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Effectiveness of a novel mobile health (Peek) and education intervention on spectacle wear amongst children in India: Results from a randomized superiority trial in India

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ABSTRACT

Background: Uncorrected refractive errors can be corrected by spectacles which improve visual functioning, academic performance and quality of life. However, spectacle wear can be low due to teasing/bullying, parental disapproval and no perceived benefit.

Hypothesis: higher proportion of children with uncorrected refractive errors in the schools allocated to the intervention will wear their spectacles 3–4 months after they are dispensed.

Methods: A superiority, cluster-randomised controlled trial was undertaken in 50 government schools in Hyderabad, India using a superiority margin of 20%. Schools were the unit of randomization. Schools were randomized to 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.

In the intervention arm, classroom health education was delivered before vision screening using printed images which mimic the visual blur of uncorrected refractive error (PeekSim). Children requiring spectacles selected one image to give their parents who were also sent automated voice messages in the local language through Peek. The primary outcome was spectacle wear at 3–4 months, assessed by masked field workers at unannounced school visits. www.controlled-trials.com ISRCTN78134921 Registered on 29 June 2016

Findings: 701 children were prescribed spectacles (intervention arm: 376, control arm: 325). 535/701 (80%) were assessed at 3–4 months: intervention arm: 291/352 (82.7%); standard arm: 244/314 (77.7%). Spectacle wear was 156/291 (53.6%) in the intervention arm and 129/244 (52.9%) in the standard arm, a difference of 0.7% (95% confidence interval (CI), -0.08, 0.09). amongst the 291 (78%) parents contacted, only 13.9% had received the child delivered PeekSim image, 70.3% received the voice messages and 97.2% understood them.

Interpretation: Spectacle wear was similar in both arms of the trial, one explanation being that health education for parents was not fully received. Health education messages to create behaviour change need to be targeted at the recipient and influencers in an appropriate, acceptable and accessible medium.

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1. Introduction

Uncorrected refractive errors (uREs) are the commonest cause of visual loss in children. Myopia (short-sightedness), the commonest form, usually starts around the age of eight years, progressing in severity throughout adolescence [1,2]. Hypermetropia (long-

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Research in context

Evidence before this study

In this study we built upon previous research implemented in Kenya and Botswana using Peek as an mHealth intervention. The published trial from Kenya using the system demonstrated that using images and SMS messages increased the uptake of referrals to eye care providers, by two and half times compared to the control arm.

Added value of this study

This study shows that non-compliance to spectacles in children requires complex and context specific interventions for children who require spectacles, their classmates who do not, as well as teachers, parents, other family members and the community. Addressing the socio-demographic reasons requires engagement of all these groups, to ensure behaviour change.

Implications of all the available evidence

There is evidence that visual impairment in children has adverse effects on a child's academic performance, visual functioning, behavioural development and quality of life.

The use of a novel mHealth 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 attempted to create behaviour change but 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.

in a rural area of India [22]. There are many reasons why children do not wear spectacles such as being teased or bullied, they perceive no benefit, and concerns by parents that spectacles will weaken their child's eyes or are stigmatizing [23,24–27]. Some of these reasons are amenable to health education. Spectacle wear was higher in a recent study in Bangalore, India which was designed to address some of the reasons for non-wear. Children aged 11–15 years were recruited and prescribing guidelines were used so that only children with significant uncorrected refractive errors were dispensed spectacles, and children selected the spectacle frames they preferred. In this study almost 75% of children were wearing their spectacles at unannounced visits 3–4 months later [28].

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 [29]. 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 slightly higher in the sub groups randomised to the health education intervention (RR 1.14 (1.03 to 1.26) but there was no difference in observed wear (RR 1.11 (0.94 to 1.30) [15].

Mobile phone technology is a rapidly expanding area in health care, including eye care and school eye health programmes [30]. 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) [31], 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 system 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 of carers. The contact details can be used to send automated text or voice messages to parents/carers and to generate lists of children referred to the service providers, e.g. optometrists or hospital. Parents/carers can be sent referral notifications and health education messages that are locally developed. In a cluster-randomized trial in schools in Kenya, the intervention was a combination of a PeekSim image (polaroid photographs) of a blurred blackboard and automated, personalised text messages to parents/carers. At eight weeks, 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 [32]. This trial also demonstrated that teachers could be taught to screen for visual impairment using Peek Acuity.

In our trial a superiority design was used with the hypothesis being that the proportion of children wearing spectacles in the 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 [33].

