Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of progressive muscle relaxation training on pain, sleep quality and disability in individuals with subacromial pain syndrome: a single-blinded randomized controlled trial

Protocol summary

Study aim
Investigating the effect of adding progressive muscle relaxation exercises in the usual treatment program on pain intensity, sleep quality, night pain and functional disability in people with subacromial pain syndrome.

Design
Clinical trial with treatment and control group, double-blind, randomization, classified on 38 patients by RANDOM NUMBER GENERATOR

Settings and conduct
First, the participants will be entered into the study and evaluated according to the entry and exit criteria. The subject and the examiner will be blind to the grouping and the examiner will not be present in the treatment process, then the subjects will receive 8 treatment sessions in hospitals and clinics affiliated to Iran University of Medical Sciences. Then they will be evaluated at the end of the sessions

Participants/Inclusion and exclusion criteria
1) Age between 25 and 60 years (52) 2) shoulder pain for more than 1 month with or without limitation of shoulder movements (53) 3) People diagnosed with subacromial shoulder pain syndrome and at least 2 of the following are positive: (52) Painful arch (with or without limitation) in flexion or abduction (between 60 and 120 degrees) (34) Neer (35) or Hawkins (36) test positive Pain during resistance contraction of external rotation, abduction 4) The average intensity of night pain and discomfort in the last week is at least 2 according to the NRPS scale

Intervention groups
Patients in both groups will receive the usual physical therapy as the basic treatment, and people in the main treatment group will additionally perform progressive muscle relaxation intervention.

Main outcome variables
Pain intensity during activity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240506061674N1**
Registration date: **2024-07-07, 1403/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-07, 1403/04/17**
Update count: **0**

Registration date
2024-07-07, 1403/04/17

Registrant information

Name
Haniye Sotoudefar

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-21, 1403/04/01

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of progressive muscle relaxation training on pain, sleep quality and disability in individuals with subacromial pain syndrome: a single-blinded randomized controlled trial

Public title
The effect of progressive muscle relaxation training on pain, sleep quality and disability in individuals with subacromial pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 25 and 60 years Shoulder pain for more than 1 month with or without limitation of shoulder movements People with the diagnosis of subacromial shoulder pain syndrome who are positive for at least 2 of the following: painful arch (with or without limitation) in flexion or abduction (between 60 and 120 degrees), positive Neer or Hawkins test, pain during resistance contraction of external rotation, abduction Average intensity of night pain and discomfort in the last week at least 2 according to the NRPS scale

Exclusion criteria:
Movement limitation of shoulder movements more than 50% of the normal range History of surgery or fracture or dislocation in the neck and upper limbs Traumatic shoulder pain Complete rupture of rotator cuff or biceps tendon Joint degenerative changes or labrum damage History report of rheumatology and systemic diseases Skeletal neuromuscular disorders such as cervical radiculopathy or referred pain from the neck, which is confirmed by the spurling test (52). The sensitivity of this test is 30% and its specificity is reported as 93% pregnant women history of steroid injection in the last 3 months Joint capsule adhesion History of receiving treatment or physiotherapy for shoulder problem during the last 6 months Cognitive dysfunction (according to MMSE questionnaire) The presence of neurological disorders such as stroke, epilepsy, and Parkinson's severe spinal deformity thoracic outlet syndrome

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation is done by block method, blocks of 4 letters consisting of letters A and B are randomly selected. Blocks are created by Random Number Generator and their sequence is specified. The letter A represents the intervention group and the letter B represents the control group. A random sequence of random blocks is then generated. The participants are placed in one of two intervention or control groups based on the order of referral with the help of this random sequence. The individual generating the randomization sequence will not participate in any other phase of the study.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the method of blinding the examiner will be used; Therefore, the present research will be a blind strain. In this way, the examiner will not know about the grouping (treatment or control group) before and after the intervention. Also, to reduce possible biases, both groups will be given the same brochures and videos to teach how to perform therapeutic exercise to reduce the risk of bias in basic treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran

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Tehran

Province
Tehran

Postal code
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Approval date
2023-11-21, 1402/08/30

Ethics committee reference number
IR.IUMS.REC.1402.749

Health conditions studied

1

Description of health condition studied
Subacromial pain syndrome

ICD-10 code
M75.4

ICD-10 code description
Impingement syndrome of shoulder

Primary outcomes

1

Description
Pain intensity during activity based on NRPS scale
Timepoint
At the beginning of the sessions and after the end of 8 treatment sessions
Method of measurement
Numeric pain rating scale

Secondary outcomes

1

Description
Sleep quality
Timepoint
At the beginning of the sessions and after the completion of 8 treatment sessions
Method of measurement
Persian version of Petersburg Sleep Quality Questionnaire (PSQI)

2

Description
Night pain
Timepoint
At the beginning of the sessions and after the completion of 8 treatment sessions
Method of measurement
Numeric pain rating scale

3

Description
Disability
Timepoint
At the beginning of the sessions and after the completion of 8 treatment sessions
Method of measurement
Persian version of Arm, Shoulder and Hand Disability Questionnaire (DASH) and Pain, Shoulder and Disability Questionnaire (SPADI)

