

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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 were enrolled as group A and odd group numbers were 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

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

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Riphah College of rehabilitation and allied health sciences QIE campus Lahore

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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

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Person responsible for scientific inquiries

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Muzna Munir

Position

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Latest degree

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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