2. Methods

This study was undertaken in government and public-funded schools in and around Hyderabad, India. The rationale for our study

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 more common in Asian children, particularly in South East Asia where it has an earlier age of onset and can be more severe. Approximately 12.8 million children worldwide are visually impaired from uREs [3], 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 [4,5]. In Singapore, China, Taiwan, Hong Kong, Japan and Korea, 80–90% of children completing high school are now myopic [4,6]. All types of RE are less common in African children [7].

The increase in myopia is attributed to environmental factors associated with urbanisation, particularly prolonged near work and lack of time spent outdoors [6,8]. 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 [9–13]. Correcting RE in children can lead to improvement in visual functioning [14] academic performance [15], social development [16,17] and quality of life [18].

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 [19]. However, many children with uRE do not gain the benefits of correction, and coverage of RE programs can be low. 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. In all settings a relatively high proportion of children do not wear their spectacles [20,21], which was recently reported to be 70% in a study undertaken

Table 1

An overview of the two arms of the trial.

	Intervention arm	Comparator arm
Age group	11–15 years	11–15 years
Screening method	Peek Acuity	Standard ETDRS chart
Screening VA level	<6/9.5 in one or both eyes	<6/9.5 in one or both eyes
Health education	<ul style="list-style-type: none"> 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
Data collection	Entered directly into Peek Solutions software using tablets	
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	Children selected their preferred frame	
Delivery of spectacles	Delivery of free spectacles to schools within 2 weeks by trained field workers, and VA re-tested with correction	
Assessment of primary outcome	Observation during unannounced visits 3–4 months after spectacles were delivered	

was that greater awareness of the benefits of spectacles amongst all children and parents of affected children would increase wear. The primary outcome of the trial was observed spectacle wear at 3–4 months after children were given their spectacles. Reporting follows the CONSORT 2010 checklist for randomized controlled trials [34].

Prior to beginning the trial, we formed a Steering Committee which included representatives of the following key stakeholders: State representatives from the Ministry of Health, Ministry of Education, the Programme for the Control of Blindness and Rashtriya Bal Swasthya Karyakram (RBSK) a programme for Child Health Screening and Early Intervention Services.

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 class. Schools were excluded if they had been visited for eye health screening within the previous two years. Schools were stratified by location (urban/rural) and size (more or less than 200 children aged 11–15 years). Schools were randomly allocated (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. All children eligible to be recruited to the trial provided assent.

2.1. Participants

Recruitment took place between 5 January 2017 and 14 February 2017. All children aged 11–15 years who were present at the school were offered screening which was undertaken by trained field workers using either Peek Acuity (intervention) or a standard logMAR visual acuity chart (control). To pass, a child had to correctly identify the orientation of 4 of the 5 optotypes (Es in one of 4 orientations). Children who failed screening i.e. presenting visual acuity 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 then retested their visual acuity 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 visual acuity 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.

2.2. Interventions

The intervention was a complex intervention delivered using Peek Solutions. In this trial, PeekSim images deemed 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 aged 11–15 years in different age groups. The 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. Teachers recommended that the classroom health education sessions using PeekSim images be delivered by members of the study team, as they were the “experts”. The teachers sat in the classroom when education was delivered. 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’, (Fig. 2) 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 were given an A6 image of their choice to take home to show their parents, to demonstrate how much clearer their child’s world would be if they wore their spectacles. Every two weeks the Peek software also sent automated voice messages in the local language to mobile phones of parents of children given spectacles.

In the control arm, the 6/9.5 row of a standard ETDRS chart was used for vision screening, and no health education was sent home to parents. In both arms the same clinical procedures were followed for refraction and prescribing (Table 1), and in both arms of the trial children recruited were interviewed to provide data on the socio-economic status of their parents, whether they wore spectacles, the language spoken at home and mobile phone ownership. Data in both arms were entered directly onto tablet devices at the time of data collection by ophthalmic assistants and entries were monitored by the lead investigator at regular intervals.

2.3. 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 images and voice messages. 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. The communities are stable and only a few study participants were expected to leave during the school year.

2.4. Eligibility criteria

Eligibility criteria for the trial were a) children aged 11–15 years b) parents do not refuse participation, and c) presenting visual acuity (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 visual acuity was $\leq 6/60$ in one or both eyes regardless of the cause; if their best-corrected visual acuity 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 or referred, as required.

Children were eligible for immediate spectacle correction if their binocular visual acuity 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.

2.5. Randomisation and masking

Head teachers were visited and those giving permission were allocated a unique school 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 and 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 intervention arm of the trial was not described in detail in the information sheets. 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.

2.6. 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 identity was confirmed and checked against the prepopulated list in the Peek system. Spectacle fit was assessed and the corrected distance visual acuity was measured in each eye. Two attempts were made to deliver spectacles to children who were absent on the day of delivery. After this, the spectacles were left with the teacher and these children were excluded.

