Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Efficacy of Manual Treatment According to Fascial Distortion Model Versus Joint Mobilization in Pain Reduction of Patients With Shoulder Impingement Syndrome Who Refer to Pirouzi Physiotherapy Clinic

Protocol summary

Study aim

Comparison of Manual Treatment According to Fascial Distortion Model Versus Joint Mobilization in Reducing Pain, Increasing Range of Motion and Improving Function of Patients With Shoulder Impingement Syndrome

Design

Single-blinded randomized clinical trial with parallel groups and phase 3 on 26 patients. Randomization is carried out by coin toss method.

Settings and conduct

Study population are patients with shoulder impingement syndrome that are referred to Pirouzi physiotherapy clinic in Mashhad.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: pain by arm elevation with Intensity of ≥3 on VAS and positive Neer & Hawkins-Kennedy tests. Exclusion criteria are: stroke, rheumatoid arthritis, full-thickness rotator cuff tear; trauma; surgery or freezing of the shoulder; osteoporosis or malignancy.

Intervention groups

In FDM group, the diagnosis is based on body language, subjective complaints, objective findings and mechanism of injury. In mobilization group, related accessory movements in glenohumeral, scapulothoracic, acromioclavicular and sternoclavicular joints are assessed in regard to the presence of pain and/or restriction. Treatment includes oscillatory movements with Maitland grading and frequency of two times per second that first is done in comfortable position and progressively toward painful position. Grades I-II and III-IV are used for pain and restriction respectively.

Main outcome variables

Pain intensity (VAS); pain-free abduction ROM (Goniometry); function (SPADI); patient satisfaction with treatment (Likert Scale)

General information

Reason for update

Acronym

FDM (Fascial Distortion Model)

IRCT registration information

IRCT registration number: **IRCT20200922048803N1**
Registration date: **2021-04-20, 1400/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-20, 1400/01/31**
Update count: **0**

Registration date

2021-04-20, 1400/01/31

Registrant information

Name

Mahmood Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3851 6396

Email address

m.moradi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-01, 1398/10/11

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Efficacy of Manual Treatment According to Fascial Distortion Model Versus Joint Mobilization in Pain Reduction of Patients With Shoulder Impingement Syndrome Who Refer to Pirouzi Physiotherapy Clinic

Public title
Comparison of the Efficacy of Manual Treatment according to Fascial Distortion Model Versus Joint Mobilization in Patients With Shoulder Impingement Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Pain By Arm Elevation With Intensity of ≥3 on VAS Positive Neer & Hawkins-Kennedy Tests
Exclusion criteria:
Stroke Rheumatoid Arthritis Full-thickness Rotator Cuff Tear Trauma Surgery of the Shoulder Freezing of the Shoulder Osteoporosis Malignancy

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization would be carried out by coin toss method for patients with odd number, and the patients with even number would receive the other treatment. Heads side is indicative of FDM treatment and tails side is indicative of joint mobilization.

Blinding (investigator's opinion)
Single blinded

Blinding description
The patients would be blinded in respect to allocation in either of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
School of Rehabilitation of Tehran University of Medical Sciences, Piche Shemiran, Enghelab Ave, Tehran
City
Tehran
Province
Tehran
Postal code
1148956111

Approval date
2020-02-05, 1398/11/16

Ethics committee reference number
IR.TUMS.VCR.REC.1398.880

Health conditions studied

1

Description of health condition studied
Shoulder Impingement Syndrome

ICD-10 code
M75.4

ICD-10 code description
Impingement syndrome of shoulder

Primary outcomes

1

Description
Pain Intensity

Timepoint
Before and after every treatment session and after a 2 week follow up

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Pain-free Abduction ROM

Timepoint
Before and after every treatment session and after a two week follow up

Method of measurement
Goniometry

2

Description
Function

Timepoint
Before the first treatment session, after the last session

and after a two week follow up

Method of measurement

Persian Version of SPADI

3

Description

Patient Satisfaction With Treatment

Timepoint

After a two week follow up

Method of measurement

Likert Scale

Intervention groups

1

Description

Intervention group: Three Sessions of Manual Treatment according to Fascial Distortion Model (Including Triggerband, Herniated Triggerpoint, Continuum, Folding, Cylinder And Tectonic) Every Other Day And Each Session Lasting 30 Minutes

Category

Rehabilitation

2

Description

Intervention group: Three Sessions of Joint Mobilization (Including Oscillatory Movements With Maitland Grading and a Frequency of Two Times per Second Which Are Done Initially in Resting Position and Progressively Into Painful Position of the Patient) Every Other Day and Each Session Lasting 30 Minutes

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Pirouzi Physiotherapy Clinic

Full name of responsible person

Mahmood Moradi

Street address

No. 536, Between 16 & 18, Pirouzi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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Qods Ave., Keshavarz Blvd.

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msahrai@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahmood Moradi

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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