Navigation ability after stroke

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Primary objective: To create diagnostic and treatment tools for navigation ability in stroke patients, that can be used in clinical practice.Secondary objective: To increase knowledge about the cognitive structure and neuroanatomical correlates of...

Ethical review	Not approved
Status	Will not start
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35666

Source
ToetsingOnline

Brief title
Navigation ability after stroke

Condition

- Structural brain disorders

Synonym
brain damage, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Meerwaarde beurs

Intervention

Keyword: navigation, stroke, training, virtual reality

Outcome measures

Primary outcome

The main parameter is navigation performance. This is measured in multiple ways: self-report (questionnaire), behavioural screening session, and the pre and post training assessment. For all patients joining in the behavioural screening session available lesion location information will also be considered to analyse the link between lesion location and type of navigation impairment.

Secondary outcome

n.a.

Study description

Background summary

When one is not able to navigate properly, this can have a severe impact on one*s autonomy and psychosocial wellbeing. Approximately 25 % of stroke patients report such navigation problems. However, current standardized neuropsychological tests are insufficient to identify such navigation problems in an objective manner. The implementation of appropriate diagnostic tests and treatment could increase autonomy in such patients as well as reduce secondary psychosocial problems. The proposed study is aimed at developing a rehabilitation programme that incorporates virtual reality navigation exercises.

Study objective

Primary objective: To create diagnostic and treatment tools for navigation ability in stroke patients, that can be used in clinical practice.
Secondary objective: To increase knowledge about the cognitive structure and neuroanatomical correlates of navigation ability in humans

Study design

A large sample of stroke patients will be screened by means of a navigation questionnaire. Those who show impairment on the questionnaire and a subset of

the patients that do not show impairment will be included in a behavioural screening session. In this session, all main aspects of navigation ability will be tested with a computer task that includes virtual environments. A comparable task will also be performed in a real environment, along with some standardized neuropsychological tests. Patients who objectively show impairment in navigation ability will be included in the training program. This group of patients will be split in half and randomly assigned to the training condition or the alternative training condition. Training entails explicit instructions for and feedback on performance. During those training sessions patients will practice navigation tasks in virtual environments, presented on a regular computer. The alternative training condition serves as a control for repeated testing and the individual attention provided during training. The potential long term effects of the training will be measured by sending out the navigation questionnaire six months after participation in the training.

Study burden and risks

Participation includes filling out four questionnaires (duration approximately 30 minutes), performing a behavioural screening session, including navigation in a virtual and a real environment (approximately 2.5 hours), and enrolment in the training program. The training program includes 3 sessions of 60 minutes each. During training subjects will be placed in front of a large, regular computer screen on which a virtual environment is presented. Responses will be given verbally or with a computer keyboard and mouse. Prior to participation, explicit permission of the patient after informed consent is warranted, and participation will be voluntary and can be terminated without any consequences for the participants.

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, 18 years or older, no severe mobility problems, no history of psychiatric disorders or substance abuse, lesions are visible on a CT or MRI scan, written informed consent is provided

Exclusion criteria

not being able to communicate in Dutch, severe global aphasia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	20-01-2012
Application type:	First submission
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	NL38973.041.11