Reading Training in Hemianopia - Pilot study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26239

Source
Nationaal Trial Register

Brief title
RTHp

Health condition

Homonymous Visual Field Disorders due to Acquired Brain Injury

Sponsors and support

Primary sponsor: Royal Dutch Visio, Bartiméus
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

The following information will be collected in order to answer the feasibility pilot objectives:
• Qualitative data from the self-developed semi-structured interviews after pre-training measurement and post-training measurement
• Number of participants in the pilot phase who want to participate
• Number of participants in the pilot phase meeting the inclusion criteria

• Number of participants completing the intervention and post-training assessment vs. withdrawn participants
• Distribution of scores on RCT parameters
• Assessment logbook notes from the researchers
• Subjective experiences from health care professionals involved about the study procedure (as indicated on surveys which will be distributed at the end of the feasibility phase as well as reflection sessions between health care professionals and the researchers)

Secondary outcome

RCT outcomes:

Primary objective: To objectively compare and establish the effects of two reading training programs with each other and with a control group on reading performance.
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)
● Number of correct answers (text comprehension)
● Subjective report on reading behavior and participation (index scores)
● Subjective report on reading difficulties

Secondary objective (1): To establish the effect of the reading training programs on vision-related quality of life. Related parameter:
● Vision-related quality of life questionnaire (NEI-VFQ-25)
Secondary objective (2): To identify common patient characteristics related to training outcome. Related parameters:
● Fatigue questionnaire
● Training motivation
● Reading history
● Education
● Sustained attention task
● Working memory task
● Long-term memory task
● Executive functioning task

The following parameters are included to be able to make a justified decision on inclusion of a participant:
● Etiology
● Side and shape of the VFD
● Amount of macular sparing
● Near visual acuity
● Contrast sensitivity
● Date of onset acquired brain damage
● Sex, age, comorbidity (e.g. neglect or aphasia)

Study description

Background summary

Rationale: 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.

Objective: This project aims to determine the feasibility of an RCT on the effectiveness of two reading interventions: Vistra and Rotated Reading. The effects will be investigated on the level of functions, activities and participation.

Study design: Feasibility pilot study of randomised controlled trial

Study population: Adult patients with reading difficulties due to homonymous visual field defects after acquired brain injury referred for care at a visual rehabilitation centre will be included in the study.

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.
Main study parameters/endpoints: The main parameters are the objective and subjective effectiveness of the reading training. Effect measures are reading tests, reading questionnaires and vision-related quality of life questionnaires.

Study objective

The objective of the feasibility pilot is to explore the following questions which will guide proper set-up of the RCT:
1. What is the number of potential participants registered monthly?
2. What is the number of potential participants accepting or declining study participation?
3. What is the percentage of participants completing the intervention + post-training assessment?
4. Are the eligibility criteria clear when put to practice?
5. Are the eligibility criteria adequate, too lenient or too strict from a clinical point of view?
6. Are the participants able to perform adequately on the tests and questionnaires during pre- and post-training assessment?
7. What is the duration of the pre- and post-training assessments in practice?
8. Are all devices and instruments present at all times at every assessment location?
9. Do the performances of the participants on the effect measures show enough variability?
10. Is the study protocol clear to all occupational therapists involved?
11. What is the subjective experience of the involved occupational therapists with the training protocols?

12. What is the subjective experience of the participants with the training protocols and study assessments?

RCT objectives:
Primary Objective:
1. To objectively compare and establish the effects of two reading training programs with each other and with a control group on reading performance.
Secondary Objective(s):
1. To establish the effect of the reading training programs on vision-related quality of life.
2. To identify common patient characteristics related to training outcome.

Study design

1-3 weeks before start of intervention
1-3 weeks after end of intervention
3 months after end of intervention

Intervention

The goal of the Vistra training method is that patients with hemianopia gain insight in the nature of the visual field defect, the consequences this has for reading and to compensate for this during reading. Subgoals are increasing reading speed, reducing the number of errors, being able to read for a prolonged period of time and better understanding. The protocol consists of a reading exploration, training phase and an evaluation. Vistra comprises a large number of exercises of different nature and level of difficulty. All exercises aim at improving saccadic eye movements in the direction of the blind hemifield. Exercises are displayed on a computer screen and on paper. Between sessions, homework is given to the patients. The duration of the training is 10-12 sessions.

The rationale of Rotated Reading training is that people with hemianopia will be better able to read a text when it is rotated in a certain, personalized angle. The text is rotated to such an extent that the complete text emerges in the intact visual field, based on precise measurements of the visual field of the individual patient. The optimal rotation can be applied both digitally for training purposes and manually. For the latter a template is being used. The training starts with an exploration phase in which the patients gains understanding of the visual field defect and corresponding reading difficulties, after which face-to-face therapy and homework assignments help the patient to adapt to the rotation strategy. The duration of the training is 5 sessions.

Contacts

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Eligibility criteria

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 participant 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 follow the intervention:
● Communication difficulties (e.g. severe hearing impairment, no fluent understanding of Dutch language, severe aphasia 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 of drugs/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)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-09-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-09-2021
Application type:	First submission

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
NTR-new	NL9726
CCMO	NL76790.042.21

Study results