SCORE: Proces en uitkomsten van revalidatie na een beroerte

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23526

Source
Nationaal Trial Register

Brief title
SCORE

Health condition

- Stroke
- Rehabilitation

Sponsors and support

Primary sponsor: Rijnlands Revalidatie Centrum, Leiden
Sophia Revalidatie, Den Haag
Leids Universitair Medisch Centrum, Leiden
Source(s) of monetary or material Support: Rijnlands Revalidatie Centrum and Sophia Revalidatie. No external funding source. Stichting Kwaliteitsgelden Medisch Specialisten

Intervention

Outcome measures

Primary outcome

Functioning

Community participation

Quality of life

Patient satisfaction

Structure of rehabilitation

Process of rehabilitation

Costs of rehabilitation

Secondary outcome

Illness perceptions

Self-management

Depression

Fatigue

Pain

Unmet Needs

Expectations and fulfilment of goals

Caregiver satisfaction

Caregiver burden

Study description

Background summary

background: Stroke leads to substantial disability in the majority of patients and imposes a considerable financial burden to society. Rehabilitation is an effective management strategy, however there is variation between centres with respect to its structure and process. Treatment diversity and outcomes, patient perspectives and costs of rehabilitative treatment are understudied, as well as the predictors of long-term participation in society. Aims: 1. To describe: a) physical and cognitive functioning, quality of life and participation of stroke patients at short and long term; b) structure and process of in- and outpatient stroke rehabilitation; c) patient perspectives on illness and treatment; d) caregiver perspectives on

caregiving and treatment; e) rehabilitation-related costs. 2) To explore differences between two rehabilitation centres in a) structure and process of treatment; b) patients' satisfaction; c) physical functioning; and d) costs of treatment; 3) To determine which factors are associated with community participation of stroke survivors on the long term.

Study design: This project has a multicentre, observational, longitudinal design, and includes stroke patients in the Rijnlands Rehabilitation Center Leiden and Sophia Rehabilitation The Hague. The duration of the study is 4.5 years, with the inclusion period being 2 years. Study population: Patients admitted to inpatient or outpatient rehabilitation for a first ever stroke, time since stroke not longer than 6 months, age 18 years or older, and having provided written informed consent. We aim to include a minimum of 432 patients within the initial recruitment period. Main study parameters: Assessments will be done at baseline, discharge (if applicable) and at 3, 6, 12, 18, 24 and 30 months. The following outcomes will be assessed: 1) Functioning (Barthel Index, 2 SIS-scales); community participation (CIQ), quality of life (SAQOL-39g, EQ-5D), depression (HADS), fatigue (FSS), pain (VAS); 2) Structure (rehabilitation center's protocols), and process (e.g. type, frequency, duration of treatment) of rehabilitation (rehabilitation center's administrative database); 3) patients' satisfaction with stroke care (SASC), illness perceptions (IPQ-R), longer term unmet needs (LUNS), self-management (TBD); 4) caregiver strain (CSI) and caregiver satisfaction (C-SASC); 5) Costs of rehabilitation (rehabilitation center's administrative database), health care usage and absenteeism (self-developed questionnaires). At baseline, sociodemographic characteristics, stroke characteristics (NIHSS), comorbidities (based on POLS), and frailty (GFI) will be registered.

Study objective

1. Differences in usual care between rehabilitation centers lead to differences in functioning, patient satisfaction and costs

2. Community participation depends on various person- and disease-related variables.

Study design

Baseline (upon entrance at rehabilitation as an in- or outpatient), discharge (if applicable), and 3, 6, 12, 18, 24, and 30 months after baseline.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

-First ever stroke

-Time since stroke < 6 months

-Age 18 years or older

-Written informed consent

Exclusion criteria

- Severe psychiatric condition or premorbid dementia

- Impossible to communicatie in the Dutch language

- Concurrent acquired brain injury (traumatic or non-traumatic) or pre-existent brain disease that was diagnosed before the onset of stroke.

- Drug or alcohol abuse

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	432
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4147
NTR-old	NTR4293
Other	: ABR46531
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A