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Glasses in classes: A cluster-randomised controlled trial to evaluate the effects of a school-based intervention to improve academic, social and emotional learning, visual acuity, and adherence to glasses wear in young children in a disadvantaged multi-ethnic community

Submission date
04/12/2019

Recruitment status
No longer recruiting

Registration date
21/01/2020

Overall study status
Completed

Last Edited
21/01/2020

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
In the UK it is recommended that all children receive an eyesight test in their Reception year. This is provided by health services and results are shared with families, but not schools. Roughly 10–15% of children fail their eyesight test, and of these around a third are not taken to the opticians to obtain glasses.
This project will test an intervention designed to increase the number of children who obtain and consistently wear glasses, following the eye test. The results of the eye test will be shared with schools, school staff will be trained to support pupils and their families to get glasses and encourage pupils to wear them, and funding will be provided for a second pair of glasses for pupils to keep at school.

Who can participate?
Children aged 4-5 years of age enrolled in reception year in state-funded primary schools based in the Metropolitan area of Bradford, United Kingdom

What does the study involve?
At the start of the reception year, parents from the treatment and control schools will receive an information letter about the study, with the right to withdraw their children from the study. Children will then receive a vision screening, along with academic pretests. Schools will then be randomly assigned to conditions. Vision screening results will be revealed (Pass/Fail) and letters will be sent to parents with instructions to go to the optician (this applies to both intervention and control groups); if they attend the appointment, they will receive a pair of home glasses. For the intervention group only, vision coordinators will be trained (after pretests are completed). If the parents and children attend the appointment at the opticians, a spare pair of

glasses will be sent to the school and will be made available in the classroom. The intervention will run for the academic school year, with teachers ensuring children prescribed glasses wear them, and that their spare pair are available if they attend school without their home pair, as well as working with families to prioritise glasses wear at home. Parents are asked to report to schools if the home glasses are lost or broken and they will be asked to attend the optometrist with their children for the fitting of the replacement glasses. School glasses replacement will be organized by the intervention team, once informed by the school. Number of replacement glasses will be monitored by the developer.

What are the possible benefits and risks of participating?
Benefits: Children will receive glasses if they are required.
Risks: None expected.

Where is the study run from?
1. Bradford Institute for Health Research, UK
2. Centre for Applied Education Research, UK
3. University of Nottingham, UK

When is the study starting and how long is it expected to run for?
June 2019 to May 2021

Who is funding the study?
Education Endowment Foundation, UK

Who is the main contact?
Prof. Roisin Corcoran
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https://educationendowmentfoundation.org.uk/projects-and-evaluation/projects/glasses-in-classes/

Study website
https://educationendowmentfoundation.org.uk/projects-and-evaluation/projects/glasses-in-classes/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
253681

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 253681; CPMS 41579

Study information

Scientific Title
Glasses in classes: A cluster-randomised controlled trial to evaluate the effects of a school-based intervention to improve academic achievement, visual acuity, and adherence to glasses wear in young children in a disadvantaged multi-ethnic community

Acronym
GiC

Study objectives
1. What is the impact on the reading achievement (letter-word identification) of pupils in reception classes participating in Glasses in Classes as opposed to participating in a business-as-usual control group?
2. What is the impact on the mathematics and reading achievement (word attack) of pupils in reception classes participating in Glasses in Classes as opposed to participating in a business-as-usual control group?
3. What is the impact of Glasses in Classes in comparison to business-as-usual control group on student mathematics and reading achievement among pupils eligible for FSM (defined as any student who has ever been classified as in receipt of free school meals)?
4. What is the impact on the visual acuity of pupils in reception classes participating in Glasses in Classes as opposed to participating in a business-as-usual control group?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/05/2019, NHS Bradford Teaching Hospitals Foundation Trust (Health Research Authority,
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44(0)2071048083; nrescommittee.yorkandhumber-bradfordleeds@nhs.net), ref: 19/YH/0124

2. Approved 08/05/2019, University of Nottingham (School of Education Ethics Committee, Dearing Building, Jubilee Campus, Wollaton Road, Nottingham, NG8 1BB, UK; +44 (0)115 846 8405; educationresearchethics@nottingham.ac.uk), ref: 2019/24

Study design
Interventional 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Vision requiring correction

Interventions
Interventional cluster randomised controlled trial involving reception year children in primary schools in Bradford. Randomisation is at school-level and target is 100 schools (50 treatment = T; 50 control = C) with each school providing close to full two reception classes of approximately 27 pupils per class . All reception pupils (2019–2020) in both treatment and control schools will undergo vision screening assessment, but only a sub-sample of pupils (~15%) who fail the vision screening assessment will be included in the intention-to-treat (ITT) analysis and contribute to the pre- and posttests. Baseline reading and mathematics achievement for pupils in reception classes will be assessed in autumn 2019, prior random assignment. Posttest will be administered in spring 2020. The ITT sample will include the pupils in reception classes in 2019, who are enrolled in the intervention schools at the point of random assignment. Pupils not enrolled at the point of random assignment are considered joiners. The final analysis sample will exclude the joiners, but they will receive the intervention as usual.

Schools are randomised into treatment and control using simple randomisation.

Intervention Type
Other

Primary outcome measure
Reading achievement measured using Letter-Word Identification sub-scale from the Woodcock-Johnson IV at baseline (autumn 2019) and follow up (Spring 2020)

Secondary outcome measures

1. Reading achievement measured using Word Attack sub-scale from the Woodcock-Johnson IV at baseline (autumn 2019) and follow up (Spring 2020)
2. Reading achievement measured using Applied Problems from the Woodcock-Johnson IV at baseline (autumn 2019) and follow up (Spring 2020)

Overall study start date
01/12/2018

Completion date
31/05/2021

Eligibility

Key inclusion criteria
1. Children aged 4-5 years of age
2. Enrolled in reception year in state-funded primary schools based in the Metropolitan area of Bradford, United Kingdom

Participant type(s)
Other

Age group
Child

Lower age limit
4 Years

Upper age limit
5 Years

Sex
Both

Target number of participants
700 students in 100 schools

Key exclusion criteria
Joiners (children who joined the class after the start of the study)

Date of first enrolment
01/06/2019

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Institute for Health Research
Temple Bank House
Bradford Royal Infirmary
Duckworth Lane
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BD9 6RJ

Study participating centre
Centre for Applied Education Research
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Study participating centre
University of Nottingham
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Jubilee Campus
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Sponsor information

Organisation
Education Endowment Foundation

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info@eefoundation.org.uk

Sponsor type
Charity

Website
https://educationendowmentfoundation.org.uk

Funder(s)

Funder type
Charity

Funder Name
Education Endowment Foundation

Alternative Name(s)
EducEndowFoundn, Education Endowment Foundation | London, EEF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		30/09/2019	21/01/2020	No	No
HRA research summary			28/06/2023	No	No