Navigation ability after stroke

Published: 30-08-2012
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Primary objective: To provide a detailed description of the prevalence and cognitive characteristics of navigation impairment in stroke patientsSecondary objectives: To increase knowledge about the neuroanatomical correlates of navigation ability...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37409

Source
ToetsingOnline

Brief title
Navigation and stroke

Condition

- Central nervous system vascular disorders

Synonym
brain damage, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: MeerWaarde subsidie

Intervention

Keyword: navigation, stroke, virtual reality

Outcome measures

Primary outcome

questionnaire scores

cognitive task battery scores

lesion location

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. A pilot study indicates that approximately 25 % of stroke patients report such navigation problems. However, little is known about the nature of these problems. It is well known that navigation consists of a number of components, such as recognition, temporal order memory, and sense of direction. However, it is not known which of these neuropsychological components are most often affected in stroke patients, what the neuroanatomical correlates of these components are, and how navigation impairment affects quality of life of stroke patients. The proposed study is aimed at providing a detailed description of the prevalence and cognitive characteristics of navigation impairment in a large sample of stroke patients.

Study objective

Primary objective: To provide a detailed description of the prevalence and cognitive characteristics of navigation impairment in stroke patients
Secondary objectives: To increase knowledge about the neuroanatomical correlates of navigation ability and about relationships between navigation ability and quality of life in stroke patients.

Study design

A large sample of stroke patients will fill out self-reported measures of navigation, quality of life, cognitive functioning, mobility, and anxiety and depression. The patients who score below the cut-off for navigation ability and

a subset of the patients who do not show navigation problems on this questionnaire will be included into a behavioural test battery. In this session, all main aspects of navigation ability will be tested with a computer task that includes virtual environments. The session also includes a similar navigation task in a real environment, along with a set of standardized neuropsychological tests.

Study burden and risks

The risks are assumed to be negligible. The burden is kept to a minimum

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 of age or older, six months or longer after stroke, living at home after rehabilitation (inpatient or outpatient) at rehabilitation centre De Hoogstraat, no severe mobility problems, ability to walk or bike outside without supervision, lesions are visible on a CT or MRI scan, written informed consent is provided

Exclusion criteria

Not being able to communicate in Dutch or severe global aphasia (exclusion if SAN score < 5), history of psychiatric disorders or substance abuse

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	30-08-2012
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-11-2012
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	NL40322.041.12