

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Effectiveness of Medical Exercise Therapy (MET) with Traditional Exercises on Pain, Range of Motion and Function in Adults with Idiopathic Adhesive Capsulitis

#### Protocol summary

##### Study aim

To evaluate the effect of Medical Exercise Therapy on Pain, ROM and Function in Adults with Unilateral Idiopathic Adhesive Capsulitis

##### Design

Randomised, parallel-group trial with blinded patient, assessor, and analyst.

##### Settings and conduct

A patient and investigator blinded trial conducted at Ghurki Trust and Teaching Hospital Lahore.

##### Participants/Inclusion and exclusion criteria

1. Patients with at least a 1-month history of progressively worsening symptoms will be included. 2. Patients with restricted shoulder mobility due to causes other than idiopathic will be excluded.

##### Intervention groups

The patient will receive directly supervised 3 sessions per week for 1 month. MET will consist of 7 exercises that combine global, semi-global, and local exercises. Global exercises involve working the whole organism dynamically, while semi-global exercising involves working an entire limb in a closed or open-chain activity. Local exercises involve specifically working the affected joint, with activation of a smaller number of muscles including grade III and IV mobilizations and capsular stretching. The treatment will be initiated with 10–20 minutes of stationary bicycling/treadmill, followed by 3 to 4 different semi-global and local exercises with three sets of 30 repetitions. Afterward, the patient will perform another global exercise of 5–10 minutes of stationary bicycling/treadmill. Immediately after this, another 3 to 4 semi-global and local exercises with three sets of 30 repetitions will be performed. The treatment ends with another global exercise of 10 minutes of stationary bicycling/treadmill.

##### Main outcome variables

1.Pain 2.ROM 3.Functional Disability

#### General information

##### Reason for update

##### Acronym

Medical Exercise Therapy (MET)

##### IRCT registration information

IRCT registration number: **IRCT20200514047437N1**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

##### Registration date

2020-06-22, 1399/04/02

##### Registrant information

##### Name

Maleeha Fuad

##### Name of organization / entity

Lahore Medical and Dental College

##### Country

Pakistan

##### Phone

+92 42 36603199

##### Email address

maleehafuad2@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-01, 1398/08/10

##### Expected recruitment end date

2020-07-31, 1399/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Effectiveness of Medical Exercise Therapy (MET) with Traditional Exercises on Pain, Range of Motion and Function in Adults with Idiopathic Adhesive Capsulitis

**Public title**

Effects of Medical Exercise Therapy on Pain, Range of Motion and Function in Adults with Idiopathic Adhesive Capsulitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Shoulder ROM loss of greater than 25% in at least 2 planes and passive external rotation loss that is greater than 50% of the uninvolved shoulder or less than 30°. Patients presenting with painful and restricted active and passive ROM of the affected shoulder in both elevation and rotation that occurs for at least 1 month and has either reached a plateau or worsened Patients presenting with a gradual and progressive onset of pain, at end ranges of movements of the affected shoulder. Functional activities such as reaching overhead, behind the back, or out to the side became increasingly difficult due to pain and/or stiffness.

**Exclusion criteria:**

Patients presenting with shoulder pain and stiffness due to cerebral vascular accident, intrathoracic conditions of intra-abdominal conditions. Patients with cervical disc disease, distal extremity fracture, or self-imposed immobilization as well as patients with a known pathology of the glenohumeral joint soft tissues or structures, such as rotator cuff tendinopathy, biceps tendinopathy, calcific tendinitis, acromioclavicular or glenohumeral joint arthropathy, or proximal humeral or scapular fracture or post-operative stiffness.

