

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effects of Instrument-Assisted soft tissue mobilization (IASTM) and myofascial release (MFR) in alleviating post-surgical elbow stiffness

#### Protocol summary

##### Study aim

This study aims to evaluate the efficacy of myofascial release and instrument-assisted soft tissue mobilization (IASTM) in reducing pain, stiffness, and range of motion associated with post-surgical elbow stiffness.

##### Design

Randomized clinical trial, single blinded, parallel group, sample size 24

##### Settings and conduct

Ahmad Poly Care Clinic, Faisalabad (APCC) , Allied Hospital, Faisalabad (AHF)

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female , Age 8-40 years, ROM of elbow extension  $\geq$ -30 degrees & flexion  $\leq$ 120 degrees, At least six weeks following surgery, with internal fixation and open reduction. Exclusion Criteria: Participants with any diagnosed auto-immune disorder, Pathological fractures, associated ipsilateral injuries, Injury to both upper limbs, Neuro-vascular disorders, IASTM contraindications (according to the IASTM guidelines), Rheumatic conditions, Circulatory disorders or diabetes.

##### Intervention groups

Baseline Treatment Both groups received conventional treatments, which included a 5- to 10-minute warm-up with active range-of-motion exercises for the shoulder, elbow, and wrist, gentle passive stretching with 30-second holds for three repetitions, and progressive low-load strengthening activities (for the major upper limb muscle groups). Group A Group A was administered IASTM therapy by means of the "S-shape tool," an ergonomic stainless-steel instrument with multiple hand grips that reduce operator fatigue. . Group B Group B received myofascial release technique was given. Myofascial release treatment is a kind of continuous, mild massage that helps your myofascial tissues become less painful and tense. Group C Group C received both Instrument-assisted soft tissue mobilization (IASTM) and Myofascial release technique (MFR) to check the effect of

both treatments collectively.

##### Main outcome variables

Pain, Range of motion, Functional disability

#### General information

##### Reason for update

##### Acronym

IASTM , MFR

##### IRCT registration information

IRCT registration number: **IRCT20210528051415N1**

Registration date: **2024-07-28, 1403/05/07**

Registration timing: **retrospective**

Last update: **2024-07-28, 1403/05/07**

Update count: **0**

##### Registration date

2024-07-28, 1403/05/07

##### Registrant information

##### Name

Shaheer Masood

##### Name of organization / entity

The University of Faisalabad, Faisalabad, Pakistan

##### Country

Pakistan

##### Phone

+92 41 8750274

##### Email address

shaheer\_masood@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-17, 1402/11/28

##### Expected recruitment end date

2024-03-16, 1402/12/26

##### Actual recruitment start date

2024-02-17, 1402/11/28  
**Actual recruitment end date**  
2024-03-16, 1402/12/26  
**Trial completion date**  
2024-05-31, 1403/03/11

**Scientific title**  
Effects of Instrument-Assisted soft tissue mobilization (IASTM) and myofascial release (MFR) in alleviating post-surgical elbow stiffness

**Public title**  
How IASTM and Myofascial Release Alleviate Post-Surgical Elbow Stiffness"

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Male and female Age: 8-40 years ROM of elbow extension  $\geq$ -30 degrees & flexion  $\leq$ 120 degrees Least 6-week post-surgery with open reduction and internal fixation Patient with U/L or B/L post-surgical elbow stiffness Willing to participate were included in this study  
**Exclusion criteria:**  
Participants with any diagnosed auto-immune disorder Pathological fractures, associated ipsilateral injuries Bilateral upper extremity injuries Neuro-vascular disorders Contraindications for IASTM (as per the IASTM guidelines) Rheumatic conditions Circulatory disorders or diabetes Pregnancy Inability to Follow Rehabilitation Protocols

**Age**  
From **8 years** old to **40 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: **24**  
Actual sample size reached: **24**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization will be done with the help of the lottery method. With a lottery method, each member of the population is assigned a number, after which numbers are selected at random

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Single blinded: outcomes assessors were kept unaware of which participants received the experimental treatment and which received a comparative intervention. This blinding helps to prevent conscious and unconscious biases that could influence the assessment of study outcome.

**Placebo**  
Not used

**Assignment**

Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research and ethics/ technical committee for The University of Faisalabad

##### Street address

Faisal town, west canal road, Faisalabad, Punjab.

