

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative Effects of Calisthenic Exercises and Sensory-Motor Training in Patients with Knee Osteoarthritis Randomized trail

#### Protocol summary

##### Study aim

To compare the effects of calisthenic exercises and sensory-motor training on pain, range of motion, balance and functional disability in patients with knee osteoarthritis.

##### Design

Randomized clinical trial, single blinded study, two parallel groups with 108 patients from Gosha e Shifa and Riaz Mansoor trust hospital.

##### Settings and conduct

Gosha-e-Shifa trust hospital and Riaz Mansoor trust hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Both male and female patients Age 40 to 65 years Exclusion criteria Patients with any systemic disease Patients who had any neurologic deficit Patients with any mental illness

##### Intervention groups

Group A: Calisthenic exercises will be given to group A.  
Group B: Sensory-motor training will be given to group B.

##### Main outcome variables

Pain, range of motion, balance and functional disability

#### General information

##### Reason for update

To update the blinding description

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190717044238N11**  
Registration date: **2023-12-14, 1402/09/23**  
Registration timing: **registered\_while\_recruiting**

Last update: **2024-12-24, 1403/10/04**

Update count: **2**

##### Registration date

2023-12-14, 1402/09/23

#### Registrant information

##### Name

Fareeha Amjad

##### Name of organization / entity

The University of Lahore

##### Country

Pakistan

##### Phone

+92 42 99200600

##### Email address

fari\_fairy22@yahoo.com

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2023-08-01, 1402/05/10

##### Expected recruitment end date

2024-12-30, 1403/10/10

##### Actual recruitment start date

2023-08-07, 1402/05/16

##### Actual recruitment end date

2024-01-15, 1402/10/25

##### Trial completion date

2024-03-18, 1402/12/28

#### Scientific title

Comparative Effects of Calisthenic Exercises and Sensory-Motor Training in Patients with Knee Osteoarthritis Randomized trail

#### Public title

Comparative Effects of Calisthenic Exercises and Sensory-Motor Training in Patients with Knee Osteoarthritis

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Both male and female patients Age 40 to 65 years  
Patients with clinical and radiographic findings of

tibiofemoral osteoarthritis Patients fulfilling Kellgren and Lawrence classification for knee OA Patients with chronic OA symptom for more than 3 months Patients with unilateral grade III OA

**Exclusion criteria:**

Patients with any systemic disease Patients who had any neurologic deficit Patients with any mental illness Subjects with any history of lower limb fracture, knee joint, ligament or meniscal injury Patients having metal implants in the lower limb Any history of surgery related to lower extremity

**Age**

From **40 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **108**

Actual sample size reached: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Fishbowl method method will be used for randomization process. each patient will be numbered using separate slips of paper and put into fishbowl and shuffled and each slip is randomly picked out.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In the trial the participant is blinded by not knowing or being unaware which intervention they are receiving , but the researcher know. This trial will be single blinded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Research and ethics Committee Riphah College of Rehabilitation and Allied Health Sciences

**Street address**

Riphah International University Gulberg campus lahore

**City**

Lahore

**Postal code**

54000

**Approval date**

2023-08-03, 1402/05/12

**Ethics committee reference number**

REC/RCR&AHS/23/0141

**Health conditions studied**

**1**

**Description of health condition studied**

Knee Osteoarthritis

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Pain

**Timepoint**

Before intervention, 4 and 8 weeks

**Method of measurement**

Visual analogue scale(VAS)

**2**

**Description**

Range of motion

**Timepoint**

Before intervention, 4 and 8 weeks

**Method of measurement**

Goniometer

**3**

**Description**

Balance

**Timepoint**

Before intervention

**Method of measurement**

Time up and go(TUG)

**4**

**Description**

Quality of life

**Timepoint**

Before intervention

**Method of measurement**

Western Ontario and McMaster Universities(WOMAC)

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group B: These patients will be treated with

Sensory motor training. : Exercises will be performed following verbal commands from the therapist. Crossing steps while walking, crossing steps while walking backwards, implementing sudden changes of direction, walking on several types of surfaces (including mattresses) and maintaining posture during use of a balance board.

#### **Category**

Rehabilitation

## **2**

#### **Description**

Intervention group A: This group will be treated with Calisthenic exercises. 10 repetitions of each exercise with no rest periods. Abductors leg raise , adductor leg raise, prone leg extension, knee bend, alternate toe touch, lunges, calf raises, leg kicks and jack twists.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Gosha-e-Shifa Trust Hospital Lahore

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

Zainia Tariq

##### **Street address**

Gulshan-e-Ravi A block Lahore

##### **City**

Lahore

##### **Postal code**

54000

##### **Phone**

+92 340 4486197

##### **Email**

zainiatariq@gmail.com

### **2**

#### **Recruitment center**

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

Riaz Mansoor Trust Hospital Lahore

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

Zainia Tariq

##### **Street address**

Gulsha-e-Ravi H block Lahore

##### **City**

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##### **Postal code**

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##### **Email**

zainiatariq@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Riphah International University Lahore

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

Dr. Fareeha Amjad

##### **Street address**

Riphah International University Gulberg Campus

##### **City**

Lahore

##### **Postal code**

54000

##### **Phone**

+92 334 3372779

##### **Email**

fari\_fairy22@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Riphah International University Lahore

#### **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**

Riphah International University Lahore

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

Zainia Tariq

##### **Position**

Student

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

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##### **Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Riphah International University Lahore Gulberg campus

**Full name of responsible person**

Fareeha Amjad

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Riphah International University Lahore

**Full name of responsible person**

Zainia Tariq

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

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**City**

Lahore

**Province**

Punjab

**Postal code**

54000

**Phone**

+92 340 4486197

**Email**

zainiatariq@gmail.com

## 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**

There is no further information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

Not applicable

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Consent Form in its original format with no information about any participant study protocol- how the intervention was given to both groups

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

Data would be available after the completion of the research.

**To whom data/document is available**

People working in an academic and clinical setting can have access to the above-mentioned information/documents

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

Data can only be used for Research Purposes

**From where data/document is obtainable**

Data can be asked for at the following email address: zainiatariq@gmail.com

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

One can ask for data at the given email address and it would be provided after knowing the general implications of sharing that particular data.

**Comments**