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Subacromial pain syndrome of the shoulder - comparisons between guided training and home based training with or without mobilizations and a control, in terms of clinical outcome at 6 week, 3 and 6 month follow-up.

Submission date
27/03/2017

Recruitment status
No longer recruiting

Registration date
02/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Subacromial pain syndrome (SAPS) is the most common musculoskeletal complaint after low-back and neck pain in patients seeking primary care. It involves the rotator cuff tendon – a tough, rubbery cord that connects the muscles in the shoulder to the top of the arm. The tendon and muscle run through a narrow space at the top of the shoulder called the subacromial space. About 70-85% of cases of SAPS are caused by tendon injuries, rotator cuff tears, and shoulder impingement, where the tendon becomes trapped and scrapes against the bone above, causing pain. Forty percent of patients still have pain after one year. Little is known about the natural recovery of patients with SAPS. Therefore a number of treatment options have been used in the past. Today there is a consensus to use resistance exercises for physiotherapy. Mobilization is suggested to reduce pain through a number of possible mechanisms, but it´s still unclear whether mobilization therapy added to an exercise program is beneficial. The aim of this study is to compare the effect of supervised physiotherapy and home-based training with or without mobilizations in patients with SAPS.

Who can participate?
Patients aged between 20 and 59, who have SAPS for 4 weeks to 1 year

What does the study involve?
This study consists of two separate studies. In study 1, patients from general practice/primary care in Tyresö, Älta and Haninge are randomly allocated into one of three groups. Group A receive guided training at a clinic twice a week for weeks 1-5 and weeks 7-11. Group B receive the same treatment as group A with additional mobilizations (eight times). Group C receive no treatment (control group). In study 2, patients from general practice/primary care in Stockholm (and from Tyresö after the end of study 1) are randomly allocated into two groups. Group A receive home training for weeks 1-5 and weeks 7-11. Group B receive the same treatment as

group A with additional mobilizations (eight times). Both groups are compared with the control group from study 1. All participants in both studies are examined at the start of the study and after 6 weeks, 3 and 6 months.

What are the possible benefits and risks of participating?
All patients receive a thorough investigation of their shoulder, including an x-ray and ultrasound scan. As of the start of the study it is not known which treatment is the most effective. No risks are expected for the patients as they are carefully followed and examined. They can stop their participation in the study at any time.

Where is the study run from?
1. Primärvårds rehab (primary care) in Tyresö (Sweden)
2. Innerstadsrehab, primary care (Sweden)

When is the study starting and how long is it expected to run for?
April 2009 to June 2015

Who is funding the study?
Karolinska Institutet (Sweden)

Who is the main contact?
Anna Eliason

Contact information

Type(s)
Public

Contact name
Ms Anna Eliason

Contact details
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Box 5605
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114 86

Additional identifiers

Study information

Scientific Title
Subacromial pain syndrome of the shoulder - comparisons between different physical therapy treatments in terms of change in the Constant and Murley score index: two randomised controlled trials

Acronym
-

Study objectives
1. Does treatment with exercises give a better outcome than a control that don't receive any treatment in patients with subacromial shoulder pain (SAPS)?
2. To determine possible differences in the Constant Score Index in patients with subacromial pain, SAPS treated with a combination of mobilization and guided training of the shoulder stabilizers, guided training alone versus a control group who received no treatment
3. Are there any differences in outcome between guided training or home based training?
4. Is the addition of passive mobilisation of the gleno-humeral joint more effective than exercises alone?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee in Stockholm, Sweden, 01/11/2010, ref: 2009/1197-31/2

Study design
Two single-center double-blinded controlled interventional randomized trials

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Subacromial pain syndrome

Interventions
Two double-blinded controlled interventional randomized trials, methodically built in the same way in order to be able to compare the results. Randomization with sealed envelopes (4 envelopes for each age group; 20-29, 30-39, 40-49, 50-59 years of age at baseline for women and for men). The patients were randomized in the order they sought care in Primary care in Tyresö in study 1 and in Stockholm City in study 2. After closing study 1, patients were also randomized to study 2 from Primary care in Tyresö. The physical therapist performing the examinations was blinded for allocation. Every third patient went to the control group. The same control group was used in study 2.

Study 1: 120 patients aged between 20-59 years were recruited from general practice/primary care in Tyresö, Älta and Haninge between the years 2010-2014. The patients were randomized into two intervention groups with sealed envelopes. Every third patient went to the control group.
Group A: week 1-5: guided training at a clinic twice a week, week 7-11 guided training for another 5 weeks, twice a week
Group B: additional mobilizations 8 times + same treatment for group A
Group C: control: no treatment

Study 2: 89 patients with shoulder pain were recruited from general practice/primary care from 3 centers in Stockholm between the years 2011-2015 and from Primary care in Tyresö after closure of data collection to study 1. The patients were randomized into two intervention groups with sealed envelopes. The control group from study 1 was used.

Group A: week 1-5: home training, week 7-11 home training another 5 weeks
Group B: additional mobilizations 8 times + same treatment as group A
Group C: control: no treatment

One physiotherapist conducted the examinations at baseline, 6 weeks, 3 and 6 months follow-up in both studies and was blinded for allocation. The patients were blinded for the different treatments.

Intervention Type
Other

Primary outcome(s)
Shoulder pain, activities of daily living, range of motion and strength, measured using the Constant and Murley Score at baseline, after 6 week, 3 and 6 months

Key secondary outcome(s))
1. Pain, measured using the visual analogue scale (VAS) at baseline, 6 weeks, 3 and 6 months
2. Range of motion (ROM), measured using in degrees using a goniometer and a Myerin meter at baseline, 6 weeks, 3 and 6 months
3. Personality, measured using Swedish universities Scales of Personality (SSP) at 6 weeks
4. Health related quality of life (physical symptoms, sports and recreation, work, lifestyle and emotion), measured using the Western Ontario Rotator Cuff (WORC) Index at baseline, 3 and 6 months
5. Single Assessment Numeric Evaluation (SANE) with only one question: "How would you rate your shoulder today as a percentage of normal (0% to 100% scale with 100% being normal)?", at baseline, 3 and 6 months

Completion date
05/06/2015

Eligibility

Key inclusion criteria
1. Aged 20-59 years
2. SAPS for 4 weeks to 1 year
3. Normal passive glenohumeral range of motion, a positive Hawkins sign and/or pain with isometric contraction of any of the rotator cuff muscles. For inclusion at least two of these tests must be positive together with a positive painful arc. Patients with rotator cuff ruptures were included if they met these criteria and didn't present with any lag signs

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

20 years

Upper age limit
59 years

Sex
All

Key exclusion criteria
1. Bilateral shoulder pain
2. Earlier corticosteroid injection
3. Diabetes mellitus
4. Signs of full-thickness rotator cuff tears with a positive drop arm test
5. Rheumatoid arthritis
6. Arthroses
7. Frozen shoulder
8. Severe fibromyalgia
9. Earlier dislocation of the shoulder and previous operations in the shoulder
10. Thoracic or cervical syndromes

Date of first enrolment
01/08/2010

Date of final enrolment
30/12/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Primärvårds rehab (Primary care) in Tyresö
Bollmoravägen 14
Stockholm
Sweden
135 40

Study participating centre
Innerstadsrehab, primary care
Dalagatan 9
Stockholm
Sweden
113 61

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Anna Eliason or statistician Gunnar Edman (Gunnar.Edman@ki.se).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Study 1	11/05/2021	11/07/2023	Yes	No
Results article	Study 2	23/02/2022	11/07/2023	Yes	No