ISRCTN70463299 https://doi.org/10.1186/ISRCTN70463299

Correcting short-sightedness among secondary school children to increase academic high school attendance rates in rural communities in Northwestern China

Submission date 10/06/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/06/2022	**Overall study status** Ongoing	
Last Edited 16/07/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
Chinese children are some of the most short-sighted in the world, but only one in five children in poor areas who need glasses have them. Other trials have shown that giving children free glasses leads to better grades and that free glasses have a bigger impact on grades than factors like parents' education level and the amount of money a family has. The effect on grades from glasses is greater than from other health services in school, like giving vitamins. Only about one in three children in rural western China go on to a regular, non-vocational high school. The investigators would like to show the Chinese government strong evidence of what glasses can do to help children continue their education, in order to help convince the government to carry out national programs to provide free glasses for children who need them.

Who can participate?
Children in Year 1 and 2 classes (likely aged 12-15 years) who need glasses

What does the study involve?
The investigators will choose 130 middle schools at random in Ningxia, western China, and all children in Years 1 and 2 (one class each) at each school will go at random into one of two groups: either a group getting free glasses, with support from teachers to push them to wear the glasses ("Intervention") or a group getting just glasses prescriptions ("Control"). The main study outcome will be the proportion of children going on to academic (as opposed to vocational) high school, and the study is powered to detect a 10% difference in this figure between groups. The study will also assess children's test scores, whether they wear their glasses at school, and how often they use blackboards (which disadvantage short-sighted children) vs textbooks to learn from. The researchers will also study the total cost of providing glasses and the teacher support to wear them per additional student attending academic high school.

What are the possible benefits and risks of participating?
The principal risk to children is failure to receive spectacles to correct their poor vision. No school vision screening programs exist in this part of Ningxia, and previous studies in western China suggest that only 15-20% of children who could potentially benefit from glasses will own them. Providing the families of control participants with prescriptions for glasses and notes detailing their refractive condition delivers a higher level of service than they would otherwise receive, and has been satisfactory to ethics committees in China, the US and the UK during our previous similar studies. All children will receive complete examinations from optometrists, and those with eye conditions requiring treatment will be referred to the local county hospital. All control group children will receive free spectacles at the end of the study, at the completion of their third year of middle school.

Where is the study run from?
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
October 2022 to July 2027

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. Clearly Initiative (UK)

Who is the main contact?
Prof. Nathan Congdon, n.congdon@qub.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Prof Nathan Congdon

ORCID ID
https://orcid.org/0000-0001-9866-3416

Contact details
School of Medicine, Dentistry and Biomedical Sciences
Institute of Clinical Science
Centre for Public Health
Royal Victoria Hospital
Queen’s University
Belfast
United Kingdom
BT12 6BA
+44 (0)7748751393
n.congdon@qub.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT04077086

Secondary identifying numbers
MR/S023208/1

Study information

Scientific Title
SWISH (See Well to Stay In ScHool): a randomised trial of spectacle distribution to secondary school children with myopia to increase academic high school attendance rates in rural communities

Acronym
SWISH

Study objectives
Providing free glasses to myopic rural Chinese students, with a teacher incentive to promote use, increases academic high school attendance

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/07/2021, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast (Queen's University Belfast, Whitla Medical Building 97, Lisburn Road, Belfast, BT9 7BL, UK; +44 (0)28 9097 5858; smdbs@qub.ac.uk), ref: 19.25v7

Study design
Cluster-randomized 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 to request a participant information sheet

Health condition(s) or problem(s) studied
Myopia

Interventions
Current interventions as of 16/07/2025:
The investigators will choose 130 middle schools at random in Ningxia, western China, and all first-year middle school students (typically aged 12-15) in the selected schools will go at random into one of two groups: either a group getting free glasses, with support from teachers to push them to wear the glasses (Intervention) or a group getting just glasses prescriptions (Control).

Randomization and allocation concealment:
Schools will be stratified by prior high school attendance rates. This stratification will assure balance between the study groups on the main trial outcome at baseline. Within each stratum, a school will be randomly allocated to one of the two intervention groups. Stratification and random assignment will be carried out at a central location (Zhongshan Ophthalmic Centre, Sun Yat-sen University, Guangzhou, China) by the main study statistician using R software (R Foundation for Statistical Computing, Vienna, Austria) and concealed from the study team until the school has agreed to join the trial and the eligible students have undergone vision screening.

