ISRCTN14668034 https://doi.org/10.1186/ISRCTN14668034

Eye-movement training improves reading function in children and young people with eye-movement disorders after acquired brain injury

Submission date
17/09/2024

Recruitment status
No longer recruiting

Registration date
22/09/2024

Overall study status
Completed

Last Edited
08/10/2024

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Acquired brain injury (ABI) often causes a worsening of reading function. This may decrease motivation for school activities. Eye-movement training has been shown to have positive effects, but its feasibility and effectiveness are unknown, as is its optimal duration, frequency and intensity. The aim was to develop and evaluate eye-movement training for children and young people with ABI.

Who can participate?
Children and young people aged between 10-19 years old with eye-movement disorders after ABI

What does the study involve?
The intervention involves 20 minutes of training each day for three weeks. Each participant and caregiver will be introduced to the home training program and will receive individual support by phone calls and/or text messages during the intervention. Vision assessments, a reading speed test and a survey will record results at baseline, at the end of the training, and three months after the end of the training.

What are the possible benefits and risks of participating?
The participants might benefit regarding their reading function, and possible risks including headaches from the training are expected to be minimal.

Where is the study run from?
The study is run from the Child and Youth Rehabilitation Center in Lund, Sweden.

When is the study starting and how long is it expected to run for?
January 2020 and February 2024

Who is funding the study?
Region Skåne (Sweden)

Who is the main contact?
Dr. Katarina Lauruschkus, katarina.lauruschkus@med.lu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Katarina Lauruschkus

ORCID ID
https://orcid.org/0000-0002-1801-8503

Contact details
Brannarevagen 6
Veberöd
Sweden
24763
+46 0707519888
katarina.lauruschkus@med.lu.se

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Eye-movement training improves reading function in children and young people with eye-movement disorders after acquired brain injury

Study objectives
Three weeks of eye-movement training is feasible and improves the reading function in children and young people with eye-movement disorders after acquired brain injury.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/11/2020, Swedish Ethical Review Authority (Box 2110, Uppsala, SE-750 02, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: EPM-Dnr 2020-04154

Study design
Single-centre interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Eye-movement disorders after acquired brain injury

Interventions
The materials for the eye-movement training with instructions were provided for each participant by the occupational therapist or the special education teacher. The materials are described and visualized in the manuscript that will be submitted and is available upon request.

The intervention involves 20 minutes of training each day for three weeks. Each participant and caregiver is introduced to the home training program and receives individual support during the intervention. Vision assessments, a reading speed test and a survey records results at baseline, at the end of the training, and three months after the end of the training.

The paediatrician, the occupational therapist and the special education teacher all worked at the Child and Youth Rehabilitation Center and were trained for the intervention. They were all well experienced for working with the target group.

Intervention Type
Behavioural

Primary outcome(s)
Reading speed measured using a reading speed test at baseline, at the end of the training, and three months after the end of the training

Key secondary outcome(s))
Clinical signs of convergence insufficiency measured using vision assessments and the modified Convergence Insufficiency Symptom Survey (CISS) at baseline, at the end of the training, and three months after the end of the training

Completion date
20/02/2024

Eligibility

Key inclusion criteria
1. Aged 10-19 years old
2. Eye-movement disorders after ABI
3. Live in the Skåne Region in Southern Sweden
4. Being followed up by the Child and Youth Rehabilitation Center in Lund, Sweden
5. Able to read independently before the injury

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
10 years

Upper age limit
19 years

Sex
All

Total final enrolment
16

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
20/11/2020

Date of final enrolment
12/11/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Child and Youth Rehabilitation Center
Lovisastigen 9
Lund
Sweden
22100

Sponsor information

Organisation
Region Skåne

Funder(s)

Funder type
Government

Funder Name
Region Skåne

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study will be available upon request from Katarina Lauruschkus, katarina.lauruschkus@med.lu.se

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Poster results		06/09/2022	20/09/2024	No	No