Quality of life and health state valuations of patients with spinal cord injury.

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The aim of this study is to investigate if adaptation could cause a change in the valuations of the patient*s health state and other health states over time.

Ethical review Approved WMO

Status Pending

Health condition type Spinal cord and nerve root disorders

Study type Observational non invasive

Summary

ID

NL-OMON30333

Source

ToetsingOnline

Brief title

The impact of adaptation on utilities.

Condition

Spinal cord and nerve root disorders

Synonym

spinal cord injury

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum **Source(s) of monetary or material Support:** ZonMw

Intervention

Keyword: adaptation, quality of life, spinal cord injury, utility assessment

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Outcome measures

Primary outcome

The primary outcomes of this study are adaptation and change over time in valuations of the patients* health state and other health states.

Secondary outcome

Besides adaptation, lack of scope, due to the scenario not matching the experience of patients, or the positive aspects of the illness can explain the difference in valuation of health-states between patients and the general public.

To investigate if patients include other aspects besides health when valuing their quality of life, we ask patients to indicate which dimensions are important for their quality of life.

In the questionnaire we ask if patients experienced benefit of their spinal cord injury to indicate if they experience positive aspects.

Study description

Background summary

In health care decision-making, valuations of health outcomes, so-called health state utilities play an important role. Differences in valuations of health states have been seen between the general public and patients. An empirically confirmed explanation for these differences is not yet available, but suggestions have been forwarded. One of these suggestions is that patients might adapt to their situation, whereas the general public anticipates not (enough) to this adaptation in their valuation.

Study objective

The aim of this study is to investigate if adaptation could cause a change in

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the valuations of the patient*s health state and other health states over time.

Study design

Patients will be interviewed three times within one year. In the first interview the patients value their own health state, their imaginary health state over one year, and a scenario for a health state of rheumatoid arthritis. They rate their functioning on five dimensions and indicate if there are additional dimensions that are important for their quality of life. Finally the patient completes, together with the interviewer, several questionnaires about different topics such as positive and negative affect, mastery, social comparison, health related quality of life, benefit finding, purpose in life, and adjustment. The second and third interview will be shorter then the first interview.

Study burden and risks

Participation in this study includes one interview of about two hours and two interviews of about one and a half hour. Besides this time investment, the topics in the interview could be difficult for the patients to discuss. Patients might experience discussing these topics as positive of helpful but they might experience it as burdensome.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Recent and acute spinal cord injury Between 18 and 75 years old Dutch speaking

Exclusion criteria

Cognitive disability emotional instability Spinal cord injury caused by cancer

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-11-2006

Enrollment: 60

Anticipated

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 NL14221.058.06