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The emotional impact of restoring sight

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

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
http://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

EudraCT/CTIS number
Nil known

IRAS number
356506

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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)
Not yet submitted, 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

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact deetails to request a participant information sheet

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 measure

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

Secondary outcome measures
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 pre-treatment, months 1, 3, 6 and 12
4. Qualitative findings from participant and parent interviews at pre-treatment and month 12

Overall study start date
01/01/2025

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

Age group
Mixed

Lower age limit
10 Years

Upper age limit
20 Years

Sex
Both

Target number of participants
Up to 36

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/09/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor details
UCLH/UCL Joint Research Office
4th Floor, West
250 Euston Road
London
England
United Kingdom
NW1 2PG
+44 (0)20 3447 5696
UCLH.RandD@nhs.net

Sponsor type

University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Medical Research Foundation

Alternative Name(s)
MedResFdn, 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

Publication and dissemination plan

The researchers will disseminate their research to clinicians, scientists, people with vision impairment and their families through:
1. Clinical presentations (e.g., Hospital Optometrists' Annual Conference, Royal College of Ophthalmologists Annual Congress, European Academy of Optometry and Optics and 100% optical/100% ophthalmology)
2. Research presentations (e.g., the International Society for Low Vision Research and Rehabilitation)
3. Research papers in peer-reviewed scientific journals
4. Public information events including BBC Radio 4's In Touch and through charities such as VICTA, Stargardt's Connected, the Macular Society, Retina UK and the Royal Society for Blind Children.

Intention to publish date

31/12/2028

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