Aspecific Complaints of the Arm: Demonstration and Evaluation of Measurement Instruments (ACADEMI).

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To gain insight into the measurement properties of three questionnaires (part I) and the measurement properties of the upper limb functional capacity evaluation (part II). To gain insight in the effects of disorders of hand or wrist on health-...

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

Summary

ID

NL-OMON41867

Source
ToetsingOnline

Brief title
Measuring symptoms and disability in hand/wrist disorders.

Condition

- Muscle disorders

Synonym
complaints of the arm., Specific and non-specific CANS

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Disability Evaluation, Hand, Investigative Techniques, Upper Extremity

Outcome measures

Primary outcome

Each part (I, II and III) of the study has its own main study parameters.

Part I. Scores of single items, subscales and a total score of three questionnaires (QuickDASH, PRWHE, HFS).

Part II. Scores of eight different tests composing the upper extremity FCE.

Part III. Maximal oxygen uptake (VO2max in l/min).

Secondary outcome

Part I. Scores of single items, subscales and a total score of the RAND-36, Pain Disability Index (PDI), Pain Numeric Rating Scale, Upper Extremity Work Demands (UEWD). External criterium for assessing responsiveness, after hand therapy: global rating scale (global perceived effect of change).

Part II. Scores of single items, subscales and a total score of three questionnaires (QuickDASH, PRWHE, HFS). Scores of single items, subscales and a total score of the RAND-36, Pain Disability Index (PDI), Pain Numeric Rating Scale, Upper Extremity Work Demands (UEWD).

Part III. Scores of single items, subscales and a total score of three questionnaires (QuickDASH, PRWHE, HFS). Scores of single items, subscales and a total score of the RAND-36, Pain Disability Index (PDI), Pain Numeric Rating Scale, Upper Extremity Work Demands (UEWD). Anaerobic threshold (AT, % of VO2max), W/kg. Handheld dynamometry of both hands. Weight, height, BMI, fat

free mass (bio-impedance).

Study description

Background summary

Upper limb disorders frequently occur and cause symptoms and disability. Several instruments to assess symptoms and disability in patients with upper extremity problems are available, such as questionnaires and Functional Capacity Evaluation. Measurement properties of those instruments have not been properly assessed in (Dutch) patients with (non)specific complaints of the hand or wrist. Furthermore, upper limb disorders are related to lower levels of self-reported physical fitness. It is unknown if objectively measured physical fitness is also reduced.

Study objective

To gain insight into the measurement properties of three questionnaires (part I) and the measurement properties of the upper limb functional capacity evaluation (part II). To gain insight in the effects of disorders of hand or wrist on health-related physical fitness (part III).

Study design

The study design is an observational study with three parts:
Part I. Assessing measurement properties (internal consistency, construct validity, reproducibility, responsiveness and floor or ceiling effects) of Dutch language versions of three questionnaires (QuickDASH, PRWHE, HFS).
Part II. Assessing measurement properties (construct validity and reproducibility) of a (comprehensive) upper extremity functional capacity evaluation (FCE).
Part III. Assessing health-related physical fitness.

Depending on inclusion/exclusion criteria and informed consent, a patient might participate in one or more parts of the study.

Study burden and risks

Part I: Fill out three questionnaires at two (or three in case of hand therapy) times, no risks.
Part II: Visit the University Medical Center Groningen at two times to fill out three questionnaires and perform the FCE. Participants risk a temporary increase in symptom intensity/muscle soreness the day(s) following FCE.
Part III: Single visit to the University Medical Center Groningen to perform

cardiopulmonary exercise testing. Participants risk a temporary increase in symptom intensity/muscle soreness the day(s) following exercise testing. The risk of medical complications is very low and further minimized by careful screening procedures.

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

- Aged 18 years or over.
- Complaints of hand, wrist and/or forearm, classified as either specific or nonspecific complaints of the arm, neck and/or shoulder (CANS).

Exclusion criteria

- Insufficient understanding of Dutch to fill out questionnaires.
- Other medical condition(s) causing considerate disability.

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):	17-12-2015
Enrollment:	434
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2015
Application type:	First submission
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

ID: 22312
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51584.042.15