

# 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.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON21275

### Source

NTR

### Health condition

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

## Sponsors and support

**Primary sponsor:** OLVG

**Source(s) of monetary or material Support:** none

## Intervention

## Outcome measures

### Primary outcome

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.

## Study description

### Background summary

**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.

### Study objective

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.

### Study design

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.

### Intervention

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.

## Contacts

**Public**

**Scientific**

## Eligibility criteria

### Inclusion criteria

- 18 years or older at time of visiting the orthopaedic outpatient clinic
- Compos mentis
- Dutch fluency and literacy

### Exclusion criteria

- Signs of cognitive impairment
- Patients visiting the outpatient clinic without a relative / friend

## Study design

## Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2018
Enrollment:	120
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	29-08-2018
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	NL7310

**Register**

NTR-old

Other

**ID**

NTR7526

: WO 18.059

## Study results