

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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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**

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

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

THE UNIVERSITY OF FAISALABAD

**Full name of responsible person**

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**Position**

Student

**Latest degree**

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**Name of organization / entity**

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**Full name of responsible person**

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**Email**

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**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](mailto: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**