Reliability and agreement of FCE for patients with chronic nonspecific nek pain

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To determine the test-retest reliability and agreement of the neck-FCE in patients with chronic non-specific neck pain.

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

Summary

ID

NL-OMON36621

Source
ToetsingOnline

Brief title
Reliability and agreement FCE chronic nek pain

Condition

- Other condition
- Musculoskeletal and connective tissue disorders NEC
- Changes in physical activity

Synonym
musculosceletal pain, nek pain

Health condition

Chronische pijn

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting Beatrixoord

Intervention

Keyword: Agreement, FCE, Nek pain, Reliabilty

Outcome measures

Primary outcome

The test results of the FCE are the outcome parameters. These are expressed in

kilograms

when lifting and carrying, in Newton's forces for neck muscle strength tests

and in

seconds with the other test items.

Secondary outcome

not applicable

Study description

Background summary

Neck pain is, after low back pain and shoulder complaints, the most common musculoskeletal complaint and has a major impact on society because of the reduced working capacity. The prognosis of recovery from non-specific neck pain is positive; 50-70% recovers
within a few months. Neck pain, however, can also persist for an extended period or be recurrent. Incidence of neck pain in the general medical practice is around 16 per 1000 patients (Bot et al, 2005, Feleus et al. 2008). About 1.2 per 1000 patients a year will visit a
hospital for neck pain (Verhagen et al. 2009). Main factors negatively influencing recovery are higher age, higher pain intensity, longer duration of pain and previous episode(s) with non-specific neck pain.

Performing repetitive movements, forceful movements, unusual positions and static contraction of neck and/or shoulder musculature are physical risk factors for developing chronic non-specific neck pain (Reesink et al. 2007). To determine the capacity to perform physical work a Functional Capacity evaluation (FCE) is used. The FCE is a standardized set of tests that each represents a work-related activity (Isernhagen, 1997). The FCE for neck pain (neck-FCE) consists of 6 tests. This neck-FCE is considered to be a valid representation of the capacity to perform physical work specific for people with neck pain (Reneman et al, 1997; Reneman et al., 2005b; Reesink et al 2007; Soer et al, 2009). The neck-FCE has been proven to be reliable in healthy subjects. The full FCE, wrom which is is derived, has demonstrated reliability in in patients with chronic non-specific low back pain and in patients with osteoarthritis in knees and hips (Brouwer et al, 2003; Gross et al, 2002; Reneman et al 2002a; 2004; 2005a; Soer et al, 2006; van Ittersum et al. 2009). Construct validity is good in healthy subjects and in patients with chronic low back pain
(Gross & Battie, 2003; Reneman et al, 2002b; Reneman et al, 2003). The safety of the FCE is good in patients with chronic low back pain and healthy subjects (Reneman et al. 2006; Kuijer et al, 2006; Soer et al. 2008). The reliability of the neck-FCE has not yet been studied.

Study objective

To determine the test-retest reliability and agreement of the neck-FCE in patients with
chronic non-specific neck pain.

Study design

Test-retest design. The neck-FCE is performed twice with a two week interval, by the same tester. . At session 2 (T1) the tester and patient are blinded for the results of session 1 (T0). The researcher has no contact with the patients.

- When a patient is diagnosed with chronic non-specific neck pain and is enrolled for outpatient pain rehabilitation at the Centre for Rehabilitation (CvR) UMCG, location Beatrixoord, the rehabilitation physician will assess whether the patient is suitable for participation in this study. The rehabilitation physician will ask whether the patient will consider participation. The patient will than receive the brochure 'information for patients' and a sign-up form with a postage free return envelope.
- When the patient wants to participate he sends the sign-up form to the CvR secretary of Pain Rehabilitation. By telephone two appointments will be arranged for both sessions. The patient will receive a confirmation letter with the appointments and a consent form at his / her home address.
- T0: Prior to the first test session patient will fill in a questionnaire and

read the consent form. Before starting the first session the tester will ask whether the information is understood and if there are any questions pending, if necessary, there will be additional explanation/information. The tester will take in the completed questionnaire. After signing the consent form T0 is performed. After the first test the patient receives a questionnaire to fill in at home 24-hours after the test (T0+) and a travel allowance form (travel expense reimbursement ¤ 0.19 per km for the second visit).
- T0+: Patient fills in questionnaire T0+ about the experienced pain 24 hrs after completion of T0 (duration 5 min).
- T1: Retest after 2 weeks. Patient takes along the completed questionnaire T0+ and the form for the travel allowance. Patient fills in questionnaire T1 (10 min). The test leader takes completed questionnaires and checks the completeness. Performing T1.
- Test leader hand over the gift voucher (¤ 20).
- Within 1 month travel expenses will be paid to the participant.

Patients voluntarily participate in this research. There is an Informed Consent procedure followed as written above. Patients will be invited in the CvR UMCG, location Beatrixoord (Dilgtweg 5). Questionnaires will be used to check if the self-reported functional status of patients is equal on T0 and T1.

Study burden and risks

Patients will be invited to come twice to the CvR. The sessions will take about 1.5 hours the first time and approximately 1 hour the second session. The first visit is similar to "Care as Usual". For the second session travel expenses will be reimbursed (19 euro cents per km) because it is an additional test. After performing the second test patients get a gift voucher (20 euros) for their participation in het research.
Both sessions enclose filling in questionnaires and conducting tests. It is to be expected that patients will experience muscular pain and / or a temporary increase of already existing neck pain as a result of each test session. This, however is considered a normal reaction to effort (Reneman et al, soer et al). The risk that healthy patients will suffer injury during this research is minimal, because of the safety procedures and also based on previous research. In studies with healthy subjects and in patients with low back pain it has been demonstrated that risks are very low (Matheson et al (1995), Reneman et al (2006), ,(Soer et al. 2008).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Chronic nonspecific nek pain for minimal 3 months
age: 16-64 years
Dutch language
With work or possibility of returning to work

Exclusion criteria

Bloodpressure: Diastolic>100mmHg, Systolic >160mmHg. Comorbidity with effect on condition. Medication with effect on heartrate

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2012
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-11-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL34820.042.10