Control of attention by the motor system: an explorative intervention study in neglect patients

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48849

Source ToetsingOnline

Brief title Control of attention by the motor system

Condition

• Other condition

Synonym lateralized attentional deficit, visuospatial neglect

Health condition

beroerte

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht **Source(s) of monetary or material Support:** NWO

Intervention

Keyword: attention, eye movements, intervention, neglect

Outcome measures

Primary outcome

1) The difference scores (post training - baseline) for the shape cancellation task and line bisection task. Per neuropsychological task, scores will be obtained that will indicate severity of neglect.

- Shape cancelation task: the number of omissions (contralesional, ipsilesional side), number of perseverations, start position and the time used to finalise the task will be computed.

- Line bisection task: the deviation from the center (mm), endpoint weightings bias and endpoints weightings sum will be computed (McIntosh et al. 2005).

2) The difference score (post training - baseline) on the visual discrimination task. Performance (% correct responses) will be calculated per hemifield.

3) The difference score (post training - baseline) regarding the observations as measured with the Catherine Bergego scale. The Catherine Bergego Scale is an observation list designed to assess the presence and severity of neglect in a range of daily activities. For all primary endpoints, beneficial effects after CMT will be compared to effects after EMT. Also, all outcome measures will be compared to performance of healthy controls and non-neglect CVA patients.

Secondary outcome

1) Virtual Reality supermarket: Performance on the number of items found on the list, efficiency of finding items and eye movement characteristics (such as number of saccades, number of fixations) will be computed.

2) Performance during training: Correct responses, time needed to complete trial, number of pointing movements and eye movement characteristics (such as number of saccades, number of fixations) will be computed.

3) Eye movement characteristics (such as saccade latencies, number of fixations) during shape cancellation task and line bisection task will be computed.

4) Visual exploration task: performance on the number of elements reported and eye movement characteristics per hemifield (such as number of saccades, number of fixations) will be computed.

For all secondary endpoints, beneficial effects after CMT will be compared to effects after EMT. Also, all outcome measures will be compared to performance of healthy controls and non-neglect CVA patients.

Study description

Background summary

About 30% of all stroke patients admitted in a rehabilitation centre show unilateral visuospatial neglect (Appelros et al 2002). This disorder is characterized by the inability to respond to sensory stimuli in the affected hemispace, due to damage to the right hemisphere (Kerkhoff 2001). Visual scanning therapy, a training aimed at provoking eye movements to the affected hemifield, is often applied to attenuate neglect. Recent views on the attentional and motor system suggest new approaches to treat neglect. Congruence between different effectors of the motor system may produce a powerful bias in the motor system, which can counteract pathological biases in the attentional system. Therefore, an intervention with congruent eye and hand movements may result in greater attenuation of neglect compared to an intervention with single eye movements (as applied in visual scanning therapy).

Study objective

The current study will investigate the beneficial effects of an experimental congruent movement training (eye and hand movements), compared to a control intervention with only eye movements (visual scanning therapy). Primary objectives are changes in performance on standard neuropsychological neglect tasks, a visual discrimination task and severity of neglect in daily life activities (ADL; as measured with the Catherine Bergego Scale). Secondary objectives are to gain insight in the generalizability of potential beneficial effects of congruent/single movement training as measured with a Virtual Reality supermarket task and changes in eye movement characteristics and patterns (i.e. during the training itself, the neuropsychological tasks and a visual exploration tasks).

Study design

An explorative intervention study. Patients will be randomly assigned to one of two groups: one group of patients will receive eye movement training (control group); the other group will receive congruent eye and hand movement training (experimental group). Each patient will receive 10 sessions (\pm 30 minutes each) of training within two weeks. Performances before and after intervention will be compared. Also, performance will be compared to two other control control groups who will not receive any intervention (healthy controls, n=15 and stroke patients without neglect, n=15).

Intervention

Half of the neglect patients (n=15) will receive eye movement training (visual

scanning therapy) and the other half (n=15) will receive congruent movement training (visual scanning therapy + congruent hand movements).

Study burden and risks

The risks of this study are negligible. The burden is medium, as the patients are tested twice (before and after 10-sessions of 30mins training). This research can only be performed with this patient group and the intervention may provide direct benefits for the patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Intervention group (neglect patients):;* Clinical diagnosed symptomatic stroke (ischemic or intracerebral haemorrhagic lesion), first or

recurrent, if possible verified by Magnetic Resonance Imaging (MRI) and/or Computed Tomography

(CT) data

* Signs of neglect:

o asymmetry between the left and right side of the stimulus field in number of missed items of at

least 2 on a shape cancelation task, and/or

o a bias towards the left or right side of space on a line bisection task, and/or

o Catherine Bergego Scale score higher than 6.

* 18-85 years of age

* Sufficient ability to comprehend and to communicate, as observed during neuropsychological

assessment and/or neglect screening

* Sufficient motivation to participate in a daily rehabilitation treatment programme for two weeks.

* Written informed consent

Exclusion criteria

Patients who recovered from neglect between inclusion and start of the training (i.e. no signs of neglect anymore on all baseline measurements) will be excluded

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	25-05-2018

Enrollment:	60
Туре:	Actual

Ethics review

Approved WMO Date:	18-04-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21965 Source: NTR Title:

In other registers

Register	ID
Other	7005
ССМО	NL64626.041.18