Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Questionaire

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