

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

**Effect of weight bearing functional exercises and non-weight bearing quadriceps strengthening along with breathing exercises on pain, functional activity, stress, lipid profile , cellular hypoxia and BDNF levels in people with knee osteoarthritis and obesity.**

### Protocol summary

#### Study aim

To determine the effects of weight bearing functional exercises and non-weight bearing quadriceps strengthening along with breathing exercises on pain, functional activity, stress, lipid profile, cellular hypoxia and BDNF levels in people with knee osteoarthritis and obesity.

#### Design

Randomized clinical Trial

#### Settings and conduct

Riphah Rehabilitation Centre Lahore Pakistan

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. age 40 to 60 years 2. Have had knee pain for 3 months or more 3. pain severity of minimum 3 on NPRS 4. Demonstrate tibiofemoral osteophytes on x-ray 5. Both genders Exclusion criteria: 1. Lateral joint space narrowing greater than or equal to medial joint space narrowing on x-ray according to a radiographic atlas 2. Knee surgery/joint injection in past 6 months or planned surgery in the next 9 months 3. Current or past (4 weeks) oral corticosteroids use 4. Systemic arthritic conditions; 5. Past knee fracture or malignancy; 6. Past hip/knee joint replacement/tibial osteotomy 7. Unable to walk unaided

#### Intervention groups

Group A: Non- weight bearing exercises (along with base line treatment) Group B: Weight bearing exercises (along with base line treatment)

#### Main outcome variables

1. Functional activity level 2. Pain Intensity 3. Stress, anxiety and Depression 4. BDNF levels 5. Levels of HDL and LDL 6. Cellular oxygen levels

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230427058007N1**

Registration date: **2023-08-14, 1402/05/23**

Registration timing: **retrospective**

Last update: **2023-08-14, 1402/05/23**

Update count: **0**

#### Registration date

2023-08-14, 1402/05/23

#### Registrant information

##### Name

Muzna Munir

##### Name of organization / entity

Riphah International University

##### Country

Pakistan

##### Phone

+92 334 4265125

##### Email address

muznafmh@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-01-01, 1401/10/11

#### Expected recruitment end date

2023-03-01, 1401/12/10

#### Actual recruitment start date

2023-01-01, 1401/10/11

#### Actual recruitment end date

2023-03-01, 1401/12/10

#### Trial completion date

2023-06-05, 1402/03/15

## Scientific title

Effect of weight bearing functional exercises and non-weight bearing quadriceps strengthening along with breathing exercises on pain, functional activity, stress, lipid profile, cellular hypoxia and BDNF levels in people with knee osteoarthritis and obesity.

## Public title

Effect of weight bearing functional exercises and non-weight bearing quadriceps strengthening along with breathing exercises in people with knee osteoarthritis and obesity.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Are aged 40 to 60 years Both genders Have had knee pain for 3 months or more Report a minimum of 3 overall pain severity on 11-point numeric rating scale (NPRS) Demonstrate tibiofemoral osteophytes on x-ray

### Exclusion criteria:

Lateral joint space narrowing greater than or equal to medial joint space narrowing on x-ray according to a radiographic atlas Knee surgery/joint injection in past 6 months or planned surgery in the next 9 months Current or past (4 weeks) oral corticosteroids use Systemic arthritic conditions Past knee fracture or malignancy Past hip/knee joint replacement/tibial osteotomy Unable to walk unaided

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Care provider
- Outcome assessor

## Sample size

Target sample size: **30**

Actual sample size reached: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Even Odd method was used for Randomization. even group numbers was enrolled as group A and odd group numbers was enrolled as Group B

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The care provider was blinded to the groups of the study as well as the outcome Assessor was also blinded to the treatment protocols and study hypothesis.

## Placebo

Not used

## Assignment

Parallel

## Other design features

No

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research & Ethics Committee

##### Street address

Riphah College of Rehabilitation and allied health sciences, QIE campus Lahore

##### City

Lahore

##### Postal code

53770

#### Approval date

2021-10-08, 1400/07/16

#### Ethics committee reference number

REC/RCR & AHS/21/16

## Health conditions studied

### 1

#### Description of health condition studied

osteoarthritis

#### ICD-10 code

M17

#### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

base line and after 6 weeks

#### Method of measurement

Numeric Pain Rating Scale

### 2

#### Description

functional disability

#### Timepoint

base line and after 6 weeks

#### Method of measurement

The Western Ontario and McMaster universities Arthritis Index

### 3

#### Description

Brain Derived Neurotrophic levels levels

#### Timepoint

base line and after 6 weeks

#### Method of measurement

ELISA

#### **4**

##### **Description**

oxygen saturation

##### **Timepoint**

base line and after 6 weeks

##### **Method of measurement**

Arterial blood gases

#### **5**

##### **Description**

Stress, Anxiety & Depression

##### **Timepoint**

base line and after 6 weeks

##### **Method of measurement**

Depression Anxiety and Stress Scale

#### **6**

##### **Description**

HDL and LDL

##### **Timepoint**

base line and after 6 weeks

##### **Method of measurement**

Lipid profile

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group 1: non weight bearing quadriceps strengthening exercises along with breathing exercises for 6 weeks. Each session will last 30–40 min.

Participants will be provided with adjustable ankle cuff weights (0.65 kg to 10 kg) and elastic resistance bands.

They will commence the program with two sets of ten repetitions for each exercise for the first 2 weeks and progress to three sets thereafter or as quickly as able.

The starting weight will be the participant's 10-repetition maximum weight or determined by the participant's level of effort aiming for between 5 and 8 out of 10 (hard to very hard) on the modified Borg Rating of Perceived Exertion CR-10 scale for strength training .

##### **Category**

Rehabilitation

#### **2**

##### **Description**

Intervention group 2: weight bearing functional exercises along with breathing exercises for 6 weeks. Each session will last 30–40 min. . Participants will be provided with an adjustable step (10 cm to 15 cm height), foam mat, and elastic resistance bands. A major emphasis is on the quality of performance of each exercise. Participants will

be instructed to maintain alignment of the pelvis and trunk in the frontal plane (avoid pelvic drop and trunk lateral flexion) and to neutrally align their knee (position the knee over the foot as much as possible) throughout the movements. Knee flexion should not exceed 30° (except when performing the chair stand exercise) to reduce the risk of increasing knee pain. Having hand support within easy reach or using hand support is important for maintaining balance and quality of performance throughout the movements. Exercise progression is essential and is determined by the physiotherapist, based on a combination of the participant's pain and rating of perceived exertion score for each exercise (at least 5 out of 10 on a modified Borg Rating of Perceived Exertion CR-10 scale) and the physiotherapist's assessment of the quality of the exercise performance.

##### **Category**

Rehabilitation

### **Recruitment centers**

#### **1**

##### **Recruitment center**

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

Riphah Rehab Training and Research Centre

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

Muzna Munir

###### **Street address**

Riphah College of rehabilitation and allied health sciences QIE campus Lahore

###### **City**

Lahore

###### **Postal code**

54700

###### **Phone**

+92 334 4265125

###### **Email**

muznafmh@gmail.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

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

Riphah International University

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

Syed Shakil Rehman

###### **Street address**

Riphah International University, QIE campus, Lahore

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##### **Grant name**

ORIC Riphah international Univeristy

**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Riphah International University

**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

**Full name of responsible person**

Muzna Munir

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

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**Postal code**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Riphah International University

**Full name of responsible person**

Muzna Munir

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Riphah International University

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Muzna Munir

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Assistant Professor

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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**

we have recruited the data and completed the trial because things have to be streamline later

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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