2.7. Ascertainment of the primary outcome

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 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 [23]. Categories a) and b) were defined as wearing and categories c) and d) as non-wearing [23,28]. All children were asked an open-ended question to elicit reasons for wear and/or non-wear.

2.8. Statistical analysis

After data cleaning and range and consistency checks, the primary analysis was undertaken. Analyses were pre-specified, and were undertaken using STATA 14.1 (StataCorp, Texas, USA). 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. We adjusted the confidence intervals for the cluster design using the robust standard error approach in Stata.

All analyses were undertaken according to the group to which the child had been allocated. No interim or subgroup analyses were planned or performed. However, we undertook a post hoc analysis of spectacle wear in children whose parents received the images. We observed that the two trial arms were not balanced for VA at baseline. From previous research we know that poorer presenting VA is a predictor of spectacle wear [35] and we undertook post hoc analysis that stratified the risk difference of spectacle wear by baseline VA.

2.9. 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 Pushpagiri Eye Hospital, Hyderabad for free examination, and all spectacles were provided at no cost.

2.10. 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).

3. Results

All school head teachers approached agreed that their school take part in the trial and no parent or child refused consent. 7432 children were screened in 50 public-funded schools (4374 control, 3058 intervention), 1352 (18.2%) of whom failed the screening test i.e. they had presenting visual acuity $< 6/9.5$ in one or both eyes. 277 (20%) children were excluded as their visual acuity was $6/9.5$ in both eyes on retesting (174/604 (29%) control, 103/748 (14%) intervention). A further 79 were excluded after refraction and basic eye examination and were referred (63 control, 16 intervention). 299 children required

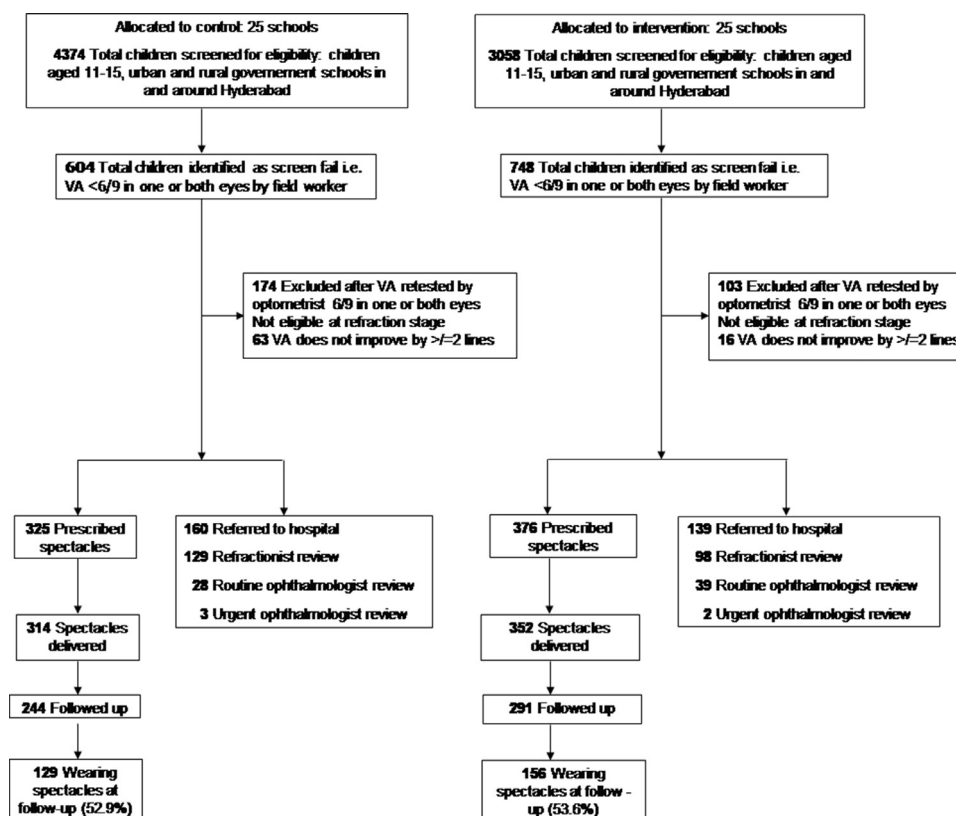


Fig. 1. Participant flow chart.

Table 2

Baseline characteristics of study children, by trial arm.

