you understand it's OK to stop taking part at any time?			
Are you happy to take part?			

If any answers are 'no' or you **don't** want to take part, **don't** sign your name

If you do want to take part, please write your name and today's date

Your name _____ Age_____

Date _____

The researcher who explained this project to you needs to sign too:

Print Name _____

Sign _____

Date _____

Thank you for your help

#

Trial 2: Information sheet 5: Parents of children taking part in FDGs (Formative research)

School spectacle project, Hyderabad

Information sheet for parents of children taking part in group discussions

Dear Parent

In India about one in 25 children aged 11 to 15 years cannot see clearly because they need a pair of spectacles. However, we know from other projects that children given spectacles often do not wear their spectacles and so do not benefit.

We are undertaking a project in schools in and around Hyderabad and would like to ask your child what they think about children wearing spectacles, and to find out what they think children who need spectacles cannot do because they cannot see clearly. The opinion of children will be of value in helping to decide the best way to explain refractive errors to children.

What will happen if my child takes part?
If you agree that you child can take part, they will be asked to take part in a discussion with 4-5 other children of the same sex and age group. A member of the project team will lead the discussion which will take about an hour.

Do I have to agree that my child take part?
No, this is entirely voluntary.

Confidentiality
We will not use your child's name at any time, and so what they say will not be linked to them.

If you would like additional information please contact the Project Manager

Name Ms. Jayanthi Sagar
Mobile phone number 093913 86548

#

Trial 2: Consent sheet 5: Parents of children taking part in FDGs (Formative research)

School spectacle project, Hyderabad

Consent form for parents of children taking part in group discussions

I confirm that I have read and understood the information sheet about the study, and any questions I have about the study have been answered.

	Yes	No
I agree that my child can take part in the project	☐	☐

Name of child _____

Name of parent _____

Signature of parent _____

Date ---------- / ---------- / ----------
Day *Month* *Year*

#

Trial 2: Information sheet 6: Parents of children taking part in pre- and post-assessment of classroom teaching (Formative research)

School spectacle project, Hyderabad

Information sheet for parents of children taking part in pre- and post-assessment of classroom teaching

Dear Parent

In India about one in 25 children aged 11 to 15 years cannot see clearly because they need a pair of spectacles. However, we know from other projects that children given spectacles often do not wear their spectacles and so do not benefit.

We are undertaking a project in schools in and around Hyderabad and would like to ask your child what they think about children wearing spectacles. We have developed some educational materials for children, which will be delivered by older school children, and we would like to find out whether this is a good way to explain refractive errors to children.

What will happen if my child takes part?
If you agree to that you child takes part, he or she will be given a piece of paper with some questions written on it, which we would like them to complete. They will then listen to the older child, and your child will then be given questions to answer again. This will take about half an hour.

Do I have to agree that my child take part?
No, this is entirely voluntary.

Confidentiality
We will ask your child to write their name on the sheets of paper, so that we can compare what they say before and after listening to theolder child. But your child's name will not be used in the analysis.

If you would like additional information please contact the Project Manager

Name Ms. Jayanthi Sagar
Mobile phone number 093913 86548

#

Trial 2: Consent sheet 6: Parents of children taking part in pre- and post-assessment of classroom teaching (Formative research)

School spectacle project, Hyderabad

Consent form for parents of children taking part in group discussions and pre- and post-assessment of classroom teaching

I confirm that I have read and understood the information sheet about the study, and any questions I have about the study have been answered.

	Yes	No
I agree that my child can take part in the project	☐	☐

Name of child _____

Name of parent _____

Signature of parent _____

Date ---------- / ---------- / ----------
Day *Month* *Year*

#

Trial 2: Information sheet 7: Field workers taking part in validity of field worker screening

School refractive error study, Hyderabad
Information sheet and consent form for validity assessment of vision screening by field workers

Dear Sir / Madam,
We are conducting a study on refractive errors among children aged 11-15 years in schools in and around Hyderabad. The study is a collaboration between the Public Health Foundation of India, the Pushpagiri Eye Institute, Hyderabad, and the London School of Hygiene & Tropical Medicine (LSHTM). A Steering Committee has been convened, which includes State representatives from the Ministry of Education, the Ministry of Health, the Program for the Control of Blindness and RBSK. We would be grateful if you would consider and agree to take part in this study, which is explained below.
In India approximately one in 25 school students aged 11-15 years have refractive errors but do not have spectacles which would enable them to see clearly. The Government of India recognizes that uncorrected refractive errors are a problem, as they impact on children's ability to learn and their social development, and has allocated resources for refractive errors. The study has ethical approval from The Public Health Foundation of India, The Indian Council of Medical Research and LSHTM.

What is the purpose of the study?
In this study we want to compare two different ways of screening for vision problems, one of which will entail field workers measuring vision using a mobile phone application.

What will I be asked to do?
We will train you to screen vision in students using the mobile phone application (see below), and show you how to enter the findings into the phone's software. We anticipate that this will take up to half a day.

We will ask you to screen the vision of 100 children, who will then be screened using standard methods by an optometrist. We will compare the findings.

Confidentiality
We will not use your name or the name of the school on any documents, and so all the information we obtain will be anonymous.

Do I have to take part?
No, your participation is purely voluntary. Any travel expenses will be reimbursed, and we will provide refreshments.
If you agree to take part we can offer a free eye examination, and can provide free reading spectacles, if required.

If you would like additional information please contact the Project Manager
Name Ms. Jayanthi Sagar Mobile phone number 093913 86548

#

Trial 2: Consent sheet 7: Field workers taking part in validity of field worker screening

School spectacle project, Hyderabad

Consent form for field workers taking part in validity testing

I confirm that I have read and understood the information sheet about the study, and any questions I have about the study have been answered.

	Yes	No
I agree that to take part in the study	☐	☐

Name of field worker _____

Signature of field worker _____

Name of Researcher _____

Signature of Researcher _____

Date ---------- / ---------- / ----------
Day *Month* *Year*

#

Trial 2: Information sheet 8: Head Teachers for school participation (Main study)

School refractive error study, Hyderabad

Information sheet for Head Teachers for the main study

Dear Sir / Madam,

We are conducting a study on refractive errors among children aged 11-15 years in schools in and around Hyderabad. The study is a collaboration between the Public Health Foundation of India, the Pushpagiri Eye Institute, Hyderabad, and the London School of Hygiene & Tropical Medicine (LSHTM). A Steering Committee has been convened, which includes State representatives from the Ministry of Education, the Ministry of Health, the Program for the Control of Blindness and RBSK. We would be grateful if you would consider and agree to your school taking part in this study, which is explained below.

In India approximately one in 25 school students aged 11-15 years have refractive errors but do not have spectacles which would enable them to see clearly. The Government of India recognizes that uncorrected refractive errors are a problem, as they impact on children's ability to learn and their social development, and has allocated resources for refractive errors. The study has ethical approval from the Public Health Foundation of India, the Indian Council of Medical Research and LSHTM.

What is the purpose of the study?
Despite uncorrected refractive errors causing blurred vision and reducing quality of life, a relatively high proportion of children given spectacles do not wear them. Indeed, a recent study in India showed that only 30% of children given spectacles actually wore them. There are many reasons for this, including children not liking the spectacle frames, they do not see any improvement in their vision, their parents have concerns or the children are teased by their peers. In our study we will address several of these factors, as we will only dispense spectacles to children whose vision improves a significant amount with spectacles, children will select the frames they prefer, the spectacles will be provided at no cost to the families, and there will also be a health education component. In this study we will compare different approaches to screening for reduced vision and different types health education. The overall purpose is to assess whether the different approaches influence spectacle wearing amongst children.

Why is my school being considered for the study?
A list of schools with children aged 11-15 years has been provided by the State Ministry of Education and schools have been ranked according to size. Your school is being considered for inclusion in the study on account of the large number of children of this age group who attend your school. We hope that around 36 Head Teachers will agree that their school can participate.

#

We will plan the timing of all the activities so that they do not interfere with examination times, or other times when this would not be convenient.

What will take place at the school?
In each school, the vision of children aged 11-15 years will be measured at the “6/9” level of vision. In all schools, children who fail the vision screening will be refracted in the schools by a highly qualified optometrist, who will decide whether the child needs spectacles. Children will be allowed to select the spectacle frames they prefer and all children needing spectacles will be given information to take home for their parents. You will be given a list of all the children needing spectacles. All the spectacles will be delivered to the school by field workers as soon as possible. To find out how many children are wearing their spectacles, field workers will visit the school again 3 to 4 months after the children were given their spectacles and will visit the relevant classrooms to see if children are wearing their spectacles. So that children do not change how they behave, we plan that the field worker will not give advance warning of when they will visit the school for follow up.

In all schools trained field workers will measure vision.

In some schools we would like older children in the school deliver a short session of health education to the relevant classes which will last 10-15 minutes. A simple manual will be developed for this. In these schools children will be given some additional educational materials to take home.

At the end of the study, in schools where older school children do not give the classroom health education session, we plan that a field worker will deliver the same health education and all children given spectacles will be given the additional information to take home.

All children found to have eye conditions which need more specialist care will be referred to Pushpagiri Eye Institute where they will be examined, and treatment provided, if needed. The study will cover all the costs.

Does my school have to take part?
Your permission that your school participate in this study is voluntary, being entirely up to you.

Confidentiality
We will only use codes numbers to identity each school, and your name and the name of your school will not be used in any analysis, reports or publications arising out of the study. The same applies to children, and so their identities will also remain completely anonymous.

Should you agree that your school take part in the study we would be grateful if you do not discuss the study with other head teachers or classroom teachers in other schools in the area until the study has been completed.

Dissemination
At the end of the study the results will be presented to the Steering Committee and you will be invited to attend. You will also be sent a short summary of the results.

If you would like additional information please contact the Project Manager
Name Ms. Jayanthi Sagar
Mobile phone number 093913 86548

#

Trial 2: Consent sheet 8: Head Teachers for school participation (Main study)

School refractive error study, Hyderabad

Consent form for Head Teachers

I confirm that I have read and understood the information sheet about the study, and any questions I have about the study have been answered.

	Yes	No
I agree that my school can take part in the study	☐	☐

Name of school _____

Name of Head Teacher _____

Signature of Head Teacher _____

Name of Researcher _____

Signature of Researcher _____

Date ---------- / ---------- / ----------
Day *Month* *Year*

#

Trial 2: Information sheet 9: Parents of children recruited to study (opt-out) (Main study)

School spectacle project, Hyderabad

Information sheet and opt-out for parents

Dear Parent,

Staff from Pushpagiri Eye Institute in Hyderabad are helping in a project in which schools in and around Hyderabad will be visited to assess the vision of students, and to make sure that any child found with a problem with their eyes or vision receive the treatment they need. The Director of Education is aware of this and has approved this project.

The head teacher at your child's school has given permission that children aged 11-15 years will have their vision measured by a trained field worker, and all children with poor vision will be examined in the school by highly qualified staff from Pushpagiri Eye Institute. All children who can benefit from spectacles will be allowed to choose the spectacle frames they prefer, and will be given a free pair of spectacles. If your child is found to have any other eye problem they will be referred to Pushpagiri Eye Institute where they will receive treatment at no cost, if required.

All the children needing spectacles will bring home some information for you to read about why your child needs spectacles, and how to look after their spectacles. Your child will also be given some additional information about why some children need to use spectacles, either at the start of the project or at the end.

So that we can send you some additional information about your child's eyes, we would be grateful if you could share your mobile phone number. Your number will not be given to anyone else, and will be deleted at the end of the project.

If you would like further information about your child's vision or the project please contact the Project Manager, {name……} +91 {number……..}.

To confirm that you agree that your child can take part in this project please add your name and signature below, and put a cross in the box labelled Yes. If you do not agree put a cross under the box labelled No. Whether you tick Yes or No, please give this letter to your child to take back to the school.

	Yes	No
I agree that my child can take part in this project	☐	☐

Childs name …… Age……..
Class……

Your name ……..

Your signature…… Mobile telephone number…….

#

Trial 2: Information sheet 10: Children recruited to the study (Main study)

School spectacle project, Hyderabad

Information sheet for children recruited to the study

Dear Student,

When your vision was tested we found that you have some blurring of your vision. When we examined you today we found that a pair of spectacles will help you to see more clearly, and we will give you a pair of spectacles. You will be able to choose which style and type of frame you would prefer, and the spectacles will be delivered to the school in about two weeks. You will not need to wear the spectacles all the time, but only when you need to see more clearly, such as while at school or watching television. It may take you a little while to get used to wearing spectacles if you have not worn them before.

We will give you some information about your eyes for you to take home for your parents, which also explains how to look after your spectacles and we may send your parents a text message.

We will come back to the school in a few months to find out how you are getting on with the spectacles and may ask you a couple of questions.

In a few months time we may also give you some additional information to take home.

We will analyse all the information we collect but your name will not be used in the analysis and only the project team will have access to all the information.

You do not have to take part in the project. If you decide you do not want to take part you will still be given a pair of high quality spectacles.

Please sign the form that the project staff will show you.

#

Trial 2: Assent sheet 10: Children recruited to the study (Main study)

School spectacle project, Hyderabad

ASSENT FORM FOR STUDENTS

To be completed by the child with a researcher

Student to tick all they agree with:

	Yes		No
Have you read (or had read to you) about this project?			
Has somebody else explained this project to you?			
Do you understand what this project is about?			
Have you asked all the questions you want?			
Have you had your questions answered in a way you understand?			
Do you understand it's OK to stop taking part at any time?			
Are you happy to take part?			

If <u>any</u> answers are 'no' or you **don't** want to take part, **don't** sign your name

If you <u>do</u> want to take part, please write your name and today's date

Your name _____ Age_____

Date _____

The researcher who explained this project to you needs to sign too:

Print Name _____

Sign _____

Date _____

Thank you for your help

#

సమ్మతి పత్రము 1: ప్రధాన ఉపాధ్యాయులు మరియు ఉపాధ్యాయులు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల వక్రీభవన దోష అధ్యయనము, హైదరాబాద్

ప్రధాన ఉపాధ్యాయులు మరియు తరగతి ఉపాధ్యాయుల సమ్మతి

ఈ అధ్యయనం గురించి సమాచార పత్రమును నేను చదివాను మరియు అర్థం చేసుకున్నాను మరియు అధ్యయనము గురించి నాకు ఉండిన ఏవైనా ప్రశ్నలకు జవాబులు ఇవ్వడమైనదని నేను ధ్రువీకరిస్తున్నాను.

	అవును	లేదు
అధ్యయనములో పాల్గొనేందుకు నేను అంగీకరిస్తున్నాను	☐	☐

ప్రధాన ఉపాధ్యాయులు/ఉపాధ్యాయుని పేర _____

ప్రధాన ఉపాధ్యాయులు/ఉపాధ్యాయుని సంతకం _____

పరిశోధకుని పేరు _____

పరిశోధకుని సంతకం _____

తేదీ ---------- / ---------- / ----------
రోజు నెల సంవత్సరం

సమ్మతి పత్రము 2: ఎఫ్‌జిడి లలో పాల్గొనే తల్లిందడ్రులు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్

కేంద్రీకృత సామూహిక చర్చలలో పాల్గొను తల్లిదండ్రుల కొరకు సమ్మతి పత్రము

ఈ అధ్యయనం గురించి సమాచార పత్రమును నేను చదివాను మరియు అర్థం చేసుకున్నాను మరియు అధ్యయనము గురించి నాకు ఉండిన ఏవైనా ప్రశ్నలకు జవాబులు ఇవ్వడమైనదని నేను ధృవీకరిస్తున్నాను.

	అవును	లేదు
అధ్యయనములో పాల్గొనేందుకు నేను అంగీకరిస్తున్నాను	☐	☐

తల్లిదండ్రుల పేరు _____

తల్లిదండ్రుల సంతకం _____

పరిశోధకుని పేరు _____

పరిశోధకుని సంతకం _____

తేదీ ---------- / ---------- / ----------
రోజు నెల సంవత్సరం

సమాచార పత్రము 1: ప్రధానోపాధ్యాయులు మరియు ఉపాధ్యాయులు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల వక్రీభవన దోష అధ్యయనము, హైదరాబాద్

సమాచార పత్రము మరియు ప్రధానోపాధ్యాయులు మరియు తరగతి ఉపాధ్యాయుల సమ్మతి

ప్రియమైన సర్/మేడమ్,

మేము హైదరాబాద్ మరియు చుట్టుపక్కల 11-15 సంవత్సరాల వయస్సు గల పిల్లలలో వక్రీభవన దోషాల పైన ఒక అధ్యయనాన్ని నిర్వహిస్తున్నాము. ఈ అధ్యయనము పబ్లిక్ హెల్త్ ఫౌండేషన్ ఆఫ్ ఇండియా, పుష్పగిరి ఐ ఇన్స్టిట్యూట్, హైదరాబాద్ మరియు లండన్ స్కూల్ ఆఫ్ హైజీన్ అండ్ ట్రాపికల్ మెడిసిన్ (LSHTM) మధ్య సహకారంతో నడుస్తున్నది. ఒక నిర్వహణ కమిటీ ఏర్పరచబడినది, ఇందులో విద్యా మంత్రిత్వ శాఖ, ఆరోగ్య మంత్రిత్వ శాఖ, అంధత్వ నియంత్రణ ప్రోగ్రామ్, మరియు ఆర్బిఎస్కె (RBSK) నుండి ప్రతినిధులు ఉంటారు. క్రింద వివరించబడిన ఈ అధ్యయనములో మీరు పాల్గొనటాన్ని పరిగణించి, అంగీకరిస్తే మేము మీకు రుణపడి ఉంటాము.

భారతదేశంలో 11-15 సంవత్సరాలు గల 25 మంది పాఠశాల విద్యార్థులలో దాదాపు ఒకరికి వక్రీభవన దోషాలు ఉన్నాయి, కానీ వారు స్పష్టంగా చూడటానికి వీలుకల్పించే కళ్ళజోడు వారికి లేవు. భారత ప్రభుత్వం సరిచేయని వక్రీభవన దోషాలు పిల్లల యొక్క నేర్చుకునే సమర్థతపైన మరియు వారి సామాజిక అభివృద్ధిపైన ప్రభావం చూపుతాయి కాబట్టి వాటిని ఒక సమస్యగా గుర్తించింది మరియు వక్రీభవన దోషాలను సరిచేయడానికి వనరులను కేటాయించింది. ఈ అధ్యయనానికి పబ్లిక్ హెల్త్ ఫౌండేషన్ ఆఫ్ ఇండియా , ఇండియన్ కౌన్సిల్ ఆఫ్ మెడికల్ రీసర్చ్ మరియు ఎల్ఎస్హెచ్టిఎమ్ (LSHTM) నుండి నైతికపరమైన ఆమోదం ఉన్నది.

ఈ అధ్యయనము యొక్క ఉద్దేశ్యం ఏమిటి?