Intervention groups

1

Description
Intervention group: people in the intervention group perform progressive muscle relaxation in addition to the usual physiotherapy. At first, the subjects are trained in the technique under the supervision of a physiotherapist familiar with the intervention in the first session during one hour. During the training session, first the goals and effects of the progressive muscle relaxation technique and then instructions on how to implement the technique verbally and step by step. It is explained to the patient. Then, in the implementation phase, the therapist performs the technique once for the patient, and then the patient is asked to perform the technique completely in the presence of the therapist. To perform this treatment method, a voice message and a brochure are given to the patient. The audio message contains verbal instructions related to PMR exercise steps for about 20 minutes, which is accompanied by a soft background sound of music and the sound of water, and patients should listen to this tape through an audio player during the exercise. In addition, a brochure containing the steps of PMR exercise is presented to people in visual and written form. At first, to start the PMR exercise, the subjects must prepare the conditions for the exercise, for this purpose, the patients must not wear tight clothes, and before starting, they must go to the bathroom and be in a quiet place, preferably in dim light, and all distractions fix it After preparing the basic conditions, the patient lies on the bed or the floor and listens to the voice message with headphones. Then, based on the verbal instructions in the voice message, the patient should focus on the mentioned muscle group and With the given order, he will contract the muscle group voluntarily and consciously at first, and he will maintain this voluntary contraction for 5 to 7 seconds, and again, with the therapist's order, he will relax and release the same muscle group voluntarily, and this relaxation will continue. It also maintains for the next 10 to 15 seconds and the patient should focus his attention on the stages of creating contraction and relaxation as well as the difference between these two stages. The order in which the muscle groups of the upper limbs are under tension and relaxation is as follows: 1) hands 2) wrists 3) forearms 4) elbows 5) shoulder girdle 6) neck 7) face. Also, during the entire time of the exercise, the subjects perform slow and deep diaphragmatic breathing by inhaling through the nose and exhaling through the mouth. Termination of the treatment is done by counting down from 4 to 1. With the number 4, the patient moves the legs and legs, and with the number 3, the person moves the hands and arms, and with the number 2, the person moves the head and neck, and in the number 1 person opens the eyes. Patients in the intervention group are asked to do PMR exercises every day, 2 times, once at night before going to sleep and once during the day in the morning to afternoon for 4 weeks at home, and also in Face-to-face sessions also perform the exercise under the supervision of the patient's physiotherapist, and the therapist examines and corrects the way the exercise is performed and possible errors.
Category
Treatment - Other

2

Description
Control group: In this study, the usual physiotherapy treatment includes surface electrical nerve stimulation and exercise therapy, which both intervention and control groups receive as basic treatment. In face-to-face sessions, subjects will receive superficial electrical nerve stimulation and heat packs for 20 minutes. Surface electrical nerve stimulation wet pads will be placed in the front and back of the shoulder joint. The frequency and

wavelength used will be 100 Hz and 150 microseconds, respectively. In the next step, a series of exercises will be presented to the individual based on the recommendations of the latest guidelines. At first, the subjects will start with postural exercises including shoulder pull up and shoulder pull back, then 3 stretching exercises including Cross body adduction to stretch the anterior shoulder capsule and pectoralis minor. corner stretch to stretch the posterior capsule of the shoulder and stretch the upper trapezius muscle. Subjects are asked to perform each stretch in 3 sets of 30 seconds with 30 seconds of rest between sets. Then, in the last place, strengthening exercises are performed using 1-meter elastic resistance bands (traband) in three progressive resistance levels, which are determined by the color of the band (red, green, and blue). The strengthening exercises include 4 shoulder external rotation exercises, shoulder extension, There are shoulder protraction and shoulder retraction. To externally rotate the person's shoulder in a standing position, the elbow is placed at 90 degrees and the arm is placed by the side, and the person performs the external rotation movement. In the shoulder extension exercise, in order to strengthen the lower trapezius muscle, the person stands in front of the bandage and keeps his elbow and arm straight at the side of the body and tries to move the bandage backwards and extend the shoulder. In the shoulder protraction movement, to strengthen serratus anterior muscle, the person stands with his back to the band and puts his arm in a 90 degree flexion position with a straight elbow and tries to move the band forward, and finally in the shoulder retraction exercise, in order to strengthen the rhomboid and middle trapezius muscles, the person It is placed in front of the bandaging and the arms are in 90 degree flexion with bent elbows and tries to pull the band back and bring the shoulders closer to each other from behind. As the strengthening exercises in the standing position cause pain for the patients, the patient is asked to start the exercises in the lying position on the bed and then progress to the standing position. All the exercises with the band are done in three sets of 10 with 30 seconds of rest between each set. The total duration of the exercises is around 20 to 30 minutes, and the amount of resistance and determination of the color of the bandage is determined for each person in supervised sessions during the treatment process, based on the level of challenge of each person in the last repetition, so that the quality of movement is maintained. The subjects of both groups are asked to do the exercises once a day at home, and also in weekly face-to-face sessions, how to do the exercises correctly and the required amount of resistance are examined under the supervision of the therapist.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

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Faculty of Rehabilitation in Iran
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available