

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Iliotibial band Myofascial release Combined with valgus Controlled exercises on pain, range of motion, balance and quality of life in patients with grade II knee osteoarthritis.

#### Protocol summary

##### Study aim

The objective and aim of this study are: To find out the effectiveness of myofascial release technique with Valgus correction exercise on balance, quality of life, range of motion and pain in patients with grade II knee osteoarthritis.

##### Design

parallel group randomized clinical trial and Randomization will be achieved through computer generated random number table.

##### Settings and conduct

Allied Hospital. it will be assessor who will be blinded about the type of intervention. Treatment will be given by principal /investigator

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: age: 40-60 years Both gender Iliotibial band tightness Knee osteoarthritis ACR (American college of Rheumatology) Exclusion Criteria: knee arthroplasty bone tumor Any other pathology Osteomyelitis

##### Intervention groups

Group A: Intervention group. Myofascial release technique The individuals in the Group A will be treated using hot pack on knee area, quadricep isometrics 10 \*10 and myofascial release Technique for iliotibial band. Patients will be asked to perform knee flexion and extension for another 5 minutes. Frequency: Two Times a Week for 6 weeks Group B: valgus correction exercise (VCE) Technique: The individuals in the Group B will be treated using hot pack on knee area, quadricep isometrics 10 \*10 and myofascial release Technique. In addition to this patient will perform valgus correction exercise (VCE) for 10 minutes. Valgus correction exercise (VCE) • Squat in front of mirror (0°-60° of knee flexion, performed in front of mirror to ensure the knee does not exceed the midfoot) • Hip lateral rotation • Lateral walk with elastic resistance around forefoot Frequency: Two

Times a Week for 6 weeks The outcome measures will be assessed at baseline, third and at 6 weeks of intervention.

##### Main outcome variables

Pain, knee Range of motion, balance and quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230216057434N3**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

##### Registration date

2023-03-14, 1401/12/23

##### Registrant information

##### Name

Zainab Sheraz

##### Name of organization / entity

Riphah International University, Faisalabad

##### Country

Pakistan

##### Phone

+92 301 7070941

##### Email address

zainab.48@hotmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-08, 1401/12/17

##### Expected recruitment end date

2023-05-15, 1402/02/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of Iliotibial band Myofascial release Combined with valgus Controlled exercises on pain, range of motion, balance and quality of life in patients with grade II knee osteoarthritis.

**Public title**

Effectiveness of two manual therapy technique in osteo arthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

age: 40-60 years Both gender Iliotibial band tightness Knee osteoarthritis diagnosed as per ACR (American college of Rheumatology) criteria

**Exclusion criteria:**

knee arthroplasty bone tumor Any other knee pathology Osteomyelitis limb length shortening

**Age**

From **40 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization was done through a computer software "Random allocation". The total sample size was entered with requirement to be allocated in two groups. An automated randomization list was achieved with attrition rate included.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Blinding was done on part of outcome assessor who was an experienced therapist. Patients were assessed by him at the end of treatment session. He was blinded about the type of intervention patient has received.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Riphah International University Faisalabad

**Street address**

Riphah International University, Faisalabad

**City**

Faisalabad

**Postal code**

38000

**Approval date**

2023-02-15, 1401/11/26

**Ethics committee reference number**

RCRAHS/REC/08

## Health conditions studied

1

**Description of health condition studied**

Knee osteoarthritis

**ICD-10 code**

M17.9

**ICD-10 code description**

Osteoarthritis of knee, unspecified

## Primary outcomes

1

**Description**

Pain

**Timepoint**

Assessment will be performed at 0 week (baseline) at 3rd week and at completion of 6 weeks treatment

**Method of measurement**

Visual Analogue scale

2

**Description**

Range of motion

**Timepoint**

Assessment will be performed at 0 week (baseline) at 3rd week and at completion of 6 weeks treatment

**Method of measurement**

Goniometer

## Secondary outcomes

1

**Description**

Quality of life

**Timepoint**

Assessment will be performed at 0 week (baseline) at 3rd week and at completion of 6 weeks treatment

## Method of measurement

KOOS (Knee injury osteoarthritis outcome score)

### 2

#### Description

Balance

#### Timepoint

Assessment will be performed at 0 week (baseline) at 3rd week and at completion of 6 weeks treatment

#### Method of measurement

Berg Balance Scale

## Intervention groups

### 1

#### Description

Intervention group 1 (Iliotibial Band Myofascial Release)

#### Category

Treatment - Other

### 2

#### Description

Control group: (Iliotibial Band Myofascial Release + Valgus control exercise)

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Allied Hospital

##### Full name of responsible person

Dr Laiba Fatima

##### Street address

Jail Road, Adjacent Faisalabad Medical University,  
Near Sargodha Road, Faisalabad, Pakistan

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 335 2536667

##### Email

laibafatima2535@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Self funded

##### Full name of responsible person

Zainab Sheraz

##### Street address

house no. 32, street no. 2, Rehman Town, adjacent

Shahzad Colony, Satyana Road, Faisalabad

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 335 6600141

##### Email

zainab.48@hotmail.com

##### Grant name

N/A

##### Grant code / Reference number

N/A

##### Is the source of funding the same sponsor organization/entity?

No

##### Title of funding source

N/A

##### 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

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Riphah International University, Faisalabad

##### Full name of responsible person

Zainab Sheraz

##### Position

Senior Lecturer

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

house no. 32, street no. 2, Rehman Town, adjacent  
Shahzad Colony, Satyana Road, Faisalabad

##### City

Faisalabad

##### Province

Punjab

##### Postal code

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##### Phone

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Riphah International University, Faisalabad

**Full name of responsible person**

Zainab Sheraz

**Position**

Punjab

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**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**

Real patient involved

**Study Protocol**

Undecided - It is not yet known if there will be a plan to  
make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available