The emotional impact of restoring sight

Submission date	Recruitment status	[X] Prospectively registered
14/03/2025	Not yet recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
27/03/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
02/09/2025	Eye Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

More treatment options than ever before are available for young people with vision impairment, but very little is known about the impact of these sight restoration therapies on wellbeing and mental health. In adults, sight restoration is often associated with depression and a reduction in mental wellbeing.

The aim of this study is to fully understand the wellbeing and mental health of adolescents undergoing sight restoration therapy and will develop clinical guidelines for the psychological support of young people receiving this treatment.

Who can participate?

Children and adolescents (age 10-20 years) with vision impairment who are receiving treatment expected to improve their vision.

What does the study involve?

Completing age-appropriate questionnaires five times: before receiving sight restoration treatment, then 1, 3, 6 and 12 months after treatment. Participating in a short interview before treatment and at the final visit. Participants' parent(s)/carer(s) will also complete a questionnaire at each assessment and a short interview at the first and last assessment.

What are the possible benefits and risks of participating?

Benefits: This is an exploratory study and is not likely to directly benefit participants. However, if needed, participants will be referred or signposted to appropriate mental health services. Risks: It is possible that some of the interview questions may raise uncomfortable issues for participants or their parents/carers. The researchers have well-established risk management protocols, written in conjunction with clinical psychologists, which have been used for similar studies to ensure appropriate signposting and referral for participants who express signs of mental ill-health, up to and including emergency care.

Where is the study run from?

UCL Institute of Ophthalmology, part of University College London, in association with Moorfields Eye Hospital, Great Ormond Street Hospital for Children, and the NIHR Moorfields Biomedical Research Centre (UK)

When is the study starting and how long is it expected to run for? January 2025 to December 2027

Who is funding the study?

- 1. The Medical Research Foundation (UK)
- 2. Moorfields Eye Charity (UK)

Who is the main contact?
Michael Crossland, m.crossland@ucl.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Michael Crossland

ORCID ID

https://orcid.org/0000-0001-6833-6043

Contact details

UCL Institute of Ophthalmology 11-43 Bath Street London United Kingdom EC1V 9EL +44 (0)2076086800 m.crossland@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

356506

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

The emotional impact of restoring sight (EIRS): well-being and mental health in children and adolescents receiving sight restoring therapy for eye disease

Acronym

EIRS

Study objectives

This study will use mixed qualitative and quantitative research methods to understand how sight-restoring treatment (for example, gene therapy for inherited retinal disease) affects the wellbeing and mental health of young people with vision impairment.

Ethics approval required

Ethics approval required

Ethics approval(s)

notYetSubmitted, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided; Email not provided), ref: Reference number not provided

Study design

Longitudinal observational study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Any eye disease causing bilateral vision impairment

Interventions

Participants will complete age-appropriate questionnaires to assess their mental health and wellbeing five times: before receiving sight restoration treatment, and 1, 3, 6 and 12 months after treatment. Before treatment and at the end of the study, participants will also complete a short qualitative interview.

Participants' parent(s)/carer(s) will also complete a questionnaire at each assessment and a short interview at the first and last assessment.

Intervention Type

Not Specified

Primary outcome(s)

Mental wellbeing assessed using the Warwick Edinburgh Mental Wellbeing Scale at pretreatment, months 1, 3, 6 and 12

Key secondary outcome(s))

- 1. Participation assessed using the Child and Adolescent Scale of Participation at pre-treatment, months 1, 3, 6 and 12
- 2. Depression and anxiety assessed using the Revised Children's Anxiety and Depression Scale at pre-treatment, months 1, 3, 6 and 12

- 3. Sleep assessed by parental completion of the Children's Sleep Habits Questionnaire at pretreatment, months 1, 3, 6 and 12
- 4. Qualitative findings from participant and parent interviews at pre-treatment and month 12

Completion date

31/12/2027

Eligibility

Key inclusion criteria

- 1. Young people aged 10-20 years
- 2. Meeting the ICD-11 criterion of having mild, moderate or severe vision impairment, or blindness, in their better eye
- 3. Receiving treatment intended to improve their visual function
- 4. With sufficient English comprehension to understand the age-appropriate questionnaires

Participant type(s)

Patient, Carer

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

10 years

Upper age limit

20 years

Sex

All

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/01/2026

Date of final enrolment

31/12/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre NIHR Moorfields Biomedical Research Centre

Moorfields Eye Hospital NHS Foundation Trust 162 City Road London United Kingdom EC1V 2PD

Study participating centre Dept. of Clinical & Academic Ophthalmology

Great Ormond Street Hospital Great Ormond Street London United Kingdom WC1N 3JH

Sponsor information

Organisation

University College London

ROR

https://ror.org/02jx3x895

Funder(s)

Funder type

Charity

Funder Name

Medical Research Foundation

Alternative Name(s)

MedResFdn, The Medical Research Foundation, MRF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Moorfields Eye Charity

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Datasets generated and/or analysed during the current study will be made available upon request from Michael Crossland (m.crossland@ucl.ac.uk). To preserve the confidentiality of the participants, potentially identifiable data will be redacted.

IPD sharing plan summary

Available on request

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes