Stroke Cohort Outcomes of Rehabilitation 2.1

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24488

Bron
NTR

Verkorte titel
SCORE 2.1

Aandoening

Stroke

Ondersteuning

Primaire sponsor: Basalt
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Contactpersonen

Publiek

Basalt
Daniella Oosterveer

0715195195

Wetenschappelijk

Basalt
Daniella Oosterveer

0715195195

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2021
Aantal proefpersonen:	351
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	21-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9509
Ander register	METC Leiden-the Hague-Delft : N21.070

Resultaten