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)
Phone
+98 51 3259 3324
Email address
mohadesehhosseini169@gmail.com

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
Seyyedah Tahereh Faezi
Street address
Kargar Avenue
City
Tehran
Province
Tehran
Postal code
۱۵۴۴۷۳۳۱۱۱
Phone
+98 21 8822 0065
Email
s.t_faezi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi University, Tehran
Full name of responsible person
Dr. Malihe Haddadnejad
Street address
Shahid Keshvari Sports Complex, end of South Razan Street (Shahid Hesari), Mirdamad Boulevard
City
tehran
Province
Tehran
Postal code
1544733111
Phone
+98 21 8832 9220
Email
info@khu.ac.ir
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
Street address
Shahid Keshvari Sports Complex, end of South Razan Street (Shahid Hesari), Mirdamad Boulevard
City
Tehran
Province
Tehran
Postal code
۱۵۴۴۷۳۳۱۱۱
Phone
+98 939 970 8760
Email
Mohadesehhosseini169@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kharazmi University, Tehran
Full name of responsible person
Dr. Malihe Haddadnejad
Position
Associate Professor, Department of Biomechanics and Sports Pathology
Latest degree
Ph.D.
Other areas of specialty/work
Sport Medicine
Street address
Shahid Keshvari Sports Complex, end of South Razan Street (Shahid Hesari), Mirdamad Boulevard
City
tehran
Province
Tehran
Postal code
1571914911
Phone
+98 21 8832 9220
Email
m.hadadnezhad@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kharazmi University, Tehran
Full name of responsible person
Dr. Malihe Haddadnejad
Position
Associate Professor, Department of Biomechanics and Sports Pathology
Latest degree
Ph.D.

Other areas of specialty/work
Sport Medicine
Street address
Shahid Keshvari Sports Complex, end of South Razan Street (Shahid Hesari), Mirdamad Boulevard
City
Tehran
Province
Tehran
Postal code
1571914911
Phone
+98 21 8832 9220
Email
m.hadadnezhad@yahoo.com

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