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The effects of scanning training for patients with hemianopia (visual field defects)

Submission date
13/02/2015

Recruitment status
No longer recruiting

Registration date
25/02/2015

Overall study status
Completed

Last Edited
08/03/2023

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
The largest group of visual disorders after acquired brain injury are homonymous visual field defects (HVFDs). HVFDs cause the patient to lose their left or right hand field of vision. It can affect only one eye, but it usually affects both. It has been estimated that 20-30% of all patients with stroke have HVFDs and that many of these patients have mobility problems. Often unaware of what they are not able to see, they bump or walk into things and trip over objects. This has a detrimental effect on their daily mobility-related activities and such patients are often unable or afraid to walk or cycle independently. This has far-reaching, disabling repercussions on their lives and participation in society. However, when patients become aware of their deficits and learn to apply a new scanning strategy in order to compensate for the visual field defect, daily life mobility may be significantly improved. In a recently published systematic review, it was found that compensatory scanning training is the most promising approach when it comes to the level of participation in society. This training teaches patients to apply large eye and head movements towards the blind hemifield (blind size of the field of vision). The patient learns to enlarge the functional field of view and to compensate for the loss of visual information that would occur if no eye movements were made. Evidence for the effects of compensatory scanning training has been found, but the training protocols that have been tested so far have differed from each other and little attention has been paid to the effects on mobility. Furthermore, only studies using within-patient repeated measures designs have been performed. The protocol that will be used in this study provides a solution for these problems. The aim of this study is to examine the effect of a compensatory scanning training treatment on people with a HVFD.

Who can participate?
Adults (aged between 18 and 75 years) with a HVFD and mobility-related difficulties due to the HVFD.

What does the study involve?
All participants are given compensatory scanning training which teaches patients to make systematic compensatory eye movements. The participants are randomly allocated into two groups, a training group and a control group. Both groups receive the same treatment, or intervention. The training group are given the training first and undergo visual tests, mobility tests and fill in a variety of questionnaires before and after the treatment. The control group has

an additional early pre- assessment while they are on the waiting list for the same treatment once the study is complete.

What are the possible benefits and risks of participating?
The effect measures are not invasive and have no adverse consequences for the participant, nor for his/her treatment at Royal Dutch Visio and there are no risks involved. When patients agree to participate in the study, the only thing they need to do is come to Groningen for the effect measurements on two or three separate days. Expenses for traveling and accommodation are provided. Patients know they can refuse or end participation in the study at any time, without any effect on their individual treatment at Royal Dutch Visio or Bartiméus.

Where is the study run from?
The interventions are provided at several regional departments of Visio or Bartiméus. The effect measurements take place at the Department of Clinical and Developmental Neuropsychology of the University of Groningen located in the University Medical Center Groningen.

When is the study starting and how long is it expected to run for?
September 2009 to May 2013

Who is funding the study?
1. Royal Dutch Visio (Netherlands)
2. The University of Groningen (Netherlands)
3. ZonMw-InZicht (Netherlands)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL31718.042.10 (registered at CCMO; www.ccmo.nl/en)

Study information

Scientific Title
The effects of scanning compensatory therapy for patients with homonymous visual field defects: a randomised controlled trial

Study objectives
It was hypothesized that this training would improve scanning and mobility related activities, while visual functions, such as visual field size, and reading performance would not be affected by the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee of the University Medical Center Groningen, 13/08/2010, ref: METc 2010/078

Study design
Intervention study with pre and post assessments; single-center trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Hemianopia, a form of homonymous visual field defects restricted to one side of the visual field (either left or right), due to acquired post-chiasmatic brain injury

Interventions
Compensatory scanning training: teaching patients to make systematic compensatory eye movements. Both groups receive the same intervention. Training group is tested before and after the intervention, control group has an additional early pre-assessment while they are on the waiting list for the same intervention.

Intervention Type
Behavioural

Primary outcome measure
Scanning strategy based on eye tracking (fixation and saccade parameters) on a dot counting task. Measured on all time points (i.e. early pre-assessment in control group, pre-assessment, post assessment)

