Prism adaptation as a 2 week treatment

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The current study will focus on the effects of an intensive programme of exposure of prism adaptation (i.e. daily exposure during two weeks) and compare these to sham adaptation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON39530

Source
ToetsingOnline

Brief title
PAir: Prism Adaptation in Rehabilitation

Condition

- Structural brain disorders

Synonym
CVA, hemispatial neglect

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum De Hoogstraat
Source(s) of monetary or material Support: NWO Vernieuwingsimpuls (Veni)

Intervention

Keyword: Neglect, Prism adaptation, Short versus long-term effect, Treatment

Outcome measures

Primary outcome

The effects of prism adaptation will be measured using several neuropsychological tests: star cancellation, line bisection, landmark task, drawing/copying, describing photographs, etc. Of all these tasks measures, such as reaction times, accuracy, number of perseverations, starting point/endpoint, procedure (e.g. systematic, random, etc) will be analysed.

The second outcome measure will be differences in severity of neglect and daily impairments (as measured with the Catherine Bergego scale)

Secondary outcome

- balance board: laterale shift of centre of pressure in cm

- force plate (posture): lateral shift of centre of pressure in cm

- questionnaires: severity and frequency of neglect symptoms

Study description

Background summary

Lesions to the right temporo-parietal cortex typically result in neglect, a disorder in which patients fail to respond to information in the contralesional (mostly left) space. In severe cases, neglect patient act as if the left half of their world does not exist. For example, a patient with neglect might ignore food on the left half of their plate or fail to shave or make up the neglected side of their face. It is now widely accepted that neglect is a complex, heterogenous disorder that includes spatially lateralised deficits (e.g. attentional biases) as well as non-lateralised deficits (e.g. sustained temporal attention, temporal perception). Patients with neglect have been found to have a poorer functional outcome compared to patients without neglect, hence, rehabilitation of neglect has been the subject of many scientific studies. In lab situations, with usually small groups of neglect patients, prism adaptation appears to ameliorate the signs of neglect on a variety of (neuropsychological) tests as well as some more *natural tasks*, such as

wheelchair navigation, or posture. These beneficial effects of prism adaptation have been reported to last 2 hours up to one week after a single adaptation session, and even up to 6 weeks following repetitive adaptation.

Study objective

The current study will focus on the effects of an intensive programme of exposure of prism adaptation (i.e. daily exposure during two weeks) and compare these to sham adaptation.

Study design

Patients will be tested 6 times:
* baseline: at start of the study (T0)
* one week after starting adaptation (T1)
* two weeks after starting adaptation (T2)
* one week after ending adaptation (T3)
* two weeks after ending adaptation (T4)
* four weeks after ending adaptation (T5)
* twelve weeks after ending adaptation (T6)

During all session, neuropsychological neglect screening tests will be presented along with a balance board test. During sessions 2, 4, and 6, tests for posture and mobility will be performed and questionnaires will be filled in. Nurses, physiotherapist, and the occupation therapist will fill out questionnaires and observation scales also.

Intervention

During prism adaption, patients wear prisms that shift their vision in one direction (e.g. 10° to the right). They will initially misreach in the direction of the prismatic shift (i.e. to the right), when they intend to point directly to a target. After a few pointing movements, they quickly learn to point accurately in the direction of the target to compensate for the shift in vision. When the prisms are removed after multiple pointing trials (approximately 100), patients will misreach in the direction opposite to the prismatic shift.

Study burden and risks

Each patient will be seen 10 times during 2 weeks.
Patients will be tested 6 times:
* baseline: at start of the study (T0)
* one week after starting adaptation (T1)
* two weeks after starting adaptation (T2)
* one week after ending adaptation (T3)

* two weeks after ending adaptation (T4)
* four weeks after ending adaptation (T5)
* twelve weeks after ending adaptation (T6)

The risks of prism adaptation are negligible. Investigations of the possible effect of treatment on neglect can only be assessed in a group of hemispatial neglect 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

stroke, signs of neglect, 18-85 years of age, sufficient ability to comprehend and to communicate, as observed during speech therapy, neuropsychological assessment and/or neglect screening , sufficient motivation to participate in an intense rehabilitation treatment

programme for two weeks

Exclusion criteria

expected admission to the rehabilitation centre of less than 4 weeks

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2013
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	prism goggles
Registration:	No

Ethics review

Approved WMO Date:	06-08-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	13-01-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-11-2014
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

No registrations found.

In other registers

Register	ID
CCMO	NL38055.041.12