

A cross-sectional study on the determinants of lack of scope: adding positive factors

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30263

Source

ToetsingOnline

Brief title

Quality of life and health state valuations of patients with RA

Condition

- Joint disorders

Synonym

Rheumatoide Artritis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: VIDI-award voor dr.ir. A.M. Stiggelbout

Intervention

Keyword: health state valuations, positive factors, quality of life, Rheumatoid Arthritis

Outcome measures

Primary outcome

health state valuations;

differences in valuation of own health state, hypothetical health states and

personally described health

Secondary outcome

positive factors, such as psychological well being, happiness, self esteem,

mastery and self-efficacy.

Study description

Background summary

In health care decision-making, valuations of health outcomes, so-called health state utilities, play an important role. Utilities are used at various levels of decision-making, and depending on the level they should be assessed either from the general public or from patients. Differences in valuations of health states have been seen between the general public and patients, and between patients anticipating health states and patients experiencing those states. Our research project aims to explain this difference in health state valuations.

Study objective

In this study, we study whether there is a difference between the utilities that patients with Rheumatoid Arthritis assign to their own health and those that they assign to the EQ-5D scenario describing that health (lack of scope). Further, we aim to find out whether this difference is explained by positive factors not incorporated in the scenario (psychological well-being, meaning in life, happiness).

Study design

A sample of 300 patients with Rheumatoid Arthritis will be selected from all

patients who in the last 18 months have been treated at the department of Rheumatology of LUMC. These patients will receive a letter from the head of the out patients clinic to inform them about this study. A patient information leaflet, an informed consent form and an answer envelope will be included. The patients will be interviewed about the following topics: the valuation of their health state, quality of life, the valuation of six hypothetical health states, and aspects of life that they said they incorporated when valuing their own health status. After the interview, the patient will receive a written questionnaire and is asked to fill out this questionnaire within a week and to return it to the researchers. The questionnaire contains questions about general and disease-specific quality of life, mood, meaning in life, acceptance, life satisfaction, well being, self-efficacy, mastery, social comparison and optimism.

Study burden and risks

We expect that participation in the study (interview, questionnaire, and time for traveling if applicable) takes about two hours for each patient. Besides the costs in terms of time, this study asks patients to express their opinion about their quality of life and the valuation of their health state. Patients can experience this as positive, but also as burdensome.

Contacts

Public

Leids Universitair Medisch Centrum

Postbus 9600
2300 RC Leiden
Nederland

Scientific

Leids Universitair Medisch Centrum

Postbus 9600
2300 RC Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Rheumatoid Arthritis

between 18 and 75 years old

speaking Dutch

Exclusion criteria

included in pilot study about individual quality of life (P05.123)

cognitive restrictions

severe emotional/psychological problems

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-01-2008

Enrollment: 120

Type: Actual

Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL14330.058.06