ఈ అధ్యయనంలో దృష్టి సమస్యల కొరకు స్క్రీనింగ్ యొక్క రెండు విభిన్న మార్గాలను మేము పోల్చిచూడాలని మేము అనుకుంటున్నాము, వీటిలో ఒకటి ఉపాధ్యాయులు ఒక మొబైల్ ఫోన్ అప్లికేషన్ ఉపయోగించి దృష్టిని కొలవటం ఉంటుంది. మేము ఆరోగ్య విద్యకు విభిన్న దుక్కాదాల ప్రభావాన్ని కూడా, ఇది తదుపరి కళ్ళజోడును ధరించే పిల్లల అనుపాతాన్ని ప్రభావితం చేస్తుందేమో మదింపు చేయడానికి, మదింపు చేస్తాము. ఈ అధ్యయనములో చేర్చుకోబడిన అన్ని పాఠశాలలో, కళ్ళజోడు ఇవ్వబడిన అందరు పిల్లలకు వారి తల్లిదండ్రుల కోసం ఇంటికి తీసుకెళ్ళడానికి ఒక కరపత్రము ఇవ్వబడుతుంది. కొన్ని పాఠశాలలో ఉపాధ్యాయులు స్వల్పకాల తరగతి సెషన్ తీసుకుని ఒక మొబైల్ ఫోన్ అప్లికేషన్ ద్వారా జనింపబడిన చిత్రాలను ఉపయోగించి వక్రీభవన దోషాలు మరియు కళ్ళజోడు ధరించడం వలన ప్రయోజనాలను వివరించవలసిందిగా కోరాలనుకుంటున్నాము.. ఇంటికి తీసుకెళ్ళడానికి కూడా పిల్లలకు ఒక చిత్రం మేము ఇస్తాము. ఒక ఉదాహరణ క్రింద చూపబడినది.

కళ్ళజోడు అవసరమైన బిడ్డ ప్రపంచాన్ని ఎలా చూస్తాడు

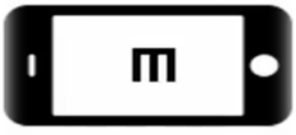
అంబిడ్డ ఎళ్ళ కళ్ళజోడు ధరించి ప్రపంచాన్ని ఎలా చూస్తాడు

నన్ను ఏమి చేయమని అడుగుతారు?

ఎన్నోనడానికి మీరు అంగీకరించితేమము మీతో ఎన్నికలలో వక్రీభవన దోషాల గురించి మీ అభిప్రాయాలనుకోరడానికి క్లుప్తంగా సర్వే నిర్వహించాలనుకున్నాము. మొబైల్ ఫోన్ అప్లికేషన్ ఉపయోగించి ఉపాధ్యాయులు దృష్టిని స్క్రీనింగ్ చేయడంలో మీ అభిప్రాయానికి కూడా విలువనిస్తాము మరియు మేము తరగతి బోధనలో మేము ఉపయోగించుమరియు ఇంటికి తీసుకెళ్లడాని విద్యార్థులకు ఇచ్చే చిత్రాలలో మీ అభిప్రాయానికి స్థానంకల్పించాలనుకుంటున్నాము.

ఇందుకు సుమారుగా20 నిమిషాలు తీసుకోవచ్చని మేము ఊహిస్తున్నాము మరియు మీరు ఎన్నుకున్న సమయంలోమరియు ప్రదేశంలో నిర్వహించబడుతుంది.

మొబైల్ ఫోన్ అప్లికేషన్ (క్రింద చూడండి) ఉపయోగించి విద్యార్థులలో దృష్టిస్క్రీనింగ్ చేయడానికి మరియు ఫోన్ యొక్క ఎక్యూవేర్‌లో కనబడేవి ఎలా ఎందుకో చేయాలో కూడా మేము మీకు శిక్షణని ఇవ్వాలనుకున్నాము. ఇది ఇంకొక ఎప్పుడు జరగవచ్చు ఇది సగం రోజు తీసుకుంటుందని మేము ఊహిస్తున్నాము.



గోపనీయత

మేము మీ పేరు లేదా ఎక్కడ పేరు ఏదైనా దస్తావేజు పైన ఉపయోగించము కాబట్టి మీరు చెప్పింది అంతా పూర్తి గోప్యంగా ఉంచబడుతుంది మరియు మీరు చెప్పింది ప్రాజెక్టు వెలుపల వెల్లడి చేయబడదు

నేనుఎన్నోనవలసిఉంటా?

లేదుమీరు ఎన్నోనడంపూర్తిగాస్వచ్ఛందంవైనా ప్రయాణ ఖర్చులు తిరిగి చెల్లించబడతాయి మరియు మేము ఫలహారంఅనుఅందజేస్తాము.

మీరు ఎన్నోనటకు అంగీకరిస్తే మేము ఉచిత కంటి పరీక్షనంటిస్తాము మరియు అవసరమైతేఉచితంగాకళ్ళజోడు అందజేయగలము.

సమాచార పత్రము 2: ఎఫ్‌జిడిలలో తల్లిదండ్రులు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE, PUBLIC HEALTH FOUNDATION OF INDIA, పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్

కేంద్రీకృత సామూహిక చర్చలలో పాల్గొను తల్లిదండ్రుల కొరకు సమాచార పత్రము

ప్రియమైన తల్లిదండ్రులు,

ఇండియాలో 11 నుండి 15 సంవత్సరాల వయస్సుగల పిల్లలు స్పష్టంగా చూడలేరు ఎందకంటే వారికి కళ్ళజోడు అవసరం ఉన్నది. అయినప్పటికీ, పిల్లలకు కళ్ళజోడు ఇచ్చినా వారు వాటిని ధరించడం లేదని మరియు తద్వారా వారు లాభం పొందలకపోతున్నారని ఇతర ప్రాజెక్టుల నుండి మేము తెలుసుకున్నాము.

మేము హైదరాబాద్ చుట్టుపక్కల పాఠశాలలలో ఒక ప్రాజెక్టును చేపడుతున్నాము మరియు మీ పిల్లలు కళ్ళజోడు ధరింపుల గురించి మీ అభిప్రాయాలను అడగాలనుకున్నాము. పిల్లలు, ఉపాధ్యాయులు మరియు తల్లిదండ్రులలో కళ్ళజోడు ధరింపుల యొక్క లాభాల గురించి అవగాహనను పెంచడానికి మేము కొన్ని పాఠశాలలలో చిత్రాలను ఉపయోగించాలని ప్రణాళిక చేస్తున్నాము మరియు ఉపయోగించడానికి ఏ చిత్రాలు ఉత్తమమైనవో అని మీ అభిప్రాయాలకు మేము విలువనిస్తాము. ఒక ఉదాహరణ క్రింద చూపబడినది.

కళ్ళజోడు అవసరమైన బిడ్డ ప్రపంచాన్ని ఎలా చూస్తాడు

అదే బిడ్డ వారి కళ్ళజోడు ధరించి ప్రపంచాన్ని ఎలా చూస్తాడు

కొన్ని పాఠశాలలలో మేము కళ్ళజోడు అవసరమైన పిల్లల యొక్క తల్లిదండ్రులకు ఏసెమినార్ సందేశాలు పంపాలని కూడా ప్రణాళిక చేస్తున్నాము మరియు ఏ సందేశాలు అత్యంత సహాయకరంగా ఉంటాయో మీ అభిప్రాయానికి విలువనిస్తాము.

నేను పాల్గొంటే ఏమి జరుగుతుంది? పాల్గొనుటకు మీరు అంగీకరిస్తే, మీ బిడ్డ వెళ్ళే పాఠశాలలో ఇతర తల్లిదండ్రులతో ఒక సమూహంలో చేరడానికి మిమ్మల్ని ఆహ్వానిస్తారు మరియు ప్రాజెక్టు బృందం సభ్యుడు ఒకరు చర్చను నడిపిస్తారు. ఇది దాదాపు ఒక గంట తీసుకుంటుంది.

పాల్గొనడానికి మీరు అంగీకరిస్తే ఏవైనా ప్రయాణ ఖర్చులు తిరిగి చెల్లిస్తారు మరియు మీకు ఫలహారాలు అందించబడతాయి. మేము మీకు ఒక కంటి పరీక్షను కూడా అందజేస్తాము మరియు అవసరమైతే, మీరు ఒక రీడింగ్ కళ్ళజోడు కూడా ఇస్తాము.

నేను పాల్గొనాలా? లేదు, ఇది పూర్తిగా స్వచ్ఛందం.

గోప్యనీయత మీరు చెప్పేది అంతా పూర్తిగా రహస్యంగా ఉంచబడుతుంది మరియు ప్రాజెక్టు వెలుపల ఎవ్వరితోనూ పంచుకోబడదు. ఏవైనా నివేదికలు మొదలగు వాటిలో మీ పేరును మేము ఉపయోగించము.

మీరు అదనపు సమాచారము కోరుకుంటే దయచేసి ప్రాజెక్ట్ మేనేజరని సంప్రదించండి

పేరు టిటిసి మొబైల్ ఫోన్ నంబర్ టిటిసి

అంగీకార పత్రము 3: ఎఫ్‌జిడి లలో పాల్గొంటున్న పిల్లలు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE, PUBLIC HEALTH FOUNDATION OF INDIA, పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్
విద్యార్థులకు అంగీకార పత్రము
ఒక పరిశోధకునితో బిడ్డ ద్వారా పూర్తి చేయబడాలి

విద్యార్థి హారు అంగీకరించే అన్నిటినీ టిక్ చేయాలి:

	అవును	లేదు
ఈ ప్రాజక్టు గురించి చదివారా (లేదా మీకు చదివి వినిపించారా)?		
ఈ ప్రాజెక్టు గురించి ఎవరైనా మీకు వివరించారా?		
ఈ ప్రాజెక్టు దీని గురించే మీరు అర్థం చేసుకున్నారా?		
మీరు అడగాలనుకున్న అన్ని ప్రశ్నలు అడిగారా?		
మీరు అర్థం చేసుకునే విధానంలో మీ ప్రశ్నలు అన్నింటికి జవాబు పొందారా?		
ఏ సమయంలోనైనా పాల్గొనటం ఆపవచ్చని మీరు అర్థం చేసుకున్నారా?		
పాల్గొనటానికి మీరు సంతోషంగా ఉన్నారా?		

ఏవైనా జవాబులు 'లేదు' అయినా లేదా మీరు పాల్గొన **కూడదు** అనుకుంటే, మీ పేరును సంతకం చేయకండి

మీరు ఫాల్ోవాలని కోరుకుంటే, దయచేసి మీ పేరు వ్రాయండి మరియు ఈ రోజు తేదీ వేయండి

మీ పేరు _____ వయస్సు_____

తేదీ _____

మీకు ఈ ప్రాజెక్టు గురించి వివరించిన పరిశోధకుడు కూడా సంతకం చేయాలి:

పేరు ముద్రించండి _____

సంతకం _____

తేదీ _____

మీ సహాయానికి ధన్యవాదాలు

సమాచార పత్రము 3: ఎఫ్‌జిడి లలో పాల్గొంటున్న పిల్లలు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE, PUBLIC HEALTH FOUNDATION OF INDIA, పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

కేంద్రీకృత సామూహిక చర్చలలో పాల్గొను పిల్లల కొరకు సమాచార పత్రము

ప్రియమైన విద్యార్థి

ఇండియాలో 11 నుండి 15 సంవత్సరాల వయస్సుగల 25 మంది పిల్లలలో సుమారు ఒకరు స్పష్టంగా చూడలేరు ఎందుకంటే వారికి కళ్ళజోడు అవసరం ఉన్నది. అయినప్పటికీ, పిల్లలకు కళ్ళజోడు ఇచ్చినా వారు వాటిని ధరించడం లేదని మరియు తద్వారా వారు ప్రయోజనం పొందలకపోతున్నారని ఇతర ప్రాజెక్టుల నుండి మేము తెలుసుకున్నాము.

మేము హైదరాబాద్ మరియు చుట్టుపక్కల పాఠశాలలలో ఒక ప్రాజెక్టును చేపడుతున్నాము మరియు పిల్లలు కళ్ళజోడు ధరింపుల గురించి మీరు ఏమనుకుంటున్నారో అడగాలనుకున్నాము. పిల్లలు, ఉపాధ్యాయులు మరియు తల్లిదండ్రులలో కళ్ళజోడు ధరింపుల వలన కలిగే ప్రయోజనాల గురించి అవగాహనను పెంచడానికి మేము కొన్ని పాఠశాలలలో చిత్రాలను ఉపయోగించాలని ప్రణాళిక చేస్తున్నాము మరియు ఉపయోగించడానికి ఏ చిత్రాలు ఉత్తమమైనవి అనే విషయంలో మీ అభిప్రాయాలకు మేము విలువనిస్తాము. ఒక ఉదాహరణ క్రింద చూపబడినది.

కళ్ళజోడు అవసరమైన బిడ్డ ప్రపంచాన్ని ఎలా చూస్తాడు

అదే బిడ్డ వారి కళ్ళజోడు ధరించి ప్రపంచాన్ని ఎలా చూస్తాడు

నేను పాల్గొంటే ఏమి జరుగుతుంది?

పాల్గొనుటకు మీరు అంగీకరిస్తే, మీ పాఠశాలలో ఇతర పిల్లల ఒక సమూహంలో చేరడానికి మిమ్మల్ని ఆహ్వానిస్తారు మరియు ప్రాజెక్టు బృందం సభ్యుడు ఒకరు చర్చను నడిపిస్తారు. ఇది దాదాపు అరగంట తీసుకుంటుంది.

నేను పాల్గొనవలసి ఉందా?

లేదు, ఇది పూర్తిగా స్వచ్ఛందం.

గోప్యనీయత

మీరు చెప్పేది అంతా పూర్తిగా రహస్యంగా ఉంచబడుతుంది మరియు ప్రాజెక్టు వెలుపల ఎవ్వరితోనూ పంచుకోబడదు. ఏవైనా నివేదికలు మొదలగు వాటిలో మీ పేరును మేము ఉపయోగించము.

మీరు అదనపు సమాచారము కోరుకుంటే దయచేసి ప్రాజెక్ట్ మేనేజరని సంప్రదించండి

పేరు టిటిసి మొబైల్ ఫోన్ నంబర్ టిటిసి

అంగీకార పత్రము 4: తరగతి బోధనకు ముందు మరియు తరువాతి మదింపులో పాల్గొనే పిల్లలు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE, PUBLIC HEALTH FOUNDATION OF INDIA, పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్
విద్యార్థులకు అంగీకార పత్రము
ఒక పరిశోధకునితో బిడ్డ ద్వారా పూర్తి చేయబడాలి

విద్యార్థి హారుఅంగీకరించే అన్నిటినీ టిక్ చేయాలి:

	అవును	లేదు
ఈ ప్రాజక్టు గురించి చదివారా (లేదా మీకు చదివి వినిపించారా)?		
ఈ ప్రాజెక్టు గురించి ఎవరైనా మీకు వివరించారా?		
ఈ ప్రాజెక్టు దీని గురించే మీరు అర్థం చేసుకున్నారా?		
మీరు అడగాలనుకున్న అన్ని ప్రశ్నలు అడిగారా?		
మీరు అర్థం చేసుకునే విధానంలో మీ ప్రశ్నలు అన్నింటికి జవాబు పొందారా?		
ఏ సమయంలోనైనా పాల్గొనటం ఆపవచ్చని మీరు అర్థం చేసుకున్నారా?		
పాల్గొనటానికి మీరు సంతోషంగా ఉన్నారా?		

ఏవైనా జవాబులు 'లేదు' అయినా లేదా మీరు పాల్గొన **కూడదు** అని కోరుకుంటే, మీ పేరును సంతకం చేయకండి

మీరు ఫాల్ోవాలని కోరుకుంటే, దయచేసి మీ పేరు వ్రాయండి మరియు ఈ రోజు తేదీ వేయండి

మీ పేరు _____ వయస్సు_____

తేదీ _____

మీకు ఈ ప్రాజెక్టు గురించి వివరించిన పరిశోధకుడు కూడా సంతకం చేయాలి:

పేరు ముద్రించండి _____

సంతకం _____

తేదీ _____

మీ సహాయానికి ధన్యవాదాలు

సమాచార పత్రము 4: తరగతి బోధన ముందు మరియు తరువాత మదింపులో పాల్గొనే పిల్లలు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, *to add*

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పుప్పగిరి ఐ ఇన్స్టి ట్యూట్,

తరగతి బోధనకు ముందు మరియు తరువాత మదింపులో పాల్గొనే పిల్లల కొరకు సమాచార పత్రము

ప్రియమైన విద్యార్థి

ఇండియాలో 11 నుండి 15 సంవత్సరాల వయస్సుగల 25 మంది పిల్లలలో సుమారు ఒకరు స్పష్టంగా చూడలేరు ఎందుకంటే వారికి కళ్ళజోడు అవసరం ఉన్నది. అయినప్పటికీ, పిల్లలకు కళ్ళజోడు ఇచ్చినా వారు వాటిని ధరించడం లేదని మరియు తద్వారా వారు లాభం పొందలేక పోతున్నారని ఇతర ప్రాజెక్టుల నుండి మేము తెలుసుకున్నాము.

మేము హైదరాబాద్ మరియు చుట్టుపక్కల పాఠశాలలలో ఒక ప్రాజెక్టును చేపడుతున్నాము మరియు పిల్లలు కళ్ళజోడు ధరించుట గురించి మీరు ఎమనుకుంటున్నారో అడగాలనుకున్నాము. మేము దీనిని రెండు సార్లు చేస్తాము, మీ ఉపాధ్యాయులు చక్కోభవన దోషాల గురించి కొద్దిగా మీకు చెప్పడానికి ముందు ఒకసారి మరియు వెంటనే తరువాత మళ్లీ చేస్తాము. సరియైన లేదా సరికాని జవాబులు లేవు - మీరు ఎమనుకుంటున్నారో అని మాత్రమే మేము తెలుసుకోవాలనుకున్నాము.

నేను పాల్గొంటే ఏమి జరుగుతుంది?

పాల్గొనడానికి మీరు అంగీకరిస్తే, మీకు కొన్ని ప్రశ్నలు కలిగిన పేపరు ఇవ్వబడుతుంది, మీరు దానిని పూర్తి చేయాలని మేము కోరుతున్నాము. తరువాత మీరు ఉపాధ్యాయులు చెప్పేది వింటారు మరియు మీరు మళ్లీ జవాబు ఇవ్వడానికి ప్రశ్నలు ఇస్తారు. ఇది దాదాపు ఆరగంట తీసుకుంటుంది.

నేను పాల్గొనవలసి ఉందా?

లేదు, ఇది పూర్తిగా స్వచ్ఛందం.

