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 ḍouble-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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotohi

Street address
Vice chancellor for research and technology, 6th floor, Central building of Tehran University of Medical Sciences, Ghods street, Keshavarz boulevard

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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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Department of Sports Medicine, Imam Khomeini Hospital Complex, Gharib Street, Keshavarz Boulevard

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Person responsible for scientific inquiries

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Full name of responsible person
Zahra Alizadeh

Position
Associate professor

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Person responsible for updating data

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Position
Associate professor

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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