Effectiveness of scapulothoracic exercise with myofeedback in patients shoulder complaints

Published: 31-10-2018
Last updated: 13-04-2024

To determine the added value of myofeedback during scapulothoracic training at home in adults with subacromial shoulder pain.

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

Summary

ID

NL-OMON46930

Source
ToetsingOnline

Brief title
ESTEEM study

Condition

- Tendon, ligament and cartilage disorders

Synonym
bursitis of the shoulder, tendonitis of the shoulder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: European Union

Intervention

Keyword: biofeedback, non-traumatic glenohumeral instability, shoulder, subacromial impingement syndrome

Outcome measures

Primary outcome

Primary outcome measures is the change self reported shoulder function measured with the Shoulder Pain And Disability Index.

Secondary outcome

Patient characteristics; age, gender, duration of complaints, smoking history, medication use.

- Relative muscle onset time

Relative muscle onset time will be measured using sEMG for the M. Trapezius Descendens, M. Trapezius Ascendens, M. Serratus Anterior. The muscle onset time will be measured relative to the M. Deltoid. Feedforward activity of the scapulothoracic muscles will be defined as activation of the M. Trapezius Ascendens or M. Serratus Anterior 100ms before to 50ms after M. Deltoid Anterior, in mili-seconds.

- Maximum voluntary isometric contraction

Maximum voluntary isometric contraction will be measured using a MicroFet (Hoggan Health Industries Inc, Utah, The United States of America) for the M. Trapezius Descendens, M. Trapezius Ascendens, M. Serratus Anterior, and M.Deltoid Anterior.

- Patients pereived satisfaction

We will use the Net Promotor Score to assess patient perceived satisfaction.

Patient perceived satisfaction wil only be measured during the follow-up

measurement.

- Adherence

Adherence to the exercise schedule will be tracked using a paper journal in all

three groups. At each session the participant will receive a journal from the

physical therapist performing the treatment. Then at the next session the

journal can be handed in.

Adherence will be expressed in percentages relative to the planned amount of

exercises, sets, and repetitions to be completed.

Study description

Background summary

Shoulder complaints, such as submacromial shoulder pain, occur frequently in the general population.
Exercise therapy, often used as a treatment strategy to decrease complaints. However, these specific exercises are difficult to perform, which contributes to a suboptimal compliance especially with home exercises. To increase compliance exercise therapy could be be augmentened using real-time myofeedback. Real-time myofeedback can show a person if an exercise is being performed correctly. With modern technology real-time biofeedback can be provided at home to guide performance of the home exercise schedule. We intend to investigate the added value of myofeedback during home exercise performance in patients with subacromial shoulder pain

Study objective

To determine the added value of myofeedback during scapulothoracic training at home in adults with subacromial shoulder pain.

Study design

prospective multicenter single-blinded randomized controlled trial

Intervention

The eight week intervention will start directly after the baseline measurement. All treatments will be provided by one physical therapist. Each treatment session will take one hour. During the first treatment session patient will receive an explanation regarding the treatment and their first exercises. Patients from all treatment groups will follow the same exercise schedule. Group 1 will just regular training on how to perform the exercises and no myofeedback training. Patients from group 2 and 3 will be trained using myofeedback. Group 2 will receive myofeedback during the physical therapy sessions, and group 3 will receive myofeedback during the physical therapye sessions and during home exercise performance. Group 2 and 3 will be instructed on how to perform myofeedback training. Previous studies have shown that it is possible to improve scapulothoracic muscle control using myofeedback training within one hour.
For all groups the intervention will be focused on training the scapuothoracic muscles. Further procedures and details regarding the treatment are described in chapter 4.1.

Study burden and risks

- Nature and extent of the burden:
The burden of the intervention is practically no greater than with the regular treatment. Patients in all three groups wil perform the same exercises, however the patients in group 2 and 3 will receive myofeedback during the physical therapy session and myofeedback during the physical therapy sessions and during home exercise performance respectively.
The burden of the intervention is 10 sessions of 60minutes (8 treatment sessions, and 2 measurement sessions). Further during home exercise performance patients in group 3 will be required to attach sEMG devices, start the app to be able to use the myofeedback. This will require 1-2 minutes.

- Risks associated with the intervention
There is no added potential risk to the intervention compared to regular physical therapy.

- Benefit
A possible benefit is that the intervention consists of regular exercises augmented with a method of monitoring the quality of performance by using a smartphone app and SEMG also known as myofeedback.

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

1. Age between 18 and 60 years;
2. Presence of scapular dyskinesis, defined as aymetrically moving scapulae during forward flexion or abduction.
3. Established diagnosis of SPS by physical therapist. diagnostic criteria voor subacromial shoulder pain:
i. Presence of pain during active shoulder elevation.
ii. Presence of pain during passive external rotation or isometric resistance against external rotation.
iii. Presence of at least two positive test, from the following tests: Hawkins-Kennedy test, isometric resistance external rotation, painful arc test.

Exclusion criteria

1. Presence of any of the following items:
a. Bilateral shoulder complaints.

b. Traumatic onset of shoulder complaints.
c. Duration of the shoulder complaints of more than nine months.
d. History of one or more surgeries on either shoulder.
e. Patient is on the waiting list for shoulder surgery.
f. Presence of systemic diseases(for example diabetes, rheumatoid arthritis, COPD).
g. Presence of neurological diseases (for example multiple slerosis, or other neurological diseases).
2. Presence of any of the following items in the physical examination
a. A limitation of the range of motion of the glenohumeral joint compared to the heterolateral glenohumeral joint.
b. Shoulder complaints which can be reproduced by cervical spine physical examination.
c. Shoulder complaints which can be reproduced by thoracic spine physical examination.
d. Positive horizontal adduction test.
e. Positive lag test for any of the following muscles; M. Supraspinatus, M. Infraspinatus, M. Subscapularis.
f. Positive tests for glenohumeral instability; apprenhension test, relocation test.
3. Inability to come to the physical therapy clinics for the duration of the intervention.
4. The use of paracetamol, or aspirine, or other non-steroidal anti-inflammatory drugs (ibuprofen, diclofenac, naproxen) during the treatment or refusing to discontinue the use of non-steroidal anti-inflammatory drugs during the study period;
5. Visus or cognitive limitations that inhibit the use of the sEMG devices. The potential participant needs to be able to clearly see, and interpret the screen of the sEMG devices/smartphones. For example blind patients will not be eligable for participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2018
Enrollment:	84

Type:	Actual

Ethics review

Approved WMO Date:	31-10-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL58382.042.17

Study results

Date completed:	07-07-2023
Actual enrolment:	0

Summary results
Trial is onging in other countries