గోపనీయత

పేపరు ముక్కల పైన మీ పేర్లు వ్రాయవలసిందిగా మేము మిమ్మల్ని అడుగుతాము, కానీ అందరు విద్యార్థులు ఎమి వ్రాసారో మేము చూసినప్పుడు మీ పేరుని ఉపయోగించము. ఎవైనా నివేదికలు మొదలగు వాటిలో మీ పేరును మేము ఉపయోగించము.

మీరు అదనపు సమాచారము కోరుకుంటే దయచేసి ప్రాజెక్ట్ మేనేజర్‌ని సంప్రదించండి
పేరు టిబిసి
మొబైల్ ఫోన్ నంబర్ టిబిసి

సమ్మతి పత్రము 5: ఎఫ్‌డిజి లలో పాల్గొనే పిల్లల తల్లిదండ్రులు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ,

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పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్

సామూహిక చర్చలలో పాల్గొను పిల్లల యొక్క తల్లిదండ్రుల కొరకు సమ్మతి పత్రము

ఈ అధ్యయనం గురించి సమాచార పత్రమును నేను చదివాను మరియు అర్థం చేసుకున్నాను మరియు అధ్యయనము గురించి నాకు ఉండిన ఏవైనా ప్రశ్నలకు జవాబులు ఇవ్వడమైనదని నేను ధ్రువీకరిస్తున్నాను.

	అవును	లేదు
ప్రాజెక్టులో నా బిడ్డ పాల్గొనడానికి నేను అంగీకరిస్తున్నాను.	☐	☐

బిడ్డ పేరు _____

తల్లిదండ్రుల పేరు _____

తల్లిదండ్రుల సంతకం _____

తేదీ ---------- / ---------- / ----------

రోజు నెల సంవత్సరం

సమాచార పత్రము 5: ఎఫ్‌డిజి లలో పాల్గొనే పిల్లల తల్లిదండ్రులు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, *to add*

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పుప్పగిరి ఐ ఇన్స్టి ట్యూట్,

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సామూహిక చర్చలలో పాల్గొను పిల్లల తల్లిదండ్రుల కొరకు సమాచార పత్రము

ప్రియమైన తల్లిదండ్రులు

ఇండియాలో 11 నుండి 15 సంవత్సరాల వయస్సుగల 25 మంది పిల్లలలో సుమారు ఒకరు స్పష్టంగా చూడలేరు ఎందుకంటే వారికి కళ్ళజోడు అవసరం ఉన్నది. అయినప్పటికీ, పిల్లలకు కళ్ళజోడు ఇచ్చినా వారు వాటిని ధరించడం లేదని మరియు తద్వారా వారు లాభం పొందలేకపోతున్నారని ఇతర ప్రాజెక్టుల నుండి మేము తెలుసుకున్నాము.

మేము హైదరాబాద్ మరియు చుట్టుపక్కల పాఠశాలలలో ఒక ప్రాజెక్టును చేపడుతున్నాము మరియు కళ్ళజోడు ధరించే పిల్లల గురించి వారు ఎమనుకుంటుంటున్నారో మీ బిడ్డను అడగాలనుకుంటున్నాము మరియు కళ్లజోడు అవసరమైన పిల్లలు స్పష్టంగా చూడలేరు కనుక వారి గురించి ఎమనుకుంటున్నారో అడగాలనుకున్నాము. పిల్లలకు చక్కోభవన దోషాలు వివరించడానికి ఉత్తమమైన మార్గము నిర్ణయించుటలో సహాయపడటానికి పిల్లల అభిప్రాయాలకు విలువ ఉంటుంది.

నా బిడ్డ పాల్గొంటే ఏమి జరుగుతుంది?

మీ బిడ్డపాల్గొనటానికి మీరు అంగీకరస్తే, అదే లింగం మరియు ఆగే వయస్సు సమూహం గల 4-5 మంది పిల్లలతో చర్చలో పాల్గొనవలసిందిగా వారిని అడుగుతారు. ప్రాజెక్టు బృందం సభ్యుడు ఒకరు చర్చను నడుపుతారు దీనికి దాదాపు ఒక గంట పట్టవచ్చు.

నా బిడ్డపాల్గొనుటకు నేను అంగీకరించవలసి ఉందా?

లేదు, ఇది పూర్తిగా స్వచ్ఛందం.

గోపనీయత

ఏ సమయంలోనూ మేము మీ బిడ్డయొక్క పేరును ఉపయోగించము, కావున వారు చెప్పేది వారికి జోడింపబడదు.

మీరు అదనపు సమాచారము కోరుకుంటే దయచేసి ప్రాజెక్ట్ మేనేజర్‌ని సంప్రదించండి
పేరు టిబిసి

మొబైల్ ఫోన్ నంబర్ టిబిసి

సమ్మతి పత్రము 6: తరగతి బోధనకు ముందు మరియు తరువాత మదింపులో పాల్గొనే పిల్లల తల్లిదండ్రులు (నిర్మాణాత్మక పరిశోధన)

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తరగతి బోధనకు ముందు మరియు తరువాత మదింపులో పాల్గొనే పిల్లల తల్లిదండ్రుల కొరకు సమ్మతి పత్రము

(నిర్మాణాత్మక పరిశోధన)

ఈ అధ్యయనం గురించి సమాచార పత్రమును నేను చదివాను మరియు అర్థం చేసుకున్నాను మరియు అధ్యయనము గురించి నాకు ఉండిన ఏవైనా ప్రశ్నలకు జవాబులు ఇవ్వడమైనదని నేను ధ్రువీకరిస్తున్నాను.

	అవును	లేదు
ప్రాజెక్టులో నా బిడ్డ పాల్గొనడానికి నేను అంగీకరిస్తున్నాను.	☐	☐

బిడ్డ పేరు _____

తల్లిదండ్రుల పేరు _____

తల్లిదండ్రుల సంతకం _____

తేదీ ---------- / ---------- / ----------

రోజు నెల సంవత్సరం

సమాచార పత్రము 6: తరగతి బోధనకు ముందు మరియు తరువాతి మదింపులో పాల్గొనే పిల్ల తల్లిదండ్రులు (నిర్మాణాత్మక పరిశోధన)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్

తరగతి బోధనకు ముందు మరియు తరువాతి మదింపులో పాల్గొనే పిల్లల తల్లిదండ్రుల కొరకు సమాచార పత్రము

ప్రియమైన తల్లిదండ్రులు

ఇండియాలో 11 నుండి 15 సంవత్సరాల వయస్సుగల 25 మంది పిల్లలలో సుమారు ఒకరు స్పష్టంగా చూడలేరు ఎందుకంటే వారికి కళ్ళజోడు అవసరం ఉన్నది. అయినప్పటికీ, పిల్లలకు కళ్ళజోడు ఇచ్చినా వారు వాటిని ధరించడం లేదని మరియు తద్వారా వారు లాభం పొందలేకపోతున్నారని ఇతర ప్రాజెక్టుల నుండి మేము తెలుసుకున్నాము.

మేము హైదరాబాద్ మరియు చుట్టుపక్కల పాఠశాలలలో ఒక ప్రాజెక్టును చేపడుతున్నాము మరియు మీ పిల్లలు కళ్ళజోడు ధరించుట గురించి ఏమనుకుంటున్నారో అడగాలనుకున్నాము. మేము పిల్లలకు కొంత విద్యాసంబంధ విషయాన్ని రూపొందించాము, దీనిని తరగతి ఉపాధ్యాయులు వివరిస్తారు మరియు ఇది పిల్లలకు వక్రీభవన దోషాలు వివరించడానికి మంచి మార్గమేమో అని మేము తెలుసుకోవాలనుకున్నాము.

నా బిడ్డ పాల్గొంటే నాకు ఏమి జరుగుతుంది?

మీ బిడ్డ పాల్గొనడానికి మీరు అంగీకరిస్తే, అతనికి లేదా ఆమెకు కొన్ని ప్రశ్నలు కలిగిన పేపరు ఇవ్వబడుతుంది, వారు దానిని పూర్తి చేయాలను మేము కోరుతున్నాము. వారు వారి ఉపాధ్యాయులు చెప్పినది వింటారు మరియు తరువాత మీ బిడ్డకు జవాబు ఇవ్వమని ప్రశ్నలు ఇస్తారు. ఇది దాదాపు అరగంట తీసుకుంటుంది.

నా బిడ్డ పాల్గొనుటకు నేను అంగీకరించవలసి ఉందా?

లేదు, ఇది పూర్తిగా స్వచ్ఛందం.

గోపనీయత

మీ బిడ్డను వారి పేర్లు పేపర్లపైన వ్రాయవలసిందిగా మేము అడుగుతాము, తద్వారా ఉపాధ్యాయుడు చెప్పడానికి ముందు చెప్పిన తరువాత వారు ఏమి చెబుతారో మేము పోల్చగలము. కానీ మీ బిడ్డయొక్క పేరు విశ్లేషణలో ఉపయోగించబడదు.

మీరు అదనపు సమాచారము కోరుకుంటే దయచేసి ప్రాజెక్ట్ మేనేజరిని సంప్రదించండి

ఏరు టిపిసి

మొబైల్ ఫోన్ నంబర్ టిపిసి

సమ్మతి పత్రము 7: ఉపాధ్యాయ స్క్రీనింగ్ యొక్క చెల్లుబాటులో పాల్గొంటున్న ఉపాధ్యాయులు

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్

చెల్లుబాటు పరీక్షించుటలో పాల్గొంటున్న ఉపాధ్యాయుల కొరకు సమ్మతి పత్రము

ఈ అధ్యయనం గురించి సమాచార పత్రమును నేను చదివాను మరియు అర్థం చేసుకున్నాను మరియు అధ్యయనము గురించి నాకు ఉండిన ఏవైనా ప్రశ్నలకు జవాబులు ఇవ్వడమైనదని నేను ధ్రువీకరిస్తున్నాను.

	అవును	లేదు
అధ్యయనములో పాల్గొనేందుకు నేను అంగీకరిస్తున్నాను	☐	☐

ఉపాధ్యాయుని ఏరు _____

ఉపాధ్యాయుని సంతకం _____

పరిశోధకుని ఏరు _____

పరిశోధకుని సంతకం _____

తేదీ ---------- / ---------- / ----------

రోజు నెల సంవత్సరం

సమ్మతి పత్రము 8: పాఠశాల పాల్గొనుటకు ప్రధాన ఉపాధ్యాయులు (ప్రధాన అధ్యయనము)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల వక్రీభవన దోష అధ్యయనము, హైదరాబాద్

ప్రధాన ఉపాధ్యాయుల కొరకు సమ్మతి పత్రము

ఈ అధ్యయనం గురించి సమాచార పత్రమును నేను చదివాను మరియు అర్థం చేసుకున్నాను మరియు అధ్యయనము గురించి నాకు ఉండిన ఏవైనా ప్రశ్నలకు జవాబులు ఇవ్వడమైనదని నేను ధ్రువీకరిస్తున్నాను.

	అవును	లేదు
అధ్యయనములో నా పాఠశాల పాల్గొనేందుకు నేను అంగీకరిస్తున్నాను	☐	☐

పాఠశాల ఏరు _____

ప్రధాన ఉపాధ్యాయుని ఏరు _____

ప్రధాన ఉపాధ్యాయని సంతకం _____

పరిశోధకుని ఏరు _____

పరిశోధకుని సంతకం _____

తేదీ ---------- / ---------- / ----------

రోజు నెల సంవత్సరం

సమాచార పత్రము 8: పాఠశాల పాల్గొనుటకు ప్రధాన ఉపాధ్యాయులు (ప్రధాన అధ్యయనము)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల వక్రీభవన దోష అధ్యయనము, హైదరాబాద్

ప్రధాన అధ్యయనము కొరకు ప్రధాన ఉపాధ్యాయుల కొరకు సమాచార పత్రము

ప్రియమైన సర్/మేడమ్,

హైదరాబాద్ మరియు చుట్టుపక్కల పాఠశాలలలో 11-15 సంవత్సరాల వయస్సు గల పిల్లలలో వక్రీభవన దోషాల పైన ఒక అధ్యయనాన్ని మేము నిర్వహిస్తున్నాము. అధ్యయనము పబ్లిక్ హెల్త్ ఫౌండేషన్ ఆఫ్ ఇండియా, పుష్పగిరి ఐ ఇన్స్టిట్యూట్, హైదరాబాద్ మరియు లండన్ స్కూల్ ఆఫ్ హైజీన్ అండ్ ట్రాపికల్ మెడిసిన్ (ఎల్ఎస్హెచ్టిఎమ్) మధ్య సహకారంతో నడుస్తున్నది. ఒక నిర్వహణ కమిటీ ఏర్పరచబడినది, ఇందులో విద్యా మంత్రిత్వ శాఖ, ఆరోగ్య మంత్రిత్వ శాఖ, అంధత్వ నియంత్రణ ప్రోగ్రామ్ మరియు ఆర్బిఎస్కె నుండి ప్రతినిధులు ఉంటారు. క్రింద వివరించబడిన ఈ అధ్యయనములో మీ పాఠశాల పాల్గొనటానికి పరిగణించి మరియు అంగీకరిస్తే మేము సంతోషిస్తాము.

భారతదేశంలో 11-15 సంవత్సరాలు గల విద్యార్థులు 25 మందిలో సుమారుగా ఒకరికి వక్రీభవన దోషాలు ఉన్నాయి కానీ వారు స్పష్టంగా చూడటానికి వీలుకల్పించే కళ్ళజోడు వారికి లేవు. భారత ప్రభుత్వం సరిచేయని వక్రీభవన దోషాలు, పిల్లల యొక్క నేర్చుకునే సమర్థతపై మరియు వారి సామాజిక అభివృద్ధిపైన ప్రభావం చూపుతాయి కావున ఒక సమస్యగా గుర్తించింది మరియు వక్రీభవన దోషాల పరిష్కారానికి వనరులను కేటాయించింది. అధ్యయనము పబ్లిక్ హెల్త్ ఫౌండేషన్ ఆఫ్ ఇండియా , ఇండియన్ కౌన్సిల్ ఆఫ్ మెడికల్ రీసర్చ్ మరియు ఎల్ఎస్హెచ్టిఎమ్ నుండి నైతిక ఆమోదాన్ని కలిగి ఉన్నది.

ఈ అధ్యయనము యొక్క ఉద్దేశ్యం ఏమిటి? సరిచేయని వక్రీభవన దోషాలు మసక దృష్టి కలిగిస్తున్నప్పటికీ మరియు జీవన నాణ్యతను తగ్గిస్తున్నప్పటికీ, పిల్లలలో ఒక సాపేక్ష అధిక నిష్పత్తిలో ఇచ్చిన కళ్ళజోడును వారు ధరించటం లేదు. వాస్తవానికి, భారతదేశంలో ఒక ఇటీవల అధ్యయనములో కళ్ళజోడు ఇచ్చిన పిల్లలలో 30% మాత్రమే వాటిని ధరిస్తున్నారని చూపినది. దీనికి చాలా కారణాలు ఉన్నాయి, వాటిలో పిల్లలకు కళ్ళజోడు ఫ్రేమ్ ఇష్టం లేకపోవడం, వారికి వారి దృష్టిలో ఎటువంటి మెరుగుదలను కనిపించక పోవడం, వారి తల్లిదండ్రులకు ఆందోళనలు ఉండటం లేదా పిల్లలను వారి తోటి వారు ఏడిపించడం ఉన్నాయి. మేము మా అధ్యయనంలో ఈ అంశాలలో చాలా వాటిని పరిష్కరిస్తాము, ఎందుకంటే కళ్ళజోడుతో గణనీయ పరిమాణంలో దృష్టి మెరుగయ్యే పిల్లలకు మాత్రమే కళ్ళజోడు పంపిణీ చేస్తాము, పిల్లలు వారికి ఇష్టమైన ఫ్రేమ్లు ఎన్నుకుంటారు, కుటుంబాలకు కళ్ళజోడు ఖర్చు లేకుండా అందజేయబడుతుంది మరియు ఒక ఆరోగ్య బోధన భాగం కూడా ఉంటుంది. ఈ అధ్యయనములో తగ్గిన దృష్టి స్క్రీనింగ్ కోసం విభిన్న విధానాలను మరియు విభిన్న రకాల ఆరోగ్య విద్యను పోల్చుతాము. ఈ విభిన్న విధానాలు పిల్లలలో కళ్ళజోడు ధరించడాన్ని ప్రభావితం చేస్తాయేమో మదింపు చేయడం మొత్తం మీద ఉద్దశ్యం.

అధ్యయనానికి నా పాఠశాల ఎందుకు పరిగణించబడినది? 11-15 సంవత్సరాల వయస్సుగల పిల్లలు గల పాఠశాలల ఒక జాబితాను చేర్చుకొనుటకు పరిగణించబడినది. దాదాపు 36 మంది ప్రధాన ఉపాధ్యాయులు వారి పాఠశాల పాల్గొనడానికి అంగీకరిస్తారని మేము ఆశిస్తున్నాము.

పరీక్ష సమయాలు లేదా ఇతర సమయాలతో జోక్యం చేసుకోకుండా ఉండేలా మేము అన్ని కార్యకలాపాలను మేము ప్రణాళిక చేస్తాము.

పాఠశాలలో ఏమి జరుగుతుంది? ప్రతి పాఠశాలలో, 11- 15 సంవత్సరాల వయస్సు గల పిలల్ల దృష్టిని, దృష్టి యొక్క "6/9" స్థాయిలో కొలవడం జరుగుతుంది. అన్ని పాఠశాలలో, దృష్టి స్క్రీనింగ్లో విఫలమయిన పిల్లలను అధిక ప్రావీణ్యం గల ఆప్టోమెట్రిస్ట్ ద్వారా పాఠశాలలో వక్రీభవనం చేయబడి, పిల్లలకు కళ్ళజోడు అవసరము అవుతుందేమో నిర్ణయిస్తారు. పిలలు వారికి ఇష్టమైన కళ్ళజోడు ఫ్రేమ్ ఎన్నుకోవడానికి అనుమతించబడతారు మరియు కళ్ళజోడు అవసరమైన అందరు పిల్లలకు వారి తల్లిదండ్రుల కోసం ఇంటికి తీసుకెళ్లటానికి సమాచారము ఇవ్వబడుతుంది. కళ్ళజోడు అవసరమైన అందరు పిల్లల జాబితా మీకు ఇవ్వబడుతుంది. వీలైనంత త్వరలో క్షేత్ర స్థాయిలో పని చేయువారి ద్వారా అన్ని కళ్ళజోడులు పంపిణీ చేయబడుతాయి. ఎంత మంది పిల్లలు వారి కళ్ళజోడు ధరిస్తున్నారో కనుగొనడానికి, పిల్లలకు వారి కళ్ళజోడు ఇచ్చిన తరువాత 3 నుండి 4 నెలల తరువాత క్షేత్ర స్థాయి పనివారు మళ్లీ పాఠశాలను సందర్శిస్తారు మరియు వారి కళ్ళజోడు ధరిందారేమో చూడటానికి సంబంధిత తరగతిని సందర్శిస్తారు. పిల్లలు వారి ప్రవర్తనను మార్చకుండా చూడటానికి, క్షేత్ర స్థాయి పనివారు అనుసరణీయత కొరకు పాఠశాలను ఎప్పుడు సందర్శిస్తారో ముందస్తు సమాచారం ఇవ్వకూడని మేము ప్రణాళిక చేసాము.

