Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of proprioceptive neuromuscular facilitation (PNF) and elastic band trainings on pain and range of motion in women with frozen shoulder syndrome

Protocol summary

Study aim

The effects of proprioceptive neuromuscular facilitation and elastic band trainings on pain and range of motion in women with frozen shoulder syndrome

Design

A randomized, single-blind clinical trial with two experimental groups and one control group will be conducted on 39 female patients diagnosed with frozen shoulder syndrome.

Settings and conduct

The study at Arak University will randomly assign participants to three groups: proprioceptive training, elastic band exercises, or control. Interventions will run for six weeks, three sessions per week. While participants and therapists are aware of the interventions, the outcome assessor will remain blinded to reduce evaluation bias.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1.Ageed 35 to 50 years. 2.Female gender. 3.Presence of night pain or pain during activities. 4.Diagnosis of frozen shoulder by a physician. 5.No structural damage in the shoulder joint Exclusion Criteria: 1.Absence from more than 2 consecutive or 3 non consecutive training sessions. 2.Unwillingness to continue participation in the study. 3.Muscular, joint, or bone injuries occurring during the study

Intervention groups

Intervention Group 1: Female patients with frozen shoulder who receive proprioceptive neuromuscular training to evaluate its effect on shoulder range of motion and pain. Intervention Group 2: Female patients with frozen shoulder who perform resistance exercises using elastic bands to assess their impact on shoulder range of motion and pain. Control Group: Female patients with frozen shoulder who will not receive any exercise intervention.

Main outcome variables

Shoulder pain; Shoulder range of motion; Upper limb functional performance; Shoulder related quality of life; Patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250709066423N1**
Registration date: **2025-10-02, 1404/07/10**
Registration timing: **prospective**

Last update: **2025-10-02, 1404/07/10**
Update count: **0**

Registration date

2025-10-02, 1404/07/10

Registrant information

Name

Mitra Salehi

Name of organization / entity

The University of Arak

Country

Iran (Islamic Republic of)

Phone

+98 21 3300 9876

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-17, 1404/07/25

Expected recruitment end date

2025-12-11, 1404/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of proprioceptive neuromuscular facilitation (PNF) and elastic band trainings on pain and range of motion in women with frozen shoulder syndrome

Public title

Investigating the effect of two types of exercise on shoulder pain and mobility in women with frozen shoulder

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Female gender Age between 35 and 50 years Diagnosis of frozen shoulder syndrome confirmed by a physician Presence of pain during daily activities and night pain No history of trauma, dislocation, or fracture in the upper limb, especially the shoulder joint No shoulder joint instability

Exclusion criteria:

Absence from more than two consecutive training sessions or three non-consecutive sessions Lack of willingness to continue participation in the study Occurrence of muscular, articular, or skeletal injuries during the intervention period

Age

From **35 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **39**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization will be used. The unit of randomization is the individual. The allocation sequence will be generated prior to participant enrollment using a random number table produced in Microsoft Excel. To ensure allocation concealment, the sequence will be kept by a person who is not involved in the study team. The researcher responsible for recruiting and assessing participants will be blinded to the allocation sequence to minimize the risk of systematic bias. Each eligible participant, after screening and signing the informed consent form, will be assigned to one of the three study groups (PNF, elastic band, or control) according to the pre-prepared randomization list, following the sequence order.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, due to the nature of the interventions (PNF and elastic band exercises), blinding of participants and the researcher is not possible, as the type of exercise is clearly recognizable to both the participants and the trainer. Similarly, the personnel responsible for data collection and outcome assessment will also be aware of the group allocations due to the structure of the study. However, the data analyst, who is responsible for the statistical analysis of the results, will be blinded to group assignments in order to prevent bias in the final analysis. Group allocation information will be provided to the analyst using specific codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University

