Does a patient-based version of the Constant-Murley score produce similar and reliable results, as compared to the original clinician-based Constant-Murley score?

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To evaluate the validity, reproducibility and scale functioning of the Dutch clinician-based Constant-Murley (CM) score and of a Dutch patient-derived Constant-Murley score in patients with shoulder arthroplasty. To define the smallest detectable...

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28025

Bron NTR

Verkorte titel CMS

Aandoening

Shoulder arthroplasty Shoulder prosthesis Total shoulder Totale schouder Schouder arthroplastiek Schouder prothese

Ondersteuning

Primaire sponsor: Department of Orthopaedic Surgery, Reinier de Graaf Hospital, Delft, the

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters are:

•Validity of both CM scores

oConstruct validity of both CM scores

•Reproducibility of both CM scores

oExact agreement on ordinal item scores of both CM scores between T0 and T1

oSEM for continuous item scores and total composite score of both CM scores between T0 and T1

oExact and adjacent agreement between both CM ordinal item scores at T0 and T2

oSEM for continuous item scores and total composite score between both CM scores at T0 and T2

IRT analysis

oDiscrimination a and threshold b parameters of each item (+ ICC) and answer category (+ CRC) in both CM scores at T0 and T2

oIIF for each item in both CM scores

oSIF for both CM scores

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY

Rationale: The Constant-Murley (CM) score is one of the most commonly used scoring systems for shoulder arthroplasty, combining assessment by the clinician (range of movement (ROM) and strength) and by the patient (pain and activities of daily living (ADL)).

A patient-based CM score was developed in the United Kingdom (UK) and tested for its reliability in a population of patients with mixed diagnoses, not including shoulder arthroplasty.

However, both scores have not been evaluated in a Dutch setting and there are varied reports regarding the reliability of the CM score, justifying further analysis alongside translation and validation of both scores in Dutch. Rating scale analysis with item response theory (IRT) modeling can evaluate the performance of items and overall scores more

thoroughly.

Objective: To assess the validity, reproducibility and performance of the clinician-based and patient-based CM scores, and to determine the smallest detectable change (SDC) and minimal clinically important difference (MCID) of both CM scores in a population of patients undergoing shoulder arthroplasty.

Study design: Clinimetric study

Study population: Patients scheduled to undergo shoulder arthroplasty, aged 18 years and older.

Main study parameters/endpoints: The main study parameters are the construct validity, reproducibility (exact and adjacent agreement for ordinal scores, standard error of measurement (SEM) and smallest detectable change (SDC) for continuous scores) and performance of the separate items and overall scores assessed with IRT modeling.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: We expect no risks associated with participation, due to the nature of the study (filling out questionnaires and undergoing physical assessment in the same manner as routine care). The extra burden placed on patients will consist of two extra visits to the orthopaedic surgeon (T1 and T2) for administration of the clinician-based score, completing four extra questionnaires at baseline, completing two questionnaires at T1 and completing seven questionnaires at T2.

The MEC declared that ethical approval for this study is not necessary.

Doel van het onderzoek

To evaluate the validity, reproducibility and scale functioning of the Dutch clinician-based Constant-Murley (CM) score and of a Dutch patient-derived Constant-Murley score in patients with shoulder arthroplasty.

To define the smallest detectable change (SDC) and minimal important change (MIC) of both the clinician-derived and patient-derived CM score in patients with shoulder arthroplasty

Onderzoeksopzet

- T0: within 6 months pre-operatively
- T1: 2 weeks after T0
- T2: 6 months post-operatively

The treating orthopaedic surgeon will perform the clinician-based CM score during a clinic visit. All other questionnaires will be completed by the patients, either on paper or digital (according to patient preference)

Onderzoeksproduct en/of interventie

T0: clinician-based CM score, patient-based CM score, Oxford Shoulder Score (OSS), Simple Shoulder Test (SST), Numeric Rating Scale (NRS), EuroQoL-5D (EQ-5D)

T1: clinician-based CM score, patient-based CM score, anchorquestion

T2: clinician-based CM score, patient-based CM score, Oxford Shoulder Score (OSS), Simple Shoulder Test (SST), Numeric Rating Scale (NRS), EuroQoL-5D (EQ-5D), anchorquestion

Contactpersonen

Publiek

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Wetenschappelijk

Reinier Haga Orthopedisch Centrum Brechtje Hesseling Delft 2625 AD The Netherlands +31792065595

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age 18 years or older

Scheduled to undergo shoulder arthroplasty

Able to speak and write Dutch

Willing to participate

Able to provide written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Cognitive impairment

Difficulty with the Dutch language

Onderzoeksopzet

Opzet

Туре:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	26-09-2016
Aantal proefpersonen:	125
Туре:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

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 NTR-new NTR-old Ander register ID NL5900 NTR6088 MEC ZWH : 16-084

Resultaten