Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of lower limb rehabilitation protocol using mobile health on physical disability and exercise adherence among knee osteoarthritis (OA) patients who are overweight and obese.

Protocol summary

Study aim
The study objective is to investigate the effectiveness of LLRPw-mHeath on physical disability and exercise adherence among knee osteoarthritis patients who are overweight and obese.

Design
A parallel group, single blinded randomized control trial. Sixty participants will be randomly divided into three groups by computer generated numbers. It is a single centered.

Settings and conduct
Study will be conducted at the Teaching Bay of Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology. Participants are blinded in this study. Afetr randomization only one group will be called for their intervention in order to secure the blinding process.

Participants/Inclusion and exclusion criteria
Inclusion criteria Overweight and obese Knee OA patients; Both males and females; Aged between 45 to 60 years; Living in urban area of Punjab, Lahore. Non-inclusion criteria: Rheumatoid arthritis; Flat feet; Spinal deformities; Surgery or injections of knee/s of any cause; System lupus erythematosus (SLE).

Intervention groups
Intervention group 1 (LLRPw-mHeath): The researcher will teach the lower limb rehabilitation protocol by using mHealth and instructions of daily care and will advice them to carry out three times a week for 12-weeks at their houses. The researcher will send the reminder with the mHealth in the form of periodic manual WhatsApp messages two times a day for three days a week for 12 weeks. Intervention group 2 (LLRPwo-mHealth): The researcher will teach the lower limb rehabilitation protocol and instructions of daily care and will advice them to carry out three times a week for 12-weeks at their houses. Control group: The researcher will teach the instructions of daily care to the control group keeping in mind the ethical consideration of patients.

Main outcome variables
Physical disability; Exercise adherence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191221045846N1**
Registration date: **2020-02-11, 1398/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-11, 1398/11/22**
Update count: **0**

Registration date
2020-02-11, 1398/11/22

Registrant information

Name
Muhammad Tariq Rafiq

Name of organization / entity
Punjab Employees Social Security Institution

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-25, 1398/10/04

Expected recruitment end date
2020-03-24, 1399/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of lower limb rehabilitation protocol using mobile health on physical disability and exercise adherence among knee osteoarthritis (OA) patients who are overweight and obese.

Public title

Role of advising exercises using mobile health in treatment of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Overweight and obese Knee OA patients Both males and females Aged between 45 to 60 years Living in urban area of Punjab, Lahore,

Exclusion criteria:

System lupus erythematosus (SLE) Previous surgery of knee/s of any cause Flat feet Spinal deformities Participants having history of metabolic, hormonal, orthopaedic, cardiovascular diseases The patients who had any injections of knee/s in the last six months.

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random technique by computer number generator

Blinding (investigator's opinion)

Single blinded

Blinding description

Four research coordinators will be involed in data collection. The two coordinators will be involved in baseline data collection and two coordinators will be invoved in the assessment of outcomes.Participants will be blinded of other group interventions by calling them on different days.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology, Punjab Employees Soci

Street address

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

City

Lahore

Postal code

54000

Approval date

2019-08-28, 1398/06/06

Ethics committee reference number

NO.RAIC PESSI/Estt/2019/487

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

Physical disability

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Composite Indian Functional Knee Assessment Scale (CIFKAS)

Secondary outcomes

1

Description

Exercise adherence

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Numeric rating scale from 0 to 10

Intervention groups

1

Description
Intervention group 1 (LLRPw-mHeath): It will consist of strengthening exercises of the lower limbs in sitting and lying positions and instructions of daily care. The training session of strengthening exercises will be of 30-40 minutes with 10 minutes warm up at the start and 10 minutes cooling down at the end. It will consist of three times a week for 12 weeks at their houses. The reminder in the form of mobile health (periodic manual WhatApp messages) will be send to carry on the training sessions. The messages will be send two times a day for three days a week for a duration of 12-weeks as a reminder.

Category
Other

2

Description
Intervention group 2 (LLRPwo-mHealth): It will consist of strengthening exercises of the lower limbs in sitting and lying positions and instructions of daily care. The training session of strengthening exercises will be of 30-40 minutes with 10 minutes warm up at the start and 10 minutes cooling down at the end. It will consist of three times a week for 12 weeks at their houses. No reminder will be send by using mobile health in this intervention.

Category
Rehabilitation

3

Description
Control group: It will consist of instructions of daily care only as a usual care for duration of 12 weeks at their houses. No reminder will be send by using mobile health in this intervention.

Category
Prevention

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

Street address
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?
No

Title of funding source
Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology, Punjab Employees Social Security Institution, Multan Chongi, Multan Road Lahore

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
Academic

2

Sponsor

Name of organization / entity
University of Malaya

Full name of responsible person
Dr Eliza Hafiz

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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
University of Malaya, Kuala Lumpur, Malaysia
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Rehmatul-Lil-Alameene Post Graduate Institute of Cardiology
Full name of responsible person
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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
Principal investigator doesn't allow.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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

No - There is not a plan to make this available

Data Dictionary

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