కొన్ని పాఠశాలలో మేము ఉపాధ్యాయులు దృష్టిని కొలవడానికి శిక్షణ ఇవ్వాలనుకున్నాము; ఇతర పాఠశాలలో శిక్షణ పొందిన క్షేత్ర స్థాయి పనివారు దృష్టిని కొలుస్తారు.

ఉపాధ్యాయులు దృష్టిని కొలిచే పాఠశాలలలో, 11-15 సంవత్సరాల వయస్సు గల పిల్లల ఉపాధ్యాయులను 10-15 నిమిషాలు ఉండే ఆరోగ్య విద్య సెషన్ని సంబంధిత తరగతిలో బోధించవలసిందిగా మేము కోరుతున్నాము. దీని కొరకు ఒక సులువైన మాన్యువల్ రూపొందించబడుతుంది. ఈ పాఠశాలలో పిల్లలు ఇంటికి తీసుకెళ్లడానికి కొంత అదనపు విద్యాసంబంధ వస్తువులు ఇవ్వబడతాయి.

అధ్యయనము ముగింపు వద్ద, ఉపాధ్యాయులు తరగతిలో ఆరోగ్య విద్య సెషన్ ఇవ్వని పాఠశాలలో, క్షేత్ర స్థాయి పనివారు ఒకరు అదే ఆరోగ్య విద్యను బోధించుటకు మేము ప్రణాళిక చేసాము మరియు ఇంటికి తీసుకెళ్ళడానికి అదనపు సమాచారము, కళ్ళజోడు అందరు పిల్లలకు ఇవ్వబడుతాయి.

మరింత నిపుణుని సంరక్షణ అవసరమని కనుగొనబడిని కంటి పరిస్థితులు కలిగిన అందరు విద్యార్థులు పుష్పగిరి ఐ ఇన్స్టిట్యూట్కు పంపబడతారు అక్కడ వారు పరీక్షించబడతారు మరియు అవసరమైతే, చికిత్స అందజేయబడుతుంది. అన్ని ఖర్చులను అధ్యయనము కవర్ చేస్తుంది.

నా పాఠశాల పాల్గొనవలసిందేనా? ఈ అధ్యయనములో మీ పాఠశాల పాల్గొనడానికి మీ అనుమతి స్వచ్ఛందం, పూర్తిగా మీ ఇష్టం. **గోపనీయత** ప్రతి పాఠశాలని గుర్తించడానికి కోడ్లను మాత్రమే ఉపయోగిస్తాము, ఎటువంటి విశ్లేషణ, నివేదికలు లేదా అధ్యయనము నుండి జనింపబడే ప్రచురణలలో మీ పేరు మరియు మీ పాఠశాల పేరు ఉపయోగించబడదు. అదే పిల్లలకు వర్తిస్తుంది మరియు వారి గుర్తింపులు కూడా పూర్తిగా అనామకంగా ఉండిపోతాయి.

అధ్యయనములో మీ పాఠశాల పాల్గొనుటకు మీరు అంగీకరిస్తే అధ్యయనము పూర్తయ్యే వరకు మీ ప్రాంతంలోని ఇతర పాఠశాలలలోని ప్రధాన ఉపాధ్యాయులు లేదా తరగతి ఉపాధ్యాయులలో అధ్యయనము గురించి చర్చించకపోతే మేము సంతోషిస్తాము. **వ్యక్తి** అధ్యయన ముగింపులో ఫలితాలు స్టీరింగ్ కమిటీకి సమర్పించబడుతాయి మరియు వాజరు కావలసిందిగా మీరు ఆహ్వానించబడతారు. ఫలితాల యొక్క క్లుప్త సంగ్రహం కూడా మీకు పంపబడుతుంది.

మీరు అదనపు సమాచారము కోరుకుంటే దయచేసి ప్రాజెక్ట్ మేనేజర్ని సంప్రదించండి

పేరు టిబిసి మొబైల్ ఫోన్ నంబర్ టిబిసి

సమాచార పత్రము 9: అధ్యయనములో చేర్చుకోబడిన పిల్లల యొక్క తల్లిదండ్రులు (పాల్గొనకూడదని నిర్ణయించుకోవడం) (ప్రధాన అధ్యయనము)

విద్యా మంత్రిత్వ శాఖ,

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

PUBLIC HEALTH FOUNDATION OF INDIA

పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్

తల్లిదండ్రుల కోసం సమాచార పత్రము మరియు పాల్గొనకూడదని నిర్ణయించుకోవడం

ప్రియమైన తల్లిదండ్రులు,

హైదరాబాద్ లోని పుష్పగిరి ఐ ఇన్స్టిట్యూట్ నుండి సిబ్బంది హైదరాబాద్ మరియు చుట్టుపక్కల పాఠశాలలలో విద్యార్థుల యొక్క దృష్టిని మందింపు చేసే మరియు కండ్లు లేక దృష్టిలో సమస్య ఉన్న ఎవరైనా బిడ్డకు అవసరమైన చికిత్స అందేలా రూఢీపరచుకునే ఒక ప్రాజెక్టులో సహాయపడటానికి పాఠశాలలను సందర్శిస్తున్నారు. విద్యా సంచాలకులకు దీని గురించి తెలుసు మరియు ఈ ప్రాజెక్టుకు అనుమతి ఇచ్చారు.

మీ బిడ్డ యొక్క పాఠశాల వద్ద ప్రధాన ఉపాధ్యాయులు 11-15 సంవత్సరాల పిల్లలకు మరియు బలహీనమైన దృష్టి గల పిల్లలకు ఒక ఉపాధ్యాయుని ద్వారా లేదా పుష్పగిరి ఇన్స్టిట్యూట్ నుండి వచ్చే అధిక నైపుణ్యం గల సిబ్బంది ద్వారా పాఠశాలలో దృష్టి కొలవడానికి అనుమతి ఇచ్చారు. కళ్లజోడుతో ప్రయోజనం పొందగల పిల్లలు అందరినీ వారికి ఇష్టమైన ఫ్రేము ఎంచుకోవడానికి అనుమించబడుతుంది మరియు ఉచితంగా కళ్లజోడు ఇవ్వబడుతుంది. మీ బిడ్డకు ఏదైనా ఇతర కంటి సమస్య ఉన్నదని కనుగొంటే వారిని పుష్పగిరి ఐ ఇన్స్టిట్యూట్‌కి పంపుతారు అక్కడ అవసరమైతే, వారికి ఖర్చు లేకుండా చికిత్సను అందజేస్తారు.

కళ్ళజోడు అవసరమైన పిల్లలు అందరూ, మీ బిడ్డకు కళ్ళజోడు ఎందుకు అవసరము మరియు వారి కళ్ళజోడును జాగ్రత్తగా ఎలా చూడాలి అనేదాన్ని గురించి మీ కొరకు చదవడానికి కొంత సమాచారాన్ని ఇంటికి తీసుకువస్తారు. ప్రాజెక్టు ప్రారంభంలో కానీ లేదీ ముగింపు వద్ద కానీ, కొందరు పిల్లలు కళ్ళజోడును ఎందుకు ఉపయోగించాలి అనేదాన్ని గురించి కొంత అదనపు సమాచారము కూడా మీ బిడ్డకు ఇవ్వబడుతుంది.

మీ బిడ్డ యొక్క కళ్ళ గురించి కొంత అదనపు సమాచారం మేము మీకు పంపగలగడానికి వీలుగా మీరు మీ మొబైల్ ఫోన్ నంబరు మాతో పంచుకుంటే మేము సంతోషిస్తాము. మీ నంబరు ఇంకెవ్వరికీ ఇవ్వబడదు మరియు ప్రాజెక్ట్ చివరలో తొలగించబడుతుంది.

మీ బిడ్డ యొక్క దృష్టి లేదా ప్రాజెక్ట్ గురించి మీరు తదుపరి సమాచారం కోరుకుంటే దయచేసి ప్రాజెక్ట్ మేనేజర్,{ఏరు.....}ని +91 {నంబర్.....} వద్ద సంప్రదించండి.

ఈ ప్రాజెక్టులో మీ బిడ్డ పాల్గొనగలదని ధ్రువీకరించడానికి దయచేసి మీ పేరు మరియు సంతకాన్ని జోడించండి మరియు అవును అన్న డబ్బాలో ఒక క్రాస్ ఉంచండి. మీరు అంగీరించకపోతే, లేదు అనే డబ్బాలో ఒక క్రాస్ ఉంచండి. మీరు అవును లేదా లేదు టిక్ చేసినా, దయచేసి ఈ లేఖను మీ బిడ్డ తిరిగి పాఠశాలకు తీసుకెళ్లడానికి ఇవ్వండి.

	అవును	లేదు
ఈ ప్రాజెక్టులో నా బిడ్డ పాల్గొనడానికి నేను అంగీకరిస్తున్నాను	☐	☐

బిడ్డ పేరు ..... వయస్సు..... తరగతి.....మీ పేరు ..... మీ సంతకం..... మొబైల్ టెలిఫోన్ నంబర్ .....

సమాచార పత్రము 10: అధ్యయనము లోనికి చేర్చుకోబడిన పిల్లలు (ప్రధాన అధ్యయనము)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్

అధ్యయనము లోనికి చేర్చుకోబడిన పిల్లల కొరకు సమాచార పత్రము

ప్రియమైన విద్యార్థి,

మీ దృష్టి పరీక్షించినప్పుడు మీ దృష్టిలో కొంత మసక ఉన్నదని మేము కనుగొన్నాము. మేము మిమ్మల్ని ఈ రోజు పరీక్షించినప్పుడు మీరు మరింత స్పష్టంగా చూడటానికి కళ్ళజోడు అవసరమని మేము కనుగొన్నాము మరియు మీకు మేము ఒక కళ్ళజోడు ఇస్తాము. మీకు ఇష్టమైన ఫ్రేమ్ రకం ఎంపిక చేసుకోగలరు మరియు కళ్ళజోడు దాదాపు రెండు వారాలలో పాఠశాల వద్ద పంపిణీ చేయబడుతుంది. మీరు ఎల్లపేళలా కళ్ళజోడు ధరించవలసిన అవసరం ఉండదు, కానీ పాఠశాలలో లేదా టెలివిజన్ చూసే సమయాల లాంటి, మీరు మరింత స్పష్టంగా చూడవలసినప్పుడు మాత్రమే ధరించండి. మీరు గతంలో కళ్లజోడు ధరించకపోతే కళ్ళజోడు ధరించిన తరువాత అలవాటు అవడానికి మీకు కొంత సమయం పట్టవచ్చు

మీ తల్లిదండ్రుల కొరకు ఇంటికి తీసుకెళ్ళటానికి మేము మీకు కొంత సమాచారం ఇస్తాము, ఇది మీ కళ్ళజోడును ఎలా జాగ్రత్తగా చూసుకోవాలో వివరిస్తుంది మరియు మీ తల్లిదండ్రులకు మేము వచన సందేశం పంపవచ్చు.

మీరు కళ్ళజోడుతో ఎలా వ్యవహరిస్తున్నారో కనుగొనడానికి మేము కొన్ని నెలల తరువాత పాఠశాలకు వస్తాము మరియు మిమ్మల్ని కొన్ని ప్రశ్నలు అడవచ్చు.

కొన్ని నెలల సమయంలోమీ ఇంటికి తీసుకెళ్ళడానికి మేము కొంత అదనపు సమాచారాన్ని కూడా ఇవ్వవచ్చు.

మేము సేకరించిన సమాచారం అంతా విశ్లేషిస్తాము కానీ విశ్లేషణలో మీ పేరు ఉపయోగించబడదు మరియు సమాచారము అంతటికి ప్రాజెక్టు బృందానికి మాత్రమే ప్రాప్యత ఉంటుంది.

మీరు ప్రాజెక్టులో పాల్గొనక్కర లేదు. మీరు పాల్గొనకూడదని నిర్ణయించుకున్నప్పటికీ మీకు అధిక నాణ్యత గల కళ్ళజోడు ఇవ్వబడుతుంది.

ప్రాజెక్టు సిబ్బంది మీకు చూపించే పత్రము సైన దయచేసి సంతకం చేయండి.

అంగీకార పత్రము 10: అధ్యయనము లోనికి చేర్చుకోబడిన పిల్లలు (ప్రధాన అధ్యయనము)

విద్యా మంత్రిత్వ శాఖ, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA పుష్పగిరి ఐ ఇన్స్టిట్యూట్,

పాఠశాల కళ్ళజోడు ప్రాజెక్ట్, హైదరాబాద్

విద్యార్థులకు అంగీకార పత్రము

ఒక పరిశోధకునితో బిడ్డద్వారా పూర్తి చేయబడాలి

విద్యార్థి ఈరు అంగీకరించే అన్నిటినీ టిక్ చేయాలి:

	అవును		లేదు
ఈ ప్రాజక్టు గురించి చదివారా (లేదా మీకు చదివి వినిపించబడిందా)?			
ఈ ప్రాజెక్టు గురించి ఎవరైనా మీకు వివరించారా?			
ఈ ప్రాజెక్టు దేని గురించో మీరు అర్థం చేసుకున్నారా?			
మీరు అడగాలనుకున్న అన్ని ప్రశ్నలు అడిగారా?			
మీరు అర్థం చేసుకునే విధానంలో మీ ప్రశ్నలు అన్నింటికి జవాబు పొందారా?			
ఏ సమయంలోనైనా పాల్గొనటం ఆపవచ్చని మీరు అర్థం చేసుకున్నారా?			
పాల్గొనటానికి మీరు సంతోషంగా ఉన్నారా?			

ఏపైనా జవాబులు 'లేదు' అయినా లేదా మీరు పాల్గొన **కూడదని** కోరుకుంటే, మీ పేరును సంతకం చేయకండి

మీరు పాల్గొనాలని కోరుకుంటే, దయచేసి మీ పేరు వ్రాయండి మరియు ఈ రోజు తేదీ వేయండి

మీ పేరు _____వయస్సు_____

తేదీ _____

మీకు ఈ ప్రాజెక్టు గురించి వివరించిన పరిశోధకుడు కూడా సంతకం చేయాలి:

పేరు ముద్రించండి _____

సంతకం _____

తేదీ _____

మీ సహాయానికి ధ్యనవాదాలు

सहमति प्रपत्र 2: FGDs में भाग लेने वाले माता-पिता (प्रारंभिक शोध)

शिक्षा मंत्रालय,

पुष्पागिरी आई इंस्टीट्यूट,

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

फ़ोकस समूह चर्चा में भाग लेने वाले माता-पिता के लिए सहमति फ़ॉर्म

मैं पुष्टि करता/करती हूँ कि मैंने अध्ययन के बारे में जानकारी प्रपत्र को पढ़ और समझ लिया है, और अध्ययन के बारे में मेरे प्रश्नों का उत्तर दे दिया गया है।

	हाँ	नहीं
मैं अध्ययन में भाग लेने के लिए सहमत हूँ	☐	☐

माता/पिता का नाम _____

माता/पिता का हस्ताक्षर _____

शोधकर्ता का नाम _____

शोधकर्ता का हस्ताक्षर _____

तिथि ---------- / ---------- / ----------

दिन महीना वर्ष

सहमति प्रपत्र 1: प्रधान शिक्षक और शिक्षक (प्रारंभिक शोध)

शिक्षा मंत्रालय,

पुष्पागिरी आई इंस्टीट्यूट,

विद्यालय अपवर्तक दोष अध्ययन, हैदराबाद

प्रधान शिक्षकों और शिक्षकों के लिए सहमति फ़ॉर्म

मैं पुष्टि करता/करती हूँ कि मैंने अध्ययन के बारे में जानकारी प्रपत्र को पढ़ और समझ लिया है, और अध्ययन के बारे में मेरे प्रश्नों का उत्तर दे दिया गया है।

	हाँ	नहीं
मैं अध्ययन में भाग लेने के लिए सहमत हूँ	☐	☐

प्रधान शिक्षक/शिक्षिका का नाम _____

प्रधान शिक्षक/शिक्षिका का हस्ताक्षर _____

शोधकर्ता का नाम _____

शोधकर्ता का हस्ताक्षर _____

तिथि ---------- / ---------- / ----------

दिन महीना वर्ष

जानकारी प्रपत्र 1: प्रधान शिक्षक और शिक्षक (प्रारंभिक शोध)

शिक्षा मंत्रालय | LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE | PUBLIC HEALTH FOUNDATION OF INDIA | पुष्पागिरी आई इंस्टीट्यूट,

स्कूल अपवर्तक दोष अध्ययन, हैदराबाद
प्रधान शिक्षकों और शिक्षकों के लिए जानकारी प्रपत्र और सहमति फ़ॉर्म

प्रिय महाशय/महाशया,

हम हैदराबाद और आसपास के स्कूलों में 11-15 वर्षों के बच्चों में अपवर्तक दोष पर अध्ययन का संचालन कर रहे हैं। अध्ययन भारतीय सार्वजनिक स्वास्थ्य संस्थान, पुष्पागिरी आई इंस्टीट्यूट, हैदराबाद और लंदन स्कूल ऑफ़ हाइजिन एंड ट्रॉपिकल मेडिसिन (LSHTM) के बीच एक सहयोग है। एक संचालन समिति का गठन किया गया है, जिसमें शिक्षा मंत्रालय, स्वास्थ्य मंत्रालय, दृष्टिहीनता एवं RBSK नियंत्रण कार्यक्रम की तरफ से सरकारी प्रतिनिधि शामिल हैं। हम आभारी होंगे यदि आप नीचे वर्णित इस अध्ययन के बारे में विचार करते हैं और इसमें भाग लेने के लिए सहमति जताते हैं।

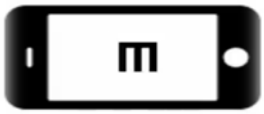
भारत में 11-15 वर्ष आयु वाले 25 स्कूली छात्रों में से लगभग एक को अपवर्तक दोष है लेकिन उनके पास चश्में नहीं हैं जो उन्हें स्पष्ट रूप से देखने में सक्षम बनाएँगे। भारत सरकार मानती है कि ठीक न हुए अपवर्तक दोष एक समस्या है, क्योंकि यह बच्चों की सीखने की क्षमता और उनके सामाजिक विकास को प्रभावित करती है, और अपवर्तक दोष के लिए संसाधन आवंटित किया है। अध्ययन को भारतीय सार्वजनिक स्वास्थ्य संस्थान, भारतीय आयुर्विज्ञान अनुसंधान परिषद और LSHTM से नैतिक अनुमोदन प्राप्त है।

