

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Developing an 8-week, tele-education weight control and exercise program, and evaluating its effects on weight and pain reduction in patients with obesity and knee osteoarthritis referred to Imam Khomeini Hospital: A double-blinded randomized clinical trial.

Protocol summary

Study aim

Developing a weight control and exercise program, and evaluating its effect on weight and pain reduction, in patients with obesity and knee osteoarthritis

Design

This study is a Double-Blind Randomized Clinical Trial that is done on 30 participants. For randomization, block randomization will be used.

Settings and conduct

This study is performed in three stages: the first stage includes assessments, the second stage provides education and intervention, and the third stage is the measurement of variables after eight weeks. All stages are performed in the sports medicine department of Imam Khomeini Hospital. In this research, participants, assessor and data analyzer are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria included age between 45 and 75 years, BMI between 30 and 50, knee osteoarthritis and no history of bariatric surgery, and no uncontrolled chronic diseases, who have the ability to use the online program. The criteria for not entering the study are pregnancy, the presence of a metal device or pacemaker in the body, recent diet therapy with weight loss, end-stage osteoarthritis, use of weight loss drugs, current intra-articular injections within the last six months and use of physical therapy devices.

Intervention groups

The intervention in this study includes online classes including nutrition, physical activity and Cognitive-behavioral therapy; in addition, a weekly knee exercise program is sent to them for eight weeks. General recommendations for aerobic exercise and weight loss are given to the control group.

Main outcome variables

Age, height, weight, gender, VAS, waist circumference,

hip circumference, body composition, KOOS questionnaire, EQ5D questionnaire, G-PAQ questionnaire, use of painkillers, 30 seconds standing up test, TUG test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220917055973N1**

Registration date: **2022-10-02, 1401/07/10**

Registration timing: **prospective**

Last update: **2022-10-02, 1401/07/10**

Update count: **0**

Registration date

2022-10-02, 1401/07/10

Registrant information

Name

Reyhaneh Khazaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2282

Email address

rkhazaei@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-03-22, 1402/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing an 8-week, tele-education weight control and exercise program, and evaluating its effects on weight and pain reduction in patients with obesity and knee osteoarthritis referred to Imam Khomeini Hospital: A double-blinded randomized clinical trial.

Public title

Developing an 8-week, tele-education weight control and exercise program, and evaluating its effects on weight and pain reduction in patients with obesity and knee osteoarthritis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 45 and 75 years Female or male
Radiographic diagnosis of knee osteoarthritis Ability to use the online application No history of bariatric surgery, uncontrolled diabetes, uncontrolled blood pressure, uncontrolled cardiovascular diseases, severe musculoskeletal and neurological disease and any other disease that can limit daily routine activities.

Exclusion criteria:

Getting pregnant Presence of a metal device or heart pacemaker in the body Recent diet therapy with weight loss (5% over 3 months or 10% over 6 months) End-stage osteoarthritis based on the Kellgren and Lawrence classification Use of weight loss medications such as appetite suppressants or any medication that has a significant effect on weight such as steroids. Recent intra-articular injections within the last 6 months Use of physiotherapy devices

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization is used. Thirty participants in this research will be placed in 3 blocks of ten that will be randomly selected by someone other than the researcher. Assigning each of the letters A and B to each of the intervention and control groups is done by a person other than the researcher (a third person).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blinded. Each candidate is blinded to their group (Intervention or control). The assessor of outcomes, including height, weight, waist circumference, hip circumference, and functional tests is blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Imam Khomeini Hospital Complex - Tehran University of Medical Sciences (Research Ethics Committee)

Street address

Deputy of Research and Technology, Imam Khomeini Hospital Complex, Gharib Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-05-21, 1401/02/31

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.037

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

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

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

Visual Analogue Scale score

Timepoint

Before the intervention, after eighth weeks

Method of measurement

Using a pain ruler with a scale of 0 to 100

2

Description

Knee Injury and Osteoarthritis Outcome Score

Timepoint

Before the intervention, after eighth weeks

Method of measurement

KOOS questionnaire

3

Description

EuroQoL five-dimension scale questionnaire

Timepoint

Before the intervention, after eighth weeks

Method of measurement

EQ5D questionnaire

4

Description

Timed up and go

Timepoint

Before the intervention, after eighth weeks

Method of measurement

Second

5

Description

30-second Chair Stand

Timepoint

Before the intervention, after eighth weeks

Method of measurement

Counting

6

Description

Body composition analysis

Timepoint

Before the intervention, after eighth weeks

Method of measurement

Body composition analysis

7

Description

Waist circumference

Timepoint

Before the intervention, after eighth weeks

Method of measurement

Meter

8

Description

Hip circumference

Timepoint

Before the intervention, after eighth weeks

Method of measurement

Meter

9

Description

Weight

Timepoint

Before intervention, week 1, week 2, week 3, week 4, week 5, week 6, week 7, end of week 8

Method of measurement

Weighting scale

Secondary outcomes

1

Description

Global physical activity questionnaire

Timepoint

Before the intervention, after eighth weeks

Method of measurement

G-PAQ questionnaire

2

Description

Use of painkillers

Timepoint

Before the intervention, after eighth weeks

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: participating in online training classes includes nutrition, physical activity, and cognitive behavioural therapy (CBT). Also, the knee exercise program including stretch and strength exercises is sent to them based on a weekly schedule for eight weeks.

Category

Lifestyle

2

Description

Control group: one session of educational recommendations on weight loss and aerobic exercise, in addition to the knee exercises for eight weeks.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Reyhaneh Khazaei

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Imam Khomeini Hospital Complex, Gharib Street,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Street address

Vice chancellor for research and technology, 6th floor,
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Email

vcr@tums.ac.ir

Web page address

<https://vcr.tums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

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

Tehran University of Medical Sciences

Full name of responsible person

Reyhaneh Khazaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Contact

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Full name of responsible person

Zahra Alizadeh

Position

Associate professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Initial results and other items at the request of
researchers.

**When the data will become available and for how
long**

The period of access starts 6 months after the
publication of results.

To whom data/document is available

Please contact this email: z_alizadeh@tums.ac.ir

Under which criteria data/document could be used

Please contact this email: z_alizadeh@tums.ac.ir

From where data/document is obtainable

Please contact this email: z_alizadeh@tums.ac.ir

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

Please contact this email: z_alizadeh@tums.ac.ir

Comments