Stroke Cohort Outcomes of Rehabilitation 2.1

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24488

Source
NTR

Brief title
SCORE 2.1

Health condition

Stroke

Sponsors and support

Primary sponsor: Basalt
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Main endpoint of this study are the responsiveness and the interpretability of the PROMIS-10 Global Health and the smRSq in stroke patients receiving rehabilitation. We will use the Standard Set for Stroke based on the recommendation by ICHOM [8] extended with several anchor questions.

Secondary outcome

Secondary endpoints of this study are the correlations between the PROMIS-10 Global Health and the smRSq -as proposed by the ICHOM- and the BI [13], the SIS hand [14], PROMIS cognition, PROMIS participation and questions concerning paid work. Furthermore, the SIS cognition and PROMIS cognition will be compared.

Study description

Background summary

Rationale: Stroke is a common disorder leading to substantial disability in many patients. This also leads to a considerable financial burden to society. Rehabilitation in an inpatient or outpatient rehabilitation centre is an effective strategy to improve outcomes of patients with stroke. According to the principles of Value-Based Health Care (VBHC) patient centeredness, multidisciplinary care pathways and routine outcome measurements, including health outcomes and costs, are needed to optimize the quality of rehabilitation.
The Stroke Cohort Outcomes of REhabilitation (SCORE) study, executed from March 2014-December 2019, included 839 patients in total, and provided insight into the structure, process and outcomes of stroke rehabilitation. It was found that patients were satisfied with care, and improvements of Barthel Index (BI), general health and quality of life (EuroQol-5Dimentions), psychiatric functioning (Hospital Anxiety and Depression Scale, HADS), motor functioning (Stroke Impact Scale (SIS) mobility) and communication (SIS communication) were seen between start of the rehabilitation and 12 months, for both inpatients and outpatients. Costs of healthcare usage, out of pocket costs, informal care, paid home care and productivity loss from the start of the rehabilitation up to one year later were substantial, namely €56.269 for inpatients and €21.896 for outpatients. Two years after the start of the rehabilitation 59% of the stroke patients aged < 66 years who had paid work before stroke were in paid work, although a quarter of them were on (extended) sick leave. The cohort that has been created is unique with regard to its size and the nature and extent of data that were gathered. A continuation of the study is therefore warranted. However, the SCORE study made it clear that some of the outcome measures used were more responsive than others. Moreover, during the study new outcome measures for stroke were proposed by the International Consortium for Health Outcomes Measurement (ICHOM). In addition, potential bias could have influenced our results: the response rate was only 60% and there was a loss to follow-up of up to 40% at 30 months. Patients experienced that the amount of questionnaires was too extensive.
For this reason, a sequel to the SCORE study is proposed: SCORE 2.1. Score 2.1 is designed to streamline outcome measures with those of a recommended Standard Set for Stroke of the ICHOM and compares these with the measurements that have previously shown a good response. The number of measurement moments and number of questionnaire has been reduced, so that response and lost-to-follow-up rates are likely to improve; and therefore generate a more unbiased sample. Outcomes of this study can be used to get insight into their potential to measure rehabilitation outcomes.

Objective: To comprehensively describe the short-term and long-term outcomes (health status and satisfaction) and costs of stroke rehabilitation. In particular to determine 1) whether or not the standard set for stroke of the ICHOM can be used to measure rehabilitation outcomes in stroke patients (e.g. are these questionnaires responsive and determine the responsiveness and the interpretability); 2) whether or not this standard set is more sensitive in measuring these outcomes than traditionally used questionnaires such as the BI and the SIS
Study design: This study has an observational, longitudinal design.
Study population: All consecutive patients aged ≥18 years, admitted for inpatient and/or outpatient rehabilitation due to first ever or recurrent stroke in Basalt Rehabilitation and having provided written informed consent.
Intervention (if applicable): Not applicable.
Main study parameters/endpoints: Main endpoints of this study are measures of health status, the Patient Reported Outcomes Measurement Information System-10 (PROMIS-10) Global Health and the Simplified Modified Rankin Scale Questionnaire (smRSq). These two questionnaires are part of the Standard Set for Stroke of the ICHOM. Secondary endpoints are the BI and the SIS hand function. Moreover, a number of key measurements similar to those used in the SCORE study are administered, so that data from the SCORE and SCORE 2.1 study can be combined.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: This study is observational in nature with all patients receiving standard treatment. Assessments are not associated with any risks for the patients.

Study objective

Our hypothesis is that the ICHOM standard set of stroke is less informative than the current stroke measurements that are used

Study design

Start of rehabilitation, end of inpatient rehabilitation, end of outpatient rehabilitation, 90days, 12months, 24months

Contacts

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Eligibility criteria

Inclusion criteria

• First ever or recurrent stroke (ischemic, haemorrhagic including subarachnoidal hemorrhage)
• Age ≥18 years
• Written informed consent

Exclusion criteria

• Inability to communicate in the Dutch language, due to severe aphasia or insufficient knowledge of the Dutch language.
• Inability to complete questionnaires reliably due to cognitive deficits or insufficient illness awareness.

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):	01-07-2021
Enrollment:	351
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	21-05-2021
Application type:	First submission

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	NL9509
Other	METC Leiden-the Hague-Delft : N21.070

Study results