इस अध्ययन का उद्देश्य क्या है?
इस अध्ययन में हम दृष्टि समस्याओं की जाँच के दो अलग-अलग तरीकों की तुलना करना चाहते हैं, जिसमें से एक में शिक्षकों द्वारा मोबाइल फ़ोन एप्लिकेशन का उपयोग करके दृष्टि मापना आवश्यक है। हम स्वास्थ्य शिक्षा के प्रति अलग-अलग दृष्टिकोणों के प्रभाव का मूल्यांकन भी करेंगे, यह जाँचने के लिए कि क्या यह बच्चों के उस अनुपात को प्रभावित करता है जो बाद में चश्में पहनने लगते हैं। अध्ययन में शामिल सभी स्कूलों में, उन सभी बच्चों को जिन्हें चश्मे दिए गए हों एक पैम्फलेट दिया जाएगा जिसे वे घर ले जाकर अपने माता-पिता को देंगे। कुछ स्कूलों में हम चाहेंगे कि शिक्षक छोटी कक्षा सत्र आयोजित करें जिसमें वे मोबाइल फ़ोन एप्लिकेशन पर बनाई गई छवियों का उपयोग करके अपवर्कत दोष समझाएँ, और चश्मे पहनने के लाभ बताएँ। हम बच्चों को एक छवि भी देंगे जिसे वे अपने घर ले जा सकेंगे। एक उदाहरण नीचे प्रदर्शित है।

एक बच्चा जिसे चश्मे की जरूरत है वह दुनिया को कैसे देखता है

वही बच्चा चश्मा पहनने के बाद दुनिया को कैसे देखता है

मछुआ क्या करने के लिए कहा जाएगा?
यदि आप भाग लेने के लिए सहमति जताते हैं तो हम आपके साथ छोटी चर्चा करेंगे ताकि बच्चों में अपवर्तक दोष के बारे में आपको विचार जान सकें। हम मोबाइल फ़ोन एप्लिकेशन का उपयोग करके दृष्टि जाँच करने वाले शिक्षकों के बारे में आपकी राय का सम्मान भी करेंगे और उन छवियों के बारे में आपके इनपुट चाहेंगे जिनका उपयोग हम कक्षा शिक्षा में कर सकते हैं, और विद्यार्थियों को घर ले जाने के लिए दे सकते हैं।
हम आशा करते हैं कि इसमें लगभग 20 मिनट लगेंगे और यह आपकी पसंद के समय और स्थान में लिया जाएगा।
हम आपके मोबाइल फ़ोन एप्लिकेशन का उपयोग करके विद्यार्थियों की दृष्टि जाँच करने के लिए भी प्रशिक्षित करेंगे (नीचे देखें), और आपको दिखाएँगे कि अपने जाँच-परिणाम फ़ोन के सॉफ्टवेयर में किस प्रकार दर्ज करें। जो किसी और समय किया जा सकता है। हम आशा करते हैं कि इस प्रशिक्षण में आधा दिन तक समय लग सकता है।



गोपनीयता
आपके द्वारा कही गई सभी बातें पूरी तरह गोपनीय रखी जाएगी क्योंकि हम किसी भी दस्तावेज़ में आपके नाम या स्कूल का नाम का उपयोग नहीं करेंगे और आप जो बातें बताएँगे उससे प्रोजेक्ट का बाहर किसी भी व्यक्ति का नहीं बताया जाएगा।

क्या मछुआ हिस्सा बने बिना
नहीं आपकी भागीदारी पूर्ण रूप से स्वेच्छिक है। हो सभी यात्रा खर्चों की प्रतिपूर्ति की जाएगी और हम आपको जलपान उपलब्ध कराएँगे।
यदि आप भाग लेने के लिए सहमति जताते हैं तो हम मछुआ आँख जाँच की पेशकश कर सकते हैं, और यदि आवश्यक हो तो बढ़ने के लिए चश्मा मछुआ प्रदान कर सकते हैं।
यदि आप अतिरिक्त जानकारी चाहते हैं तो कृपया हमारा प्रोजेक्ट मैनेजर से संपर्क करें

नाम मोबाइल फ़ोन नंबर

जानकारी प्रपत्र 2: FGDs में माता-पिता (प्रारंभिक शोध)

शिक्षा मंत्रालय

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

KNOWLEDGE TO ACTION phfi PUBLIC HEALTH FOUNDATION OF INDIA

पुष्पागिरी आई इंस्टीट्यूट,

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

फ़ोकस समूह चर्चा में भाग लेने वाले माता-पिता के लिए जानकारी प्रपत्र

प्रिय माता-पिता,

भारत में 11 से 15 वर्ष आयु वाले 25 बच्चों में से एक बच्चा स्पष्ट रूप से नहीं देख सकता है क्योंकि उसे एक चश्मे की जरूरत है। हालाँकि, हम दूसरे प्रोजेक्ट से जानते हैं कि जिन बच्चों को चश्मे दिए जाते हैं अकसर वे अपने चश्मे नहीं पहनते है और इसलिए उन्हें लाभ नहीं पहुँचता है।

हम हैदराबाद और आसपास के स्कूलों में एक प्रोजेक्ट का आयोजन कर रहे हैं और आपसे चश्मा पहनने वाले बच्चों के बारे में आपके विचार पूछना चाहेंगे। कुछ स्कूलों में हम बच्चों, शिक्षकों और माता-पिता के बीच चश्मा पहनने के लाभ के बारे में जागरूकता बढ़ाने के लिए छवियों का उपयोग करने की योजना बना रहे हैं और हम इस बारे में आपकी राय की कद्र करेंगे कि कौन सी छवियाँ उपयोग के लिए श्रेष्ठ होंगी। एक उदाहरण नीचे प्रदर्शित है।

एक बच्चा जिसे चश्मे की जरूरत है वह दुनिया को कैसे देखता है

वही बच्चा चश्मा पहनने के बाद दुनिया को कैसे देखता है

कुछ स्कूलों में हम चश्मे की जरूरत वाले बच्चों के माता-पिता को एसएमएस संदेश भेजने की भी योजना बना रहे हैं, और इस बारे में आपकी राय की कद्र करेंगे कि कौन से संदेश सबसे अधिक उपयोगी हो सकते हैं।

क्या होगा यदि मैं भाग लूँ?

यदि आप भाग लेने के लिए सहमत होते हैं, तो आपको अपने बच्चे के स्कूल में अन्य माता-पिता के समूह में शामिल होने के लिए आमंत्रित किया जाएगा, और प्रोजेक्ट टीम का एक सदस्य चर्चा की अगुवाई करेगा। इसमें लगभग एक घंटे का समय लगेगा।

यदि आप भाग लेने के लिए सहमत होते हैं तो यात्रा खर्चों की प्रतिपूर्ति की जाएगी और आपको जलपान दिया जाएगा। हम आपको आँख की जाँच-पड़ताल की पेशकश भी करेंगे, और यदि आवश्यक हुआ तो, आपको पढ़ने के लिए एक चश्मा देंगे।

क्या मुझे हिस्सा लेना होगा?

नहीं, यह पूरी तरह से स्वैच्छिक है।

गोपनीयता

आपके द्वारा कही गई सारी बातें पूरी तरह गोपनीय रखी जाएँगी और हम उन्हें प्रोजेक्ट से बाहर किसी से भी साझा नहीं करेंगे। हम आपके नाम का उपयोग किन्हीं रिपोर्ट इत्यादि में नहीं करेंगे। यदि आप अतिरिक्त जानकारी चाहते हैं तो कृपया हमारे प्रोजेक्ट मैनेजर से संपर्क करें

नाम मोबाइल फ़ोन नंबर

सहमति प्रपत्र 3: FGDs में भाग लेने वाले बच्चे (प्रारंभिक शोध)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA पुष्पागिरी आई इंस्टीट्यूट,

स्कूल चश्मा प्रोजेक्ट, हैदराबाद
विद्यार्थियों के लिए सहमति फ़ॉर्म
बच्चे द्वारा किसी शोधकर्ता के साथ भरा जाना चाहिए

विद्यार्थी को उन सब पर सही का निशान लगाना चाहिए जिससे वे सहमत हैं:

	हाँ		नहीं
क्या आपने इस प्रोजेक्ट के बारे में पढ़ा (या आपको पढ़ कर सुनाया गया) है?			
क्या किसी दूसरे व्यक्ति ने आपको इस प्रोजेक्ट के बारे में समझाया है?			
क्या आप समझते हैं कि यह प्रोजेक्ट किस बारे में है?			
क्या आपने उन सभी प्रश्नों को पूछ लिया है जो आप पूछना चाहते हैं?			
क्या आपके प्रश्नों का उत्तर ऐसे तरीके से दिया गया जिसे आप समझ सके?			
क्या आप समझते हैं कि किसी भी समय भागीदारी रोक देने में कोई दिक्कत नहीं है			
क्या आप भाग लेने के लिए खुश हैं?			

यदि कोई उत्तर 'नहीं' है या आप भाग लेना **नहीं** चाहते हैं, तो हस्ताक्षर **नहीं** करें

यदि आप भाग लेना चाहते हैं, तो कृपया अपना नाम और आज की तिथि लिखें

आपका नाम _____ आयु_____

तिथि _____

जिस शोधकर्ता ने आपको यह प्रोजेक्ट समझाया है उसे भी यहाँ हस्ताक्षर करने की जरूरत है:

प्रिंट नाम _____

हस्ताक्षर _____

तिथि _____

सहायता करने के लिए धन्यवाद

जानकारी प्रपत्र 3: FGDs में भाग लेने वाले बच्चे (प्रारंभिक शोध)

शिक्षा मंत्रालय LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA पुष्पागिरी आई इंस्टीट्यूट,

फ़ोकस समूह चर्चा में भाग लेने वाले बच्चों के लिए जानकारी प्रपत्र

प्रिय विद्यार्थी

भारत में 11 से 15 वर्ष आयु वाले 25 बच्चों में से एक बच्चा स्पष्ट रूप से नहीं देख सकता है क्योंकि उन्हें एक चश्मे की जरूरत है। हालाँकि, हम दूसरे प्रोजेक्ट से जानते हैं कि जिन बच्चों को चश्मे दिए जाते हैं अकसर वे अपने चश्मे नहीं पहनते है और इसलिए उन्हें लाभ नहीं पहुँचता है।
हम हैदराबाद और आसपास के स्कूलों में एक प्रोजेक्ट का आयोजन कर रहे हैं और आपसे पूछना चाहेंगे कि आप चश्मा पहनने वाले बच्चों के बारे में क्या सोचते हैं। कुछ स्कूलों में हम बच्चों, शिक्षकों और माता-पिता के बीच चश्मा पहनने के लाभ के बारे में जागरूकता बढ़ाने के लिए छवियों का उपयोग करने की योजना बना रहे हैं और हम इस बारे में आपकी राय की कद्र करेंगे कि कौन सी छवियाँ उपयोग के लिए श्रेष्ठ होंगी। एक उदाहरण नीचे प्रदर्शित है।

एक बच्चा जिसे चश्मे की जरूरत है वह दुनिया को कैसे देखता है

वही बच्चा चश्मा पहनने के बाद दुनिया को कैसे देखता है

क्या होगा यदि मैं भाग लूँ?
यदि आप भाग लेने के लिए सहमत होते हैं, तो आपको अपने स्कूल के अन्य बच्चों के समूह में शामिल होने के लिए आमंत्रित किया जाएगा, और प्रोजेक्ट टीम का एक सदस्य चर्चा की अगुवाई करेगा। इसमें लगभग आधा घंटे का समय लगेगा।
क्या मुझे हिस्सा लेना होगा?
नहीं, यह पूरी तरह से स्वैच्छिक है।
गोपनीयता
आपके द्वारा कही गई सारी बातें पूरी तरह गोपनीय रखी जाएँगी और हम उन्हें प्रोजेक्ट से बाहर किसी से भी साझा नहीं करेंगे। हम आपके नाम का उपयोग किन्हीं रिपोर्ट इत्यादि में नहीं करेंगे।
यदि आप अतिरिक्त जानकारी चाहते हैं तो कृपया हमारे प्रोजेक्ट मैनेजर से संपर्क करें
नाम
मोबाइल फ़ोन नंबर

सहमति प्रपत्र 4: क्लास रूम शिक्षण के पूर्व और पश्च मूल्यांकन में भाग लेने वाले बच्चे (प्रारंभिक शोध)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA *पुष्पागिरी आई इंस्टीट्यूट,*

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

विद्यार्थियों के लिए सहमति फ़ॉर्म

बच्चे द्वारा किसी शोधकर्ता के साथ भरा जाना चाहिए

विद्यार्थी को उन सब पर सही का निशान लगाना चाहिए जिससे वे सहमत हैं:

	हाँ	नहीं
क्या आपने इस प्रोजेक्ट के बारे में पढ़ा (या आपको पढ़ कर सुनाया गया) है?		
क्या किसी दूसरे व्यक्ति ने आपको इस प्रोजेक्ट के बारे में समझाया है?		
क्या आप समझते हैं कि यह प्रोजेक्ट किस बारे में है?		
क्या आपने उन सभी प्रश्नों को पूछ लिया है जो आप पूछना चाहते हैं?		
क्या आपके प्रश्नों का उत्तर ऐसे तरीके से दिया गया जिसे आप समझ सके?		
क्या आप समझते हैं कि किसी भी समय भागीदारी रोक देने में कोई दिक्कत नहीं है		
क्या आप भाग लेने के लिए खुश हैं?		

यदि कोई उत्तर 'नहीं' है या आप भाग लेना **नहीं** चाहते हैं, तो हस्ताक्षर **नहीं** करें

यदि आप भाग लेना चाहते हैं, तो कृपया अपना नाम और आज की तिथि लिखें

आपका नाम _____ आयु_____

तिथि _____

जिस शोधकर्ता ने आपको यह प्रोजेक्ट समझाया हो उसे भी यहाँ हस्ताक्षर करने की जरूरत है:

प्रिंट नाम _____

हस्ताक्षर _____

तिथि _____

सहायता करने के लिए धन्यवा

जानकारी प्रपत्र 4: क्लास रूम शिक्षण के पूर्व और पश्च मूल्यांकन में भाग लेने वाले बच्चे (प्रारंभिक शोध)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA *पुष्पागिरी आई इंस्टीट्यूट,*

क्लास रूम शिक्षण के पूर्व और पश्च मूल्यांकन में भाग लेने वाले बच्चों के लिए जानकारी प्रपत्र

प्रिय विद्यार्थी

भारत में 11 से 15 वर्ष आयु वाले 25 बच्चों में से एक बच्चा स्पष्ट रूप से नहीं देख सकता है क्योंकि उन्हें एक चश्मे की जरूरत है। हालाँकि, हम दूसरे प्रोजेक्ट से जानते हैं कि जिन बच्चों को चश्मे दिए जाते हैं अकसर वे अपने चश्मे नहीं पहनते है और इसलिए उन्हें लाभ नहीं पहुँचता है।

हम हैदराबाद और आसपास के स्कूलों में एक प्रोजेक्ट का आयोजन कर रहे हैं और आपसे पूछना चाहेंगे कि आप चश्मा पहनने वाले बच्चों के बारे में क्या सोचते हैं। हम यह दो बार करेंगे, एक बार आपके शिक्षक द्वारा अपवर्तक दोष के बारे में कुछ बताने के पहले, और दोबारा उसके तत्काल बाद। कोई सही या गलत उत्तर नहीं है - हम केवल जानना चाहते हैं कि आप क्या सोचते हैं।

क्या होगा यदि मैं भाग लूँ?

यदि आप भाग लेने के लिए सहमत होते हैं, तो आपको एक कागज़ दिया जाएगा जिस पर कुछ प्रश्न लिखे होंगे, जिन्हें हम चाहते हैं कि आप पूरा करें। फिर आप शिक्षक को सुनेंगे, और तब आपको प्रश्न दिए जाएँगे जिनका उत्तर आपको देना होगा। इसमें लगभग आधा घंटे का समय लगेगा।

क्या मुझे हिस्सा लेना होगा?

नहीं, यह पूरी तरह से स्वैच्छिक है।

गोपनीयता

हम आपको कागज़ पर अपना नाम लिखने के लिए कहेंगे, लेकिन जब हम स्टूडेंट द्वारा लिखे उत्तरों पर नजर डालेंगे तो आपके नाम का उपयोग नहीं करेंगे। हम आपके नाम का उपयोग किन्हीं रिपोर्ट इत्यादि में नहीं करेंगे।

यदि आप अतिरिक्त जानकारी चाहते हैं तो कृपया हमारे प्रोजेक्ट मैनेजर से संपर्क करें

नाम

मोबाइल फ़ोन नंबर

सहमति प्रपत्र 5: FDGs में भाग लेने वाले बच्चों के माता-पिता (प्रारंभिक शोध)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PHFI PUBLIC HEALTH FOUNDATION OF INDIA पुष्पागिरी आई इंस्टीट्यूट,

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

फ़ोकस समूह चर्चा में भाग लेने वाले बच्चों के माता-पिता के लिए सहमति फ़ॉर्म

मैं पुष्टि करता/करती हूँ कि मैंने अध्ययन के बारे में जानकारी प्रपत्र को पढ़ और समझ लिया है, और अध्ययन के बारे में मेरे प्रश्नों का उत्तर दे दिया गया है।

	हाँ	नहीं
मैं सहमत हूँ कि मेरा बच्चा अध्ययन में भाग ले सकता है	☐	☐

बच्चे का नाम _____

माता/पिता का नाम _____

माता/पिता का हस्ताक्षर _____

तिथि ---------/---------/----------

दिन महीना वर्ष

जानकारी प्रपत्र 5: FDGs में भाग लेने वाले बच्चों के माता-पिता (प्रारंभिक शोध)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PHFI PUBLIC HEALTH FOUNDATION OF INDIA पुष्पागिरी आई इंस्टीट्यूट,

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

समूह चर्चा में भाग लेने वाले बच्चों के माता-पिता के लिए जानकारी प्रपत्र

प्रिय माता-पिता

भारत में 11 से 15 वर्ष आयु वाले 25 बच्चों में से एक बच्चा स्पष्ट रूप से नहीं देख सकता है क्योंकि उन्हें एक चश्मे की जरूरत है। हालाँकि, हम दूसरे प्रोजेक्ट से जानते हैं कि जिन बच्चों को चश्मे दिए जाते हैं अकसर वे अपने चश्मे नहीं पहनते है और इसलिए उन्हें लाभ नहीं पहुँचता है।

हम हैदराबाद और आसपास के स्कूलों में एक प्रोजेक्ट का आयोजन कर रहे हैं और आपके बच्चे से पूछना चाहेंगे कि वे चश्मा पहनने वाले बच्चों के बारे में क्या सोचते हैं, और यह पता लगाना चाहेंगे कि उनके अनुसार चश्मा पहनने वाले बच्चे क्या नहीं कर सकते हैं क्योंकि वे स्पष्ट रूप से नहीं देख पाते हैं। बच्चों के विचार मायने रखते हैं क्योंकि यह निर्णय लेने में मदद करते हैं कि बच्चों को अपवर्तक दोष के बारे में समझाने का सबसे बढ़िया तरीका क्या है।

