# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## The Comparative Effect of Comprehensive Physical therapy with Focus on Scapula and Glenohumeral Joint versus Common Physical Therapy on Pain, Range of motion, Disability Level, Quality of Life and the Effectiveness of Treatment Parameters in Patients with Shoulder Impingement Syndrome

## Protocol summary

**Study aim**

The Comparative Effect of Comprehensive Physical therapy with Focus on Scapula and Glenohumeral Joint versus Common Physical Therapy in treatment of shoulder impingement syndrome

**Design**

Clinical trial, randomized grouping of individuals with sealed envelopes into intervention and control groups, blind assessment of variables by the evaluator

**Settings and conduct**

Place of study: Physical Therapy Clinic of Ghaem Hospital Evaluator: The other physiotherapist will evaluate the patients.

**Participants/Inclusion and exclusion criteria**

inclusion criteria: .aged 18-65 years/pain more than 6 weeks/ pain in the upper,outer arm especially when lifting of arm/ signs of shoulder impingement syndrome (presence of at least two of the following) 1) painful arch movement during flexion or abduction of the shoulder 2) positive Neer or Hawkins-Kennedy test 3) painful resisted external rotation, abduction or painful jobe test exclusion criteria: 1.Existence of type 3 acromion 2. Existence of frozen shoulder 3. Existence of neck radiculopathy 4.Existence of Complete rupture of rotator-cuff muscles 5.Existence of shoulder joint instability 6.History of fracture or dislocation or surgery in the shoulder complex 7.Use of Corticosteroids drugs in last 3 months 8.History of Reflex Sympathetic Dystrophy 9.History of any neurological diseases 10.History of rheumatoid diseases and shoulder osteoarthritis

**Intervention groups**

In the intervention group, a comprehensive physiotherapy focusing on scapula and shoulder joint, and in the control group a common physiotherapy in the shoulder joint will be performed.

**Main outcome variables**

Pain with VAS scale; functional level with Shoulder pain and disability index and Quick DASH questionnaires; quality of life with WORC questionnaire; effectiveness of treatment with GRC

## General information

**Reason for update**

This update is done to inform the completion of treatment, increase the sample size as well as increase the evaluation time to six months after treatment.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20161221031506N2**
Registration date: **2018-06-29, 1397/04/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-11, 1400/04/20**
Update count: **1**

**Registration date**

2018-06-29, 1397/04/08

**Registrant information**

**Name**

Salman Nazary-Moghadam

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3884 6713

**Email address**

nazaryms@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-06-05, 1397/03/15

**Expected recruitment end date**
2019-09-06, 1398/06/15

**Actual recruitment start date**
2018-06-05, 1397/03/15

**Actual recruitment end date**
2019-08-05, 1398/05/14

**Trial completion date**
2019-09-21, 1398/06/30

**Scientific title**
The Comparative Effect of Comprehensive Physical therapy with Focus on Scapula and Glenohumeral Joint versus Common Physical Therapy on Pain, Range of motion, Disability Level, Quality of Life and the Effectiveness of Treatment Parameters in Patients with Shoulder Impingement Syndrome

**Public title**
The comparative effect of two physiotherapy methods in patients with shoulder impingement syndrome

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Aged 18-65 years Pain more than 6 weeks Pain in the upper, outer arm especially when lifting of arm Signs of shoulder impingement syndrome : Presence of at least two of the following- 1) Painful arch movement during flexion or abduction of the shoulder -2) Positive Neer or Hawkins-Kennedy test- 3) Painful resisted external rotation, abduction or painful jobe (empty can) test

**Exclusion criteria:**
Existence of type 3 acromion Existence of frozen shoulder ( the loss in passive shoulder range of motion greater than 50% as compared to the uninvolved side in at least 2 shoulder movements) Existence of neck radiculopathy Existence of Complete rupture of rotator cuff muscles (MRI findings) Existence of shoulder joint instability (Positive tests of sulcus or apprehension) Use of corticosteroid drugs in last 3 months History of RSD History of any neurological diseases History of rheumatoid diseases and shoulder osteoarthritis History of fracture or dislocation or surgery in the shoulder complex

