Scanning behaviour in hemianopia: The Next Step

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Knowledge about which scanning behaviour is optimal, however, is mostly based on experiences and assumptions of professionals, and not supported by scientific literature and empirical data. Innovative techniques such as eye-tracking and Virtual...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders of the eye
Study type	Observational non invasive

Summary

ID

NL-OMON52952

Source
ToetsingOnline

Brief title
The Next Step

Condition

- Neurological disorders of the eye

Synonym
Partial cortical blindness, partial visual field defect

Research involving
Human

Sponsors and support

Primary sponsor: Clinical and developmental neuropsychology
Source(s) of monetary or material Support: Stichting NOVUM en ZonMw.

Intervention

Keyword: Activity situations, eye-tracking, Hemianopia, Rehabilitation, Scanning behavior

Outcome measures

Primary outcome

Eye movement parameters: fixations (location, duration) and saccades

(direction, amplitude) and task performance (e.g. number of errors, reaction

time) during mobility and search tasks.

Secondary outcome

Neuropsychological paramters, visual parameters, and outcomes of three

questionnaires and semi-structured interviews to evaluate VR + eye-tracking.

Study description

Background summary

The largest group of visual disorders after acquired brain injury are homonymous visual field defects (HVFDs), which refers to visual field deficits similar for both eyes and contralateral to the brain damage. Homonymous Hemianopia (HH), in which the left of right half of the visual field is not perceived, is the most common form of HVFD and occurs in 8-31% of all stroke patients. HH can have a large influence on daily living, quality of life and patient*s participation in society. People with HH mainly experience difficulties in reading, orientation and mobility and they benefit from training aimed to decrease the impact of the visual field deficit through optimizing visual scanning. Therefore, it is of utmost importance to inform patients about how their scanning behaviour relates to difficulties they experience in daily life and how they can improve their scanning behaviour to improve these difficulties.

Study objective

Knowledge about which scanning behaviour is optimal, however, is mostly based on experiences and assumptions of professionals, and not supported by scientific literature and empirical data. Innovative techniques such as eye-tracking and Virtual Reality allow us to examine scanning behaviour in a

more standardized manner. In the current project, existing prototypes using these techniques are being developed into measures that can be used in clinical practice.
Objective: The aim of this project is to use innovative techniques (i.e. eye-tracking and Virtual Reality) to examine the relationship between scanning behaviour and various behaviours (mobility, searching, reading) in patients with hemianopia, healthy people and healthy people with simulated hemianopia. This knowlegde can help to improve the rehabilitation for patients with hemianopia.

Study design

Cross-sectional

Study burden and risks

The effect measures do not include invasive testing. The effect measures have no adverse consequences for the participant, nor for his/her training at Royal Dutch Visio and there are no risks involved. Participants will be assessed using Virtual Reality (VR) and review studies conclude that VR is a safe rehabilitation training tool, and that studies do not report significant adverse effects. The assessments can require a certain level of concentration from which a participant can recover after a short break. The risks of the study and the burden on the participants are therefore negligible. Participants know they can refuse or end participation in the study at any time, without any effect on their individual training at Royal Dutch Visio. Traveling expenses will be reimbursed.

Contacts

Public
Selecteer

Grote kruisstraat 2/1
Groningen 9712 TS
NL
Scientific
Selecteer

Grote kruisstraat 2/1
Groningen 9712 TS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For patients participating in the test sessions:
- Homonymous visual field defect (at least a quadrantanopia, either right-sided or left-sided) due to acquired post-chiasmatic brain injury (based on binocular perimetry)
- At least three months between onset HVFD and the first measurement.
-Written consent including permission to obtain data from the patient file at Visio.

For all subjects participating in the test sessions:
- Age >=18 years.
- Able to walk at least 50 meters independently or by using a cane/rollator, without a wheelchair (mobility assessment has to be possible).
- Binocular visual acuity 0.5 or higher using current correction.
- Eye and head mobility undisturbed in all directions.
- MMSE score >= 24.

The inclusion criteria to participate in the training sessions for patients with HH are:
Age >= 18 years
Homonymous visual field defect.

Exclusion criteria

In the test sessions: a participant meeting any of the following criteria will be excluded from the study:
- An additional visual field defect in the ipsilesional visual hemi-field.

- Additional visual disturbances (e.g. impaired contrast sensitivity, diplopia, oscillopsia, metamorphopsia).
- No clear neurological cause of HVFD.
- An indication of severe higher order visual perception disorders, such as visual agnosia, severe unilateral neglect, or Bálint*s Syndrome.
- Severe psychiatric, cognitive or visual perception disorders.
- Misuse of drugs/alcohol/medication.
- Severe hearing impairment: hearing aids allowed (verbal communication should be possible).
- Problems with balance or orientation impairing mobility.
- Impairments in understanding or communicating Dutch (spoken) language.

There are no exclusion criteria for patients with HH participating in the training sessions.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2021
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO

Date:	12-08-2021

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-05-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-12-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL72491.042.20