Reliability of a classificationsystem for shoulderpain and of shouldertests

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28181

Source
NTR

Brief title
classification and tests for shoulderpain

Health condition

shoulder impingement syndrome; physical therapy; shoulderpain; classification; subgroups; shouldertests; subacromiaal pijn syndroom, fysiotherapie, schouderpijn, classificatie, subgroepen, schoudertesten

Sponsors and support

Primary sponsor: EMGO+/VUmc te Amsterdam
Source(s) of monetary or material Support: Het Wetenschappelijk College Fysiotherapie (WCF)

Intervention

Outcome measures

Primary outcome

1. The interrater reliability of the classification of schoudercomplaints according to the Dutch College of General Practitioners guidelines, 2. The interrater reliability of clinical

shouldertests, 3. The interrater reliability for 3 stages of tissue irritability

Secondary outcome

none

Study description

Background summary

Background: There is a lack of consensus on the appropriate diagnostic criteria for shoulder complaints. Besides, several diagnostic classifications have been proposed which complicates diagnosis. The Dutch College of General Practitioners has developed their guidelines for the diagnosis and management of shoulder complaints in 1990 (revised version in 2008). Concerning this guideline, patients are divided in three subgroups. The inter-rater reliability of this classification has never been examined.

One of the most promising clinical reasoning algorithm is published by prof Ann Cools. However several shouldertests that are used in this algorithm has not been assessed on inter-rater reliability.

Finally, the concept of tissue “irritability” is meant to reflect the tissue’s ability to handle physical stress and theoretically relates to its physical status and the degree of inflammatory activity present. Three phases of irritability have recently been developed by consensus, however they have not been assessed on inter-rater reliability.

Objective: The aim of this study is to determine the inter-rater reliability of 1. the classification algorithm as published the Dutch College of General Practitioners, 2 the inter-rater reliability of individual shouldertests used in the classification algorithm of prof. Cools and 3, of the three phases of irritability.

Study design: This is an inter-rater reliability study. Patients with non-specific and mild specific shouldercomplaints will be informed about the study. If a person fulfils the initial requirements for eligibility, the person receives written information. After 2 or more days the physical therapist will ask the person if he wants to participate in the study. If the patient agrees with participation, the patient will be assessed by two physical therapists. The first physical therapist evaluates patient's eligibility, obtains a written informed consent, collects baseline questionnaires and conducts a clinical examination according to a standardized protocol. Immediately following this examination, the patient will be examined independently by another physical therapist according to the same standardized protocol. Which of the physical therapist conduct the first and second examination will depend on availability and will not be randomized. The patient will be told not to discuss findings of the first examination with the second rater. The duration of each assessment will be approximately 30 minutes. Before each assessment, a score for current shoulder complaint will be collected to check

stability of person's pain between assessments. Unstable persons will be defined as those having 2 of more points change on an 11-point numerical rating scale (NRS, 0-10) for current shoulder complaints. The general practitioner of the person will be informed about person's participation in the study. The assessment forms of the two physical therapists will be handed over to an independent colleague.

Study population: A sample of 100 persons with non-specific and mild specific shouldercomplaints who attend a physical therapy clinic.

Outcomes: The inter-rater reliability between the two raters will be calculated for the individual shouldertests, for the 3 subgroups according to the association of the Dutch College of General Practitioners and for the three phases of irritability. Percentages of agreement and unweighted Kappa, including its 95% CI, will serve to test inter-rater agreement and reliability.

Burden and risk associated with participation: Some of the physical tests can provoke pain (painprovocative tests). It might be that some of the participating patients will experience more pain for a short period of time (maximum one day).

Study objective

Kappa values for classification shoulderpain, shouldertests and the severity of tissue irritability will range between 0.0 and 0.6.

Agreement values will range between 20% and 90%.

Study design

Most patients will be examined during the first two weeks after consultation their physiotherapy practice.

Intervention

This study does not focus on the results of an intervention, but is a reliability study of the classification of schoulderomplaints according to the Dutch College of General Practitioners guidelines and of clinical shouldertests.

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Eligibility criteria

Inclusion criteria

Pain in the shouldergirdle, with or without radiation into the arm; Age above 17 years; Accepting the consequences of participation at the study.

Exclusion criteria

Recently operated at the shoulder (<3 months); Recently fractured the shouldergirdle (<3 months); Cervico-radicular syndrome; (Suspected) severe diseases as malignities; Reumatic diseases as polymyalgia rheumatica, artritis rheumatica, lupus erythematosis or fibromyalgia;
Neurologic disease with negative consequences for the shoulder (as CVA, MS, Parkinson); Pathology of organs with negative consequences for the shoulder; Demented; Psychiatric diseases; Insufficient understanding of the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2016
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-06-2016
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	NL5668
NTR-old	NTR5905
Other	NL 4766802914 : METcVUmc 2014.482

Study results

Summary results

none