

SCORE: Stroke Cohort Outcome REhabilitation

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1. To comprehensively describe: a) the functions, activities, participation, and quality of life of stroke survivors on the short and long term; b) the structure and process of in- and outpatient stroke rehabilitation; c) the stroke patients*...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON54660

Source

ToetsingOnline

Brief title

SCORE

Condition

- Other condition
- Neurological disorders NEC

Synonym

cerebrovascular accident, stroke

Health condition

CVA

Research involving

Human

Sponsors and support

Primary sponsor: Basalt

Source(s) of monetary or material Support: Eigen budget revalidatiecentra

Intervention

Keyword: Cohort study, Community participation, Rehabilitation, Stroke

Outcome measures

Primary outcome

- Functioning (Barthel Index, USER, SIS), activities and participation (CIQ, USER-P, IPAQ, accelerometry) quality of life (SAQOL-39g, EQ-5D, SF12).
- Patients* perspective: treatment goals and fulfilment of goals (COPM), satisfaction with stroke care (SASC-19), longer term unmet needs (LUNS), illness perceptions (IPQ-R), coping (COPE-easy), expectations of treatment (interviews), self management (PAM-13). Caregiver's perspective: satisfaction with care (C-SASC), health (RAND36) and caregiver*s strain (CSI).
- Structure ('outline' of treatment) and process (i.e. types, frequency and content of therapies) of rehabilitation in various centers.
- Costs: rehabilitation costs, health care usage, out of pocket costs, absenteeism-related costs.

At the 100 months follow-up a new set of questionnaires will be used to assess long term health status (in particular complications, participation, lifestyle) and health care usage (in particular medication and walking aids).

Secondary outcome

NA

Study description

Background summary

Stroke is a relatively common condition, leading to substantial physical and cognitive disability in the majority of patients and imposing 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. Patient perspectives and costs of rehabilitative treatment are understudied, as well as physical activity, selfmanagement and (the predictors of) long-term participation in society.

Study objective

1. To comprehensively describe: a) the functions, activities, participation, and quality of life of stroke survivors on the short and long term; b) the structure and process of in- and outpatient stroke rehabilitation; c) the stroke patients* satisfaction with treatment, fulfilment of goals, illness perceptions, coping, longer term unmet needs; d) caregivers* strain and health and satisfaction with treatment; and e) stroke-related costs for rehabilitation, health care, and society.

2: To explore differences between two rehabilitation centres in a) structure and process of treatment; b) patients* satisfaction, c) fulfilment of goals; and d) costs of treatment.

3: To determine which factors are associated with community participation of stroke survivors on the long term.

4: To determine long-term health status (in particular complications, participation, lifestyle) and health care usage (in particular medication and walking aids) and healthcare needs.

Study design

This project has a multicentre, prospective, observational cohort design and includes all consecutive in- and outpatients admitted for a stroke in the Rijnlands Rehabilitation Center Leiden or Alphen a/d Rijn and Sophia Rehabilitation The Hague, Delft or Zoetermeer. The duration of the study is 7 years in total, with the inclusion period being 4.5 years and the duration of follow-up being 2.5 years. Questionnaires will be filled in at baseline, discharge (if applicable) and 3, 6, 12, 18, 24 and 30 months after baseline. An additional long-term follow-up questionnaire will be sent >4 years.

Study burden and risks

This study is observational in nature with all patients receiving standard treatment. Assessments mainly consist of questionnaires. There will be no extra visits to the rehabilitation center for the patients. The study will not impose any risks to the patients.

The questionnaire of the amendment dd. 05-22 takes 10-20 minutes to complete.

Contacts

Public

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NL

Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Time since stroke < 6 months
- Age 18 years or older

-Written informed consent

Exclusion criteria

- Severe psychiatric condition or premorbid dementia
- Impossible to communicate in the Dutch language
- Drug or alcohol abuse

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-03-2014

Enrollment: 836

Type: Actual

Ethics review

Approved WMO

Date: 17-02-2014

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 17-07-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 16-11-2016
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 27-03-2017
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 11-12-2020
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 27-05-2022
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 21-08-2023
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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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	NL46531.058.13

Study results

Date completed:	31-01-2024
Actual enrolment:	836