ReStoRe4stroke: Longitudinal Cohort study on psychosocial functioning in stroke patients and their partners

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The objective of the present study is to investigate the course of psychosocial functioning in stroke patients and their partners, during the first 2 years post-stroke, to investigate factors predicting psychosocial functioning in stroke patients...

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

Summary

ID

NL-OMON41618

Source
ToetsingOnline

Brief title
ReStoRe4stroke

Condition

- Central nervous system vascular disorders
- Vascular haemorrhagic disorders

Synonym
Cerebrovascular Accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum De Hoogstraat
Source(s) of monetary or material Support: VSBfonds;ZonMW

Intervention

Keyword: patient and partner, personal factors, psychosocial functioning, stroke

Outcome measures

Primary outcome

The primary outcome of this study is participation of stroke patients.

Participation will be measured with the Utrecht Scale for Evaluation of

Clinical Rehabilitation - Participation (USER-P).

Secondary outcome

Secondary outcomes of this study are: quality of life, life satisfaction and

emotional functioning of stroke patients and their partners.

These outcomes will be measured with the following measurements:

-Quality of Life will be assessed by two measures. The first measure assesses

stroke health-related quality of life (short Stroke Specific QoL

Questionnaire,SS-QoL-12). The second measure assesses generic health-related

quality of life in terms of utilities (Six Dimension Euro-QoL instrument,

EQ-6D).

-Life Satisfaction will be assessed with three questions which ask for

satisfaction with life before the stroke, now and a comparison between before

and now.

-Emotional functioning will be assessed in terms of depression and anxiety

(Hospital Anxiety and Depression Scale, HADS)

Study description

Background summary

In the Netherlands between 34.000 and 41.000 persons suffer a cerebral vascular accident or stroke each year. Due to the ageing of the population the number of stroke patients will increase with 27% in the year 2020. Stroke has a high burden of disease, both for the patients as well as for their partners. After discharge from hospital, most stroke patients return to their own homes with or without rehabilitation day treatment, part of them after receiving inpatient rehabilitation treatment in rehabilitation centres or nursing homes. At home, care is mostly provided by informal caregivers, mainly spouses, leading to high levels of caregiver burden. In the long-term particularly psychosocial problems have a negative impact on social reintegration and quality of life.
Psychosocial problems after stroke, such as depression, fatigue and decreased levels of social activities of both patients and their informal caregivers are underestimated and under diagnosed in clinical practice.

Stroke outcome should be studied using an integrated approach addressing the complex interplay of functional, personal and environmental factors. Cognitive and emotional consequences have never been studied within this multidomain perspective; essential information to build a comprehensive prediction model for patients with cognitive and emotional deficits at risk of long term participation and QoL problems is currently missing. In addition, the complex interplay between objective and subjective cognitive functioning needs further investigation. A new and emerging field is the study of social cognition after brain injury. Social cognition comprises the capacities of individuals to understand the behavior of others and to react adequately in social situations. Impairments in social cognition have been associated with unfavorable outcomes in terms of return to work and social reintegration in patients with moderate to severe traumatic brain injury, but has hardly been studied in stroke patients.

Study objective

The objective of the present study is to investigate the course of psychosocial functioning in stroke patients and their partners, during the first 2 years post-stroke, to investigate factors predicting psychosocial functioning in stroke patients and their partners and to determine the associated economic implications

Therefore the following research questions will be examined:
1.What is the course of psychosocial functioning (participation, emotional functioning, life satisfaction and quality of life) in stroke patients and their partners during the first 2 years post stroke?
2.Which determinants predict the outcome of psychosocial functioning

(participation, emotional functioning, life satisfaction and quality of life) in stroke patients and their partners 1 and 2 years post stroke?
3.How do patterns of received care after stroke (health care costs, productivity costs, costs of informal care) change during the time of the follow-up period of this study and what is their impact in economic terms (cost of illness study)?
4.How are the costs of received care related to the primary (participation) and secondary outcome parameters (health-related quality of life, satisfaction and emotional functioning)?
5. What is the course of cognitive and emotional functioning from the acute phase until three-four years after stroke?
6. To what extent do stroke patients experience impairments in social cognition in the long term?
7. Are impairments in cognitive (social cognition included) and emotional functioning at three-four years after stroke related to participation and QoL in the long term?
8. What is the course of participation and QoL from two years post stroke until three-four years post stroke and which factors are related to change?

