

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### comparing the effect of manual and exercise therapy on pain, function and range of motion in treatment of patients with shoulder impingement syndrome

#### Protocol summary

##### Study aim

Comparing the effect of manual and exercise therapy on pain, function and range of motion in treatment of patients with shoulder impingement syndrome

##### Design

The clinical trial has two treatment groups, parallel, double blind and randomized on 64 patients. for randomization use excel.

##### Settings and conduct

Patients will be called through universities and medical science centers. In order to blind the study, an evaluation by an examiner who does not know the patient group will be performed. Assessor will be unaware and won't have any information about patients. Patients also have no information about which group they will be categorized into. The evaluator and therapist will be two different people.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: 1.Report of pain in overhead movement 2.Report of pain in active shoulder movements. 3.Positive Neer/Hawkin Kennedy test. 4.the beginning of pain is older than 3 months 5.having Non traumatic pain. 6.Having pain in 60 -120 degree flexion. 7.Having Pain in 4/10 VAS exclusion criteria: 1.Having Red flags 2.Having background of Frozen shoulder 3.Having A.C joint dysfunction (confirm with cross over test) 4.Having G.H joint DJD 5.Having Calcification in shoulder tendons confirmed by radiology. 6.Having vivid Instability in shoulder(confirm with anterior drawer test) 7.Existence of any Traumatic shoulder disorder 8.Having any Surgery in shoulder, elbow, wrist, neck or scapula 9.Having Disc bulging. 10.Having Systematic ills such as R.A.

##### Intervention groups

1.Manual therapy 2.Therapeutic exercise

##### Main outcome variables

measurement SPADI : VAS &ROM will be obtained

#### General information

##### Reason for update

A few small typos

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191001044947N1**

Registration date: **2020-06-14, 1399/03/25**

Registration timing: **prospective**

Last update: **2020-11-15, 1399/08/25**

Update count: **1**

##### Registration date

2020-06-14, 1399/03/25

##### Registrant information

##### Name

Zeynab Azin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3735 2664

##### Email address

stud2281423808@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-15, 1399/03/26

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

comparing the effect of manual and exercise therapy on pain, function and range of motion in treatment of patients with shoulder impingement syndrome

### Public title

comparing the effect of manual and exercise therapy on pain, function and range of motion in treatment of patients with shoulder impingement syndrome

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

1. reports of pain in overhead movement 2. reports of pain in active shoulder movements 3. containing positive Neer/Hawkin Kennedy test 4. the Duration of pain lasts more than 3 months 5. having no traumatic pain 6. feeling the pain in 60 to 120 degree of flexion 7. visual analogue scale must be between 4-10

#### Exclusion criteria:

1. having any Red flags 2. history of frozen shoulder 3. AC joint dysfunction 4. G.H joint DJD 5. the existence of calcification in the shoulder tendons 6. shoulder Instability 7. Traumatic shoulder disorder 8. Surgery in shoulder, elbow, wrist, neck or scapula 9. Disc bulging 10. Systematic disease such as rheumatoid arthritis. 11. Taking painkillers, cartilage and anti-inflammatory drugs

### Age

From **25 years** old to **62 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **64**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Samples are randomly allocated into two groups. Randomization will be applied with block randomization method (4 people per block) . This method will be applied by the person how does not has any role in treatment and assessment.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Assessor will be unaware and won't have any information about patients. Patients also have no information about which group they are categorized into. The evaluator and therapist will be two different people.

### Placebo

Not used

### Assignment

Parallel

### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

No. 31, Alley 4, Isar Street, Shiraz, Boulevard Modares

##### City

Shiraz

##### Province

Fars

##### Postal code

71537-43897

#### Approval date

2019-09-18, 1398/06/27

#### Ethics committee reference number

IR.SUMS.REHAB.REC.1398.028

### Health conditions studied

#### 1

#### Description of health condition studied

shoulder impingement syndrome

#### ICD-10 code

#### ICD-10 code description

### Primary outcomes

#### 1

#### Description

Measurement Shoulder pain and disability index (SPADI), Goniometry, Visual analogue scale (VAS)