Follow-up time:
Participants in the intervention group will have undergone either 32 months (December 2024 to June 2027) of treatment by the endpoint of the trial.

Previous interventions:
The investigators will choose 130 middle schools at random in Ningxia, western China, and all children in Years 1 and 2 (one class each) at each school will go at random into one of two groups: either a group getting free glasses, with support from teachers to push them to wear the glasses (Intervention) or a group getting just glasses prescriptions (Control).

Randomization and allocation concealment:
Schools will be stratified by three variables: prefecture; mean baseline test score; and the number of students failing vision screening in Years I and II. Information on these variables will be collected during a baseline survey and screening. This stratification will assure balance between the study groups in these key variables, which are those most likely to affect the main trial outcome. Within each stratum, a school will be randomly allocated to one of the two intervention groups. Stratification and random assignment will be carried out at a central location (Zhongshan Ophthalmic Centre, Sun Yat-sen University, Guangzhou, China) by the main study statistician using R software (R Foundation for Statistical Computing, Vienna, Austria) and concealed from the study team until the school has agreed to join the trial and the eligible students have undergone vision screening.

Follow-up time:
Participants in the intervention group will have undergone either 22 months (September 2022 to July 2024 for those recruited in Year 2) or 34 months (September 2022 to July 2025 for those recruited in Year 1) of treatment by the endpoint of the trial.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Glasses

Primary outcome measure
Current primary outcome measure as of 16/07/2025:
Academic high school attendance, defined as the proportion of children who continue to academic high school as opposed to vocational high school or no additional schooling, assessed by systematically contacting parents, teachers, and students to ascertain enrolment status. It is measured after 32 months of participant follow-up for children recruited in middle school.

Previous primary outcome measure:
Academic high school attendance, defined as the proportion of children who continue to academic high school as opposed to vocational high school or no additional schooling, assessed by systematically contacting parents, teachers, and students to ascertain enrolment status. It is measured after 24 months of participant follow-up for children recruited in middle school Year 2 and after 36 months of participant follow-up for those recruited in middle school year 1.

Secondary outcome measures
Current secondary outcome measures as of 16/07/2025:
1. Compliance with spectacle wear, defined as the actual presence of spectacles on the child's face (rather than having glasses at school) at the time of an unannounced visit to the school. It is measured after 8, 20 and 32 months of participant follow-up.
2. Mathematics score measured by a standardized mathematics test after 8, 20 and 32 months of participant follow-up
3. Blackboard use measured using a questionnaire acquiring teachers' responses at 20 and 32 months of participant follow-up
4. Cost effectiveness of the intervention is calculated as the ratio of incremental cost to the proportion of children who continue to academic high school as opposed to vocational high school or no schooling, measured at study closeout after 32 months of participant follow-up for those recruited in middle school Year 1
5. Anxiety and stress measured by the Depression, Anxiety and Stress Scale (DASS-21) at baseline and 12-month post treatment
6. Self-esteem measured by the Rosenberg Self-esteem Scale at baseline and 12-month post-treatment
7. Quality of life measured by the Pediatric Quality of Life Inventory™ Generic Core Scales at baseline and 12-month post-treatment
8. Progression of shortsightedness indicated by the length of the eyeball (axial length), measured by using a biometry measuring device (A-Scan) after applying a drop of topical anesthetic (proxymetacaine/proparacaine) in the right eye at baseline, 12 and 24 months

Previous secondary outcome measures:
1. Compliance with spectacle wear, defined as the actual presence of spectacles on the child's face (rather than having glasses at school) at the time of an unannounced visit to the school. It is measured after 8, 20 and 32 months of participant follow-up.
2. Mathematics score measured by a standardized mathematics test after 8, 20 and 32 months of participant follow-up
3. Blackboard use measured using a questionnaire acquiring teachers' responses at 20 and 32 months of participant follow-up

