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# Is it feasible to conduct a trial of a new intervention to help children with cerebral visual impairment (CVI)?

**Submission date**
24/09/2019

**Recruitment status**
No longer recruiting

**Registration date**
04/10/2019

**Overall study status**
Completed

**Last Edited**
10/02/2026

**Condition category**
Nervous System Diseases

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

## Plain English summary of protocol

Background and study aims
Cerebral visual impairment (CVI or CVIs) refers to a range of vision problems caused by damage to or malfunction of the brain, rather than the eyes. CVI can affect children or adults. Children with CVIs have difficulty seeing the world around them and this can cause mental health problems and affect their ability to learn. Research has shown that brain-related vision problems (CVIs) may be present but unrecognised, particularly in children with educational, behavioural or emotional problems. Parents of children with CVI have told us that if schools had more understanding of the condition, then support for affected children would be improved, resulting in them having better educational progress, mental health and wellbeing. We know schools already have processes to support children with additional needs. This study, funded by the NIHR, aims to discover if providing schools with additional information about CVI (the "intervention") will be effective in improving outcomes for children with additional needs. Evidence also suggests all children will benefit from some of the advice in the intervention pack. The additional information is designed to help teachers better support children who may be struggling, with simple, non-expensive measures that help overcome any CVIs that may be present. We will compare two randomly selected groups of schools: one group who will get the CVI-related information pack and one group that will carry on as normal. We will collect data on child behaviour and wellbeing and compare the two groups.

Who can participate?
This study is for primary school children in years 3, 4 and 5, their parents and teachers. The study is taking place during the 2019/2020 school year in 3 local authority areas: Somerset, Gloucestershire and Southampton.

What does the study involve?
At the start of the study (September/October 2019) we will collect general information from all the schools about the children in years 3-5 including whether they have extra help with their education and any known medical diagnoses. We will ask the teachers to fill in a standard questionnaire about each child's behaviour in school and we will ask parents to complete short questionnaires about their child, family life and any costs related to caring for their child. We will

also ask parents and teachers 5 questions relating to CVI, and 6 questions related to learning, for each child. Teachers will also be asked to complete a short questionnaire about their teaching. The teachers will be asked to allocate part of one lesson for the children to fill in a short child-specific questionnaire about their wellbeing and thoughts about school. The children can be offered help by school staff if they would like or need it and will also be told they do not have answer the questions if they don't want to. Schools can request support for the children from the research team if needs be.

After we have collected this information the schools will be divided into two groups at random. Schools in one group will be given the CVI information pack and they will use that information if they find it helpful. This may change how they carry out some activities at the school including how worksheets are presented and classrooms are arranged. It will include suggestions to request an eye check for up to 5% children who are struggling with their learning or behaviour, if the child's parents and GP agree. The other group of schools will carry on as normal. At the end of the school year we will ask the teachers, children and parents to fill in the same questionnaires as at the beginning. During the study we will also be interviewing a small number of school staff and parents if they volunteer to speak to us.

What are the possible benefits and risks of participating?
Some children in the intervention schools may benefit from the intervention if it is helpful and promotes their learning and well-being. Teachers in the intervention group may benefit from being better informed as a result of the intervention. There are no risks to children or teachers anticipated as a result of participation.

Where is the study run from?
University of Bristol

When is the study starting and how long is it expected to run for?
September 2019 to October 2020

Who is funding the study?
National Institute for Health Research (NIHR), UK

Who is the main contact?
Cathy Williams
cvi-project@bristol.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Miss Cathy Williams

### Contact details
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United Kingdom

BS8 1NU
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cvi-project@bristol.ac.uk

# Additional identifiers

### Protocol serial number
Sponsor Reference 2019-3003

# Study information

### Scientific Title
The CVI Project Feasibility study for a cluster randomised trial of a new intervention to improve outcomes for primary school children at risk of cerebral visual impairments (CVIs), with nested health economic analysis and process evaluation

### Acronym
The CVI Project Feasibility study

### Study objectives
Cerebral visual impairments (CVIs) are impairments of vision due to malfunction of the brain rather than the eyes. Examples of CVIs include difficulties with seeing target objects within clutter, with recognition of people or shapes, with seeing movement or with visually judging distances, as well as the better-recognised problems of visual field loss or impaired visual acuity. Extensive evidence indicates that CVIs are a part of many brain-related disorders but are often unrecognised. In a recent survey of 2258 children in mainstream primary schools in England, we found that a minimum of 3.7% of primary school children had 1 or more CVI, and 1.1% had 2 or more. Almost all of these were unrecognised, but almost half of the children with at least one CVI were already being given extra help with their education.
There is growing concern that in children, CVIs can be mistaken for other disorders so that children are being wrongly labelled as having a learning difficulty, or a behavioural disorder, when in fact their problems are related to their visual impairment. Children with CVIs and their families report widespread problems with low self-esteem, anxieties and poor academic achievement, which can improve with recognition of their condition and appropriate supportive measures being set up. Supporting the needs of the 0.8 million children with disabilities was identified as a priority by the Chief Medical Officer Dr Sally Davies.
The CVI Project therefore aims to improve the wellbeing, mental health and academic achievement of children with brain-related visual problems (known as cerebral visual impairment or CVI). A new intervention that acts at the interface between “health” and “education” needs rigorous assessment in a full-sized cluster randomised trial (cRCT). In preparation for this future cRC, the study will assess the feasibility and acceptability of the new intervention itself and of the trial methods we propose to use. The new intervention is multilevel and comprises (a) information-sharing with the teachers and (b) a signposted pathway for referral to the hospital eye clinic for children the school thinks may have CVIs.
The hypothesis is that this multilevel intervention will improve educational and wellbeing-related outcomes for any child with CVI and potentially for their peers as well.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 12/08/2019, Faculty of Health Sciences Research Ethics Committee (FREC), University of Bristol Faculty of Health Sciences (First Floor South, Senate House, Tyndall Avenue, Bristol, BS8 1TH, UK; +44 (0)117 331 8197; Liam.McKervey@bristol.ac.uk), ref: 89144

