

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Short term effects of strengthening exercises of lower limb rehabilitation protocol (LLRP) on pain, stiffness, physical function and body mass index (BMI) among knee osteoarthritis (OA) participants who are overweight or obese.

Protocol summary

Study aim

To determine the short term effects of strengthening exercises of lower limb rehabilitation protocol on pain, stiffness, physical function and body mass index among knee osteoarthritis participants who are overweight or obese

Design

The study will be single blinded randomized controlled design. Three research coordinators will be involved in data collection. The one coordinator will be involved in baseline data collection and two coordinators will be involved in the assessment of outcomes. Participants will be blinded of other groups intervention.

Settings and conduct

The study will be conducted at the urban area of Lahore Pakistan and measurements will be assessed at the Teaching Bay of Rehmatul-Lil-Alameen Postgraduate Institute

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Overweight or obese knee osteoarthritis participants, age between 45 and 60 years, residing in the urban community of Lahore, second and third degree of knee changes according to Kellgren and Lawrence radio-graphic scale Exclusion Criteria: System lupus erythematosus, Flat feet, Spinal deformities, Participants having history of metabolic, hormonal, orthopaedic and cardiovascular diseases, Previous surgery of knee/s of any cause The patients who had any injections of knee/s in the last six months or Unable to walk independently

Intervention groups

Intervention 1: Intervention group 1 the strengthening exercises of the lower limbs and instructions of daily care. The training session will be of 30-40 minutes. It will consist of three times a week for 4 weeks at their houses. Intervention 2: Intervention group 2 the

participants in this group will follow the instructions of daily care only as a usual care for duration of 4 weeks at their houses.

Main outcome variables

Primary: Knee pain, stiffness and physical function
Secondary: Patients, s satisfaction and exercise adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191221045846N2**
Registration date: **2020-06-28, 1399/04/08**
Registration timing: **prospective**

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

Registration date

2020-06-28, 1399/04/08

Registrant information

Name

Muhammad Tariq Rafiq

Name of organization / entity

Punjab Employees Social Security Institution

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-10, 1399/04/20

Expected recruitment end date

2020-08-09, 1399/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short term effects of strengthening exercises of lower limb rehabilitation protocol (LLRP) on pain, stiffness, physical function and body mass index (BMI) among knee osteoarthritis (OA) participants who are overweight or obese.

Public title

Short term effects of exercises among knee osteoarthritis (OA) participants who are overweight or obese.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Overweight or obese knee OA participants aged between 45 to 60 years. Familiar with WhatsApp application Participants will be chosen from the urban area community of Punjab Lahore, Pakistan. The sample included males and females having OA of one or both knees confirmed by medical specialist according to the Kellgren and Lawrence radiographic scale for the assessment of OA

Exclusion criteria:

Rheumatoid arthritis System lupus erythematosus Flat feet Spinal deformities Unable to walk independently History of metabolic, hormonal, orthopaedic or cardiovascular disease Previous surgery of knee/s Injections of knee/s for the last six months.

AgeFrom **45 years** old to **60 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample sizeTarget sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

The researcher will allocate the selected knee osteoarthritis participants into two groups, namely, Rehabilitation Protocol Group (RPG) and Control Group (CG) by simple random technique using a computer-generated random number. The participants in the RPG will follow the strengthening exercise of LLRP and IDC for

duration of 4-weeks. The participants in the CG will not involved in the rehabilitation protocols, but these participants will follow only the IDC for the duration of 4-weeks at their houses.

Blinding (investigator's opinion)

Single blinded

Blinding description

The principle investigator will not be blinded. The participants receiving the intervention will be blinded by simply not informing them of their treatment allocation. The coordinators collecting data will be independent individuals from trials and will be unaware of the group allocation. There will be different coordinators at the initial and final evaluation. Individuals performing the statistical analysis will be blinded by labelling the groups with non-identifying terms (such as X and Y).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee RAIC PESSI (Rehmatul-Lil-Alameen Postgraduate Institute of Cardiology, Punjab Empl

Street address

Multan Chongi Multan Road Lahore,

City

Lahore

Postal code

54000

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

RAIC PESSI/Estt/2020/36

Health conditions studied**1****Description of health condition studied**

Osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

knee pain

Timepoint

at baseline and after 4 weeks of intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score

2

Description

Stiffness

Timepoint

At baseline and after 4 weeks of intervention

Method of measurement

WOMAC score

3

Description

Physical function

Timepoint

At baseline and after 4 weeks of intervention

Method of measurement

WOMAC score

Secondary outcomes

1

Description

Body Mass Index

Timepoint

At baseline and after 4 weeks of intervention

Method of measurement

Calculated by the formula Weight (kg)/Height(meter square)

2

Description

Patients satisfaction

Timepoint

After 4 weeks of intervention

Method of measurement

Numeric rating scale ranging from 0 to 10

3

Description

Exercise adherence

Timepoint

After 4 weeks of intervention

Method of measurement

Numeric rating scale ranging from 0 to 10

Intervention groups

1

Description

The participants in this group (Rehabilitation Protocol Group) will perform the strengthening exercises of lower limb rehabilitation protocol (LLRP) and follow the

instructions of daily care (IDC) for duration of four weeks at their houses according to the provided leaflet. Each training session of strengthening exercises will be performed three times a week for four weeks at their houses. These training sessions were the strengthening exercises of lower limbs in non-weight bearing sitting and lying positions. Each training session will consist of 45–60 minutes of training followed by 10 minutes warm up at the start and 10 minutes cool down at the end of training protocol.

Category

Treatment - Other

2

Description

The participants in this group (Control Group) will follow only the instructions of daily care (IDC) for duration of four weeks at their houses according to the provided leaflet.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Teaching Bay of Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology

Full name of responsible person

Dr Farid Ahmad Chaudhary

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Teaching Bay of Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology, Punjab Employees Social Security Institution, Multan Chongi, Multan Road Lahore

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

2

Sponsor

Name of organization / entity

University of Malaya

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

N/A

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Punjab Employees Social Security Institution

Full name of responsible person

Muhammad Tariq Rafiq

Position

Consultant Senior Physiotherapist

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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