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Seeing is learning: vision care for middle school students in China's rural areas

Submission date	Recruitment status	[_] Prospectively registered
13/05/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/05/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2020	Eye Diseases	

Plain English summary of protocol

Background and study aims
Our research team has participated in a study that showed both that a large percentage of rural Chinese school children have uncorrected vision, and that fitting myopic (nearsighted) children with glasses significantly improves their academic performance. However, our interviews suggest that nothing is being done to address the problem. In this study, we will attempt to update and duplicate the results of this earlier study, and also to build on the previous research by determining the extent to which teachers influence the health behaviour of their students regarding proper vision care. The aim of the study is to determine the impact of corrective lenses on the health, educational achievement, and mental health of children in schools.

Who can participate?
Male and female seventh and eighth grade elementary school students, ranging between ages 11 and 13, attending public middle schools in rural areas of northwestern China.

What does the study involve?
Participating schools will be randomly allocated to one of two groups. One group will continue as normal, and in the other group students and teachers will undergo a 5-minute basic vision test. Those students whose basic vision test indicates a problem will continue on to the auto-refraction test. To dilate their pupils, the children will be administered 2-3 rounds of eye drops containing 1% cyclopentolate. The drops themselves may cause a mild stinging, not lasting more than 1-2 seconds. To avoid this stinging, the children will also be administered 1-2 drops of Proparacaine, a topical anesthetic. If this test indicates that students need glasses, they will receive a free, high quality pair of glasses. They will also undergo a training session in which they will learn about the importance and proper vision care.

What are the possible benefits and risks of participating?
Students who need eyeglasses will receive a free, high quality pair of glasses. Extreme side effects of cyclopentolate include dry mouth, flushing, dry skin, dizziness, or confusion. These side effects are described in the literature as "rare", with incidence of <0.1%. There are no side effects or risks associated with Proparacaine administration at these dosages. There are two normal side effects to the dilation process (not to the drug), which are blurred vision, especially at close range, which is unavoidable, and photophobia, which can be reduced by avoiding bright

lights. The children will be indoors during the exam and will be given a dark place to sit. They will be instructed to avoid playing outside for the rest of the day.

Where is the study run from?
This study takes place in Shaanxi province, China.

When is the study starting and how long is it expected to run for?
Data collection will begin in September 2013 and finish in late May/early June of 2014.

Who is funding the study?
OneSight Research Foundation (USA).

Who is the main contact?
Matthew Boswell

Contact information

Type(s)
Public

Contact name
Mr Matthew Boswell

Contact details
Stanford University
Stanford
United States of America
94305

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
28345

Study information

Scientific Title
Seeing is learning: vision care for middle school students in China's rural areas

Study objectives
We predict that fitting middle school students in rural China with eyeglasses and educating students about eyeglasses will reduce the rate of uncorrected vision in classrooms as well as increase student performance in school.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stanford University, 30/09/2014, Protocol ID: 28345

Study design
Interventional cluster-randomized multicenter controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Refractive error

Interventions
Participants are randomized at the school level to one of two groups:
1. Control (no glasses)
2. Free eyeglasses + information: Students and teachers will undergo a 5-minute basic vision test. Those students whose basic vision test indicates a problem will continue on to the auto-refraction test. If this test indicates that students need eyeglasses, they will receive a free, high quality pair of glasses. They will also undergo a training session in which they will learn about the importance and proper vision care.

Intervention Type
Other

Primary outcome measure
Number of children wearing glasses, measured in both at baseline and follow-up survey 9 months after baseline

Secondary outcome measures
School performance, determined from a standardized test we will administer and students' grade at baseline, then 9 months after baseline

Overall study start date
01/09/2013

Completion date

31/12/2015

Eligibility

Key inclusion criteria
Male and female seventh and eighth grade elementary school students, ranging between ages 11 and 13, attending public middle schools in rural areas of northwestern China will be recruited by randomized selection. We are only enrolling students from township level schools. All students in these schools who agree to participate in the study will be enrolled as study participants.

Participant type(s)
Other

Age group
Child

Lower age limit
11 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
7000

Total final enrolment
995

Key exclusion criteria
Rich urban areas are not included in the randomized selection. These areas are not known to have major health problems.

Date of first enrolment
01/09/2013

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
China

Study participating centre

Shaanxi Normal University
China
-

Sponsor information

Organisation
Stanford University

Sponsor details
Stanford, CA
Stanford
United States of America
94305

Sponsor type
University/education

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Charity

Funder Name
OneSight Research Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/09/2020	23/10/2020	Yes	No