Measuring symptoms and disability in hand/wrist disorders.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON22312

Source
Nationaal Trial Register

Brief title
ACADEMI

Health condition

Specific and non-specific CANS, complaints of the arm, Upper Extremity, Hand, Disability Evaluation, Investigative Techniques, CANS, Bovenste extremiteit, Hand, Beoordelen van beperkingen, Onderzoekstechnieken

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen

Intervention

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

Study design

Part I: T1 (first measurement), T2 (1-3 weeks after T1), T3 (4-8 weeks after start of hand therapy, where applicable).

Part II: T1 (first measurement), T2 (1-3 weeks after T1), T3 (4-8 weeks after start of hand therapy, where applicable).

Part III: T1 (first measurement).

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study (part I, II and III), a subject must meet all of the following 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), which might have a direct influence on hand or wrist function (in practice all complaints located from the elbow towards the fingers).

Extra for assessing responsiveness in part I:

- Receiving hand therapy for these complaints at the outpatient clinic of the Department of Rehabilitation Medicine of the University Medical Center Groningen, for a duration of at least four weeks.

Extra for the functional capacity evaluation study (part II):

- Meeting the criteria of the Physical Activity Readiness Questionnaire (PAR-Q). If question 5 ('Do you have a bone or joint problem that could be made worse by a change in your physical activity') is solely answered with 'yes' because of those complaints of hand, wrist and/or forearm for which the patient visited the outpatient clinic of the Department of Rehabilitation Medicine of the University Medical Center Groningen, we consider the criteria of the PAR-Q are still being met.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study (parts I, II and III):

- Insufficient understanding of Dutch to fill out questionnaires.

- Other medical condition(s) causing considerate disability, such as neurological disorders (e.g. stroke, peripheral nerve damage) or joint diseases (e.g. osteoarthritis, rheumatoid arthritis).

Extra for part III:

- Presence of contraindications for cardiopulmonary exercise testing. This is checked using usual clinical criteria, based on the ATS/ACCP Statement on cardiopulmonary exercise testing.

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2015
Enrollment:	434
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-04-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41867
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5657
NTR-old	NTR5792
CCMO	NL51584.042.15
OMON	NL-OMON41867

Study results