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Babies in Glasses: can wearing glasses for near focus help to improve sight in babies born at risk of brain injury, and in turn, help their development in other areas? A feasibility study

Submission date
23/06/2021

Recruitment status
No longer recruiting

Registration date
30/07/2021

Overall study status
Completed

Last Edited
17/02/2026

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Complications can occur in infants who have loss of oxygen to their brain around the time of birth (known as Hypoxic Ischaemic Encephalopathy or HIE) and infants who are born prematurely. It is common in some children who have had complications around the time of birth to have problems with their sight as a result of cerebral visual impairment (CVI). CVI is the leading cause of sight problems in children in the UK and happens when parts of the brain and vision pathways responsible for processing vision are not working as they should.
There are different forms of CVI and the seriousness can range from small difficulties with sight to blindness. If CVI goes unnoticed, it can have a negative effect on the child's education and quality of life.
Newborn babies are usually (but not always) long-sighted and become less long-sighted during the early months of life; a process called emmetropisation. Another change that occurs over the first few months of life is that their focusing ability develops, allowing them to change their focus from things far away to close-up objects easily. This ability to change focus is known as accommodation.
Babies use their accommodation to focus on objects close by such as their hands, toys and parents' faces. The ability to do so is very important for their development. Many children with CVI lack good accommodation, so things that are close to them appear blurry. Glasses for long-sightedness will bring the world into focus and make everything clearer at this vital stage of development for infants with CVI.
Studies done before in older children with CVI have shown that wearing glasses for long-sightedness has improved their sight and ability to focus up close, but this has not been assessed in babies. It is well known that early correction of childhood sight problems is important because the internal changes that the brain can make in response to an injury get progressively weaker during early life.
This is a feasibility study, which means we are looking at a small sample of babies to see whether

parents are willing to take part in research involving giving glasses for their babies at a young age, as well as looking at different aspects of the research plan in preparation for a larger final study.

Vision plays an important role in facilitating normal development as children use their sight to learn to walk, talk, think and communicate. For this reason, early intervention has the potential to have positive effects on children's vision and other areas of development.

The aims of this feasibility study are:
1. To establish the willingness of parents/carers of these young babies to accept glasses at these ages.
2. Fitting and giving glasses to infants aged 8 weeks versus 16 weeks (we are quite experienced at fitting appropriate glasses for babies at these ages).
3. To establish whether patients and their parents are happy and able to follow the Optometrist advice when given glasses at 8 weeks and 16 weeks.
4. To establish whether there are any safety issues with prescribing glasses to this group of children through mechanical damage or increasing the risk of spectacle wear when these children are older.
5. To set up a patient and public involvement (PPI) committee and conduct further PPI studies to determine at what age glasses are acceptable to parents of at-risk babies.
NOTE: PPI is the way in which patients, the public, service users and carers can influence their own care and treatment, have a say in the way services are planned and run and help bring about improvements to the way care is provided.
6. To see whether we can recruit enough patients and how long it takes to do so.
7. To collect information on vision, long-or short-sightedness, ability to change focus from far to near, and developmental characteristics of infants at 8- and 16-weeks of age.
8. To see the number of families who return for their follow up visits until the study is complete in all three arms.
9. To help in our understanding of the brain haemodynamic and metabolic changes related to CVI and whether these changes can be used as early marker of disease severity. This will be tested using a light-based technique called functional broadband near infrared spectroscopy (fBNIRS).
10. The ability of the tests to correctly identify infants with improvement in visual function /development through early near vision glasses prescription in babies with and without poor accommodation.
11. Evidence for any early indicators for benefit from the glasses such as visual behaviour, long-or-short-sightedness or specific pattern of changes in brain haemodynamics and metabolism in response to a functional visual stimulus.
12. To find out what is the most appropriate and relevant cost and benefit information to collect, and how to collect this information.

Who can participate?
1. Infants born full term who have had to have brain cooling for HIE.
2. Infants born too soon (less than 29 weeks along in the pregnancy)

Infants of any sex and up until 8 weeks of age are able to take part in the study.

What does the study involve?
The infants' vision will be assessed using a range of tests specially selected for the infants' age. Infants in all three arms will receive a full vision assessment and eye health check at each visit. To determine if providing glasses to this patient group is helpful, there will be a 'control group' who will have all the vision assessments at 2 months of age but will not receive glasses (group

A). Infants in group B1 and B2 will be prescribed near vision glasses (for all waking hours) at either 2 or 4-month-old, depending on randomisation.
Vision will also be measured using brain responses to light (functional broadband Near Infrared Spectroscopy or fBNIRS) to see if there are any visual processing issues. The fBNIRS will be performed for all infants before discharge and at each follow up visit.

What are the possible benefits and risks of participating?
Prescription of near vision glasses can influence emmetropisation and accommodation. Current evidence from studies of children with developmental disability indicates that:
1) Emmetropisation is not operating normally so there is less concern about disrupting a normally functioning emmetropisation process than there would be for neurotypical children and 2) In addition to the benefits in visual acuity and visual development, early near vision correction, may lead to both improved accommodation and emmetropisation.
The level of short- or long-sightedness and accommodation will be measured at 3 and 6 months after the glasses are prescribed to ensure there is no negative impact.
There is also the potential of harm to occur from a poorly fitting pair of glasses (a poorly fitting pair of glasses can cause discomfort, permanent visual harm or even deformity). Our expert paediatric dispensing optician will check the fit every few months.
Any patients with residual long-or-short-sightedness at the end of the study will be followed up in appropriate NHS clinics and the child will be in the NHS ophthalmology system much sooner than they may normally be referred (if at all) during the critical developmental period.

