Compensatory reading training for people with homonymous visual field defects

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders of the eye
Study type	Interventional

Summary

ID

NL-OMON51525

Source
ToetsingOnline

Brief title
Reading training in hemianopia

Condition

- Neurological disorders of the eye

Synonym
halfsided blindness, Partial cortical blindness

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Acquired brain injury, Homonymous visual field defect, Reading, Rehabilitation

Outcome measures

Primary outcome

The primary outcome measures of this study reflect reading performance as well as perceived reading performance: Words per minute read out loud (((number of words read-number of errors)/time [s]) x 60), Number of reading errors, Words per minute read silently ((number of words in paragraph/time [s]) x 60), Subjective report on reading behavior and participation (index scores), Subjective report on reading difficulties.

Secondary outcome

Vision-related quality of life questionnaire, Fatigue questionnaire, Training motivation, Reading history, Education,Sustained attention task, Working memory task, Long-term memory task, Executive functioning task

Study description

Background summary

A common consequence of stroke in the posterior region of the brain is a visual field defect. People with visual field defects frequently experience difficulties with reading, such as decreased reading speed, making more errors or being less able to read for a prolonged time. Reading difficulties due to a visual field defect have a severe impact on daily life activities, social participation and reduce quality of life. In The Netherlands, the provided rehabilitation options for these difficulties are currently not empirically supported.

Study objective

This project aims to determine the effectiveness of two reading interventions:

Vistra and Rotated Reading. The effects will be investigated on the level of functions, activities and participation. A nuanced view will be provided as to which training suits which patient best.

Study design

3-arm randomized controlled trial

Intervention

The goal of Vistra is to learn patients to compensate for the visual field defect by training eye movements. Rotated Reading aims to reduce the effects of the visual field defect by learning people to read in a different direction, such as vertically or diagonally.

Study burden and risks

The effect measures do not include invasive testing. The effect measures have no adverse consequences for the participant, nor for their treatment at Royal Dutch Visio or Bartiméus and there are no risks involved. Therefore, the burden is unassuming.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* Homonymous visual field defect (at least a quadrantanopia, either right-sided or left-sided) due to acquired post-chiasmatic brain injury
* At least three months between onset HVFD and the first measurement
* Near visual acuity >= 0.5 with patient*s own current correction
* MMSE score >=24
* Age >= 18 years
* Presence of by patient formulated treatment goal regarding reading

Exclusion criteria

A subject who meets any of the following criteria will be excluded from participation in this study:
* Additional visual field defect (at least cluster) in ipsilesional visual hemi-field
* Pre-existing dyslexia/ illiteracy/ low literacy/ other pre-morbid reading problems
* No clear neurological cause of HVFD
* Presence of comorbid neglect
The following criteria are made on the premise that, when present, they will impair the ability to successfully followthe intervention:
* Communication difficulties (e.g. severe hearing impairment, no fluent understanding of Dutch language, severeaphasia as indicated by the Token test)
* Negative advice of treatment team regarding reading intervention participation, due to e.g. severe psychiatric, cognitive or visual perception disorders, problems with health, motivation or illness awareness or misuse ofdrugs/alcohol/medication
* Additional visual disturbances (e.g. diplopia, metamorphopsia, low contrast sensitivity)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2021
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO Date:	24-06-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-03-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL80795.042.22