Socio-demographic variables		Control arm		Intervention arm	
		Spectacles prescribed (n = 325)		Spectacles prescribed (n = 376)	
		Mean (SD)	Range	Mean (SD)	Range
Gender	Age	13.5 (1.30)	11 to 15	13.4 (1.30)	11 to 15
	Female	180	56.0	191	50.8
Parental literacy*		N	%	N	%
	Father only	43	14.1	70	21.3
	Mother only	25	8.2	35	10.7
	Both parents	201	66.1	135	41.2
Parental spectacle wear	Neither parent	35	11.5	88	26.8
	Father only	42	12.9	35	9.3
	Mother only	38	11.7	55	14.6
	Both parents	38	11.7	33	8.8
Mobile phone ownership	Neither parent	207	63.7	253	67.3
	Father only	54	16.6	88	23.4
	Mother only	27	8.3	44	11.7
	Both parents	238	73.2	233	62.0
Presenting binocular vision	Neither parent	6	1.8	11	2.9
	<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.

specialist refraction or examination and were referred (Fig. 1). amongst the 1352 children who screened positive, 701 (51.8%) were recruited and prescribed spectacles: 325 control, 376 intervention. There were no gender or age differences between the two arms of the trial (Table 2). Parents in the intervention arm were less well educated and only 2.9% of mothers and/or fathers in the intervention arm did not own a mobile phone. A higher proportion of children in the control arm had a binocular presenting visual acuity of <6/18 than in the intervention arm (52.0% and 40.7%, respectively).

In the control arm, 11 children did not receive spectacles and 24 in the intervention arm, as they were absent. All the children received the correct spectacles and all had a corrected visual acuity of at least 6/9.5 in each eye with their new spectacles at the time of delivery.

At follow up, 76% (535/701) children were present: 244/314 (77.7%) in the control arm and 291/352 (82.7%) in the intervention arm. All 166 children (23.7%) not present had changed schools or moved to a different area and could not be traced. None of the children could transfer to a school in the other arm as no recruitment could take place after commencement of the trial. When we

Table 3

Phone calls to parents whose children were given a PeekSim image to take home.

	Intervention arm (n = 376)		Control arm (n = 325)	
	N	%	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	145	71.8%	NA	NA
Parents understood the voice message	141	97.2%	NA	NA

* some mobile phone numbers were incorrect or unreachable

compared the characteristics of children that were absent at follow-up to those that were present, they were similar proportions of gender: absent male 44.3% and present male 47.9%. There were also more older children who were absent (14–15 years) compared to those in the younger age group 11–13 years). Overall 53.3% (285/535) of children were wearing their spectacles or had them at school; 52.9% (129/244) in the control arm and 53.6% (156/291) in the intervention arm, a difference of 0.7% (95% CI, –7.7 to 9.2). Adjusting for baseline characteristics in table 1 resulted in an adjusted risk difference of 3.7% (–5.6% to 12.6%).

Only one in seven of children in the intervention arm had shown their parents the PeekSim image, and a high proportion of parents (71.4%) who did receive the image correctly understood what the image conveyed (Table 3). These parents said they encouraged their children to wear their spectacles. The voice message reached a far higher proportion of parents (70.3%) and the vast majority understood the message.

Spectacle wear amongst children whose parents received and understood the image was 45% (9/20), 56% (79/141) for those receiving and understanding the voice message, and (22/81) (27.2%) for those receiving and understanding both.

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.

4. 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 (simulated images for classroom education and parents; voice messages for parents) 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% [36] to 58.0% [37], but lower than in our earlier trial of ready-made vs custom-made spectacles (overall 75%) [28]. 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 why there was no difference between the two arms of the trial is more conjectural and may reflect cultural or socio-economic differences.

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 arms even if in reality one intervention is better than the other. Having said this, it is important to explore why trials might have negative findings [38]. Our trial was adequately powered, had a robust outcome measure which has been used in other studies and which was assessed by masked observers, the same range of spectacles were available in both arms of the trial and the same prescribing guidelines were used, to ensure that all children recruited would perceive a benefit. Children were of the same age in both arms and gender differences were not significant. However, children in the control arm had poorer



Your child will be given spectacles, please encourage him/her to wear them
మీ అమ్మాయి / అబ్బాయి కి కళ్ళజోడు ఇస్తాము, దయచేసి ఉపయోగించడానికి ప్రోత్సహించండి



Fig. 2. Example of a PeekSim image – children playing 'kho-kho'.

Table A1

Proportion wearing and not-wearing spectacles by allocation group and presenting vision.