Secondary outcome measures
1. Visual functions:
1.1. Visual field, with Goldmann (2x monocular)
1.2. Visual acuity, with ETDRS 2000 letter chart at 500 lux
1.3. Contrast sensitivity, with Gecko at 500 lux
2. Questionnaires (see also F1.Questionnaires):
2.1. Awareness; based on theories on awareness by Crosson and Critchley and piloted in a group of patients with hemianopia.
2.2. Life events; questions based on the Life Events Questionnaire (LEQ).
2.3. Motivation; questions selected from Motivation for Traumatic Brain Injury Rehabilitation Questionnaire (MOT-Q). - only measured before onset of intervention.
2.4. Expectations (before intervention) /Evaluation (after intervention) of training; questions based on interviews from previous master thesis research at UMCG Beatrixoord.
2.5. NEI-VFQ25 (National Eye Institute - Visual Functioning Questionnaire/25 items, Dutch translation)
2.6. VOM (Vragenlijst Onafhankelijke Mobiliteit, Dutch translation of the Independent Mobility Questionnaire)
2.7. CVD (Cerebrale Visuele Stoornissen, Dutch translation by M. L. M. Tant, 1997)
3. Neuropsychological testing:
3.1. Grey Scales
3.2. NLV (Nederlandse Leestest voor Volwassenen) - only on first measurement
3.3. Zoo-map (BADS)) - only on first measurement
3.4. 15-Words Test) - only on first measurement
4. (Ecological) scanning and mobility tests:
4.1. Dot Counting Task (with eye tracking); dots are presented on a large screen and are to be counted by the patients.
4.2. Standardized search task (with eye tracking); search task on a large screen; patients have to indicate whether or not a target is present among distractors.
4.3. Hazard perception pictures (with eye tracking); photos of traffic situations; patients have to indicate what action they would perform in the given situations: brake, release gas pedal or do nothing.

4.4. Tracking Task; test in which the patient tries to keep an imaginary car on the road in the presence of cross wind using a steering wheel (road is depicted on a central monitor) while simultaneously reacting on stimuli in the left and right periphery.
4.5. Rides in a driving simulator
4.6. Mobility test; walking through a corridor, with and without obstacles and with and without a cognitive dual task (digit span).
5. Test for cross validation:
5.1. Reading test

Overall study start date
01/09/2009

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Homonymous visual field defects (quadrantanopia at minimum, three quarters affected at maximum, based on binocular Goldmann perimetry, isopters: V-4e, III-4e, I-4e, I-2e and I-1e, monocular Goldmann III-4e, and monocular Humphrey monocular 10-2), due to acquired post-chiasmatic brain injury.
2. At least six months between onset of HVFD and first effect measurement
3. Neurological condition is stable
4. Ophthalmological condition stable for at least six months
5. Age between 18 and 75 years
6. Self-reported mobility-related difficulties
7. Able to walk at least 50 meters independently or by using a cane/rollator, without a wheelchair (mobility assessment has to be possible, training is aimed at mobility in and around the house).
8. Best corrected binocular visual acuity 0.5 (Lighthouse ETDRS 2000 chart, 4m, 500 lux, using optimal correction).
9. Peak log contrast sensitivity within normal limits (Vistech VCTS6500, 4m, 500 lux, >B5 or C4)
10. Eye and head mobility undisturbed in all directions
11. MMSE score >25
12. Sufficient memory for remembering training instructions and homework assessments (based on 8WT)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

90 (45 in each group)

Key exclusion criteria
1. Only one functional eye
2. Unclear neurological cause of HVFD
3. Hemiplegia or quadraplegia
4. Psychiatric disorders influencing participation, mobility and compliance with training
5. Misuse of drugs/alcohol/medication
6. Severe hearing impairment; hearing aids allowed, verbal communication has to be possible.
7. Problems with balance or orientation impairing mobility
8. Visual field defect in 'intact' hemi-field not connected to the main visual field defect
9. Diplopia
10. Metamorphosis expected to influence scanning training (Amsler test)
11. Oscillopsia
12. Impairments in understanding (spoken) language (based on observation)
13. Severe agnosia (based on VOSP) that strongly influences the mobility problem, such as simultanagnosia
14. Severe impairments of executive functioning requiring an adapted training protocol
15. Severe unilateral neglect (based on Balloons, drawings, line bisection and Complex Rey Figure).
16. Severe memory disorders requiring an adapted training protocol
17. Strong deviance on Trailmaking, VOSP, and Balloons not explained by hemianopia
18. Strong deviance on drawings and Complex Rey Figure not explained by hemianopia
19. Optic ataxia
20. Sticky fixation (oculomotor apraxia)

Date of first enrolment
01/01/2010

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Royal Dutch Visio
Netherlands
-

Study participating centre
Bartiméus
Netherlands
-

Study participating centre
University of Groningen
Department of Clinical and Developmental Neuropsychology,
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Sponsor information

Organisation
University of Groningen

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Sponsor type
University/education

Website
www.rug.nl

ROR
https://ror.org/012p63287

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw-InZicht)

Funder Name
Royal Dutch Visio (Netherlands)

Funder Name
The University of Groningen (Netherlands)

Results and Publications

Publication and dissemination plan
We intend to publish the results of our clinical trial in 2015. This publication will also be part of a PhD dissertation by G.A. de Haan, expected to be finished in 2015 as well.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/08/2015		Yes	No
Dataset		14/08/2015	08/03/2023	No	No
Protocol (other)		14/08/2015	08/03/2023	No	No