Content and concurrent validity of the Patient Specific Functional Scale (PSFS) on patients with neck pain.

No registrations found.

Ethical review Positive opinion **Status** Recruiting

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON22924

Source

NTR

Brief title

CROMM study

Health condition

neck pain, validity, activities

Sponsors and support

Primary sponsor: Fysio-Experts

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info@fysio-experts.nl

Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

The primary outcome of this study is to evaluate the content and concurrent validity of the patient specific functional scale on patients with neck pain.

Secondary outcome

No secondary outcome

Study description

Study objective

We expect to make recommendations in choosing between the PSFS or PSFS-D answering option and to describe important items from a patient's perspective regarding relevance, comprehensiveness and comprehensibility.

We expect high correlation coefficients ($r \ge 0.60$) between the PSFS(-D) and the NDI.

Study design

At baseline and 12 week follow-up the NRS, PSFS-D, and NDI will be measured.

Intervention

Before entering the study, participants will be screened to make sure that they meet all of the inclusion criteria. Informed consent is obtained from all participants. The first ten patient entering the study will be asked to join the content validity study as well.

Individual in person interviews following a semi structured discussion will be performed, on the following topics: understanding, meaning, relevance, response options, etc. and the preference regarding the answering option and an example list.

Interviews will be audio-recorded and transcribed for analysis.

After the content validity study is finalized all participants entering the study will receive a questionnaire including the NRS, PSFS(-D) and NDI

Contacts

Public

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Eligibility criteria

Inclusion criteria

Patients with neck pain are eligible if they are over 18 years of age, adequately understand Dutch and are classified as Grade I or II as described by the Neck Pain Task Force

Exclusion criteria

Patients are excluded in the presence of serious pathology (such as infection, cancer, fracture or rheumatoid arthritis) and previous surgery.

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Control: N/A, unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-07-2018

Enrollment: 100

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 NL7265 NTR-old NTR7463

Other Erasmus Medical Center, ethics committee: MEC-2018-129

Study results