क्या होगा यदि मेरा बच्चा इसमें भाग लेगा?
यदि आप सहमत होते हैं कि आपका बच्चा भाग ले सकता है, तो उन्हें समान लिंग और आयु समूह वाले अन्य 4-5 बच्चों के साथ चर्चा में भाग लेने के लिए कहा जाएगा। प्रोजेक्ट टीम का एक सदस्य चर्चा की अगुवाई करेगा जिसमें लगभग एक घंटे का समय लगेगा।

क्या मुझे सहमत होना है कि मेरा बच्चा भाग ले?
नहीं, यह पूरी तरह से स्वैच्छिक है।

गोपनीयता
हम किसी भी समय आपके बच्चे के नाम का प्रयोग नहीं करेंगे, और इसलिए वे जो कहेंगे उन्हें उनसे नहीं जोड़ा जाएगा।

यदि आप अतिरिक्त जानकारी चाहते हैं तो कृपया हमारे प्रोजेक्ट मैनेजर से संपर्क करें
नाम
मोबाइल फ़ोन नंबर

सहमति प्रपत्र 6: क्लास रूम शिक्षण के पूर्व और पश्च मूल्यांकन में भाग लेने वाले बच्चों के माता-पिता (प्रारंभिक शोध)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA पुष्पागिरी आई इंस्टीट्यूट,

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

समूह चर्चा और क्लास रूम शिक्षण के पूर्व और पश्च मूल्यांकन में भाग लेने वाले बच्चों के लिए सहमति फ़ॉर्म

मैं पुष्टि करता/करती हूँ कि मैंने अध्ययन के बारे में जानकारी प्रपत्र को पढ़ और समझ लिया है, और अध्ययन के बारे में मेरे प्रश्नों का उत्तर दे दिया गया है।

	हाँ	नहीं
मैं सहमत हूँ कि मेरा बच्चा अध्ययन में भाग ले सकता है	☐	☐

बच्चे का नाम _____

माता/पिता का नाम _____

माता/पिता का हस्ताक्षर _____

तिथि ---------- / ---------- / ----------
दिन महीना वर्ष

जानकारी प्रपत्र 6: क्लास रूम शिक्षण के पूर्व और पश्च मूल्यांकन में भाग लेने वाले बच्चों के माता-पिता (प्रारंभिक शोध)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA पुष्पागिरी आई इंस्टीट्यूट,

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

क्लास रूम शिक्षण के पूर्व और पश्च मूल्यांकन में भाग लेने वाले बच्चों के माता-पिता के लिए जानकारी प्रपत्र

प्रिय माता-पिता

भारत में 11 से 15 वर्ष आयु वाले 25 बच्चों में से एक बच्चा स्पष्ट रूप से नहीं देख सकता है क्योंकि उन्हें एक चश्मे की जरूरत है। हालाँकि, हम दूसरे प्रोजेक्ट से जानते हैं कि जिन बच्चों को चश्मे दिए जाते हैं अकसर वे अपने चश्मे नहीं पहनते है और इसलिए उन्हें लाभ नहीं पहुँचता है।

हम हैदराबाद और आसपास के स्कूलों में एक प्रोजेक्ट का आयोजन कर रहे हैं और आपके बच्चे से पूछना चाहेंगे कि वे चश्मा पहनने वाले बच्चों के बारे में क्या सोचते हैं। हमने बच्चों के लिए कुछ शैक्षणिक सामग्रियाँ विकसित की है, जो क्लास रूम शिक्षकों द्वारा प्रदान की जाएँगी, और हम पता लगाना चाहेंगे कि क्या यह बच्चों को अपवर्तक दोष के बारे में बताने का बढ़िया तरीका है।

क्या होगा यदि मेरा बच्चा इसमें भाग लेगा?
यदि आप अपने बच्चे की भागीदारी के लिए सहमत होते हैं, तो उसे एक कागज़ दिया जाएगा जिस पर कुछ प्रश्न लिखे होंगे, जिन्हें हम चाहते हैं कि वे पूरा करें। फिर वे शिक्षक को सुनेंगे, और तब आपके बच्चे को फिर से प्रश्न दिए जाएँगे जिनका उत्तर उन्हें देना होगा। इसमें लगभग आधा घंटे का समय लगेगा।

क्या मुझे सहमत होना है कि मेरा बच्चा भाग ले?
नहीं, यह पूरी तरह से स्वैच्छिक है।

गोपनीयता
हम आपके बच्चे को अपना नाम कागज पर लिखने के लिए कहेंगे, ताकि हम तुलना कर सकें कि वे शिक्षक को सुनने के पहले और उसके बाद क्या कहते हैं। लेकिन आपके बच्चे का नाम विश्लेषण में प्रयोग नहीं होगा।

यदि आप अतिरिक्त जानकारी चाहते हैं तो कृपया हमारे प्रोजेक्ट मैनेजर से संपर्क करें

नाम
मोबाइल फ़ोन नंबर

सहमति प्रपत्र 7: शिक्षक की वैधता जाँच में भाग लेने वाले शिक्षक

शिक्षा मंत्रालय,

पुष्पागिरी आई इंस्टीट्यूट,

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

वैधता जाँच में भाग लेने वाले शिक्षकों के लिए सहमति फ़ॉर्म

मैं पुष्टि करता/करती हूँ कि मैंने अध्ययन के बारे में जानकारी प्रपत्र को पढ़ और समझ लिया है, और अध्ययन के बारे में मेरे प्रश्नों का उत्तर दे दिया गया है।

	हाँ	नहीं
मैं अध्ययन में भाग लेने के लिए सहमत हूँ	☐	☐

शिक्षक का नाम _____

शिक्षक का हस्ताक्षर _____

शोधकर्ता का नाम _____

शोधकर्ता का हस्ताक्षर _____

तिथि ---------- / ---------- / ----------
दिन *महीना* *वर्ष*

जानकारी प्रपत्र 7: शिक्षक की वैधता जाँच में भाग लेने वाला शिक्षक

शिक्षा मंत्रालय | LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE | KNOWLEDGE TO ACTION phfi PUBLIC HEALTH FOUNDATION OF INDIA | पब्लिक हेल्थ फाउंडेशन ऑफ इंडिया

विद्यालय अपवर्तक दोष अध्ययन, हैदराबाद

शिक्षकों द्वारा दृष्टि जाँच की वैधता का मूल्यांकन करने के लिए जानकारी प्रपत्र और सहमति फ़ॉर्म

प्रिय महोदय/महोदया,

हम हैदराबाद और आसपास के विद्यालयों में 11-15 वर्ष के बच्चों में अपवर्तक दोष पर अध्ययन का संचालन कर रहे हैं। अध्ययन भारतीय सार्वजनिक स्वास्थ्य संस्थान, पब्लिक हेल्थ फाउंडेशन ऑफ इंडिया, हैदराबाद और लंदन स्कूल ऑफ हाइजिन एंड ट्रॉपिकल मेडिसिन (LSHTM) के बीच एक सहयोग है। एक सलाहकार समिति का गठन किया गया है, जिसमें शिक्षा मंत्रालय, स्वास्थ्य मंत्रालय, दृष्टिहीनता एवं RBSK नियंत्रण कार्यक्रम की तरफ से सरकारी प्रतिनिधि शामिल हैं। हम आभारी होंगे यदि आप नीचे वर्णित इस अध्ययन के बारे में विचार करते हैं और इसमें भाग लेने के लिए सहमति जताते हैं।

भारत में 11-15 वर्ष आयु वाले 25 स्कूली छात्रों में से लगभग एक को अपवर्तक दोष है, लेकिन उनके पास चश्मे नहीं हैं जो उन्हें स्पष्ट रूप से देखने में सक्षम बनाएँ। भारत सरकार मानती है कि ठीक न हुए अपवर्तक दोष एक समस्या है, क्योंकि यह बच्चों की सीखने की क्षमता और उनके सामाजिक विकास को प्रभावित करता है, और अपवर्तक दोष के लिए संसाधन आवंटित किए हैं। अध्ययन को भारतीय सार्वजनिक स्वास्थ्य संस्थान, भारतीय आयुर्विज्ञान अनुसंधान परिषद और LSHTM से नैतिक अनुमोदन प्राप्त है।

इस अध्ययन का उद्देश्य है: इस अध्ययन में हम दृष्टि समस्याओं की जाँच के दो अलग-अलग तरीकों की तुलना करना चाहते हैं, जिसमें से एक में शिक्षकों द्वारा मोबाइल फ़ोन एप्लिकेशन का उपयोग करके दृष्टि मापन आवश्यक है।

मुझे क्या करने के लिए कहा जाएगा? हम आपके मोबाइल फ़ोन एप्लिकेशन का उपयोग करके विद्यार्थियों की दृष्टि जाँच करने के लिए प्रशिक्षित करेंगे (नीचे देखें), और आपको दिखाएँगे कि अपने जाँच-परिणाम फ़ोन के सॉफ्टवेयर में किस प्रकार दर्ज करें। हम आशा करते हैं कि इसमें आधे दिन तक समय लग सकता है।

हम आपको 100 बच्चों की दृष्टि जाँच के लिए कहेंगे, जो फिर किसी ऑप्टोमेट्रिस्ट द्वारा मानक विधियों का उपयोग करके जाँचे जाएँगे। हम परिणामों की तुलना करेंगे।

गोपनीयता: हम किसी भी दस्तावेज़ में आपके नाम या स्कूल के नाम का प्रयोग नहीं करेंगे, और इसलिए हमारे द्वारा प्राप्त सभी जानकारी बेनाम रहेंगी।

क्या मुझे हिस्सा बनने के लिए कुछ मिलेगा? नहीं, आपकी भागीदारी पूर्णतः स्वैच्छिक होती है। सभी यात्रा खर्चों की प्रतिपूर्ति की जाएगी, और हम आपको जलपान उपलब्ध कराएँगे।

यदि आप भाग लेने के लिए सहमति जताते हैं तो हम मुफ़्त आँख जाँच की पेशकश कर सकते हैं, और यदि आवश्यक हो तो पढ़ने के लिए चश्मा मुफ़्त प्रदान कर सकते हैं।

यदि आप अतिरिक्त जानकारी चाहते हैं तो कृपया हमारे प्रोजेक्ट मैनेजर से संपर्क करें।

नाम मोबाइल फ़ोन नंबर

जानकारी प्रपत्र 8: स्कूल भागीदारी के लिए प्रधान शिक्षक (मुख्य अध्ययन)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE, PUBLIC HEALTH FOUNDATION OF INDIA, पुष्पागिरी आई इंस्टीट्यूट,

विद्यालय अपवर्तक दोष अध्ययन, हैदराबाद

मुख्य अध्ययन हेतु प्रधान शिक्षकों के लिए जानकारी प्रपत्र

प्रिय महाशय/महाशया,

हम हैदराबाद और आसपास के विद्यालयों में 11-15 वर्षों के बच्चों में अपवर्तक दोष पर अध्ययन का संचालन कर रहे हैं। अध्ययन भारतीय सार्वजनिक स्वास्थ्य संस्थान, पुष्पागिरी आई इंस्टीट्यूट, हैदराबाद और लंदन स्कूल ऑफ़ हाइजिन एंड ट्रॉपिकल मेडिसिन (LSHTM) के बीच एक सहयोग है। एक संचालन समिति का गठन किया गया है, जिसमें शिक्षा मंत्रालय, स्वास्थ्य मंत्रालय, दृष्टिहीनता एवं RBSK नियंत्रण कार्यक्रम की तरफ से सरकारी प्रतिनिधि शामिल हैं। हम आभारी होंगे यदि आप नीचे वर्णित इस अध्ययन के बारे में विचार करते हैं और आपके स्कूल की भागीदारी के लिए सहमति जताते हैं।

भारत में 11-15 वर्ष आयु वाले 25 स्कूली छात्रों में से लगभग एक को अपवर्तक दोष है लेकिन उनके पास चश्में नहीं हैं जो उन्हें स्पष्ट रूप से देखने में सक्षम बनाएँगे। भारत सरकार मानती है कि ठीक न हुए अपवर्तक दोष एक समस्या है, क्योंकि यह बच्चों की सीखने की क्षमता और उनके सामाजिक विकास को प्रभावित करती है, और अपवर्तक दोष के लिए संसाधन आवंटित किया है। अध्ययन को भारतीय सार्वजनिक स्वास्थ्य संस्थान, भारतीय आयुर्विज्ञान अनुसंधान परिषद और LSHTM से नैतिक अनुमोदन प्राप्त है।

इस अध्ययन का उद्देश्य है? अनुपचारित अपवर्तक दोषों के कारण धुँधली दृष्टि और घटती जीवन की गुणवत्ता के बावजूद, अपेक्षाकृत काफी ज्यादा बच्चे जिन्हें चश्मा दिया जाता है वे उन्हें पहनते नहीं हैं। वास्तव में, हाल के एक अध्ययन ने दिखाया कि जितने बच्चों को चश्मा दिया जाता है उनमें से केवल 30% बच्चे ही वास्तव में उन्हें पहनते हैं। इसके कई कारण हैं, जिसमें बच्चों द्वारा चश्मे का फ्रेम पसंद नहीं करना शामिल है, वे अपनी दृष्टि में कोई सुधार नहीं देखते हैं, उनके माता-पिता की कुछ चिंताएँ होती हैं या बच्चों को उनके साथी चिढ़ाते हैं। हम अपने अध्ययन में अनेक कारकों को संबोधित करेंगे, क्योंकि हम केवल उन्हीं बच्चों को चश्में देंगे जिनकी दृष्टि में चश्मों के साथ काफी सुधार आता हो, बच्चे अपनी पसंद के फ्रेम चुनेंगे, चश्मे परिवार से कोई मूल्य लिए बगैर मुफ्त प्रदान किए जाएँगे, और इसमें एक स्वास्थ्य शिक्षा घटक भी होगा। इस अध्ययन में घटी दृष्टि की जाँच के प्रति अलग-अलग दृष्टिकोणों और स्वास्थ्य शिक्षा के विभिन्न प्रकारों की तुलना करेंगे। कुल मिलाकर उद्देश्य यह मूल्यांकन करना है कि क्या विभिन्न दृष्टिकोण बच्चों में चश्मा पहनने की संभावना को प्रभावित करते हैं।

क्यों अध्ययन के लिए मेरे स्कूल पर विचार किया जा रहा है? राज्य के शिक्षा मंत्रालय ने 11-15 वर्ष की आयु के बच्चों वाले स्कूलों की एक सूची प्रदान किया है और स्कूलों को आकार के अनुसार रैंक दिया गया है। इस अध्ययन में शामिल करने के लिए आपके स्कूल पर विचार किया जा रहा है क्योंकि इस आयु वर्ग के बहुत सारे बच्चे आपके स्कूल में पढ़ते हैं। हम आशा करते हैं कि लगभग 36 प्रधान शिक्षक सहमत होंगे कि उनके स्कूल भागीदारी कर सकते हैं।

हम सभी गतिविधियों के समय इस प्रकार तय करेंगे कि वे परीक्षण के समय, या अन्य समय में तब हस्तक्षेप न करें जब ऐसा करना सुविधाजनक न हो।

स्कूल में क्या होगा? प्रत्येक स्कूल में, 11-15 वर्ष के बच्चों की दृष्टि "6/9" दृष्टि स्तर पर मापी जाएगी। सभी स्कूलों में, दृष्टि जाँच में विफल रहने वाले बच्चों को स्कूल में उच्च योग्यता प्राप्त ऑप्टोमेट्रिस्ट द्वारा जाँचा जाए, जो इस बारे में निर्णय लेंगे कि क्या बच्चे को चश्मे की जरूरत है। बच्चों को अपनी पसंद का फ्रेम चुनने दिया जाएगा और चश्मे की जरूरत वाले सभी बच्चों को जानकारी प्रदान की जाएगी जिसे वे अपने घर माता-पिता के लिए ले जा सकते हैं। आपको चश्मे की जरूरत वाले सभी बच्चों की सूची प्रदान की जाएगी। स्कूल को सभी चश्मे फ़ील्ड वर्कर्स द्वारा यथासंभव शीघ्रता से प्रदान किए जाएँगे। यह पता लगाने के लिए कि कितने बच्चे अपने चश्मे पहन रहे हैं, फ़ील्ड वर्कर बच्चों को उनके चश्मे दे दिए जाने के 3 से 4 महीने बाद फिर से स्कूल जाएँगे और प्रासंगिक क्लास रूम जाकर देखेंगे कि कितने बच्चे अपने चश्मे पहन रहे हैं। बच्चे अपना व्यवहार न बदल लें, इसलिए हम योजना बनाते हैं कि फ़ील्ड वर्कर आगे की कार्यवाही के लिए अपने स्कूल विज़िट के बारे में पहले से जानकारी नहीं देंगे।

कुछ स्कूलों में हम शिक्षकों को दृष्टि मापने के लिए प्रशिक्षित करना चाहेंगे; अन्य स्कूलों में प्रशिक्षित फ़ील्ड वर्कर दृष्टि मापेंगे।

उन स्कूलों में जहाँ शिक्षक दृष्टि मापते हैं, हम 11-15 वर्ष आयु वाले बच्चों के शिक्षकों से चाहेंगे कि वे कम से कम 10-15 मिनट के लिए प्रासंगिक कक्षाओं में स्वास्थ्य शिक्षा पर एक छोटा शिक्षण सत्र आयोजित करें। इसके लिए एक सरल पुस्तिका तैयार की जाएगी। इन स्कूलों में बच्चों को घर ले जाने के लिए अतिरिक्त शैक्षणिक सामग्रियाँ प्रदान की जाएँगी।

अध्ययन के अंत में, उन स्कूलों में जहाँ शिक्षक क्लास रूम स्वास्थ्य शिक्षा सत्र आयोजित नहीं कर पाते हैं, हम योजना बनाते हैं कि कोई फ़ील्ड वर्कर वही स्वास्थ्य शिक्षा प्रदान करे और चश्मा पाने वाले सभी बच्चों को घर ले जाने के लिए अतिरिक्त सामग्रियाँ दी जाए।

उन सभी बच्चों को पुष्पागिरी आई इंस्टीट्यूट भेजा जाएगा जिनमें अधिक विशेषज्ञता प्राप्त देखभाल की जरूरत वाली आँख की बीमारी पाई जाती है, जहाँ उनकी जाँच-पड़ताल की जाएगी और आवश्यकता पड़ने पर उपचार प्रदान किया जाएगा। अध्ययन सभी ख़र्चों का वहन करेगा।

क्या मेरे स्कूल को भाग लेने की जरूरत है? आपकी अनुमति कि आपका स्कूल इस अध्ययन में भाग ले स्वैच्छिक होती है, और पूरी तरह पर आप पर निर्भर करती है।

गोपनीयता हम प्रत्येक स्कूल की पहचान के लिए केवल कोड नंबरों का उपयोग करेंगे, और आपके नाम और आपके स्कूल के नाम का उपयोग किसी भी विश्लेषण, रिपोर्ट या अध्ययन से निकलने वाले प्रकाशन में नहीं होगा। यही बच्चों पर लागू होता है, और इसलिए उनकी पहचान भी पूरी तरह बेनाम रहेगी।

यदि आप सहमत होते हैं कि आपका स्कूल अध्ययन में भाग ले तो हम आपके आभारी रहेंगे यदि आप अध्ययन के पूरा होने तक अन्य प्रधान शिक्षकों या स्कूल के अन्य क्लास रूम शिक्षकों के साथ अध्ययन पर चर्चा नहीं करेंगे।

प्रसार अध्ययन के अंत में परिणाम संचालन समिति को प्रस्तुत किए जाएँगे और आपको उपस्थित रहने के लिए आमंत्रित किया जाएगा। आपको परिणामों का एक संक्षिप्त सारांश भी भेजा जाएगा।

यदि आप अतिरिक्त जानकारी चाहते हैं तो कृपया हमारे प्रोजेक्ट मैनेजर से संपर्क करें
नाम
मोबाइल फ़ोन नंबर

सहमति प्रपत्र 8: स्कूल भागीदारी के लिए प्रधान शिक्षक (मुख्य अध्ययन)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA *पुष्पागिरी आई इंस्टीट्यूट,*

विद्यालय अपवर्तक दोष अध्ययन, हैदराबाद

प्रधान शिक्षकों के लिए सहमति फ़ॉर्म

मैं पुष्टि करता/करती हूँ कि मैंने अध्ययन के बारे में जानकारी प्रपत्र को पढ़ और समझ लिया है, और अध्ययन के बारे में मेरे प्रश्नों का उत्तर दे दिया गया है।

	हाँ	नहीं
मैं सहमत हूँ कि मेरा स्कूल अध्ययन में भाग ले सकता है	☐	☐

स्कूल का नाम _____

प्रधान शिक्षक का नाम _____

प्रधान शिक्षक का हस्ताक्षर _____

शोधकर्ता का नाम _____

शोधकर्ता का हस्ताक्षर _____

तिथि ---------- / ---------- / ----------

दिन महीना वर्ष

जानकारी प्रपत्र 9: अध्ययन के लिए भर्ती किए गए बच्चों के माता-पिता (ऑप्ट-आउट) (मुख्य अध्ययन)

शिक्षा मंत्रालय LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA *पुष्पागिरी आई इंस्टीट्यूट,*

स्कूल चश्मा प्रोजेक्ट, हैदराबाद

माता-पिता के लिए जानकारी प्रपत्र और ऑप्ट-आउट

प्रिय माता-पिता,

हैदराबाद के पुष्पागिरी आई इंस्टीट्यूट के स्टाफ एक ऐसे प्रोजेक्ट में मदद कर रहे हैं जिसमें हैदराबाद और आसपास के स्कूलों में जाकर बच्चों की दृष्टि का मूल्यांकन किया जाएगा, और सुनिश्चित किया जाएगा कि उन सभी बच्चों को आवश्यकता पड़ने पर उपचार मिले जिनकी आँखों या दृष्टि में समस्या पाई जाती है। शिक्षा निदेशक इससे अवगत हैं, और उन्होंने इस प्रोजेक्ट को अनुमति दी है।

आपके बच्चे के स्कूल के प्रधान शिक्षक ने अनुमति दी है कि 11-15 वर्ष आयु वाले बच्चों की दृष्टि की जाँच किसी शिक्षक या प्रशिक्षित फ़ील्ड वर्कर द्वारा की जा सकती है, और खराब दृष्टि वाले सभी बच्चों की जाँच पुष्पागिरी आई इंस्टीट्यूट के उच्च योग्यताप्राप्त स्टाफ़ द्वारा स्कूल में किया जाएगा। उन सभी बच्चों को अपनी पसंद का फ़्रेम चुनने दिया जाएगा जिन्हें चश्मे से लाभ हो सकता है, और उन्हें एक चश्मा मुफ़्त दिया जाएगा। यदि आपके बच्चे के आँख में कोई अन्य समस्या पाई जाती है तो उन्हें पुष्पागिरी आई इंस्टीट्यूट भेजा जाएगा जहाँ उन्हें आवश्यकता पड़ने पर मुफ़्त उपचार प्रदान किया जाएगा।

चश्मे की जरूरत वाले सभी बच्चे आपके पढ़ने के लिए कुछ जानकारी ले जाएँगे कि आपके बच्चे को चश्मे की जरूरत क्यों है, और उनके चश्मों की देखभाल किस प्रकार करनी चाहिए। आपके बच्चे को प्रोजेक्ट के आरंभ या अंत में इस बारे में कुछ अतिरिक्त जानकारी भी प्रदान की जाएगी कि क्यों कुछ बच्चों को चश्मा पहनने की जरूरत होती है।

चूँकि हम आपको आपके बच्चे की आँखों के बारे में अतिरिक्त जानकारी भेजना चाहते हैं, हम आपके आभारी होंगे यदि आप अपना मोबाइल फ़ोन नंबर साझा कर सकें। आपका फ़ोन नंबर किसी को भी नहीं दिया जाएगा, और प्रोजेक्ट के अंत में मिटा दिया जाएगा।

यदि आप अपने बच्चे की दृष्टि या प्रोजेक्ट के बारे में और अधिक जानकारी चाहते हैं तो कृपया प्रोजेक्ट मैनेजर, {नाम……} +91 {नंबर……..} से संपर्क करें।

यह पुष्टि करने के लिए कि आपका बच्चा इस प्रोजेक्ट में भाग ले सकता है कृपया नीचे अपना नाम और हस्ताक्षर जोड़ें, और हाँ लेबल वाले बॉक्स में क्रॉस लगाएँ। यदि आप सहमत नहीं हैं तो नहीं लेबल वाले बॉक्स के नीचे क्रॉस लगाएँ। भले ही आप हाँ या नहीं पर निशान लगाएँ, कृपया यह पत्र अपने बच्चे को स्कूल वापस ले जाने के लिए दे दें।

	हाँ	नहीं
मैं सहमत हूँ कि मेरा बच्चा इस अध्ययन में भाग ले सकता है	☐	☐

बच्चे का नाम …… आयु……

क्लास……

आपका नाम ……..

आपका हस्ताक्षर……

मोबाइल फ़ोन नंबर ……

सहमति प्रपत्र 10: अध्ययन में भर्ती किए गए बच्चे (मुख्य अध्ययन)

शिक्षा मंत्रालय, LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA *पुष्पागिरी आई इंस्टीट्यूट,*

स्कूल चश्मा प्रोजेक्ट, हैदराबाद
विद्यार्थियों के लिए सहमति फ़ॉर्म
बच्चे द्वारा किसी शोधकर्ता के साथ भरा जाना चाहिए

विद्यार्थी को उन सब पर सही का निशान लगाना चाहिए जिससे वे सहमत हैं:

	हाँ	नहीं
क्या आपने इस प्रोजेक्ट के बारे में पढ़ा (या आपको पढ़ कर सुनाया गया) है?		
क्या किसी दूसरे व्यक्ति ने आपको इस प्रोजेक्ट के बारे में समझाया है?		
क्या आप समझते हैं कि यह प्रोजेक्ट किस बारे में है?		
क्या आपने उन सभी प्रश्नों को पूछ लिया है जो आप पूछना चाहते हैं?		
क्या आपके प्रश्नों का उत्तर ऐसे तरीके से दिया गया जिसे आप समझ सके?		
क्या आप समझते हैं कि किसी भी समय भागीदारी रोक देने में कोई दिक्कत नहीं है		
क्या आप भाग लेने के लिए खुश हैं?		

यदि कोई उत्तर 'नहीं' है या आप भाग लेना **नहीं** चाहते हैं, तो हस्ताक्षर **नहीं** करें

यदि आप भाग लेना चाहते हैं, तो कृपया अपना नाम और आज की तिथि लिखें

आपका नाम _____ आयु_____

तिथि _____

जिस शोधकर्ता ने आपको यह प्रोजेक्ट समझाया हो उसे भी यहाँ हस्ताक्षर करने की जरूरत है:

प्रिंट नाम _____

हस्ताक्षर _____

तिथि _____

सहायता करने के लिए धन्यवाद

जानकारी प्रपत्र 10: अध्ययन में भर्ती किए गए बच्चे (मुख्य अध्ययन)

शिक्षा मंत्रालय LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE PUBLIC HEALTH FOUNDATION OF INDIA *पुष्पागिरी आई इंस्टीट्यूट,*

स्कूल चश्मा प्रोजेक्ट, हैदराबाद
अध्ययन में भर्ती किए गए बच्चों के लिए जानकारी प्रपत्र

प्रिय विद्यार्थी,

जब हमने आपकी दृष्टि की जाँच की थी तो हमने पाया था कि आपकी दृष्टि में कुछ धुँधलापन है। आज जब हमने आपका परीक्षण किया तो पाया कि चश्मा आपको अधिक स्पष्ट रूप से देखने में मदद करेगा, और हमलोग आपको एक चश्मा देंगे। आप यह चुन पाएँगे कि आपको किस स्टाइल और प्रकार का फ़्रेम पसंद है, और चश्मा लगभग दो सप्ताह के भीतर स्कूल में डिलीवर कर दिया जाएगा। आपको हर समय चश्मा लगाने की जरूरत नहीं है, केवल जब आपको अधिक स्पष्ट देखने की जरूरत हो, जैसे कि स्कूल में या टेलीविज़न देखते समय। यदि आपने पहले चश्मा नहीं पहना हो तो इसका आदि होने में आपको कुछ समय लग सकता है।

हम आपको आपकी आँखों के बारे में कुछ जानकारी प्रदान करेंगे जिसे आप अपने माता-पिता को दिखाने के लिए घर ले जा सकते हैं, जो यह भी समझाता है कि आप अपने चश्मे की देखभाल किस प्रकार कर सकते हैं और हम आपके माता-पिता को एक पाठ संदेश भी भेजेंगे।

हम कुछ महीने बाद यह जानने के लिए स्कूल में वापस लौटेंगे कि आप चश्मे के साथ कैसा महसूस कर रहे हैं और हम आपसे कुछ प्रश्न भी पूछ सकते हैं।

कुछ महीनों में हम आपको घर ले जाने के लिए कुछ अतिरिक्त जानकारी दे सकते हैं।

हम आपसे एकत्रित सभी जानकारी का विश्लेषण करेंगे लेकिन आपके नाम का उपयोग विश्लेषण में नहीं किया जाएगा और केवल प्रोजेक्ट टीम की पहुँच सभी जानकारी तक होगी।

आपको प्रोजेक्ट में भाग लेने की जरूरत नहीं है। यदि आप भाग नहीं लेने का निर्णय लेते हैं तो भी आपको एक उच्च गुणवत्ता वाला चश्मा दिया जाएगा।

कृपया प्रोजेक्ट स्टाफ़ द्वारा दिखाए जाने वाले फ़ॉर्म पर हस्ताक्षर करें।

Appendix 6: Data collection instruments

Trial 1:

1. Recruitment form
2. Follow-up form

Trial 2:

1. Recruitment form
2. Follow-up form
3. Screenshots from Peek Capture

Trial 1: Recruitment form

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* / *Year* (2 0 ..)

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	Yes	Yes
0	No	No	No

10 Cannot see 6/9 in both eyes — 1 Yes (May be eligible for the trial) — Complete ALL except Q 16 and 17

Can see 6/9 in one eye — 0 No (NOT eligible for recruitment) — *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

		Right eye	Left eye
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

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

Right and left eyes

34 If randomized to ready-mades [ ] . [ ] 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 _____ [ ]

Trial 1: Follow-up form

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

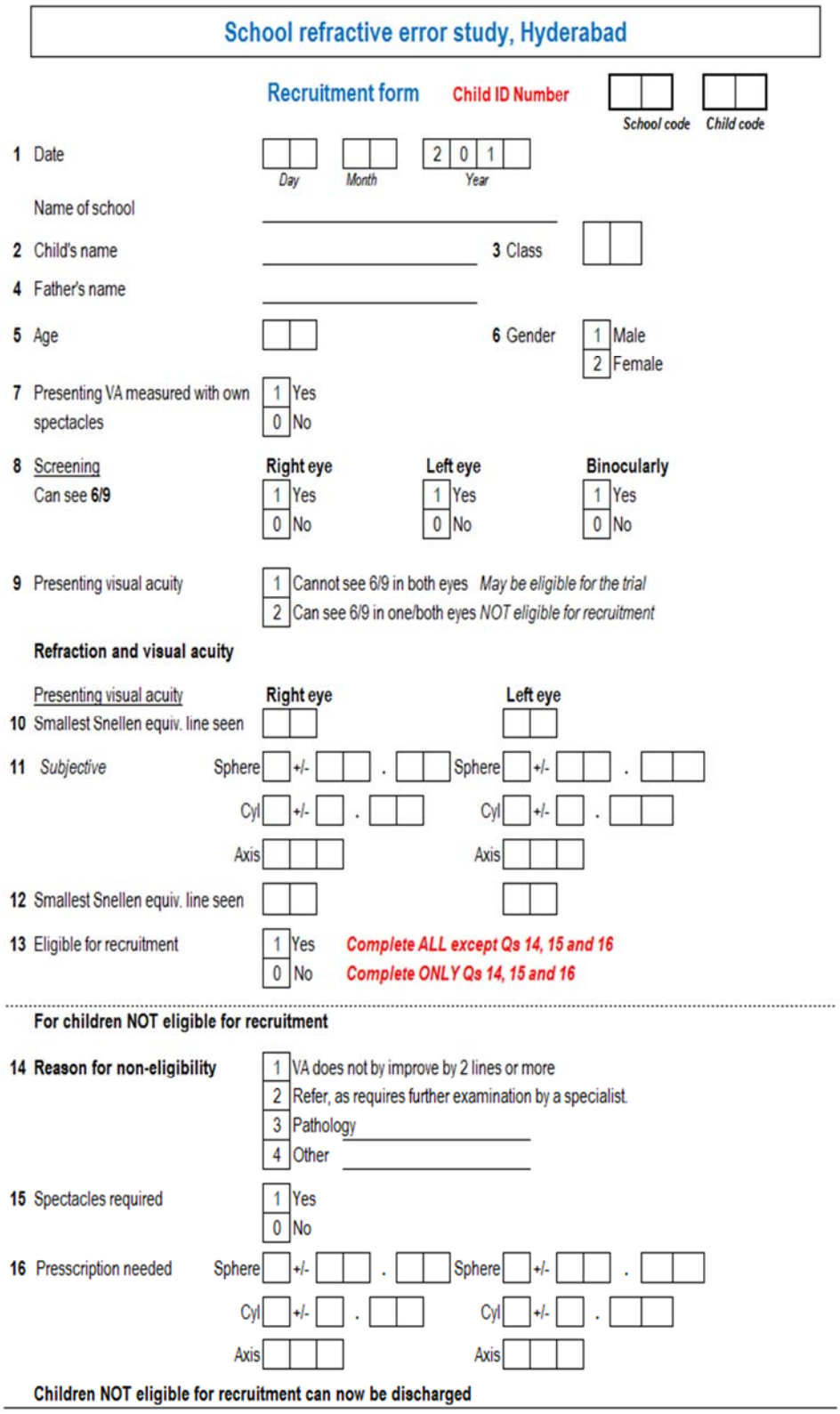
1 Wearing at time of visit
2 Not wearing at time of visit but have them at school
3 Not wearing at time of visit but have them at home — *Go to Q13*
4 No longer have spectacles as they are broken or lost — *Go to Q13*

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 _____ ☐

Trial 2: Recruitment questions – data was collected on Peek Capture



School refractive error study, Hyderabad

Recruitment form Child ID Number School code Child code

1 Date Day Month 2 0 1 Year

Name of school

2 Child's name 3 Class

4 Father's name

5 Age 6 Gender 1 Male 2 Female

7 Presenting VA measured with own spectacles 1 Yes 0 No

8 Screening Right eye Left eye Binocularly

Can see 6/9 1 Yes 0 No 1 Yes 0 No 1 Yes 0 No

9 Presenting visual acuity 1 Cannot see 6/9 in both eyes *May be eligible for the trial* 2 Can see 6/9 in one/both eyes *NOT eligible for recruitment*

Refraction and visual acuity

Presenting visual acuity Right eye Left eye

10 Smallest Snellen equiv. line seen

11 *Subjective* Sphere +/- . Sphere +/- . Cyl +/- . Cyl +/- . Axis Axis

12 Smallest Snellen equiv. line seen

13 Eligible for recruitment 1 Yes *Complete ALL except Qs 14, 15 and 16* 0 No *Complete ONLY Qs 14, 15 and 16*

For children NOT eligible for recruitment

14 **Reason for non-eligibility** 1 VA does not by improve by 2 lines or more 2 Refer, as requires further examination by a specialist. 3 Pathology 4 Other

15 Spectacles required 1 Yes 0 No

16 Presscription needed Sphere +/- . Sphere +/- . Cyl +/- . Cyl +/- . Axis Axis

Children NOT eligible for recruitment can now be discharged

ALL ELIGIBLE CHILDREN

17 Prescription needed

18 Sphere [ ] +/- [ ][ ] . [ ][ ] Sphere [ ] +/- [ ][ ] . [ ][ ]

19 Cyl [ ] +/- [ ] . [ ][ ] Cyl [ ] +/- [ ] . [ ][ ]

20 Axis [ ][ ][ ] Axis [ ][ ][ ]

21 Interpupillary distance [ ][ ] mm

22 Spectacle frame selected [ ]

23 SightSim image selected, if applicable [ ]

Ask the child the following questions

24 Language spoken at home

1	Telugu
2	Hindi
3	Other _____

25 Are both parents still alive

1	Yes, both
2	Father only
3	Mother only
4	Neither

26 What job does you father / mother have

Father _____

Mother _____

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/laptop/tablet
1	0	Bicycle
1	0	Car/jeep/van
1	0	Motorcycle / moped

