




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

<b>Submission date</b> 13/02/2015	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
		 Protocol added
<b>Registration date</b> 25/02/2015	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 08/03/2023	<b>Condition category</b> Eye Diseases	 Raw data added
		 Study completed

## Plain English Summary

### 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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## Contact information

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

NL31718.042.10 (registered at CCMO; [www.ccmo.nl/en](http://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 hypothesis

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

#### Condition

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

### **Overall study end date**

31/05/2013

## **Eligibility**

### **Participant 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)

**Participant 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)

**Recruitment start date**

01/01/2010

**Recruitment end date**

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,  
University Medical Center Groningen  
Hanzeplein 1  
Groningen  
Netherlands  
9700 RB

## **Sponsor information**

### **Organisation**

University of Groningen

### **Sponsor details**

Grote Kruisstraat 1/2  
Groningen  
Netherlands  
9712 TS

### **Sponsor type**

University/education

### **Website**

[www.rug.nl](http://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?
<a href="#">Results article</a>	results	14/08/2015		Yes	No
<a href="#">Dataset</a>		14/08/2015	08/03/2023	No	No
<a href="#">Protocol (other)</a>		14/08/2015	08/03/2023	No	No