##### City

Faisalabad

##### Postal code

38000

#### Approval date

2024-01-05, 1402/10/15

#### Ethics committee reference number

TUF/Addl Reg/SB/785

## Health conditions studied

### 1

#### Description of health condition studied

Post surgical elbow stiffness

#### ICD-10 code

M25.62

#### ICD-10 code description

Stiffness of elbow, not elsewhere classified

## Primary outcomes

### 1

#### Description

Range of motion

#### Timepoint

Baseline intervention and 3 weeks post intervention

#### Method of measurement

Goniometer

### 2

#### Description

Pain

#### Timepoint

Baseline intervention and 3 weeks post intervention

#### Method of measurement

Numeric pain rating scale

## Secondary outcomes

## 1

### **Description**

Functional Disability

### **Timepoint**

Baseline intervention and 3 weeks post intervention

### **Method of measurement**

Liverpool elbow score

## **Intervention groups**

### 1

#### **Description**

Intervention group: Group A received IASTM treatment, which was given by the "S-shape tool", that is an ergonomically designed stainless steel instrument and offers several different hands holds, eliminating operator fatigue. IASTM has drawn more attention for myofascial restriction based upon James Cyriax soft tissue mobilization.

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group: Group B received myofascial release technique was given. Myofascial release therapy is a type of gentle, constant massage that releases tightness and pain throughout your myofascial tissues. Specific techniques include massage, pressure, skin rolling, twisting, and wringing. Applying pressure and stretch in the direction of the tissue restriction, reportedly causes myofascial lengthening and decreased muscle tension.

#### **Category**

Rehabilitation

### 3

#### **Description**

Intervention group: Group C received both Instrument-assisted soft tissue mobilization (IASTM) and Myofascial release technique (MFR) in order to check the effect of both treatments collectively.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Allied Hospital, Faisalabad

##### **Full name of responsible person**

Dr. Shaheer Masood, PT

##### **Street address**

C3XJ+F38, Dr. Tusi Rd, Faisalabad, Punjab

##### **City**

Faisalabad

##### **Postal code**

38000

##### **Phone**

+92 303 8926834

##### **Email**

shaheer\_masood@hotmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Ahmad Poly Care Clinic

##### **Full name of responsible person**

Dr. Shaheer Masood, PT

##### **Street address**

Satayana Rd, Block B, Peoples Colony 1, Block B  
People's Colony No 1, Faisalabad, Punjab

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##### **Phone**

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##### **Email**

sherryr386@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

The University of Faisalabad

##### **Full name of responsible person**

Dr. Syed Saqlain Babar, PT

##### **Street address**

Faisal town, west canal road, Faisalabad, Punjab.

##### **City**

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##### **Phone**

+92 315 6205017

##### **Email**

syedsaqlainbabar21@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**

Dr. Sidra Majeed, PT

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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Faisal town, west canal road, Faisalabad, Punjab.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

The University of Faisalabad

**Full name of responsible person**

Dr. Sameer ul Haq, PT

**Position**

Clinical consultant physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

The University of Faisalabad

**Full name of responsible person**

Dr. Saqlain Haider, PT

**Position**

Clinical Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Email**

2022-ms-pt-046@tuf.edu.pk

## 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**

No - There is not 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**

Effects of instrument -assisted soft tissue mobilization and myofascial release in alleviating post- surgical elbow stiffness Pain access by NPRS, Range of motion of elbow joint by Goniometer, Functional disability by Liverpool elbow score.

**When the data will become available and for how long**

30 days after publication.

**To whom data/document is available**

30 days.

**Under which criteria data/document could be used**

Access to the data will be facilitated through a specified mechanism, such as secure online portal or data sharing platform. Request for access will be renewed by designated committee or entity responsible for insuring that they made an established criteria and comply with relevant regulations and guidelines. Additional supporting information and document may be provided to assist requesters in understanding the available data and its potential application.

**From where data/document is obtainable**

The University of Faisalabad, 38000

<https://tuf.edu.pk/0092> 41 875 0971-5 Fax +92 41 8750970

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

To receive the documents or data files, the process typically involves the following steps: 1. Request

Initiation: The applicant submits a formal request specifying the documents or data files they need. 2. Verification and Authorization: The organization verifies the request and ensures that the applicant is authorized to access the requested documents or data files. This may involve confirming the identity of the requester and checking their permissions. 3. Processing Time: The processing time varies depending on the complexity of the request, the volume of documents or data files, and any legal or regulatory requirements. It could range from a few hours to several weeks. 4. Document Retrieval or Data Extraction: Once the request is approved, the organization retrieves the documents from their archives

or extracts the requested data from their databases. 5. Quality Assurance: Before releasing the documents or data files to the applicant, the organization may conduct quality checks to ensure accuracy and completeness. 6. Delivery: The documents or data files are delivered to the applicant through a secure channel, such as encrypted email, secure file transfer protocols, or a secure online portal. 7. Confirmation of Receipt: The applicant acknowledges receipt of the documents or data files, confirming that they have received the information they requested.

#### **Comments**