

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Feb 2026

Effectiveness of adding lifestyle change approaches to comprehensive exercises on pain, strength, quality of life and function in people with knee osteoarthritis

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of adding lifestyle change approaches to comprehensive exercises on pain, strength, quality of life, and function in people with knee osteoarthritis.

Design

A controlled, single-blind, computer-based randomization clinical trial on 112 patients.

Settings and conduct

This study aims to investigate the effect of different treatment methods in patients with knee osteoarthritis. Assessments will be conducted at Shariati Hospital in Tehran and exercises will be performed at the patients' homes. Participants will be selected based on specific criteria and physician opinion and randomly divided into four groups using randomizer software. This study is a blinded study. Participants will not be aware of the treatment group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women with knee osteoarthritis, knee pain for at least 3 to 6 months, osteoarthritis grade 1-3. Exclusion criteria: Patients who have undergone knee replacement surgery, people with severe osteoporosis

Intervention groups

One group receives only combined exercises. One group receives only the lifestyle change protocol. One group receives both interventions, namely combined exercises and lifestyle change protocol, together. The control group receives no intervention. The intervention groups actively undergo exercise and/or lifestyle change programs, while the control group remains without intervention so that the effects of the interventions can be measured against it.

Main outcome variables

Knee osteoarthritis, lifestyle, comprehensive exercises, physical activity, muscle strength, pain coping strategies,

performance, weight loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250414065318N1**

Registration date: **2025-05-24, 1404/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2025-05-24, 1404/03/03**

Update count: **0**

Registration date

2025-05-24, 1404/03/03

Registrant information

Name

mohadeseh hosseini

Name of organization / entity

Kharazmi University, Tehran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-24, 1404/03/03

Expected recruitment end date

2025-08-25, 1404/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effectiveness of adding lifestyle change approaches to comprehensive exercises on pain, strength, quality of life and function in people with knee osteoarthritis

Public title
Effectiveness of adding lifestyle change approaches on the function of people with knee osteoarthritis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Knee pain for at least 3 to 6 months Have osteoarthritis grade 1 to 3 on the Kellgren and Lawrence scale of 1 to 4 Using lifestyle changes in this study Crepitus; bone tenderness; bone enlargement; absence of palpable heat
Exclusion criteria:
People with chronic heart disease People with metabolic disease People with neurological diseases People with severe osteoporosis History of tumor or cancer Patients who have had knee replacement surgery

Age
From **54 years** old to **76 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals will be enrolled in the study based on the inclusion and exclusion criteria. Participants will be randomized using a computer-assisted randomization method. The sequence generator available at www.random.com will be used for this process. Participants will not have any information about the groups they are assigned to or the group they belong to. Therefore, the study will be single-blinded (the patient is not informed of the type of intervention). They will be randomly assigned to one of 4 groups: lifestyle group, lifestyle and combined exercise group, combined exercise group, and control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Intervention method Intervention duration: 3 months of exercises for the three intervention groups and 3 months of follow-up Groups: Combined exercise group, lifestyle change protocol group, both intervention groups (combined exercise + lifestyle), control group without intervention Participants are randomly divided into four groups using a computer sequence generator (www.random.com). The study is single-blind; that is,

participants are unaware of the type of intervention they are receiving.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kharazmi University Tehran
Street address
Mirdamad Boulevard
City
Tehran
Province
Tehran
Postal code
۱۵۴۴۷۳۳۱۱۱

Approval date
2025-02-23, 1403/12/05

Ethics committee reference number
IR.KHU.REC.1403.172

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Components related to the performance variable were measured using the Time to Rise Functional Test, which is a simple and accurate test for measuring individuals' performance ability during daily activities, as well as self-report tools such as the Tampa Scale for Kinesiophobia (TSK) and assessing the level of fear of falling while performing various daily activities. Self-efficacy related to falls was assessed using a questionnaire.

Timepoint
Before and after the intervention

Method of measurement
Components related to the performance variable were measured using the Time to Rise Functional Test, which is a simple and accurate test for measuring individuals' performance ability during daily activities, as well as self-report tools such as the Tampa Scale for Kinesiophobia

(TSK) and assessing the level of fear of falling while performing various daily activities. Self-efficacy related to falls was assessed using a questionnaire.

2

Description

Strength of the quadriceps, hamstrings, and wide extensor muscles using a hand-held dynamometer

Timepoint

Before and after the intervention

Method of measurement

Strength of the quadriceps, hamstrings, and wide extensor muscles using a hand-held dynamometer

3

Description

Knee joint range of motion in flexion and extension using a goniometer

Timepoint

Before and after the intervention

Method of measurement

Knee joint range of motion in flexion and extension using a goniometer

4

Description

Lifestyle using the Lifestyle Questionnaire (LSQ) is a comprehensive tool for assessing individuals' lifestyles, as well as using the Exercise Adherence Questionnaire.

Timepoint

Before and after the intervention

Method of measurement

Lifestyle using the Lifestyle Questionnaire (LSQ) is a comprehensive tool for assessing individuals' lifestyles, as well as using the Exercise Adherence Questionnaire.

5

Description

Quality of life using the SF-12 (Short Form-12) questionnaire is a shortened and validated tool for assessing health-related quality of life.

Timepoint

Before and after the intervention

Method of measurement

Quality of life using the SF-12 (Short Form-12) questionnaire is a shortened and validated tool for assessing health-related quality of life.

6

Description

Components related to the pain variable: Level of confidence of individuals while performing physical activities despite pain using the Pain Self-Efficacy Questionnaire (PSEQ). Pain intensity using the visual analog scale. The impact of pain and its difficulty on physical activities using the WOMAC questionnaire.

Timepoint

Before and after the intervention

Method of measurement

Components related to the pain variable: Level of confidence of individuals while performing physical activities despite pain using the Pain Self-Efficacy Questionnaire (PSEQ). Pain intensity using the visual analog scale. The impact of pain and its difficulty on physical activities using the WOMAC questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (1): The combined exercise group includes resistance, isometric, aerobic, and knee strengthening exercises. Intervention group (2): The lifestyle change group includes diet modification, weight loss, increased regular physical activity, stress management, and other lifestyle-related behavioral changes. Intervention group (3): The combined exercise and lifestyle change group. This group receives both of the above interventions simultaneously. The control group does not receive any intervention.

Category

Lifestyle

2

Description

Intervention group: The lifestyle change group included dietary modification, weight loss, increased regular physical activity, stress management, and other lifestyle-related behavioral changes. Intervention group

Category

Lifestyle

3

Description

Intervention group: Combined exercise and lifestyle change group: This group receives both of the above interventions simultaneously.

Category

Lifestyle

4

Description

Control group: They do not receive any intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital, Tehran

Full name of responsible person

Seyyedeh Tahereh Faezi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kharazmi University, Tehran

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

Kharazmi University, Tehran

Proportion provided by this source

100

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**

Kharazmi University, Tehran

Full name of responsible person

Seyyedeh Mohaddeseh Hosseini

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

Sport Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared after de-identifying individuals.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

The data will be available to researchers working in academic and research institutions.

Under which criteria data/document could be used

To carry out scientific projects

From where data/document is obtainable

Dr. Malihe Haddadnezhad-Kharazmi University, Tehran
02122228001 - m.hadadnezhad@yahoo.com

What processes are involved for a request to access data/document

Submitting the project plan, and after a complete review of the individuals and organizations carrying out the project and if approved, it will be sent.

Comments