

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparative effectiveness of Myofascial Release Therapy and Post Isometric Relaxation in post-traumatic Elbow stiffness

Protocol summary

Study aim

The aim of the study was to compare the effect of myofascial release therapy (MFR), and the post-isometric relaxation (PIR) in pain reduction, improving the elbow range of motion (ROM), and strengthening the muscles in the individuals with post-traumatic elbow stiffness.

Design

A Randomized clinical trial, blinded with a parallel group design of 34 patients enrolled between March 2024 and May 2024 at Allied Hospital Faisalabad.

Settings and conduct

Allied Hospital Faisalabad.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age ranging from 15 to 50 years old . • Pain (NPRS score from 3-7). • Stiff elbow . • After 6 weeks of surgery(9). • Restricted ROM: subjects with limited active range of motion A(ROM) . • Both male & female patients. • Participants willing for the enrollment in the study. Exclusion Criteria • Open wound . • ROM not improved after 2nd session . • Acute infection to the elbow region. • Cervical radiculopathy & any other upper limb dysfunction. • Neurological impairments. • Pregnant females .

Intervention groups

In Group A, the treatment includes Maitland Mobilization to enhance joint movement, Myofascial Release Therapy to relieve muscle tension and the application of ice to reduce inflammation and pain. In contrast, Group B's approach incorporates Maitland Mobilization as well, but instead of Myofascial Release Therapy, it utilizes Post-Isometric Relaxation to reduce muscle spasms and improve flexibility, followed by ice application.

Main outcome variables

Numeric Pain Rating Scale to assess pain, Goniometer for the measurement of range of elbow and Liverpool Elbow Score for functional assessment will be used to collect the data

General information

Reason for update

Acronym

Randomized Clinical Trial

IRCT registration information

IRCT registration number: **IRCT20240528061931N1**

Registration date: **2024-11-24, 1403/09/04**

Registration timing: **retrospective**

Last update: **2024-11-24, 1403/09/04**

Update count: **0**

Registration date

2024-11-24, 1403/09/04

Registrant information

Name

Asma Zafar

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 304 0790805

Email address

asmazafar522@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-17, 1402/12/27

Expected recruitment end date

2024-05-17, 1403/02/28

Actual recruitment start date

2024-03-17, 1402/12/27

Actual recruitment end date

2024-05-17, 1403/02/28

Trial completion date

2024-05-17, 1403/02/28

Scientific title

Comparative effectiveness of Myofascial Release Therapy and Post Isometric Relaxation in post-traumatic Elbow stiffness

Public title

Myofascial Release Therapy and Post Isometric Relaxation in post-traumatic Elbow stiffness

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age ranging from 15 to 50 years old Pain (NPRS score from 3-7) Stiff elbow After 6 weeks of surgery Restricted ROM: subjects with limited active range of motion A(ROM) Both male & female patients Participants willing for the enrollment in the study.

Exclusion criteria:

Open wound ROM not improved after 2nd session Acute infection to the elbow region Cervical radiculopathy & any other upper limb dysfunction Neurological impairments Pregnant females Psychological condition Refusal to consent Any Co-morbidity

Age

From 15 years old to 50 years old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: 34
Actual sample size reached: 34

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, non-probability purposive sampling was initially used to select participants. For randomization, participants were divided into two treatment groups using the lottery method. Each participant's allocation was determined by drawing a numbered slip from a container. The slips were shuffled thoroughly to ensure randomness. Allocation concealment was maintained by keeping the process anonymous until the slip was drawn

Blinding (investigator's opinion)

Single blinded

Blinding description

participant was blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The University of Faisalabad

Street address

Sitara colony , FSD.

City

Faisalabad

Postal code

37000

Approval date

2024-02-17, 1402/11/28

Ethics committee reference number

TUF/DR/SA/MSPP/2024/401

Health conditions studied

1

Description of health condition studied

Post-Traumatic Elbow stiffness

ICD-10 code

M25.6

ICD-10 code description

Stiffness of unspecified elbow, Stiffness of right elbow, Stiffness of left elbow.

Primary outcomes

1

Description

Numeric Pain Rating Scale(NPRS)

Timepoint

pain is evaluated through NPRS once before first session and after each session , total no. of session=6

Method of measurement

The NPRS is a validated tool to quantify pain levels ranging from 0 to 10, with 0 indicating no pain and 10 representing the worst pain.

2

Description

- • Universal goniometer to measure elbow flexion and extension

Timepoint

once before and 1st session and after last session, total no. of session =6

Method of measurement

- Universal goniometer

Secondary outcomes

1

Description

- Liverpool elbow score to measure function

Timepoint

once before 1st session and then at session 6, total no. of session=6

Method of measurement

Liverpool elbow score Questionnaire

Intervention groups**1****Description**

Intervention : Group A (Myofascial Release Therapy - MFR) Frequency :3 times /2 weeks, total of 6 sessions. Hold Time (per repetition):30-60 seconds per repetition. Repetitions: 2 rep. Baseline Treatment: Ice (20-30 minutes) and Maitland mobilization. Dosage: 5 mins/session, 3 sessions/ week. Total Dosage:15mins/week, total 30 mins over 2 weeks.

Category

Treatment - Other

2**Description**

Intervention : Group B (Post-isometric Relaxation Technique - PIR). Frequency:3 times a week for 2 weeks, total of 6 sessions. Hold Time (per repetition) : 5-10 seconds per contraction. Repetitions:3-5 repetitions. Baseline Treatment: Ice (20-30 minutes) and Maitland mobilization. Dosage; 10mins/session,3sessions/week. Total Dosage :30mins/week, total 60 minutes over 2 week.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Allied Hospital

Full name of responsible person

Dr. Sobia Nawaz

Street address

Sitara colony, FSD.

City

Faisalabad

Postal code

37000

Phone

+92 304 0790805

Email

asmazafar522@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

the university of Faisalabad

Full name of responsible person

Asma Zafar

Street address

P-279, block - c, sitara colony, fsd

City

Faisalabad

Postal code

37000

Phone

+92 304 0790805

Email

asmazafar522@gmail.com

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

Yes

Title of funding source

the university of Faisalabad

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**

Academic

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

The University of Faisalabad

Full name of responsible person

Asma zafar

Position

STUDENT

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Sitara colony , FSD.

City

Faisalabad

Province

PUNJAB

Postal code

37000

Phone

+92 304 0790805

Email

Asmazafar522@gmail.com

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

THE UNIVERSITY OF FAISALABAD
Full name of responsible person
Asma Zafar
Position
Student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Sitara colony , FSD.
City
Faisalabad
Province
Punjab
Postal code
37000
Phone
+92 304 0790805
Email
Asmazafar522@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
The University of Faisalabad
Full name of responsible person
Asma Zafar
Position
Student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Sitara colony , FSD.
City
Faisalabad
Province
Punjab
Postal code
37000
Phone

+92 304 0790805

Email
Asmazafar522@gmail.com

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

Myofascial Release and Post Isometric Relaxation for the management of post operative elbow stiffness

When the data will become available and for how long

July 1, 2024, the documents/data files will become available on January 1, 2025, and will remain accessible until December 31, 2025.

To whom data/document is available

Academic Institutions

Under which criteria data/document could be used

Deidentified IPD and supporting documents will be shared for academic and policy research via a formal request process reviewed by a Data Access Committee, ensuring ethical and secure use.

From where data/document is obtainable

Applicants should email asmazafar522@gmail.com for data files, or contact at 0092 3040790805 for assistance.

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

Applicants must submit a request form via email, await review by the Data Access Committee, sign a Data Use Agreement, and this process typically takes 4-6 weeks.

Comments