ISRCTN78134921 https://doi.org/10.1186/ISRCTN78134921

Effectiveness of a novel mobile phone health education intervention (Peek: Portable Eye Examination Kit) on spectacle wear among children in India

Submission date
28/06/2016

Recruitment status
No longer recruiting

Registration date
29/06/2016

Overall study status
Completed

Last Edited
25/02/2021

Condition category
Eye Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
The aim of this study is to see whether a health education package (the intervention) for teachers, parents and children (aged 11-15 years), delivered using innovative mobile phone technology (Peek Acuity) encourages children to wear their eyeglasses (spectacles) as well as increase the number of children being referred that have been identified as needing to wear glasses during a vision screening. This study will also assess the costs of developing and delivering the health education intervention, and dispensing and delivering the spectacles. It is hoped that the study will help to improve children's vision, increase awareness of the benefits of spectacle wear and reduce the stigma surrounding it.

Who can participate?
Children aged between 11-15 years of age in urban and rural government schools in Hyderabad, India.

What does the study involve?
Participating schools are randomly allocated to one of two groups. Children attending schools in group 1 undergo a visual screening using a mobile phone application called Peek (Portable Eye Examination Kit) and are given health education though a mobile phone app that simulates the blurry vision experienced by children who need to wear spectacles. These images are printed on cards that children take back home to their parents. Larger versions of these images are also used for classroom education for all children. Children attending schools in group 2 undergo standard visual screening using letter charts and take home an information sheet for their parents. In both groups, children who need spectacles chose from a range plastic and metal frames that they are given for free. At 3-4 months, all the children that are given spectacles are followed up to see whether they are wearing them and are asked questions about why they are wearing/not wearing them. The reasons given are compared between the two groups.

What are the possible benefits and risks of participating?
Correction of blurry vision is very beneficial for the children. It has an impact on their quality of life, behavioural development and academic performance. Health education about vision problems and spectacles for parents, teachers and other children is beneficial to society at a larger scale as it will create awareness on the importance of vision correction and reduce the stigma around spectacle wear especially for girls. There are no expected risks to participation in the study.

Where is the study run from?
The International Centre for Eye Health, based at the London School of Hygiene and Tropical Medicine in collaboration with the Public Health Institute of India based in Hyderabad, India.

When is study starting and how long is it expected to run for?
January 2016 to July 2017

Who is funding the study?
1. International Agency for the Prevention of Blindness (IAPB), through the Standard Chartered Bank: Innovation Fund
2. Vision Impact Institute

Who is the main contact?
Miss Priya Morjaria
Priya.morjaria@Lshtm.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Priya Morjaria

ORCID ID
http://orcid.org/0000-0003-1648-1948

Contact details
London School of Hygiene and Tropical Medicine
International Centre for Eye Health
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)207 958 8343
priya.morjaria@Lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
Effectiveness of a novel mobile health education intervention on spectacle wear among children in India: a cluster randomized trial

Study objectives
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.

The null hypothesis is that there is no difference in spectacle wear between the two arms of the trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London School of Hygiene and Tropical Medicine (UK): Observational/interventions Research Ethics Committee, 24/06/2016, ref: 1079801
Awaiting approval from:
2. Institutional Ethics Committee: Public Health Foundation of India
3. Indian Council for Medical Research

Study design
Cluster randomized superiority trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Refractive errors in children

Interventions
For this field, we ask that you please provide more information about the interventions used in this study? We would like a brief methodology for each of your treatment arms, including the control group (if used), the treatment given, the total duration of the treatment and follow-up for all treatment arms. With this in mind, I have taken some of the information you supplied in your plain English summary and added it to this field. Please tell me if you want any changes.

Over a period of 4-8 weeks, children in government schools in Hyderabad will be screened for vision problems. Schools will be randomised to two groups. In schools in one group children will be screened using a novel mobile phone application called Peek (Portable Eye Examination Kit) and provided health education using a mobile phone app that simulates the blurry vision experienced by children who require spectacles. These images will be printed on cards that children will take back home to their parents. Larger versions of these images will also be used for classroom education for all children. The control group will have standard screening using letter charts and will take home an information sheet for their parents. In both groups, children who require spectacles will chose from a range plastic and metal frames. All children will be given spectacles free of cost and they will delivered at the same time to avoid any bias.

At 3-4 months all children given spectacles will be followed up to observe spectacle wear and asked questions about why they are wearing/not wearing their spectacles. The reasons for wearing/not wearing spectacles will be compared between the two groups.

Intervention Type
Device

Primary outcome measure
The proportion of children in each arm of the trial who are wearing their spectacles at unannounced visits 3 to 4 months after they were given their spectacles.

The trial has been powered to detect ≥20% difference in the proportion of children wearing spectacles in the intervention arm compared with the standard arm. Categories 1 or 2 below will be defined as spectacle wearing, and categories 3 or 4 as non-spectacle wearing:
1. Children were wearing their spectacles at the time of the unannounced visit
2. Children were not wearing their spectacles at the time of the visit but have them at school
3. Children were not wearing their spectacles at the time of the visit but said they were at home
4. Children said they no longer had their spectacles as they were broken or lost

Secondary outcome measures
1. Reasons for non-spectacle wear and for spectacle wear will be done by structured interviews
2. Uptake of referrals: tracking children who have been referred against hospital registers /records
3. Cost analysis: analysis of data on cost of spectacles, producing health education package etc.

Measured 3-4 months after visual screening

Overall study start date
14/01/2016

Completion date
01/07/2017

Eligibility

Key inclusion criteria
1. Age 11-15 years
2. Presenting visual acuity (i.e. with spectacles if usually worn) of less than 6/9 in both eyes
3. The visual acuity with full correction improves by two or more lines in one or both eyes
4. Parents must consent for their child to take part in the study
5. Assent is obtained from the child

Participant type(s)
All

Age group
Child

Lower age limit
11 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
450

Total final enrolment
701

Key exclusion criteria
1. Children with other causes of visual loss
2. Children whose visual acuity does not improve adequately with refraction
3. Children whose parents do not consent
4. Children who do not assent

Date of first enrolment
02/01/2017

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
India

Study participating centre

Public Health Foundation of India
Indian Institute of Public Health
Plot #1, Road number 44
Kavuri Hills, Madhapur
Hyderabad
India
500033

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine

Sponsor details
Keppel Street
London
England
United Kingdom
WC1E 7HT
+44 (0)207 6368636
ethics@lshtm.ac.uk

Sponsor type
University/education

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
International Agency for the Prevention of Blindness (IAPB)

Funder Name
Vision Impact Institute

Results and Publications

Publication and dissemination plan
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.

Intention to publish date
30/09/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/04/2017		Yes	No
Results article	results	17/10/2020	25/02/2021	Yes	No