

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

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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

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

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Phone

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Email

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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

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

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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