Study design

This is a multi-centre prospective cohort study, with 6 assessments.

The first assessment will take place during the first week post-stroke (during the hospital stay). The other assessments will take place at 2 months, 6 months, 1 year, 2 years and 3-4 years post-stroke.

We expect to test 250 patients at the added assessment 3-4 years post-stroke, based on the low drop-out rate so far.

Study burden and risks

During a 3 to 4 year follow-up cohort study participants (patients and their partners) will complete six assessments. For the patient the first assessment wil be part of care as usual and means therefore no effort and achievement for the patient. Only the partner of the patient has to fill in a premorbid participation questionnaire, which only will cost 5 minutes.
The second and third assessment of the patient will consist of questionnaires, a cognitive test, an interview of 10 minutes, and two observation measures. The cognition and observation measures will be filled in by a trained research assistent, who will visit the patient in the hospital, during the after care polyclinic, or where the patient is residing at that moment, such as home or in a rehabilitation center.
The fourth and fifth assessment of the patient will only consist of questionnaires. For the partner all five assessments consist only of questionnaires.

The sixth assessment of the patient consists of a neuropsychological testing battery and some questionnaires.

At assessment 2 and 3 part of the questionnaires will be sent to the patient and his/her partner. The research assistent will check if there are any questions of missing values during her visit. At the end of the visit the research assistent will give the patient and his/her partner the rest of the questionnaires. When all the questionnaires are filled in, they can be sent back to the researcher. The patient and his/her partner can fill in the questionnaires independently and at their own pace. Furthermore, the questionnaires can be filled in at different times, when it is too wearisome to fill them in at one moment.
At assessment 4 and 5 all questionnaires are sent to the patient and his/her partner. When all the questionnaires are filled in, the patient and his/her partner can send them back to the researcher. Just like assessment 2 and 3, the patient and his partner can fill in the questionnaires independently and at their own pace.
Assessment 6 consists of a neuropsychological testing battery and will preferably take place at the hospital and will take about 1 hour. When the patient is unable to visit the hospital, the research assistent will visit him/her at home. Furthermore, the questionnaires will be filled in by the patient.

There are no known risks for partcipating in this study.

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

Inclusion criteria patient:
1). Symptomatic stroke (ischemic or intracerebral haemorrhagic lesion), if possible verified by CT and/or MRI scan.
2). Age at least 18 years.
3). Written informed consent. ;inclusion criteria partner:
1). The partner must be married or live together with the patient.
2). The partner (patient) must participate in the study.

Exclusion criteria

Exclusion criteria patient:
1). Insufficient command of the Dutch language in order to participate and understand questionnaires, based on clinical judgement.
2). Pre-existent dependence in activities of daily living as defined by a pre-morbid Barthel Index below 18.
3.) pre-existent cognitive decline as defined by a score of 1 or higher on the HAC (Heteroanamnesis List Cognition).
4). Co-morbidity: A serious condition whereby an interference with the outcomes of the study is expected, (such as a psychiatric disorder whereby a person is under supervision of a psychiatrist or a serious cardiac disease), or a disease with a progressive course (such as cancer, arthritis, multiple sclerosis, dementia) or a life-threatening condition resulting in a life expectancy less than 6 months (such as a high risk of death from stroke or terminal kidney insufficiency).;Exclusion criteria partner:
1). Insufficient command of the Dutch language in order to participate and understand questionnaires, based on clinical judgement.
2). Pre-existent dependence in activities of daily living as defined by a pre-morbid Barthel Index below 18.
3). Co-morbidity: A serious condition whereby an interference with the outcomes of the study is expected, (such as a psychiatric disorder whereby a person is under supervision of a psychiatrist or a serious cardiac disease), or a disease with a progressive course (such as cancer, arthritis, multiple sclerosis, dementia) or a life-threatening condition resulting in a life

expectancy less than 6 months (such as a high risk of death from stroke or terminal kidney insufficiency).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	07-02-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	10-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-07-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL34676.100.10