Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Sex-Based Comparison of the Effects of a Combined Program of Myofascial Release, Codman and Elastic Band Exercises, on Pain, Range of Motion, and Function in Patients with Frozen Shoulder

Protocol summary

Study aim

To evaluate the effectiveness of a combined program of myofascial release, Codman exercises, and elastic-band training on pain, ROM, and function in men and women with frozen shoulder, and compare outcomes by sex.

Design

A randomized, single-blind, factorial, controlled clinical trial on 128 patients. The sample size was calculated using G*Power 3.1 software.

Settings and conduct

The study was conducted at Arvand Physiotherapy Clinic, Tehran. Participants were stratified by sex and randomly allocated to intervention and control groups. Assessments were performed before and after the 8-week intervention by a blinded assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Idiopathic frozen shoulder (35–60 years), Non Athletic lifestyle, chronic pain (≥3 months), VAS ≥3, and restricted ROM (abduction <135°, external rotation <40°, flexion <120°). Exclusion criteria: Anti-inflammatory drug use, secondary shoulder pathology, and session non-attendance.

Intervention groups

Pain, shoulder (ROM), and functional disability were assessed in both groups using the VAS, a standard goniometer and the DASH/SPADI questionnaires. The intervention group underwent an 8-week program consisting of three sessions per week (45–60 minutes each) involving myofascial release, Codman's pendulum exercises, and elastic band exercises while the control group was monitored via phone calls and text messages during this period and received treatment after the study concluded.

Main outcome variables

Pain, range of motion (ROM), and function indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260813070635N1**
Registration date: **2026-09-03, 1405/06/12**
Registration timing: **prospective**

Last update: **2026-09-03, 1405/06/12**
Update count: **0**

Registration date

2026-09-03, 1405/06/12

Registrant information

Name

Niloofar Kashani Siadat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2232 9237

Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-10, 1405/07/18

Expected recruitment end date

2026-12-07, 1405/09/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Sex-Based Comparison of the Effects of a Combined Program of Myofascial Release, Codman and Elastic Band Exercises, on Pain, Range of Motion, and Function in Patients with Frozen Shoulder

Public title
Sex-Based Comparison of the Effects of a Combined Program of Myofascial Release, Codman and Elastic Band Exercises, on Pain, Range of Motion, and Function in Patients with Frozen Shoulder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 35 and 60 years. Idiopathic FS diagnosed by a specialist, a non athletic lifestyle. Chronic shoulder pain for ≥3 months Pain severity ≥3 on the VAS. Motion limitation (abduction <135°, external rotation <40°, flexion <120°).

Exclusion criteria:
Use of corticosteroids or anti inflammatory drugs. History of secondary shoulder pathology. Absence from ≥3 consecutive or ≥2 non consecutive intervention sessions.

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
We reviewed the records of patients who had visited the clinic with shoulder pain—confirmed by an orthopedist—and classified them by gender. Within each gender category, the participants' records were assigned—using a completely random process and in equal numbers—to female control, female intervention, male control, and male intervention groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
“Outcome assessments were performed by an assessor who was blinded to group allocation. Due to the nature of the intervention, the participants and intervention provider could not be blinded

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University, Science and Research Branch

Street address
University Square, Shohadaye Hesarak Boulevard, End of Shahid Sattari Expressway

City
Tehran

Province
Tehran

Postal code
۱۴۷۷۸۹۳۸۵۵

Approval date
2024-08-31, 1403/06/10

Ethics committee reference number
IR.IAU.SRB.REC.1403.296

Health conditions studied

1

Description of health condition studied
Idiopathic frozen shoulder (adhesive capsulitis), characterized by shoulder pain, stiffness, restricted range of motion, and functional impairment.

ICD-10 code
M75.0

ICD-10 code description
XIII – Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description
Pain intensity

Timepoint
Baseline and immediately after the 8-week intervention

Method of measurement
Visual Analog Scale (VAS)

2

Description
Shoulder range of motion (ROM)

Timepoint
Baseline and immediately after the 8-week intervention

Method of measurement
Universal goniometer, measuring shoulder flexion, abduction, and external rotation

3

Description
Shoulder functional disability

Timepoint

Baseline and immediately after the 8-week intervention

Method of measurement

Disabilities of the Arm, Shoulder and Hand (DASH) and Shoulder Pain and Disability Index (SPADI) questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The Female intervention group underwent an 8-week supervised combined rehabilitation program, consisting of three sessions per week, each lasting 45 to 55 minutes. The program included 7 minutes of myofascial release (MFR) targeting the shoulder complex using gentle stretching, sustained manual pressure, and slow, multi-directional strokes; Codman's pendulum exercises performed with minimal active shoulder muscle engagement and progressive advancement; and elastic band exercises involving shoulder flexion, extension, abduction, adduction, and internal/external rotation. Resistance, repetitions, and exercise progression were adjusted based on the Borg RPE scale and individual therapeutic response.

Category

Rehabilitation

2

Description

Intervention group: The men in the intervention group underwent an 8-week supervised combined rehabilitation program, consisting of three sessions per week, with each session lasting 45 to 55 minutes. The program comprised 7 minutes of myofascial release (MFR) targeting the shoulder complex using gentle stretching, sustained manual pressure, and slow, multi-directional strokes; Codman's pendulum exercises performed with minimal active shoulder muscle engagement and progressive advancement; and elastic band exercises involving shoulder flexion, extension, abduction, adduction, and internal/external rotation. Resistance, repetitions, and exercise progression were adjusted based on the Borg RPE scale and individual therapeutic response.

Category

Rehabilitation

3

Description

Control group: Control Group: Following the initial assessments, the men and women in the control group were informed that they would be contacted after eight weeks to begin therapeutic interventions. Additionally, they were contacted weekly throughout this eight-week period to monitor their well-being and provide psychological support.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arvand Phhysiotheraoy

Full name of responsible person

Niloofar Kashani Siadat

Street address

Unit 21, No. 3, 1st Baharestan Alley, Kimasi Street, East Hafez Street, Kazem-Abad Neighborhood, Pasdaran Street

City

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Postal code

1665683872

Phone

+98 21 2232 9237

Email

siadatneli@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Reza Radfar

Street address

Hesarak, Daneshgah Boulevard, Tehran Province, Greater Tehran

City

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Province

Tehran

Postal code

۱۴۷۷۸۹۳۸۵۵

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+98 21 4486 5239

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eceres@srbiau.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Niloofar Kashani Siadat

Position

Graduate student

Latest degree

Master

Other areas of specialty/work

Others

Street address

No. 3, 1st Baharestan Alley, Kimasi Street, East Hafez Street, Kazem-Abad Neighborhood, Pasdaran Street.

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

Master

Other areas of specialty/work

Others

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Niloofar Kashani Siadat

Position

Graduate student

Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

There is no further information

When the data will become available and for how long

3 month after publish

To whom data/document is available

Everyone

Under which criteria data/document could be used

For research and rehabilitation

From where data/document is obtainable

Email: siadatneli@gmail.com

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

One week is required to gather the necessary data and provide it to the requester.

Comments