

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigating the effect of Mindfulness-based cognitive therapy (MBCT) on Kinesiophobia in the elderly with chronic osteoarthritis

Protocol summary

Study aim

Determining the effect of cognitive therapy based on mindfulness on Kinesiophobia in the elderly with chronic osteoarthritis

Design

A single-blind trial, parallel groups, randomized using software, on 56 elderly people with chronic osteoarthritis.

Settings and conduct

56 elderly people referred to Kashan comprehensive health centers will be selected according to the inclusion criteria. The selected individuals divided into two equal groups. A group of 28 people selected to participate in mindfulness sessions that held for 8 sessions. The questions of Kinesiophobia asked and completed before the intervention. Then, 4 weeks after the end of the sessions, the questionnaire asked again by the researcher. The control group does not participate in mindfulness sessions; they only answer a series of questions at the beginning of the study, 4 and 8 weeks after that.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 60-75 years Knee osteoarthritis At least 3 months have passed since the diagnosis of arthritis. Exclusion criteria: Inability to participate in meetings Absence of at least 3 sessions Lack of access to samples in the follow-up phase Occurrence of cognitive and psychological disorders during the study Death Hospitalization during the study

Intervention groups

The intervention group receive 8 sessions of cognitive therapy program based on mindfulness. The content of the cognitive therapy sessions based on the conscious mind taken from the study of Segal et al. (2018). The control group will receive routine treatments and educational brochures.

Main outcome variables

The degree of Kinesiophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231105059961N1**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

Fatemeh Fallahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5558 9392

Email address

fallahi-f@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Mindfulness-based cognitive therapy (MBCT) on Kinesiophobia in the elderly with chronic osteoarthritis

Public title

The effect of Mindfulness-based cognitive therapy (MBCT) on Kinesiophobia in the elderly with chronic osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Knee osteoarthritis (doctor's diagnosis) At least 3 months have passed since the diagnosis of arthritis. Obtaining a score higher than 18 from the fear of movement questionnaire Ability to communicate in Farsi Iranian nationality Consent to participate in the study

Exclusion criteria:

Presence of autoimmune diseases, malignancy, congenital anomalies (except lordosis and mild scoliosis), fracture or infection in the knee History of falling during the last month Using psychiatric drugs (to reduce fear of movement) Using non-pharmacological and complementary treatments Suffering from known mental illness and mental retardation (based on the contents of the electronic health record) Suffering from cognitive impairment (getting a score above 20 on the MMSE instrument)

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be randomly assigned to each of the two groups in the form of blocks of 4 and 6. By using www.sealedenvelope.com, 6 blocks of 4 pieces and 4 blocks of 8 pieces and a total of 10 blocks will be defined. The blocks will be divided into 4 categories based on the list taken from the mentioned site and randomly each category of blocks will be considered from one center.

Blinding (investigator's opinion)

Single blinded

Blinding description

One-way blinding process will be possible for this research. In this way, in the final analysis of the data, the statistical analyst is unaware of the test groups and they will be named A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Faculty of Nursing & Midwifery, Faculty of Health & Faculty of Parame

Street address

Doctor's Blvd., Qutb Rawandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2023-10-30, 1402/08/08

Ethics committee reference number

IR.KAUMS.NUHEPM.REC.1402.054

Health conditions studied

1

Description of health condition studied

Kinesiophobia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Kinesiophobia Score

Timepoint

Measurement of Kinesiophobia Score before intervention, 4 and 8 weeks after intervention

Method of measurement

TSK: Tampa scale of kinesiophobia

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 8 sessions of 120 minutes, twice a week for one month, a mindfulness based cognitive therapy program, taken from the study of Segal et al. (2018).

Category

Rehabilitation

2

Description

Control group: The elderly in the control group will receive routine treatments and educational pamphlets.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Comprehensive Health Centers

Full name of responsible person

Fatemeh Fallahi

Street address

Doctor's Blvd., Qutb Rawandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5558 9392

Fax

+98 31 5558 9392

Email

fallahifatema@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholamali Hamidi

Street address

Deputy of research and technology, Doctor's Blvd.,
Qutb Rawandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 2999

Fax

+98 31 5557 5057

Email

research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Fallahi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Doctor's Blvd., Qutb Rawandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5558 9392

Email

fallahifatema@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

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City

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+98 31 5558 9392

Email

fallahifatema@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Fallahi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Kashan University of Medical Sciences, Doctor Blvd., Qutb Rawandi Blvd.,

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5558 9392

Fax

+98 31 5558 9392

Email

fallahi-f@kaums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available