Street address

Arak, Sardasht, Basij Square, Karbala Boulevard, Arak University

City

Arak

Province

Markazi

Postal code

3848177584

Approval date

2025-06-18, 1404/03/28

Ethics committee reference number

IR.ARAKU.REC.1404.015

Health conditions studied

1

Description of health condition studied

Frozen shoulder syndrome

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

Range of motion of the shoulder joint

Timepoint

At the beginning of the study and after 6 weeks of

intervention

Method of measurement

Using a goniometer

Secondary outcomes

1

Description

Pain in the shoulder joint

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

Using a visual analogue scale

Intervention groups

1

Description

Intervention Group: Proprioceptive Neuromuscular Facilitation (PNF) Exercises. The training protocol includes stretching movements and PNF motor patterns using the Contract-Relax (CR) and Hold-Relax (HR) techniques, specifically targeting the shoulder joint and the surrounding musculature—particularly the flexors, extensors, abductors, and internal and external rotators. Participants will perform movements with manual resistance provided by the instructor, either in a supine or seated position. No specialized equipment is required other than a therapeutic mat. Subjects will participate in three 30-minute sessions per week over a six-week period. Each session consists of approximately five minutes of warm-up with gentle stretching, followed by around twenty minutes of PNF techniques involving three sets of each movement (each set comprising a 10-second isometric contraction and a 30-second passive stretch), and concludes with five minutes of cool-down using light stretching exercises. The intensity of the exercises will be progressively adjusted based on each participant’s pain tolerance threshold.

Category

Rehabilitation

2

Description

Intervention Group: Elastic Band Exercises. The intervention group will perform resistance training using Grade 2 elastic bands, targeting the muscles surrounding the shoulder joint—specifically the flexors, extensors, abductors, and internal and external rotators. Participants will engage in three sessions per week over a six-week period. Each session lasts approximately 30 minutes and includes five minutes of warm-up, twenty minutes of resistance exercises with the band involving shoulder flexion, extension, abduction, adduction, and internal and external rotation (three sets of 10 to 12 repetitions per movement, with one-minute rest intervals between sets), followed by five minutes of cool-down. The resistance level of the band will be progressively increased based on the principle of progressive overload. No equipment other than elastic bands and a chair or wall for stabilization will be used. The intensity of the exercises will be tailored to each participant’s physical capacity and pain tolerance.

Category

Rehabilitation

3

Description

Control group. Participants in the control group will not receive any specific intervention or exercise regimen during the six-week study period and will continue with their routine daily activities. These individuals will be assessed for shoulder range of motion only at the beginning of the study and at the end of the six weeks. To uphold ethical standards, an educational booklet containing appropriate shoulder exercises will be provided to them upon completion of the study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Clinic Medical Center Building

Full name of responsible person

Shahnaz Shahrjerdi

Street address

Imam Khomeini Street, after 12-Meteri Malek, next to Bank Maskan, Iran Clinic Medical Center Building

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Arak

Full name of responsible person

Shahnaz Shahrjerdi

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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
The University of Arak

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

Name of organization / entity
The University of Arak
Full name of responsible person
Shahnaz Shahrjerdi
Position
PhD in Sports Medicine
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All research data will be made available after publication of the study results, except for any data that could potentially lead to the identification of participants. Only de-identified datasets or aggregated information related to the primary outcome variables will be shared, if required.

When the data will become available and for how long

5 months after the publication of the results.

To whom data/document is available

All individuals, researchers, professors, and patients with frozen shoulder can benefit from this study.

Under which criteria data/document could be used

Individuals interested in studying the research can contact the researcher via email to access the documents.

From where data/document is obtainable

Initially, please contact Dr. Shahrjerdi via email at s-shahrjerdi@araku.ac.ir, and then follow up by phone at +98-9912016283. It is also possible to visit the Library of Arak University, located in Sardasht, Basij Square, Karbala Boulevard, Arak University.

What processes are involved for a request to access data/document

Researchers can receive the requested document after sending an email and obtaining approval from the researcher.

Comments