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Reading training for people with hemianopia (loss of one-half of the visual field)

Submission date
21/07/2022

Recruitment status
No longer recruiting

Registration date
15/09/2022

Overall study status
Completed

Last Edited
05/04/2024

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
People with homonymous hemianopia are not able to process information from the left or right half of their visual field. Hemianopia is caused by acquired brain injury, most often stroke. People with hemianopia can experience a variety of difficulties during reading, such losing orientation in the text and having problems understanding the information that is read. Fortunately, reading training is being increasingly developed. However, most of these are currently not proven effective. This study aims to establish the effectiveness of two types of in-practice developed reading training as well as to gain insight into which training suits which patient best.

Who can participate?
Adults aged 18 years and over with reading difficulties due to homonymous visual field defects such as hemianopia or quadrantanopia (loss of vision in one half or one of the quarters of the visual field)

What does the study involve?
Participants will be assigned to one of three study groups: Vistra reading training, Rotated Reading training or a waiting list control group. Reading performance and quality of life will be assessed directly before, after, and 3 months after reading training or a waiting list period with no intervention. Other variables will also be measured such as fatigue, cognition or the visual field. Assessments take place at local rehabilitation centers and digital/over the phone.

What are the possible benefits and risks of participating?
There are no direct benefits or risks of participation for the participant. The results of the study help guide future rehabilitation of people with reading difficulties due to a visual field defect after acquired brain injury.

Where is the study run from?
University of Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
September 2019 to July 2023

Who is funding the study?
ZonMw (Netherlands)

Who is the main contact?
Sarah Tol, s.tol@rug.nl

Study website
https://hemianopsieonderzoek.nl/index.php/onderzoek-3/

Contact information

Type(s)
Scientific

Contact name
Ms Sarah Tol

ORCID ID
http://orcid.org/0000-0003-4734-3003

Contact details
Grote Kruisstraat 2/1
Groningen
Netherlands
9712 TS
+31 (0)503635114
s.tol@rug.nl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL80795.042.22

Study information

Scientific Title
Compensatory reading training for people with homonymous visual field defects

Acronym
RTH

Study objectives
People with homonymous visual field disorders can experience a variety of difficulties during reading, such losing orientation in the text and having problems understanding the information that is read. Although in-practice reading trainings are being increasingly developed, most of these trainings are currently not empirically supported. The effectiveness of two in-practice reading trainings is examined, as well as which training suits which patient best.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/06/2022, Medical Research Ethics Committee of the University Medical Center Groningen (METc UMCG Postbus 30 001, 9700 RB Groningen, Netherlands; +31 (0)50 361 42 04 or +31 (0)50 361 18 29 (09.00-12:00 on Monday till Thursday), +31 (0)50 361 9833 (10.00-12:00 on Friday); metc@umcg.nl), ref: METc 2022/120

Study design
Partially randomized patient preference controlled trial

Primary study design
Interventional

Secondary study design
Partially randomized patient preference controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
Homonymous visual field defects after post-chiasmatic acquired brain injury

Interventions
Participants will be assigned to one of three study groups: Vistra reading training, Rotated Reading training or a waiting list control group.

Method of randomisation: adaptive randomisation or minimisation
Adaptive randomisation, also called minimization, is a dynamic procedure, in which chances for allocation to one of the groups are influenced by the characteristics of the patients already allocated. The procedure is based on the idea that with every allocation, the differences between the groups on certain relevant patient characteristics are minimized. In the current study, the minimization technique will be applied to ensure maximal balance of (1) side (left vs right) and (2) type (hemianopia vs. quadrantanopia) of visual field defect, (3) treating organization and (4) amount of macular sparing (sparing vs splitting) in the three treatment groups. Treatment allocation will be performed by the PI (S.Tol).

The goal of the Vistra saccadic compensatory training is that people with hemianopia gain insight into 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, a training phase and an evaluation. Vistra comprises a large number of exercises of different natures and levels 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.

The rationale for Rotated Reading training is that people with hemianopia will be better able to read a text when it is rotated at 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. The optimal rotation can be applied both digitally for training purposes and manually. The training starts with an exploration phase in which understanding is gained of the visual field defect and corresponding reading difficulties, after which face-to-face therapy and homework assignments help to adapt to the rotation strategy.

Frequencies/duration of the training intervention:
1. The Vistra reading training has a duration of 10 with a frequency of 1 session per week at the rehabilitation centre with the occupational therapist. Next to this, daily homework exercises are given for approximately 15 minutes
2. The Rotated Reading training has a duration of 5 weeks with a frequency of 1 session per week at the rehabilitation centre with the occupational therapist. Next to this, daily homework exercises are given for approximately 15 minutes

Reading performance and quality of life will be assessed directly before, after, and 3 months after reading training or a waiting list period with no intervention. Other variables will also be measured such as fatigue, cognition or the visual field. Assessments take place at local rehabilitation centers and digital/over the phone.

Updated 03/04/2024:
This project employs a partially randomized patient preference controlled trial to investigate the effect of reading training. The aim of such a design is to assign participants with a preference treatment accordingly. This design type shows multiple advantages with regard to the external validity of trial outcomes, especially for unblinded trials comparing different treatments such as the current study. A higher number and more diverse patient sample is to be expected from such a design, increasing the external validity. Additionally, is has been shown that patient preference does not have a significant effect on the primary outcome measure of a study.