#### Timepoint

pre treatment, post treatment and 1 month after treatment

#### Method of measurement

Shoulder pain and disability index , Goniometry, Visual analogue scale

### Secondary outcomes

empty

### Intervention groups

#### 1

#### Description

Intervention group: manual therapy: The treatment will last 3 sessions per week for patients. Manual therapy includes ischemic compression on trigger and

Mobilization points. mobilization of acromioclavicular joint, sternoclavicular joint, glenohumeral joint, scapulothoracic and thoracic joints will be done in direction of limitation by therapists hand. This technique will be done in 3 sets and duration of each set is 30 seconds. For finding trigger points some muscles like pectoralis major, pectoralis minor, supraspinatus, infraspinatus, teres minor, teres major, deltoid and levator scapula will be assessed. Ischemic compression technique will be performed for each muscle that have trigger point and at least 3 muscles from them should have trigger points. For this technique, pressure will be applied on the trigger points by the therapist's thumb. Gradually this pressure will be increased up to the patient's tolerance . This pressure will be applied for 5 to 15 seconds and based on the patient condition this time can increased up to 2 minutes.

### Category

Rehabilitation

## 2

### Description

Group2: therapeutic exercise: Treatment will last 3 months. Exercises will be done for 12 weeks. During this period, 7 visits will be done by physiotherapists. The exercises will be done in 3 sets and the repetition of exercise in each set is 15 and therapist will emphasize on posture correction. The Emphasis is on correcting the posture. List of exercises contain these elements: Stretching of capsule 2 times in a day, each time contains 3 set between 30 to 45 seconds. As the patient use his or her healthy hand to hold the back of the involved hand and stretch it on the chest. Exercises in the first 8 weeks must done 2 times per day and after 4 weeks it will be reduced to 1 time per day by 3 sets and 15 repeats. Description of the exercises: 1- Retraction the shoulders in a standing position. 2- concentric Full can Exercise for week 1 to 8 and eccentric Full can Exercise for week 9 to 12. In this exercises glenohumeral joint in scapula plane will move foe 30 to 45 degree and Dumbbell and TheraBand will be used as the patient will hold the Dumbbell in her/his hand and then lift the involved shoulder in scapula plane and then release it without help. 3- eccentric exercise of infraspinatus muscle and teres minor as the patient lie down on intact side and the involved shoulder will be upward, and elbow will bend 90 degree then Arm will stand still on body side then shoulder will turn slowly inward and then will return back to it initial position with intact hand help. From week 9 to 12 the exercise will prescription in both eccentric and concentric manner as the intact hand won't help any longer. 4- eccentric and concentric exercise for serratus anterior muscle in supine position as the patient lie down with shoulder is bend 90 degree and the elbow is straight, scapula will move upward and downward. from week 9 to 12 the push up plus exercise will substituted as the patient lie in prone position in put his/her hands palm on the ground then move shoulders forward and backward. 5- external rotation of shoulders bilateral as the patient standing straight holding a TheraBand by both hands then bend both elbows as the shoulders are turning outward. From week 9 to 12

external rotation will done as both shoulders will lift up as both elbows are bended will substituted.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz university of medical science

##### Full name of responsible person

zeynab azin

##### Street address

No. 31, Alley 4, Isar Street, Shiraz, Boulevard Modares

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##### Phone

+98 71 3648 6146

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stud2281423808@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Nejabat

##### Street address

No. 31, Alley 4, Isar Street, Shiraz, Boulevard Modares

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#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Shiraz university of medical science

#### 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Zeynab azin

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Postal code**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Zeynab azin

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

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Shiraz University of Medical Sciences

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Zeynab azin

**Position**

Student

**Latest degree**

Master

**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**

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**

Personal information will be included in the form.

Information can be shared.

**When the data will become available and for how long**

Start access period 1 year after publishing results

**To whom data/document is available**

every one can access to information

**Under which criteria data/document could be used**

Any scientific use is permitted.

**From where data/document is obtainable**

email:zeynabazin@yahoo.com 09352595647

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

Send an email to the listed alert and Call after 3 days if you do not receive a reply. Files will be sent within 2 weeks.

**Comments**