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **32**
Actual sample size reached: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Convenient sampling Randomization Tool: Sealed envelopes include paired and odd numbers (from one to 40) allocation concealment will be done randomly.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Participants choose to pick one of the sealed envelopes. Another physiotherapist who does not know how to group and do the study will evaluate the patients.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
The Ethics Committee of Mashhad University of Medical Sciences

**Street address**
Opposite University Street 18, University street

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9138813944

**Approval date**
2018-05-19, 1397/02/29

**Ethics committee reference number**
IR.MUMS.REC.1397.056

## Health conditions studied

### 1

**Description of health condition studied**
impingement syndrome of shoulder

**ICD-10 code**
M75.4

**ICD-10 code description**
Impingement syndrome of shoulder

## Primary outcomes

### 1

**Description**
functional level

**Timepoint**
Before the start of the treatment plan / after the

completion of the treatment plan / one month after the completion of the treatment plan/ Six month after the completion of the treatment plan

**Method of measurement**

Shoulder pain and disability index questionnaire

## Secondary outcomes

### 1

**Description**

pain

**Timepoint**

Before the start of the treatment plan / after the completion of the treatment plan / one month after the completion of the treatment plan/ six month after the completion of the treatment plan

**Method of measurement**

visual analogue scale

### 2

**Description**

functional level

**Timepoint**

Before the start of the treatment plan / after the completion of the treatment plan / one month after the completion of the treatment plan/ six month after the completion of the treatment plan

**Method of measurement**

Quick The Disabilities of the Arm, Shoulder and Hand Score questionnaire

### 3

**Description**

quality of life

**Timepoint**

Before the start of the treatment plan / after the completion of the treatment plan / one month after the completion of the treatment plan/ six month after the completion of the treatment plan

**Method of measurement**

Western ontario rotator cuff questionnaire

### 4

**Description**

The effectiveness of the treatment

**Timepoint**

Before the start of the treatment plan / after the completion of the treatment plan / one month after the completion of the treatment plan/ six month after the completion of the treatment plan

**Method of measurement**

global rating of change scale

## Intervention groups

### 1

**Description**

Intervention group: One-month Physical therapy program with focus on scapula and glenohumeral joint (shoulder) for twelve sessions

**Category**

Rehabilitation

### 2

**Description**

Control group: One-Months Physical Therapy Program at the shoulder joint for twelve sessions

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Physical Therapy Clinic of Ghaem Hospital

**Full name of responsible person**

Mr Javad Zarandi

**Street address**

Nursing door entrance, right side, library side, Narjes building, first floor,Physiotherapy Department, Ghaem Hospital,

**City**

Mashhad

**Province**

Razavi Khorasan

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9176699199

**Phone**

+98 51 3801 2217

**Email**

ZarandiMJ1@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Doctora Cross road, Ghoreshi Building

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**Province**

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**Email**

vcresearch@mums.ac.ir

**Web page address**
http://v-research.mums.ac.ir/
**Grant name**
Personal Grant (Dr Salman Nazary-Moghadam)
**Grant code / Reference number**
961343
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Mashhad 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**
Mashhad University of Medical Sciences
**Full name of responsible person**
Fatemeh Zarei Moghadam Ghalehamam
**Position**
Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Physiotherapy
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Mashhad- Azadi Square- East door of Ferdowsi University of Mashhad- University campus- Faculty of Paramedical Sciences
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is 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**
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**

All reports will be reported in one research paper. Raw data will be delivered to researchers for meta analysis.

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

Starting 6 months after publication

**To whom data/document is available**

For researchers

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

Only for metaanalysis

**From where data/document is obtainable**

Nazary_salman@yahoo.com

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

The response will be sent 3 months after considering the researcher request.

**Comments**