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Seeing is Learning: Vision Care for Children in Three Migrant Communities

Submission date
16/11/2014

Recruitment status
No longer recruiting

Registration date
12/12/2014

Overall study status
Completed

Last Edited
29/05/2020

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
A large number of school children in rural China have problems with their vision that are currently not being corrected by eyeglasses. Our previous research has shown that giving myopic (short sighted) children glasses to correct their vision leads to a significant improvement in their performance at school. However, we have also conducted interviews which suggest that nothing is being done to address this problem. Here, we will attempt to update and duplicate the results of our earlier study, and also to build on the previous research by determining the extent to which teachers influence the health behavior of their students as regards to eye care.

Who can participate?
Children aged 8-12 years and attending a public elementary school in a rural area of northwestern China. The schools are randomly selected from areas surrounding major cities. These areas are known to be poor and have a large migrant population.

What does the study involve?
Schools are randomly allocated into one of three groups. Children in group 1 schools do not receive any eyeglasses and carry on as usual. Children and teachers in group 2 schools are given a basic 5-minute vision test. Those children whose basic vision test suggests that they have a problem with their vision then have an auto-refraction test. Children who are found to need eyeglasses are given a free, high-quality pair of glasses. They will also be taught the importance of proper eye care. Children and teachers in group 3 are treated in the same way as those in group 2, but teachers are also given an incentive to promote the wearing of eyeglasses in the classroom.

What are the possible benefits and risks of participating?
The possible benefits for children include undergoing a high-quality vision examination, determining whether the participant has a vision problem, receiving a prescription and made-to-order pair of glasses the participant would otherwise never have acquired on their own. These services are rendered for free. The varied benefits of glasses wear among those with refractive error are documented in numerous clinical studies. Insofar as risks, a small number of subjects harbor adverse reactions to the medication used to dilate their eyes. This risk is manageable with the staff available on hand during the study.

Where is the study run from?
Schools in a rural area of northwestern China. Planning is carried out from our offices at Stanford University, and those of our collaborators in Beijing.

When is the study starting and how long is it expected to run for?
January 2013 to January 2015.

Who is funding the study?
Caterpillar (USA), Brien Holden Vision Institute (Australia) and Essilor (France).

Who is the main contact?
Professor Scott Rozelle
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
28343

Study information

Scientific Title
Seeing is Learning: Vision Care for Children in Three Migrant Communities: an interventional cluster-randomized multicentre controlled trial

Acronym
SIL II

Study objectives

We predict that fitting migrant students in China with eyeglasses, educating these students about eyeglasses and giving teachers incentives to ensure children wear eyeglasses will raise performance in school among children who receive corrective glasses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stanford University Internal Review Board Human Subjects Research, Protocol ID: 28343

Study design
Interventional cluster-randomized multicentre controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Vision care

Interventions
1. Control (no eyeglasses)
2. Free eyeglasses + information schools
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.
3. Free eyeglasses + information + teacher incentive schools
These schools will receive the same intervention as described above, but the teachers in these schools will receive an incentive to promote eyeglasses wear among the students in their class.

Intervention Type
Device

Primary outcome measure
Measured in both a baseline and follow-up survey:
1. Number of children wearing glasses regularly
2. School performance, determined from a standardized test we will administer and students grade

Secondary outcome measures
Measured at baseline by way of a survey filled out by the subjects:
1. Student interest in school
2. Student mental health
3. Student self confidence

Overall study start date
09/01/2013

Completion date
12/01/2015

Eligibility

Key inclusion criteria
1. Male and female fourth and fifth grade elementary school students,
2. Ages 8 to 12
3. Attending public elementary schools in rural areas of northwestern China
4. Schools are randomly selected from areas surrounding major cities. These areas are known to have high concentrations of migrants and are known to be relatively poor.

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
The number of students included in the study is 10,000. The study will be conducted in 150 schools in two province level administrative provinces in China.

Key exclusion criteria
Students will be excluded from the trial if they have an ailment or condition that prevents them from being safely dilated and given a proper corrective vision prescription (existing literature indicates this would be at most one percent of the sample population).

Date of first enrolment
09/01/2013

Date of final enrolment

12/01/2015

Locations

Countries of recruitment
China

United States of America

Study participating centre
Stanford University
450 Serra Mall
Stanford
United States of America
94305

Sponsor information

Organisation
Stanford University (USA)

Sponsor details
450 Serra Mall
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Sponsor type
University/education

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Industry

Funder Name
Caterpillar Inc.

Alternative Name(s)

Caterpillar Inc., CAT, Inc., CAT

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Brien Holden Vision Institute

Funder Name
Essilor

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2015	29/05/2020	Yes	No