4. Cost effectiveness of the intervention is calculated as the ratio of incremental cost to the proportion of children who continue to academic high school as opposed to vocational high school or no schooling, measured at study closeout after 24 months of participant follow-up for those recruited in middle school Year 2 and 36 months of participant follow up for those recruited in Middle School Year 1
5. Anxiety and stress measured by the Depression, Anxiety and Stress Scale (DASS-21) at baseline and 12-month post-treatment
6. Self-esteem measured by the Rosenberg Self-esteem Scale at baseline and 12-month post-treatment
7. Quality of life measured by the Pediatric Quality of Life Inventory™ Generic Core Scales at baseline and 12-month post-treatment
8. Progression of shortsightedness indicated by the length of the eyeball (axial length), measured by using a biometry measuring device (A-Scan) after applying a drop of topical anesthetic (proxymetacaine/proparacaine) in the right eye at baseline, 12 and 24 months

Overall study start date
01/10/2022

Completion date
01/07/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/07/2025:
1. Year 1 classes (likely age 12-15 years) at the recruited schools
2. Have uncorrected (without glasses) visual acuity of ≤6/12 in either eye
3. Refractive error meets cut-offs shown to be associated with significantly greater improvement in visual acuity when corrected (myopia ≤-0.75 diopters (D), hyperopia ≥2.00 D, or astigmatism (non-spherical refractive error) ≥1.00 D)
4. Visual acuity can be improved to ≥6/9 in both eyes with glasses

Previous inclusion criteria:
1. Year 1 and 2 classes (likely aged 12-15 years) at the recruited schools
2. Have uncorrected (without glasses) visual acuity of ≤6/12 in either eye
3. Refractive error meets cut-offs shown to be associated with significantly greater improvement in visual acuity when corrected (myopia ≤-0.75 diopters (D), hyperopia ≥2.00 D, or astigmatism (non-spherical refractive error) ≥1.00 D)
4. Visual acuity can be improved to >6/12 in both eyes with glasses

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
4800

Key exclusion criteria
Presence of visually-significant ocular condition besides refractive error

Date of first enrolment
01/09/2022

Date of final enrolment
01/12/2022

Locations

Countries of recruitment
China

Study participating centre
130 middle schools at random in Ningxia, western China
China
-

Sponsor information

Organisation
Queen's University Belfast

Sponsor details
Centre for Public Health, ICSB,
Block B, Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BJ
+44 (0)7598126345
Cph@qub.ac.uk

Sponsor type
University/education

Website

https://www.qub.ac.uk/

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Clearly Initiative

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/07/2028

Individual participant data (IPD) sharing plan
Data will be made available on the websites of Queen's University Belfast and Stanford University
Types of data: demographic information and personal data (name, contact details, age, gender, family wealth etc), ophthalmic examination data (visual acuity, axial length, refractive error status etc), lifestyle data (sleep time, screen time, study time etc). Outcome data such as high school attendance, spectacle wear compliance, math test scores, blackboard use, costs

(screening cost, glasses and teacher incentives and incremental costs etc), mental health (depression, anxiety, stress, quality of life, self-esteem), progression of shortsightedness.
Repository name: QUB Institutional Active data Storing Unit (PURE)
Process for request: Any outside organization wanting to access the data will need to complete a data-sharing agreement.
Timing for availability: Three months after data collection is closed once the dataset is cleaned and de-identified.
Consent from participants: Written consent from adult participants and written assent from children.
Data anonymization: Participants will be allocated a unique ID which will be used to identify all their paper and electronic records.
The principal risk to children is failure to receive spectacles to correct their poor vision. No school vision screening programs exist in this part of Ningxia, and our previous studies in western China suggest that only 15-20% of children potentially benefitting from glasses will own them. Providing the families of Control participants with prescriptions for glasses and notes detailing their refractive condition delivers a higher level of service than they would otherwise receive, and has been satisfactory to ethics committees in China, the US and the UK during previous similar trials. All children will receive complete examinations from optometrists at baseline, and those with ocular conditions requiring treatment will be referred to the local county hospital. All Control children will receive free spectacles at the end of the trial, at the completion of their third year of middle school.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 8	07/07/2021	21/06/2022	No	No
Protocol file		22/11/2024	16/07/2025	No	No