

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 ( $\geq 3$  months), VAS  $\geq 3$ , and restricted ROM (abduction  $< 135^\circ$ , external rotation  $< 40^\circ$ , flexion  $< 120^\circ$ ). 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

siadatneli@gmail.com

##### Recruitment status

**Not yet 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

Tehran

##### Province

Tehran

##### 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

Tehran

##### Province

Tehran

##### Postal code

۱۴۷۷۸۹۳۸۵۵

##### Phone

+98 21 4486 5239

##### Email

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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1665683872

**Phone**

+98 21 2232 9237

**Fax**

**Email**

siadatneli@gmail.com

**Person responsible for scientific 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

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**Phone**

+98 21 2232 9237

**Fax**

**Email**

siadatneli@gmail.com

**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**

Master

**Other areas of specialty/work**

Others

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**Email**

siadatneli@gmail.com

**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**