Presenting binocular vision	Control (n = 244)				Peek (n = 291)				Risk difference	CI
	Wearing spectacles (n)	Not wearing spectacles (n)	Total	% wearing spectacles	Wearing spectacles (n)	Not wearing spectacles (n)	Total	% wearing spectacles		
<6/9.5 - 6/12	11	18	29	38%	17	18	35	49%	10.6%	−13% to 35%
<6/12 - 6/18	38	48	86	44%	67	68	135	50%	6.2%	−80% to 19%
<6/18 - 6/60	80	49	129	62%	72	49	121	60%	−2.5%	−15% to 10%
<6/60	129	115	244	53%	156	135	291	54%	0.7%	−7% to 9%

presenting binocular VA (i.e., <6/18: 52.0% in the control arm; 40.7% in the intervention arm), which may have led to greater spectacle wear in the control arm on account of greater improvement in vision (Appendix 1).

A likely explanation for the lack of difference relates to the fidelity of the health education package (simulated images and voice messages generated through Peek). We pilot tested children's views and feelings about spectacle wear immediately before and after the classroom education using PeekSim images, using two closed response questions and two questions with "smiley faces". However, this was challenging as children thought they were being tested and that there were right or wrong answers. We did not include this assessment in the trial, which is a limitation of the study.

Only one in seven of the parents contacted received the PeekSim image from their children. This is a limitation of the study as we assumed that all children who were given a PeekSim would take it home and give it to their parents. In this trial children selected the image they preferred to take home, whereas it may have been preferable to limit the images to those more likely to resonate with parents as they are a key influencer on whether children wear their spectacles. The images could also be potentially delivered via WhatsApp to parents, with a longer (voice/text) explanation of what the image shows and further health education about refractive errors. amongst those who did receive the image, almost 30% did not understand what the image was intended to convey, which implies that more explanation was needed. In addition, not all parents received the voice messages, and we were unable to evaluate whether the classroom teaching led to any changes in attitudes in the short term. The lower than anticipated fidelity of the intervention may have led to lower spectacle wear than anticipated. These two factors in combination (i.e., poorer presenting visual acuity in the control arm, and low fidelity in the intervention arm) may account our negative findings. However, a similar intervention in Kenyan schools where parents were sent an image of blackboard that mimicked visual blur, in which the primary outcome was adherence to hospital referral, gave positive results [32]. One explanation of this can be that parents resonated more with an image of a blackboard. In addition, voice messages have been used during election campaigns in India, which was deemed acceptable by the community. Our findings align with a recent Cochrane review on vision screening found that health education initiatives (as currently formulated and tested) had little impact on spectacle wear [39].

The intervention used in this trial was based on some of the elements of the Social Ecological framework [40], 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 (PeekSim images and voice messages), interpersonal (classroom teaching), and organization elements (teachers exposure to classroom teaching) of the framework. Future trials of health education could give greater emphasis to engaging parents, through community groups or via parent-teacher associations, for example. Addressing the broader community component i.e., attitudinal and cultural factors that influence behaviour, will be

more challenging, but role models and ambassadors may have the ability to influence attitudes. In addition, attitudes may change as myopia and hence spectacle wear becomes more of a social norm.

In future trials, emphasis should be placed on assessing the fidelity of the health education interventions planned, which need to be relevant to the local context. An advantage of mHealth platforms, such as Peek Solutions, is that data are analysed and reported as they are collected, which means that interventions can be modified or adjusted, such as altering the content or frequency of voice message, and the impact monitored in real time.

Author contributions

The study was designed by the principal investigator Priya Morjaria and Clare Gilbert in collaboration with the other authors.

Data collection: Mekala Jayanthi Sagar, Pallepogula Dinesh Raj

Analysis and interpretation of data: All authors.

Drafting of the manuscript: All authors.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Priya Morjaria, Jennifer Evans, Clare Gilbert, Andrew Bastawrous

Administrative, technical, or material support: Priya Morjaria.

Declaration of Competing Interest

All authors except Dr Morjaria and Dr Bastawrous declare no conflicts of interest.

Dr. Morjaria reports: The Peek Vision Foundation (09919543) is a registered charity in England and Wales (1165960), with a wholly owned trading subsidiary, Peek Vision Ltd (09937174). Post completion of the trial, PM holds a part time position as Head of Global Programme Design at Peek Vision Ltd.

Dr. Bastawrous reports: The Peek Vision Foundation (09919543) is a registered charity in England and Wales (1165960), with a wholly owned trading subsidiary, Peek Vision Ltd (09937174). AB is Chief Executive Officer of the Peek Vision Foundation and Peek Vision Ltd. All other authors have nothing to disclose

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Data sharing

The datasets used and/or analysed during this study can be obtained from the corresponding author upon appropriate request. Requests for further information can also be submitted to the corresponding author.

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