## Study design
Feasibility study for a two-arm cluster randomised trial of primary schools with nested process and economic evaluations

## Primary study design
Interventional

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Cerebral visual impairments in primary school children

## Interventions
The study intervention is a multilevel package for schools designed to:
1. Increase the knowledge about CVI for schools, teachers and learning support assistants (LSAs)
2. Provide a “tool kit” of advice for schools and staff about how to support children with or at-risk from CVI within the classroom and across the school.
3. Provide some learning resources aligned to the curriculum relating to vision and sight, for teachers to use if wanted, to raise awareness
4. Provide signposting for schools so that they can suggest referral of children for further vision assessment as necessary, via a letter for the parents to show their General Practitioner

At the start of the study (September/October 2019) the researchers will collect general information from all the schools about the children in years 3-5 including whether they have extra help with their education and any known medical diagnoses. They will ask the teachers to fill in a standard questionnaire about each child’s behaviour in school and they will ask parents to complete short questionnaires about their child, family life and any costs related to caring for their child. They will also ask parents and teachers 5 questions relating to CVI, and 6 questions related to learning, for each child. Teachers will also be asked to complete a short questionnaire about their teaching. The teachers will be asked to allocate part of one lesson for the children to fill in a short child-specific questionnaire about their wellbeing and thoughts about school. The children can be offered help by school staff if they would like or need it and will also be told they do not have answer the questions if they don’t want to. Schools can request support for the children from the research team if needs be.

After the researchers have collected this information the schools will be divided into two groups at random. Schools in one group will be given the CVI information pack and they will use that information if they find it helpful. This may change how they carry out some activities at the school including how worksheets are presented and classrooms are arranged. It will include suggestions to request an eye check for up to 5% of children who are struggling with their learning or behaviour, if the child’s parents and GP agree. The other group of schools will carry on as normal. At the end of the school year the researchers will ask the teachers, children and parents to fill in the same questionnaires as at the beginning. During the study they will also be interviewing a small number of school staff and parents if they volunteer.

### Intervention Type
Mixed

### Primary outcome(s)
1. Recruitment - measured as N of schools recruited and as a proportion of those invited
2. Attrition rate - measured as numbers of schools who are recruited and then drop out
3. Non-agreement to data sharing - measured as numbers of parents who decline to share their children's data
4. Acceptability of intervention - ascertained in interviews with school staff and parents
5. Feasibility of intervention - measured as numbers of staff accessing the intervention material; numbers and type of changes made within the school as reported by teachers in interviews; numbers of children referred to local eye unit for an eye check

### Key secondary outcome(s))
At baseline and 12-months:
1. Child's self-reported Quality of Life (QoL) using the Generic core scales of the PedsQL
2. Teacher-report of the child's Cognitive abilities using the PedsQL Cognitive Functioning scales
3. Teacher report of the child's behaviour using the Strengths and Difficulties (SDQ) questionnaire with Impact supplement
4. Parent report of the child's behaviour using the SDQ Impact supplement
5. Parent report of child-related Family life using the PedsQL Family Impact Module
6. Parent-report of child-related costs using a bespoke Health Economics form

### Completion date
31/10/2020

## Eligibility

### Key inclusion criteria
Children in state-maintained primary schools, in Y3-Y5, in the Local Authority areas of Taunton, Southampton or Gloucester- in 2019/2020 school year

### Participant type(s)
Other

### Healthy volunteers allowed
No

### Age group
Child

### Sex
All

### Total final enrolment
1257

### Key exclusion criteria
Children in Reception, Y1, Y2, and Y6

**Date of first enrolment**
07/10/2019

**Date of final enrolment**
31/12/2019

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**University of Bristol - this is the lead centre and the study does not recruit from Bristol**
Bristol Medical School
1-5 Whiteladies Road
Bristol
England
BS8 1NU

**Study participating centre**
**Schools from Taunton Local Authority, Somerset West and Taunton District Council**
With Paediatric Ophthalmologist from Taunton and Somerset NHS Foundation Trust
Taunton
England
TA1 5DA

**Study participating centre**
**Schools from Gloucester Local Authority, Gloucestershire County Council**
With Paediatric Opthalmologist from Gloucestershire Hospitals NHS Foundation Trust
Gloucester
England
GL1 3NN

**Study participating centre**
**Schools from Southampton Local Authority, Southampton City Council**
With Paediatric Opthalmologist from University Hospital Southampton NHS Foundation Trust
Southampton
England
SO16 6YD

# Sponsor information

### Organisation
University of Bristol

### ROR
https://ror.org/0524sp257

# Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research (Senior Research Fellowship 2015-008-05)

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 03/03/2025 | 10/02/2026 | Yes | No |
| Protocol article | | 05/05/2021 | 07/05/2021 | Yes | No |
| Other publications | core outcome set development | 29/09/2021 | 04/10/2021 | Yes | No |

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|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |