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The effect of EMG biofeedback: a randomized controlled clinical trial in patients with shoulder pain

Submission date
03/11/2017

Recruitment status
No longer recruiting

Registration date
24/11/2017

Overall study status
Completed

Last Edited
23/04/2021

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The shoulder injury known commonly as shoulder impingement is the most common disorder of the shoulder and accounts for the major part of neck-shoulder pain in north and mid-western Europe. It is the most common cause of work-related sickness absence, followed by back pain. Neither surgery nor physical treatment has yet found a solution to this problem, as two-thirds of patients are still looking for one or more subsequent treatments. Electromyography (EMG) biofeedback involves using sensors to provide feedback on muscle activity. The aim of this study is to find out whether EMG biofeedback-guided training reduces shoulder pain and improves shoulder function.

Who can participate?
Patients aged 18 to 65 with shoulder impingement

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. All participants are instructed to perform the same exercises with 2x10 repetitions once a day over 8 weeks. The intervention group receive biofeedback on a computer screen from the muscles the exercises are focused on, while the control group do not receive this biofeedback. Shoulder pain and function are assessed using questionnaires at the start and end of the study.

What are the possible benefits and risks of participating?
The benefits of participation are access to free supervised shoulder muscle exercise training as well as a clinical examination of the shoulders. Participation does not involve any risks for the patients.

Where is the study run from?
University of Southern Denmark (Denmark)

When is the study starting and how long is it expected to run for?
April 2009 to July 2012

Who is funding the study?
University of Southern Denmark (Denmark)

Who is the main contact?
1. Prof. Karen Søgaard
2. Prof. Birgit Juul-Kristensen

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
The effect of eight weeks of training with and without EMG biofeedback, on pain and muscle function in patients with shoulder impingement: a randomized controlled clinical trial

Acronym
BIONEX

Study objectives
In impingement patients, an eight-week biofeedback-guided intervention exercise group with EMG feedback will compared to a control group receiving the same exercises but without EMG biofeedback:
1. Decrease more in shoulder pain measured via self-reported pain (NRS)
2. Increase level of shoulder function (measured via self-reported level of function scores, DASH and OSS)
3. Increase muscular activity in lower trapezius (LT) and serratus anterior (SA), as well as decrease muscle activity in upper trapezius (UT), thereby also decreasing the ratios UT/LT & UT /SA

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Committee of Southern Denmark, 09/11/2009, Project ID: S-20090090

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Subacromial impingement syndrome (SIS)

Interventions
The intervention program was divided into two periods. The first period was a three-week phase with instruction in different exercises with focus on LT and SA activation. The purpose was to (re) activate the muscles and thereby increase the subjects' awareness of those muscles' position and function. The purpose of the second period (a five-week phase) was to transfer the awareness gained through the first phase into the performance of more functionally complicated exercises. Here, coactivation of the LT and SA in dynamic movements was emphasised in order to master exercises and succeed to the next. Standardised progression regimes according to the subjects' individual pain levels were developed and followed in both first and second period. The subjects were supervised once a week by the same physiotherapist and instructed how to progress and to do the exercises with 2x10 repetitions once a day during the eight weeks of intervention. Also, stretching exercises and ergonomic instructions were given.

All participants in this study received the same exercises. The only difference between the interventions applied to the intervention and control group was the provision of online visual feedback of muscle activity, shown horizontally (from left to right) on a monitor (biofeedback) visible for both the subject and instructing physiotherapist in the intervention group. The no-EMG control group only received instructions from the physiotherapist based on quality of exercise and if needed, manual/tactile corrections.

Intervention Type
Other

Primary outcome measure
Self-reported pain assessed using a numeric rating scale (NRS) as part of a questionnaire filled out before commencing physical testing at baseline and follow-up (week 0 and 8):
1. "Pain now" measured on NRS (0-10) at baseline and follow-up testing
2. "Pain within the last 24 hours" measured on NRS (0-9) at baseline and follow-up testing
3. "Pain within the last 7 days" measured on NRS (0-9) at baseline and follow-up testing
Furthermore, the subjects were asked to register their daily pain level in a diary throughout the eight weeks of home exercise. This diary was used to measure the daily pain development (NRS 0-10) and then to measure compliance, as the subjects would register the execution of their home exercises.

Secondary outcome measures
1. Self-reported shoulder-scores obtained from questionnaires at baseline and follow-up:
1.1. Disability of the Arm, Shoulder and Hand questionnaire (DASH)
1.2. The Oxford Shoulder Score (OSS)
2. Muscle activity measured by surface electromyography (sEMG) signals from three muscles: upper trapezius (UT), lower trapezius (LT) and serratus anterior (SA). The measurements were carried out according to a standardized experimental procedure, containing a voluntary movement task (described in experimental procedure). During arm elevation, mean relative activity (percentage of maximal voluntary electric activity, %MVE) was measured and muscle activation ratios between the muscles (UT/LT and UT/SA) were calculated. Measured at baseline and follow-up.

Overall study start date
01/04/2009

Completion date

11/07/2012

Eligibility

Key inclusion criteria
1. At least 30 days with pain/discomfort in the shoulder/neck region within the last year
2. At least two or more positive impingement tests based on the Jobe, Neer; Hawkins and Apprehensions tests
3. 18-65 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
A total of 40 patients with 20 participants in each group

Total final enrolment
49

Key exclusion criteria
1. Equal or more than 8 in pain/discomfort - measured with Numeric Rating Scale from 0-10 (NRS) - throughout the last 24 hours (on test day)
2. Had more than three regions with pain, for at least 30 days during the last 12 months
3. Had a history of severe shoulder-neck pathology/trauma and/or orthopaedic surgery and/or received anti-inflammatory injections within the last 3 months
4. If they were pregnant (EMG precaution)
5. Any documented life threatening diseases
6. Cardiovascular diseases
7. Rheumatoid arthritis
8. Generalized pain
9. Adverse psychosocial conditions
10. Signs for cervical radiculopathy, i.e. Spurling A test, Involved Cervical Rotation test (less than 60), Neck Distraction test

Date of first enrolment
01/09/2010

Date of final enrolment

03/05/2012

Locations

Countries of recruitment
Denmark

Study participating centre
University of Southern Denmark
Dept of Sport Sciences and Clinical Biomechanics
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Sponsor information

Organisation
Forsknings- og Innovationsstyrelsen (National Research Council)

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Sponsor type
Government

Website
https://ufm.dk/forskning-og-innovation/tilskud-til-forskning-og-innovation

Organisation
Gigtforeningen (Danish Association of Rheumatism)

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Sponsor type
Charity

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Organisation
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Sponsor type
Government

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Organisation
Danish Ministry of Higher Education and Science

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Sponsor type
Government

Website
http://ufm.dk/en?set_language=en&cl=en

ROR
https://ror.org/03ge1nb22

Funder(s)

Funder type
University/education

Funder Name
Syddansk Universitet

Alternative Name(s)
University of Southern Denmark, SDU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Denmark

Results and Publications

Publication and dissemination plan
Planned publication of the results in a high-impact peer-reviewed journal. First publication expected to be submitted March 2018.

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan				No	No
Results article		01/10/2019	23/04/2021	Yes	No