Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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°. 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)

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+98 23 3330 0397

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alikhandaloo1997@gmail.com

Recruitment status
Recruitment complete

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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Semnan

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Semnan

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
dr. Majid Eslami
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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
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Ali Khandaloo
Position
Physiotherapy Ph.D. Candidate
Latest degree
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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
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