Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, accessor, 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 accessor 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 Rehablitation 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 months. MET will consists 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 performs 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 convention 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

26\3 Riffle Range Road., Walton Road., Cantt

City

Lahore

Province

Punjab

Postal code

54750

Phone

+92 42 36603199

Fax

Email

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

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

26\3 Riffle Range Road., Walton Road., Cantt

City

Lahore

Province

Punjab

Postal code

54750

Phone

+92 42 36603199

Fax

Email

maleehafuad2@gmail.com

Person responsible for updating data

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

26\3 Riffle Range Road., Walton Road., Cantt

City

Lahore

Province

Punjab

Postal code

54750

Phone

+92 42 36603199

Fax

Email

maleehafuad2@gmail.com

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