

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Impact of Shoulder Mobilization-with-Movement Based on the Mulligan Concept on Inferior Shoulder Capsule Thickness and Motor Cortex Excitability in the Frozen Stage of Idiopathic Frozen Shoulder: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of the impact of Shoulder MWM based on the Mulligan concept on inferior shoulder capsule thickness, motor cortex excitability, and functional performance in individuals with idiopathic frozen shoulder in the frozen stage.

Design

Three arm parallel group randomized clinical trial with outcome assessor blinding

Settings and conduct

This study will be conducted at the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 40–60, gradual progressive shoulder pain 3–6 months, pain at end-range motion, NPR Scale 4–6, confirmed idiopathic frozen shoulder (frozen stage), passive external rotation $<30^\circ$. Exclusion criteria: systemic diseases, other shoulder musculoskeletal disorders, contraindications to TMS, physiotherapy or corticosteroid injection in past 6 months, medications affecting cortical excitability, caffeine within 24 hours.

Intervention groups

The healthy control group includes individuals without frozen shoulder or shoulder pain and will not receive any intervention, serving only for baseline neurophysiological comparison. The other two groups comprise patients with idiopathic frozen shoulder (frozen stage), all receiving routine physiotherapy (ultrasound and TENS) for four weeks, three sessions per week. The intervention group additionally undergoes Mulligan shoulder mobilization-with-movement techniques—posterior-lateral-inferior, anterior-lateral-inferior, and internal-external rotation—in a seated position, three sets of 10 pain-free

repetitions per technique, 30 seconds rest between sets, each repetition lasting ~6 seconds.

Main outcome variables

Inferior Glenohumeral Capsule Thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251221068399N1**

Registration date: **2025-12-26, 1404/10/05**

Registration timing: **prospective**

Last update: **2025-12-26, 1404/10/05**

Update count: **0**

Registration date

2025-12-26, 1404/10/05

Registrant information

Name

Ali Khandaloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3330 0397

Email address

alikhandaloo1997@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-20, 1404/10/30

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Shoulder Mobilization-with-Movement Based on the Mulligan Concept on Inferior Shoulder Capsule Thickness and Motor Cortex Excitability in the Frozen Stage of Idiopathic Frozen Shoulder: A Randomized Clinical Trial

Public title

The Impact of Shoulder Joint Mobilization in Patients with Idiopathic Frozen Shoulder: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being 40–60 years of age; experiencing gradual and progressive shoulder pain over the past 3–6 months; reporting pain at the end ranges of shoulder motion; having a Numeric Pain Rating Scale score between 4 and 6; presenting with a confirmed diagnosis of idiopathic frozen shoulder in the frozen stage; and demonstrating passive external rotation restricted to less than 30 degrees.

Exclusion criteria:

The presence of systemic diseases; coexisting musculoskeletal disorders of the shoulder; any contraindications to transcranial magnetic stimulation; a history of physiotherapy or corticosteroid injections within the preceding six months; use of medications known to influence cortical excitability; and consumption of caffeine within 24 hours prior to the assessments.

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, to ensure allocation concealment, permuted block randomization will be used in conjunction with sequentially numbered, opaque, sealed envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this clinical trial, the outcome assessor will be blinded to both the participants' health status and the type of treatment they receive, and all assessments will be

conducted in a blinded manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences and Health Services

Street address

Basij Blvd

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Postal code

3514799442

Approval date

2025-12-21, 1404/09/30

Ethics committee reference number

IR.SEMUMS.REC..1404.222

Health conditions studied

1

Description of health condition studied

Frozen Shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

Inferior Glenohumeral Capsule Thickness

Timepoint

Before treatment, immediately after treatment, and two months after treatment

Method of measurement

Ultrasound Imaging

Secondary outcomes

1

Description

Motor Cortex Excitability

Timepoint

Before treatment, immediately after treatment, and two months after treatment

Method of measurement

Transcranial Magnetic Stimulation

2

Description

Shoulder Cardinal Range of Motion

Timepoint

Before treatment, immediately after treatment, and two months after treatment

Method of measurement

Goniometer

3

Description

Shoulder Functional Performance

Timepoint

Before treatment, immediately after treatment, and two months after treatment

Method of measurement

Shoulder Pain and Disability Index (SPADI questionnaire)

Intervention groups

1

Description

Control group: healthy control group

Category

Other

2

Description

Intervention group: Intervention Group 1 (Patient Control)

Category

Rehabilitation

3

Description

Intervention group: Intervention Group 2

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

Full name of responsible person

Ali Khandaloo

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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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

Semnan 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

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Ali Khandaloo

Position

Physiotherapy Ph.D. Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All individual participant data will be de-identified (anonymized) prior to sharing. If ethical restrictions apply, at minimum, data on primary and secondary outcomes—including capsule thickness, range of motion, SPADI scores, and motor cortex excitability measures—will be made available.

When the data will become available and for how long

Access period begins 6 months after publication of the results.

To whom data/document is available

Data and study-related documents will be made available upon reasonable request to qualified researchers. Eligible applicants include researchers affiliated with academic and scientific institutions, and, provided that a clear research purpose and compliance with ethical and data confidentiality requirements are demonstrated, researchers from industry settings may also apply. All requests will be reviewed and approved by the study research team.

Under which criteria data/document could be used

Access to de-identified individual participant data and other study-related documents will be granted upon submission of a formal written request outlining the research objectives, proposed analyses, and intended duration of data use. The data may be used solely for scientific and research purposes, including secondary analyses or meta-analyses, and any direct commercial use, attempts at participant re-identification, or sharing with third parties without written permission are prohibited. Applicants must adhere to all ethical, legal, and data confidentiality requirements, and provide appropriate citation of the original study in any resulting publications. All requests will be reviewed and approved by the study research team.

From where data/document is obtainable

Eligible applicants seeking access to de-identified data or other study-related documents should submit a formal request primarily via email to the principal investigator,

with postal correspondence available if needed. Contact details—including the principal investigator’s name, institutional affiliation, email address, telephone number, and postal address—are provided in the study information. Requests should specify the intended use of the data, proposed analyses, and the applicant’s contact information, and will be reviewed and responded to following approval by the study research team.

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

After receiving a formal request, it will first be reviewed by the principal investigator to assess completeness,

research purpose, and compliance with ethical requirements. If necessary, additional information may be requested from the applicant. Following this initial review, the request will be discussed within the research team and a final decision regarding data access will be made. Upon approval, the requested data and documents will be provided in a de-identified format through a secure electronic platform. This process typically takes 2 to 4 weeks from receipt of a complete request, and applicants will be informed of the status of their request throughout the review period.

Comments