

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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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

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Phone

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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

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Lahore

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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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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

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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

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