The COMPAS study: research on the experience and meaning of subjective cognitive complaints after stroke.

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(1) Evaluate whether stroke patients differ from healthy controls on the experience and the course of subjective cognitive complaints during the first two years after stroke;(2) Evaluate potential predictors for cognitive complaints during the first...

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

Summary

ID

NL-OMON34829

Source
ToetsingOnline

Brief title
COMPAS: Cognitive Complaints After Stroke

Condition

- Central nervous system vascular disorders

Synonym
stroke - cerebrovascular accident

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cognitive complaints, Stroke, Subjective

Outcome measures

Primary outcome

(1) Cognitive complaints.

(2) cognitive performances.

Secondary outcome

Quality of Life.

Study description

Background summary

The cognitive consequences of stroke can be examined either objectively or subjectively. Most of the research to date has focused on objective cognitive impairments which are assessed through neuropsychological examination. Less attention has been devoted to subjective cognitive complaints stroke patients experience in daily life. It is known from clinical practice and the few studies that have investigated this issue that many patients have cognitive complaints after their strokes. It is however unknown whether these complaints differ from those reported in the healthy population, how they develop over time, and what the significance of these cognitive complaints is. It is also not known whether there can be defined specific risk factors for the experience of cognitive complaints after stroke, how cognitive complaints relate to cognitive disturbances and whether cognitive complaints affect quality of life.

Study objective

(1) Evaluate whether stroke patients differ from healthy controls on the experience and the course of subjective cognitive complaints during the first two years after stroke;
(2) Evaluate potential predictors for cognitive complaints during the first two years after stroke;
(3) Evaluate the predictive value of subjective cognitive complaints for current and future cognitive functioning;
(4) Evaluate the effect from cognitive complaints on quality of life.

Study design

The project is a prospective follow-up study. Patients and controls will be evaluated on subjective and objective variables using questionnaires and/or neuropsychological examination on four separate occasions: 3 months (T1), 6 months (T2), 12 months (T3), and 24 months (T4) after stroke. T1, T3 and T4 consist of an interview, neuropsychological examination and questionnaires. T2 includes a couple of questionnaires only. The interview and neuropsychological examination will take place at a test setting: patients will be invited to the hospital in which they were treated for their stroke; healthy controls will be invited to the Tilburg University. The questionnaires will be given to the participants to be filled in at home.

Study burden and risks

The study consists of 4 assessments during 2 years. Three assessments include an interview and neuropsychological examination (about 2 hours per assessment) and questionnaires (about 30 minutes per assessment). One assessment includes a couple of questionnaires only (about 15 minutes). The total burden for participants is estimated to be 8 hours divided over 4 measurements in 2 years. The study is non-invasive, there are no specific risks, and participants are compensated by ¤20,- in total.
The results of the study are relevant for both clinical practice and society. Stroke is highly prevalent and due to ageing of the population, the number of stroke patients will increase in the upcoming years. It is the now the leading cause of chronic disability in adults. Stroke is also related to a reduced quality of life and high health care consumption. With the results of the study we will gain more insight into the subjective cognitive complaints of stroke patients in daily life. This will help clinicians in making a prognosis of cognitive complaints, which is important for both patients and their relatives. The results will furthermore be useful in determining and/or developing adequate treatment for cognitive complaints.

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

Clinical diagnosis of stroke (first or recurrent), ischaemic or intracerebral haemorrhagic.
Age > 18 years.
Sufficient understanding of the Dutch language.

Exclusion criteria

Clinical diagnosis of Transcient Ischemic Attack (TIA) or Subarachnoidal bleeding (SAB).
Premorbid cognitive decline as defined by a IQCODE score >3.6.
Premorbid severe psychiatric or neurological problems.
Communication problems which make neuropsychological examination and/or the use of questionnaires impossible (e.g. blindness, deafness, severe aphasia).

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):	01-03-2010
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	22-02-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-01-2011
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL31208.008.10