Participants with no preference will be randomized by means of adaptive randomization. This randomization technique, also called minimization, is a dynamic procedure in which chances for allocation to one of the groups are influenced by the characteristics of the patients already allocated. The procedure is based on the idea that with every allocation, the differences between the groups on certain relevant patient characteristics are minimized. In the current study, the minimization technique will be applied to ensure maximal balance of (1) side (left vs. right) and (2) type (hemianopia vs. quadrantanopia) of visual field defect, (3) treating organization and (4) amount of macular sparing (sparing vs. splitting) in the three treatment groups. Treatment allocation will be performed by the PI (S.Tol).

Intervention Type
Behavioural

Primary outcome measure
Timepoints:
A1: Pre-training assessments (0-3 weeks before starting training)
A2: Post-training assessments (0-3 weeks after end of training)
FU: Follow-up assessment (3 months after end of training)

1. Out loud reading speed is measured as words per minute ((number of words read-number of errors)/time [s]) x 60) on a paragraph of the International Reading Speed Test (IReST) at A1, A2 and FU
2. Reading errors are measured as the amount of verbal errors during reading on the IReST at A1, A2 and FU
3. Silently read reading speed is measured on a digitally presented IReST paragraph at A1, A2 and FU
4. Subjective reading behavior and activities are measured with the newly-developed questionnaire Hemianopia Reading Questionnaire (HRQ) at A1, A2 and FU. Currently, a validation study in a large community sample is performed on the HRQ
5. Subjective reading difficulties are measured with the newly-developed questionnaire Hemianopia Reading Questionnaire at A1, A2 and FU. Currently, a validation study in a large community sample is performed on the HRQ

Secondary outcome measures
1. Vision-related quality of life is measured using the vision-related quality of life questionnaire (NEI-VFQ-25) at A1, A2 and FU
2.1. Fatigue is measured using the Fatigue Severity Scale at A1
2.2. Training motivation is measured using self-developed questions on training motivation and confidence in training at A1
2.3. Reading history is measured using self-developed questions as part of the HRQ at A1. A publication on the validity and index scores of this questionnaire is planned.
2.4. Level of education will be asked for at A1
2.5. Sustained attention is measured using the Bourdon-Wiersma task at A1
2.6. Long-term memory is measured using the subtask 'Story' (immediate and delayed recall) of the Rivermead Behavioral Memory Task at A1
2.7. Executive functioning is measured using the Fluency task (letter and word fluency) at A1

Overall study start date
01/09/2019

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Homonymous visual field defect (at least a quadrantanopia, either right-sided or left-sided) due to acquired post-chiasmatic brain injury
2. At least 3 months between onset homonymous visual field defect (HVFD) and the first measurement
3. Near visual acuity ≥0.5 with patient’s own current correction
4. Mini-mental state examination (MMSE) score ≥24
5. Age ≥18 years
6. Presence of by participant formulated treatment goal regarding reading

Updated 03/04/2024:
An amendment was approved on 21/03/2023 where inclusion criterium 6 was dropped for participants who wanted to participate in the control group.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
135

Total final enrolment
24

Key exclusion criteria
A subject who meets any of the following criteria will be excluded from participation in this study:
1. Additional visual field defect (at least cluster) in ipsilesional visual hemi-field
2. Pre-existing dyslexia/illiteracy/low literacy/other pre-morbid reading problems
3. No clear neurological cause of HVFD
4. 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:
5. Communication difficulties (e.g. severe hearing impairment, no fluent understanding of the Dutch language, severe aphasia as indicated by the Token test)
6. 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
7. Additional visual disturbances (e.g. diplopia, metamorphopsia, low contrast sensitivity)

Date of first enrolment
05/07/2022

Date of final enrolment
05/09/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
University of Groningen
Department of Clinical and Developmental Neuropsychology
Grote Kruisstraat 2/1
Groningen
Netherlands
9712 TS

Study participating centre
Royal Dutch Visio
Amersfoortsestraatweg 180
Huizen
Netherlands
1272 RR

Study participating centre
Bartiméus
Van Renesselaan 30a
Zeist
Netherlands
3703 AJ

Sponsor information

Organisation
University of Groningen

Sponsor details
Grote Kruisstraat 2/1
Groningen
Netherlands
9712 TS
+31 (0)50 363 9111
communicatie@rug.nl

Sponsor type
University/education

Website
https://www.rug.nl/

ROR

https://ror.org/012p63287

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
The researchers intend to publish the results of the clinical trial in 2024. This publication will also be part of a PhD dissertation by S. Tol, expected to be finished in 2024 as well.

Intention to publish date
31/08/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request by contacting Sarah Tol (s.tol@rug.nl). Participant-level data will be shared according to the FAIR principles. In cooperation with the Research Data Office of the University of Groningen, an official Data Availability Statement has yet to be made for this trial. The researchers will share this statement as soon as it has been finalized.

IPD sharing plan summary
Available on request