Reading Training in Hemianopia - Pilot study

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26239

Bron
Nationaal Trial Register

Verkorte titel
RTHp

Aandoening

Homonymous Visual Field Disorders due to Acquired Brain Injury

Ondersteuning

Primaire sponsor: Royal Dutch Visio, Bartiméus
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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• Number of participants completing the intervention and post-training assessment vs. withdrawn participants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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-09-2021
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-09-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9726
CCMO	NL76790.042.21

Resultaten