Which questionnaire outcome of two different perspectives is most comparable with the self-completed questionnaire outcome when assessing the quality of life in orthopedic patients.

Gepubliceerd: 29-08-2018 Laatst bijgewerkt: 13-12-2022

The proxy-patient perspective outcome has a higher level of agreement with the outcome of the self-completed EQ-5D-5L, compared with the proxy-proxy perspective outcome in mentally healthy patients.

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

Samenvatting

ID

NL-OMON21275

Bron
Nationaal Trial Register

Aandoening

EQ-5D-5L, EQ-5D, Orthopedic, Quality of life, proxy, self-completed, PROM, patient reported outcome measure, agreement

Ondersteuning

Primaire sponsor: OLVG
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the level of agreement for domain scores weighted kappa, and the interclass correlation coefficient (ICC) for the overall health state visual analogue scale (VAS) and utility scores.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: There are two by proxy versions of the EQ-5D-5L questionnaire if the patient is not able to self complete the questionnaire. Currently there is no conclusive evidence which of these two by proxy versions reflects the self-completed EQ-5D-5L most accurately.

Objective: To compare the self-completed EQ-5D-5L questionnaire and its proxy versions in a population of adult orthopaedic patients at the outpatient clinic.

Study design: A randomised monocenter agreement study.

Study population: All orthopaedic patients of 18 years of older with no signs of cognitive impairment based on the judgement of the clinician, who are visiting the outpatient clinic with a relative.

Agreement study: The outcomes of the proxy-proxy and the proxy-patient version of the EQ-5D-5L questionnaire will be compared with the self-completed EQ-5D-5L questionnaire to estimate which by proxy version is superior.

Main study parameters/endpoints: The level of agreement between the outcomes of the self-completed EQ-5D-5L questionnaire and its proxy versions.

Doel van het onderzoek

The proxy-patient perspective outcome has a higher level of agreement with the outcome of the self-completed EQ-5D-5L, compared with the proxy-proxy perspective outcome in mentally healthy patients.

Onderzoeksopzet

The EQ-5D-5L questionnaire will be assessed at the Orthopaedic outpatient clinic. The patient and proxy giver should independently complete the questionnaire, without helping each other.

Onderzoeksproduct en/of interventie

The EQ-5D-5L is a generic HRQoL measurement tool where respondents choose 1 of 5 descriptors in 5 domains of their health (mobility, personal care, usual activities, pain/discomfort, and anxiety/depression) followed by a Visual Analogue Scale (VAS) of their overall current health state.

Patients allocated to the proxy-proxy group A will receive the proxy A version of the EQ-5D-5L: The proxy giver is asked to rate the patient¡¯s health-related quality of life in their (the proxy¡¯s) opinion.

Patients allocated to the proxy-patient group B will receive the proxy B version of the EQ-5D-5L: The proxy giver is asked to rate how he/she (the proxy) thinks the patient would rate his/her own health-related quality of life if the patient were able to communicate it.

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years or older at time of visiting the orthopaedic outpatient clinic

- Compos mentis

- Dutch fluency and literacy

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Signs of cognitive impairment

- Patients visiting the outpatient clinic without a relative / friend

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-08-2018
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	NL7310
NTR-old	NTR7526
Ander register	: WO 18.059

Resultaten