Where is the study run from?
University College London Hospital (UCLH) (UK)

When is the study starting and how long is it expected to run for?
August 2018 to July 2023

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

Who is the main contact?
Richard Bowman, richard.bowman@gosh.nhs.uk

Contact information

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT05048550

Integrated Research Application System (IRAS)
265584

Central Portfolio Management System (CPMS)
44176

National Institute for Health and Care Research (NIHR)
PB-PG-0418-20006

Sponsor ref
18BA36

Study information

Scientific Title
Can the provision of near vision glasses as an early intervention improve visual and developmental outcomes in children with perinatal brain insult? A feasibility study

Acronym
BiG

Study objectives
Early use of glasses will improve near vision in infants at risk of development of cerebral visual impairment, leading to further improvement in other neurodevelopmental domains. This

proactive intervention is hypothesised to be more effective than waiting until a problem is detected. The hypothesis for the feasibility study is that the intervention and a randomised controlled trial to investigate the above hypothesis are both feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/11/2020, South-Central Oxford C Research Ethics Committee (Level 3, Block B, Whitefriars Building, Lewins Mead, Bristol, UK BS1 2NT; +44(0)207 104 8379; oxfordc.rec@hra.nhs.uk), ref: 20/SC/0004

Primary study design
Interventional

Study design
Single-centre randomized interventional study a 3-arm parallel group open-label clinical feasibility trial for a definitive RCT with equal arm allocation and a superiority design

Study type(s)
Other

Health condition(s) or problem(s) studied
Cerebral visual impairment

Interventions
Eligible children with consenting parents will be screened for severe refractive error prior to randomisation by the research optometrist. Evidence of severe refractive error will result in a referral to ophthalmology and exclusion from the study.
We will randomise children using random permuted blocks. Children will be stratified and blocked by diagnosis (HIE vs preterm) and then randomised using Sealed Envelope.

Children will be randomised to one of three arms:
Group A (control arm): First assessment at 8 weeks corrected gestational age (CGA). No glasses prescribed.
Group B1 (intervention arm): First assessment and given intervention at 8 weeks (CGA). Add+3.00DS to the cycloplegic refraction and prescribe.
Group B2 (intervention arm): First assessment and given intervention at 16 weeks (CGA). Add+3.00DS to the cycloplegic refraction and prescribe.

Full time spectacle wear is prescribed to group B1 and B2 (use of an existing product within its CE market intended purpose) and spectacles will be changed to reflect changes in refractive error or frame fit as appropriate at follow up.
Random monthly interviews with a semi-structured questionnaire will be conducted on random days of the week from when they are dispensed.
Infants in all 3 arms will be followed up 3- and 6-months (+/- 3 weeks) after the first assessment.

Intervention Type
Device

Phase

Not Applicable

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

Primary outcome(s)
Feasibility is assessed using the acceptance of randomisation over the 10-month recruitment period – this will be measured as the proportion of patients/parents who accept the offer of randomisation

Key secondary outcome(s)
1. Success rate of compliance with glasses for infants in groups B1 and B2. The proportion of infants (%) who are still wearing their glasses at the 3 and 6 month follow-up appointments. Time frame: 6 months
2. Success rate in dispensing glasses to children in groups B1 and B2. The percentage of infants dispensed vs. the total number of infants randomised to the intervention arms will be recorded at the end of the study. Timeframe: 6 months
3. The distribution of visual acuity at the 3 and 6-month follow ups compared with visual acuity at the first visit in all 3 arms. Time frame: 6 months
4. The distribution of refractive outcomes (measured in dioptres) at 3 and 6-month follow ups as compared to the first visit in all 3 groups. Time frame: 6 months
5. Evidence of impaired emmetropisation following administration of FMT will be measured by combining refractive error and visual acuity measures. The trial will not be feasible if there is a 2SD difference without compensatory benefit eg 2 lines improvement in visual acuity. Timeframe: 6 months
6. The distribution of accommodative outcomes (measured in dioptres) at 3 and 6-month follow-ups as compared to the first visit in all 3 groups. Time frame: 6 months
7. Determination of appropriate resource-use data collection methods. A targeted paediatric CSRI form has been designed specifically for this population and will be used for the duration of the feasibility study. Time frame: 15 months
8. Proportion of families completing phone questionnaire on spectacle compliance as a percentage of those in the intervention groups (B1 & B2). Timeframe: 6 months
9. Significant mechanical trauma will be measured as the percentage of infants who have had an adverse event (from mechanical trauma) vs. the total number of infants prescribed glasses in groups B1 and B2. The study will not be feasible if this is more than 30% of infants in the intervention arms. Timeframe: 6 months
10. Consent rate - this will be measured as the number of infants recruited vs. number of infants, who fulfil the inclusion/exclusion criteria, approached. Time frame: 10 months
11. Retention rate - this will be measured by the median number of infants reported per month. Time frame: 15 months

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Term infants undergoing therapeutic hypothermia for hypoxic ischaemic encephalopathy (HIE)
2. Preterm infants born at <29 weeks' gestational age
3. No gender criteria
4. Age range: newborn to <8 weeks CGA

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Infants who are still an inpatient at 8 weeks CGA
2. Ocular exclusion criteria: children with unrelated congenital or developmental ocular abnormality such as cataract requiring surgery, genetic retinal disease, coloboma. Retinopathy of prematurity will not be an exclusion criterion
3. Infants with severe refractive error (more than -6.00D spherical equivalent or +8.00D spherical equivalent)

Date of first enrolment
09/06/2021

Date of final enrolment
09/09/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College Hospital
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Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/02/2026	17/02/2026	Yes	No
Protocol article		21/09/2022	22/09/2022	Yes	No
Basic results			21/01/2026	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	version v5	16/10/2020	27/07/2021	No	Yes
Statistical Analysis Plan		04/09/2024	21/01/2026	No	No