The interrater reliability of the classification of schouldercomplaints according to the Dutch College of General Practitioners guidelines and of clinical shouldertests

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45231

Source
ToetsingOnline

Brief title
Interrater reliability of shouldertests

Condition

- Tendon, ligament and cartilage disorders

Synonym
classificationalgorithm, shouldercomplaint

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Wetenschappelijke Commissie Fysiotherapie financieert het project voor 9.600 euro. Overige kosten worden gefinancieerd door de VUmc en de deelnemende klinieken.

Intervention

Keyword: algorithm, physical therapy, reliability, shoulder

Outcome measures

Primary outcome

The inter-rater reliability between the two raters will be calculated for the

individual shouldertests and for the 3 subgroups of he Dutch College of General

Practitioners and the three phases of irritability. Percentages of agreement

and unweighted Kappa, including its 95% CI, will serve to test inter-rater

agreement and reliability.

Secondary outcome

NA

Study description

Background summary

There is a lack of consensus on the appropriate diagnostic criteria for shoulder complaints as well as the fact that several diagnostic classifications have been proposed 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 devided in three subgroups. The inter-rater reliability of this classification has never been examined.
Recently, an interesting clinical reasoning algorithm based on clinical tests has been published by prof Ann Cools. However several shouldertests that are used in this algorithm has not been assessed on inter-rater reliability.

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.

Study objective

The aim 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 aspecific 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 will evaluate patient's eligibility, will obtain a written informed consent, will collect baseline questionnaires and will conduct a clinical examination according to a standardized protocol. Immediately following this examination, the person 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 persons 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 burden and risks

Some of the physical tests can provoke pain (painprovocative tests). It might be that the some of the participating persons will experience more pain for a short period of time (maximum one day).

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

Aspecific and mild specific shouldercomplaints, 18 years
of age or older, and agreement of the patient with the research protocol

Exclusion criteria

- severe trauma last 3 months
- signs of cervical nerve root compression
- severe diseases (e.g. cancer)
- presence of specific rheumatic disorders
- shoulder disorders due to neurologic diseases (e.g. CVA, MS, M. Parkinson)
- insulin dependant diabetes

• shoulder disorders due to general internal thoracic and abdominal pathology
• presence of dementia
• severe psychiatric, emotional or behavioural disorders
• inability to complete Dutch written questionnaires.

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):	18-01-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL47668.029.14