Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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+92 334 4265125

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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 Accessor 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 quardiceps 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Riphah International University
Full name of responsible person
Syed Shakil Rehman
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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
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Person responsible for updating data

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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