Early psychological intervention in stroke patients independent in activities of daily living to reduce symptoms of anxiety and depression of influence on long-term functional outcome.

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Primary: to determine whether an early psychological intervention poststroke in order to reduce symptoms of anxiety and depression, is feasible.Secondary: To evaluate if an early individual psychological intervention in patients independent in...

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

Summary

ID

NL-OMON39234

Source
ToetsingOnline

Brief title
Early intervention after stroke to reduce anxiety and depression.

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Depression, Psychological Intervention, Stroke

Outcome measures

Primary outcome

Feasibility outcome measures:

- Patient satisfaction

- Response rates, the number of drop-outs and reasons.

- Evaluation the characteristics of respondent versus non-participants.

Secondary outcome

Anxiety and depression as measured with the Hospital Anxiety and Depression

scale (HADS)

Perceived quality of life measured with the Shortform 36 (SF-36)

Fatigue with the Fatigue severity scale (FSS)

Risk factors for anxiety and depression:

Coping style Utrecht Coping List (UCL)

Illness cognitions Illness Cognition questionnaire (ICQ)

Posttraumatic stress Impact of Event Scale (IES)

Social support Social support List (SSL)

Study description

Background summary

Stroke frequently affects mood and behaviour. The negative impact of mood and adjustment disorders on recovery and reintegration has been recognized. Major improvement in stroke prognosis has been achieved by the implementation of stroke units in the hospital and increased use of thrombolysis. Therefore the proportion of patients with favorable outcome has been rising. Patients with mild stroke (hemorrhagic or ischemic, subarachnoid hemorrhages) or Transient Ischemic Attack (TIA) are expected to return to their normal pre-stroke status relatively quick and are mostly discharged directly to their home environment, often without follow-up consultation by a rehabilitation physician. These patients however, often struggle to regain their pre-morbid functional status despite little or no physical disabilities. Anxiety and depression are thought to be of influence on functional outcome in patients with mild stroke and TIA. There are only few studies regarding these subjects in the general stroke population, and even less evidence can be found in the mild stroke group.

We believe that early detection and treatment of anxiety and depression in mild stroke and TIA patients may improve functional outcome. Thereby reducing the needs for intensive and expensive rehabilitation diagnostics and treatment in a later phase when patients get stuck in their work and social life. Therefore we have developed an early individual psychological intervention aimed at reducing symptoms of anxiety and depression. This prospective cohort study in minor stroke patients is designed to examine the feasibility of such a psychological intervention in an early phase.

Study objective

Primary: to determine whether an early psychological intervention poststroke in order to reduce symptoms of anxiety and depression, is feasible.

Secondary: To evaluate if an early individual psychological intervention in patients independent in activities of daily living poststroke leads to a reduction of symptoms of anxiety and depression after 6 months poststroke.

Study design

The study is designed as a prospective cohort study.

Intervention

Four to six weeks after discharge home the patients will visit a psychologist at the department of rehabilitation. At the first visit, symptoms of anxiety

and depression will be analysed using questionnaires and also the potential risk factors for anxiety and depression will be assessed; psychiatric history, coping-strategies, the patient*s cognitions to disease processes and the amount of social support that is perceived will be assessed. The influence of possible cognitions and misconceptions to the disease and occurrence of anxiety and depression after TIA/minor stroke are examined. In the second and third visit the psychologist will educate the patient about general brain functioning and the influence of stroke; also the possible development of anxiety after stroke is discussed with patient and caregiver. Active coping strategies will be promoted and illness perceptions will be reviewed. These sessions are tailored to the patients* needs and questions. If, after 3 visits, the psychologist finds continuation of psychological support advisable, the patient will be referred for further treatment.

Study burden and risks

Burden: All patients will receive questionnaires to fill out at home and return back to the investigators. The total duration of completing the questionnaires is estimated at 1.0 to 1.5 hours. Travelling costs for the outcome assessments will be reimbursed. Questionnaires will be send back in envelopes with a freepost number.

Potential risks: No risks are associated with psychological counselling.

Potential benefits for the patients: Considering the positive effects of psychological counselling known from preliminary research it can be concluded that the benefits outweigh the burden associated with this study.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9 A01-420
Amsterdam 1100 DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9 A01-420
Amsterdam 1100 DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Consecutive patients who are admitted to the AMC hospital Amsterdam, from august 2012 tuntil december 2013 with a stroke (ischemic or hemorrhagic, subarachnoid hemorrhage) or TIA, independent in activities of daily living at the moment of discharge of the hospital (modified Rankin Scale 0-1) and discharged home without multidisciplinary rehabilitation treatment are eligible for this study.

Exclusion criteria

Age younger than 18 years old, difficulty comprehending the Dutch language, a history of anxiety disorder, major depression or psychiatric diseases.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2012
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	06-09-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL39971.018.12