**Age**

From **25 years** old to **44 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Consecutive sampling and consecutive assignment using simple random sampling. The basic strategy used for randomization will be the development of an ordered list with group assignments made in advance using simple random sampling by random number generator. As participants enter the study, they will be given consecutive numbers and assigned to the group

indicated for each number.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patients will be blinded from their group allocation. They will receive their allocated treatment without the knowledge of whether they belong to the control group or interventional group. The duration of the treatment session will be the same for both groups. The assessor will be a physical therapist who will have no role in the treatment of the patients in both groups. At the end, the collected data will be analyzed by a biostatistician who will be unaware of group specification of the data

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Riphah College of Rehabilitation Sciences (RCRS)  
Research Ethical Committee (REC)

**Street address**

near Hajj Complex, I-14, Islamabad, Islamabad Capital Territory

**City**

Islamabad

**Postal code**

46000

**Approval date**

2020-01-01, 1398/10/11

**Ethics committee reference number**

REC/RCRS/20/1024

**Health conditions studied****1****Description of health condition studied**

Adhesive shoulder capsulitis, is a term attributed to a pathological process which involves scarring and adhesion formation across the joint capsule of the glenohumeral joint. It is characterized by restricted and pain full shoulder movements which deleteriously effects the patient's quality of life. Through out its course of disease it goes through various stages from freezing to frozen to thawing.

**ICD-10 code**

M75.0

**ICD-10 code description**

Adhesive capsulitis of shoulder

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

before intervention and 2, 4 weeks after intervention.

#### Method of measurement

Pain will be measured using numeric rating pain scale.

### 2

#### Description

Functional Disability

#### Timepoint

Before intervention and 2, 4 weeks after intervention.

#### Method of measurement

The Shoulder Pain and Disability Index (SPADI)

### 3

#### Description

Range of Motion

#### Timepoint

The Shoulder Pain and Disability Index (SPADI)

#### Method of measurement

Goniometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: The patients' history and clinical tests, including muscle tests, specific joint tests, and functional tests, will be used to form the basis for choosing the right grading of the exercises, with emphasis on the appropriate weight resistance and range of motion. Patients will be instructed that the exercises might result in muscle fatigue but should not increase the shoulder pain significantly. Patient will receive directly supervised 3 sessions per week for one month. MET will consist of 7 exercises that combine global, semi-global and local exercises. Global exercises involve working the whole organism dynamically, while semi-global exercising involves working an entire limb in a closed or open chain activity. Local exercises involve specifically working the affected joint, with activation of a smaller number of muscles including grade III and IV mobilizations and capsular stretching. In the attempt to establish a close to pain-free treatment, the dosage is optimized by combining global, semi-global and local exercises. The treatment will be initiated with 10-20 minutes of stationary bicycling/treadmill at a level the patient manages with a goal of ~70% of max, followed by three to four different semi-global and local exercises with three sets of 30 repetitions. After the semi-global and local exercises, the patient will perform another

global exercise of 5-10 minutes of stationary bicycling/treadmill. Immediately after this, another three to four semi-global and local exercises with three sets of 30 repetitions will be performed. The treatment ends with another global exercise of 10 minutes of stationary bicycling/treadmill.

#### Category

Rehabilitation

### 2

#### Description

Conventional treatment: Patients in this group will similarly receive 3 supervised sessions per week for one month. The treatment protocol will include conventional pain modulating electrotherapeutic modalities i.e. TENS and cold pack. Followed by mobilization of grade III and IV, capsular stretching, ROM and strengthening exercises of shoulder.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghurki Trust and Teaching Hospital

##### Full name of responsible person

Hafiz Muhammad Asim

##### Street address

G.T RD-Burki Rd Link, Band Road, Jallo More

##### City

Lahore

##### Postal code

53401

##### Phone

+92 42 37392201

##### Email

marketing.ghurkihospital@gmail.com

##### Web page address

<https://www.ghurkitrust.org.pk/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ghurki Trust and Teaching Hospital, Lahore

##### Full name of responsible person

Maleeha Fuad

##### Street address

GT RD-Burki Rd Link, Band Road, Jallo More

##### City

Lahore

##### Postal code

53401

##### Phone

+92 42 37392201

##### Email

marketing.ghurkihospital@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ghurki Trust and Teaching Hospital, Lahore

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Other

**Person responsible for general inquiries****Contact****Name of organization / entity**

Lahore Medical and Dental College

**Full name of responsible person**

Maleeha Fuad

**Position**

Lecturer

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

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54750

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maleehafuad2@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Lahore Medical and Dental College

**Full name of responsible person**

Maleeha Fuad

**Position**

Lecturer

**Latest degree**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

there is no further information

**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