30 Can your father read and write easily

1	Yes
0	No
9	Not applicable

31 Can your mother read and write easily

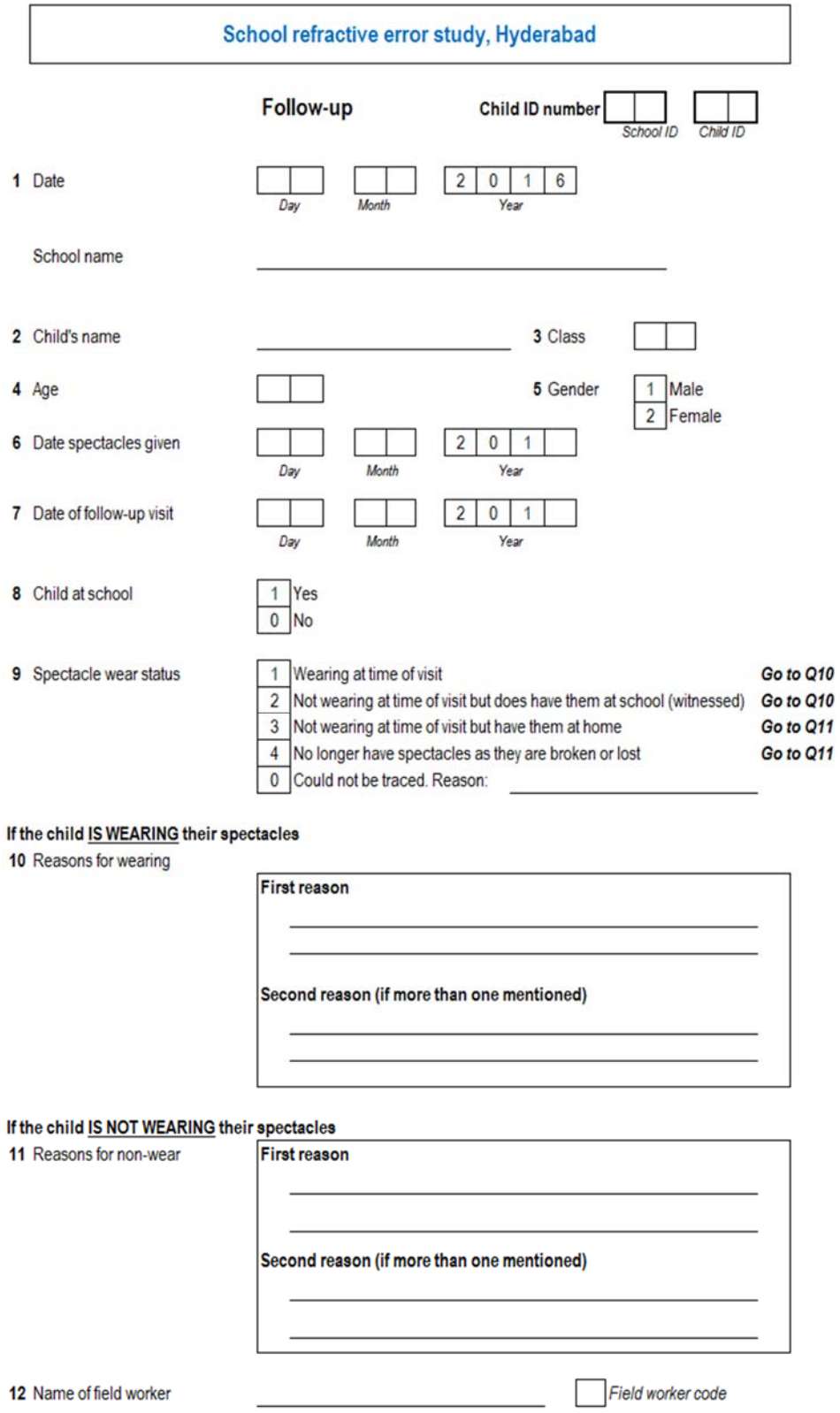
1	Yes
0	No
9	Not applicable

32 Date spectacles given [ ][ ] *Day* [ ][ ] *Month* 2 0 1 [ ] *Year*

33 Refraction done by _____ [ ] *Optometrist code*

_____ [ ] *Field worker code*

Trial 2: Follow-up questions – data was collected on Peek Capture



School refractive error study, Hyderabad

Follow-up

Child ID number ☐☐ (School ID) ☐☐ (Child ID)

1 Date ☐☐ (Day) ☐☐ (Month) 2016 (Year)

School name _____

2 Child's name _____ 3 Class ☐☐

4 Age ☐☐ 5 Gender 1 Male 2 Female

6 Date spectacles given ☐☐ (Day) ☐☐ (Month) 201☐ (Year)

7 Date of follow-up visit ☐☐ (Day) ☐☐ (Month) 201☐ (Year)

8 Child at school 1 Yes 0 No

9 Spectacle wear status

1 Wearing at time of visit — Go to Q10
2 Not wearing at time of visit but does have them at school (witnessed) — Go to Q10
3 Not wearing at time of visit but have them at home — Go to Q11
4 No longer have spectacles as they are broken or lost — Go to Q11
0 Could not be traced. Reason: _____

If the child IS WEARING their spectacles

10 Reasons for wearing

First reason
_____
_____

Second reason (if more than one mentioned)
_____
_____

If the child IS NOT WEARING their spectacles

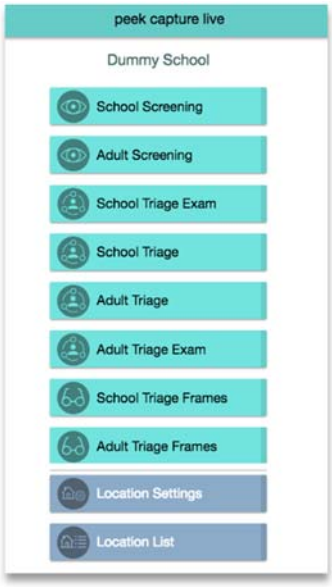
11 Reasons for non-wear

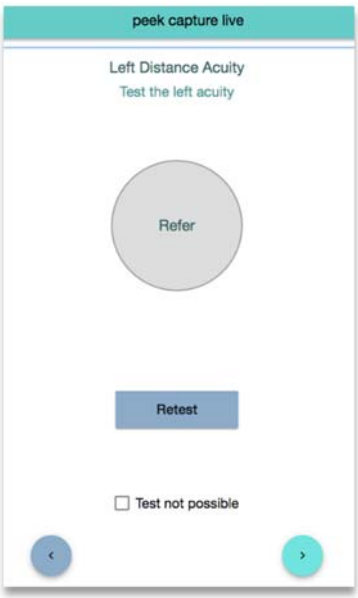
First reason
_____
_____

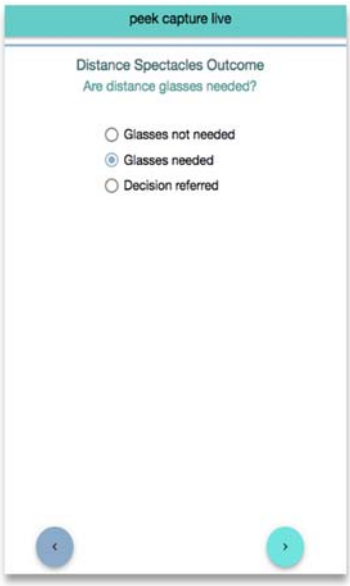
Second reason (if more than one mentioned)
_____
_____

12 Name of field worker _____ ☐ Field worker code

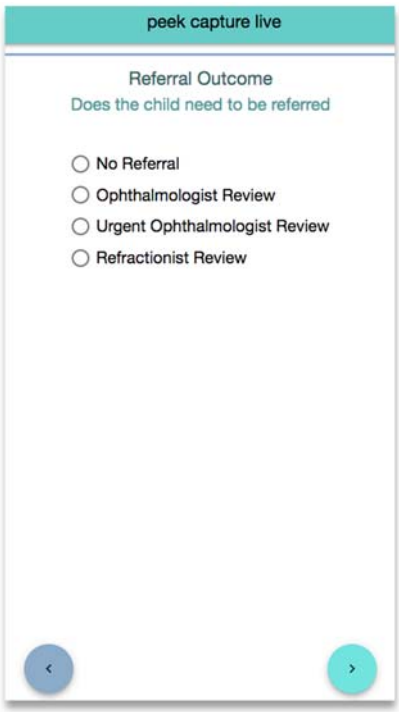
Trial 2: Examples of screenshots from Peek Capture

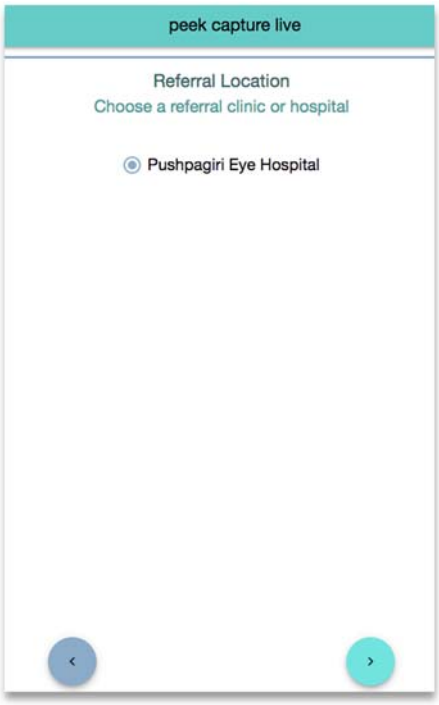



peek capture live
Left Distance Acuity
Test the left acuity
Refer
Retest
Test not possible


peek capture live
Distance Spectacles Outcome
Are distance glasses needed?
Glasses not needed
Glasses needed
Decision referred

peek capture live
Non-refractive Eye Condition
Enter dominant non-refractive eye condition of the child
None
Cornea not transparent
Discharge or watering
Eyes not straight
Injury
Eyelid problem
Patch on conjunctiva
Pupil not round
Pupil white
Red Eye


peek capture live
Referral Outcome
Does the child need to be referred
No Referral
Ophthalmologist Review
Urgent Ophthalmologist Review
Refractionist Review


peek capture live
Referral Location
Choose a referral clinic or hospital
Pushpagiri Eye Hospital

To Priya,

I agree that our work indicated below can be included in its/their published format in your thesis titled “Evidence to improve the effectiveness and efficiency of school eye health programs.”

1. Morjaria P, Murali K, Evans J, Gilbert C. Spectacle wearing in children randomised to ready-made or custom spectacles, and potential cost savings to programmes: study protocol for a randomised controlled trial. Trials. 2016;17:36. doi:10.1186/s13063-016-1167-x.

2. Morjaria P, Evans J, Murali K, Gilbert C. Spectacle Wear Among Children in a School-Based Program for Ready-Made vs Custom-Made Spectacles in India: A Randomized Clinical Trial. JAMA Ophthalmology. 2017;135(6):527-533. doi:10.1001/jamaophthalmol.2017.0641.

3. Morjaria P, Bastawrous A, Murthy GVS, Evans J, Gilbert C. Effectiveness of a novel mobile health education intervention (Peek) on spectacle wear among children in India: study protocol for a randomized controlled trial. Trials. 2017;18:168. doi:10.1186/s13063-017-1888-5.

Name: Clare Gilbert

Sign:

Date: 2 May 2018

To Priya,

I agree that our work indicated below can be included in its/their published format in your thesis titled “Evidence to improve the effectiveness and efficiency of school eye health programs.”

1. Morjaria P, Murali K, Evans J, Gilbert C. Spectacle wearing in children randomised to ready-made or custom spectacles, and potential cost savings to programmes: study protocol for a randomised controlled trial. Trials. 2016;17:36. doi:10.1186/s13063-016-1167-x.

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3. Morjaria P, Bastawrous A, Murthy GVS, Evans J, Gilbert C. Effectiveness of a novel mobile health education intervention (Peek) on spectacle wear among children in India: study protocol for a randomized controlled trial. Trials. 2017;18:168. doi:10.1186/s13063-017-1888-5.

4. Evans JR, Morjaria P, Powell C. Vision screening for correctable visual acuity deficits in school-age children and adolescents. Cochrane Database of Systematic Reviews 2018, *Issue* 2. *Art. No.: CD005023. DOI: 10.1002/14651858.CD005023.pub3.*

Name: Jennifer Evans

Sign:

Date: 30/4/2018

To Priya,

I agree that our work indicated below can be included in their published format in your thesis titled “Evidence to improve the effectiveness and efficiency of school eye health programs.”

1. Morjaria P, Bastawrous A, Murthy GVS, Evans J, Gilbert C. Effectiveness of a novel mobile health education intervention (Peek) on spectacle wear among children in India: study protocol for a randomized controlled trial. *Trials*. 2017;18:168. doi:10.1186/s13063-017-1888-5.

2. Morjaria P, Bastawrous A. Helpful developments and technologies for school eye health programmes. *Community Eye Health*. 2017;30(98):34-36.

Name: Andrew Bastawrous

Sign:

Date: 28.04.2018

To Priya,

I agree that our work indicated below can be included in their published format in your thesis titled “Evidence to improve the effectiveness and efficiency of school eye health programs.”

1. Morjaria P, Bastawrous A, Murthy GVS, Evans J, Gilbert C. Effectiveness of a novel mobile health education intervention (Peek) on spectacle wear among children in India: study protocol for a randomized controlled trial. *Trials*. 2017;18:168. doi:10.1186/s13063-017-1888-5.

2. Morjaria P, Raj PD, Murthy G. Improving spectacle wear in school children. *Community Eye Health*. 2017;30(98):31-32.

Name: GVS Murthy

Sign:

Date: 30th April 2018

To Priya,

I agree that our work indicated below can be included in its published format in your thesis titled “Evidence to improve the effectiveness and efficiency of school eye health programs.”

1. Morjaria, Priya, P Dinesh Raj, and GVS Murthy. “Improving Spectacle Wear in School Children.” Community Eye Health 30.98 (2017): 31–32. Print.

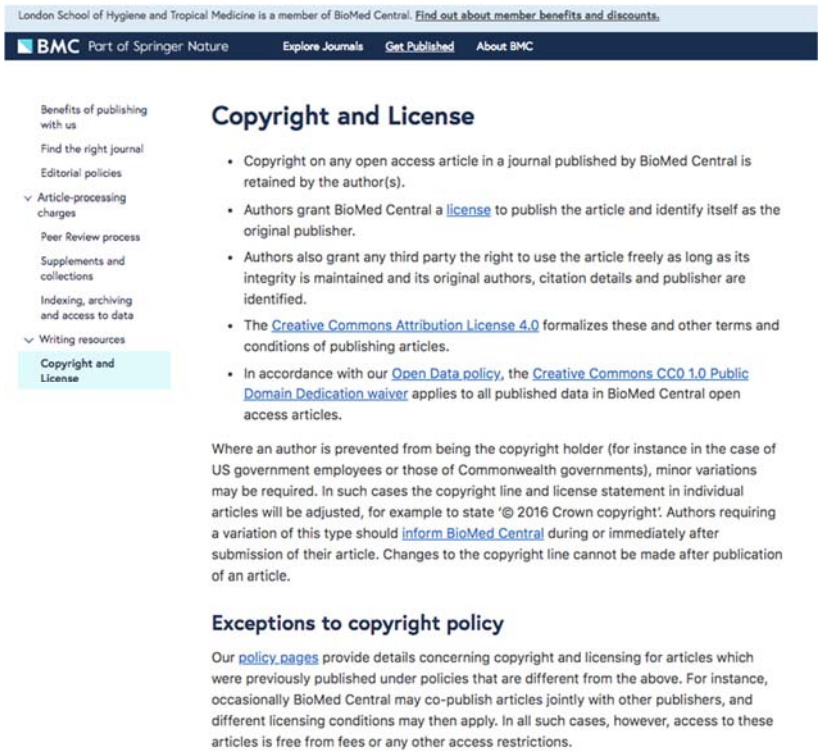
Name: P Dinesh Raj

Sign:

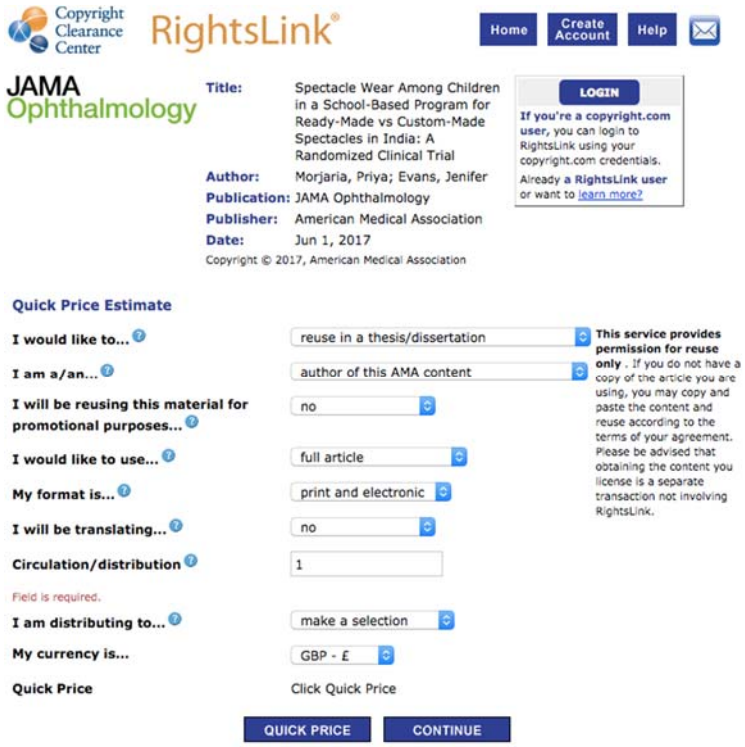
Date: 30.04.2018

Appendix 8: Permissions from publishers

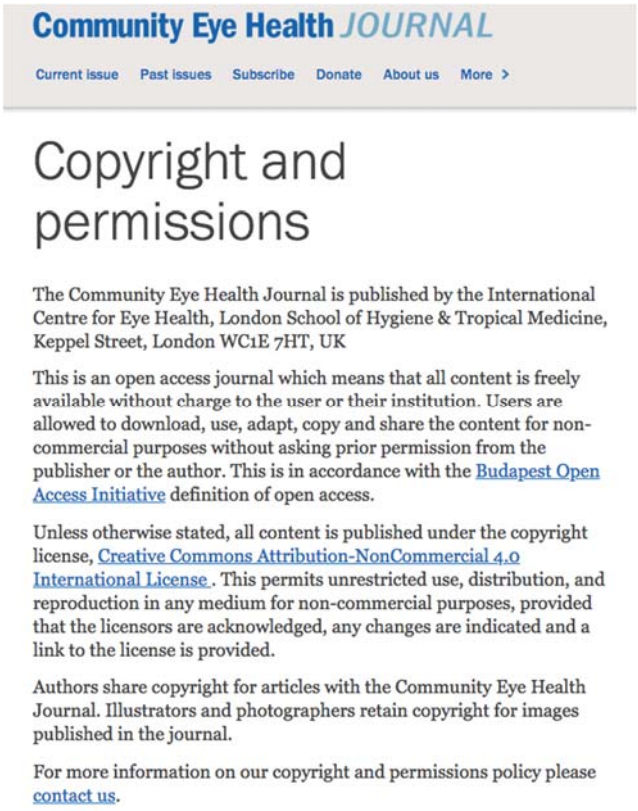
1. Trials



2. JAMA Ophthalmology



3. Community Eye Health Journal



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