

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Designing and evaluating an educational package on pain management in women with osteoarthritis of the knee near menopause

Protocol summary

Study aim

Design and evaluation of an educational package on pain management in women with osteoarthritis of the knee

Design

A clinical trial with intervention and control groups

Settings and conduct

Self-report of Kohgiluyeh and Boyer-Ahmad provinces of Yasuj city

Participants/Inclusion and exclusion criteria

Inclusion criteria: age around menopause (40-55), people with moderate knee pain, having knee pain for three months or more (chronic pain), dry knee when sitting and standing, no history of trauma, injury or surgery and lower limb fractures in the last 6 months, those who have not been previously trained in protective behaviors, have at least a basic education. Exclusion criteria: Joint surgery, joint replacement, intra-articular injection in 6 months, age over 55, knee joint infections, oral administration of corticosteroids for 6 weeks (current or past), Any other disease that affects the function of the lower limbs, the patient does not participate in one of the training sessions, women with musculoskeletal disabilities (due to restrictions in performing therapeutic exercise movements).

Intervention groups

The intervention and control group included fifty women between the ages of 40 and 55 who had grade 2 or 3 knee osteoarthritis.

Main outcome variables

Protective behaviors, muscle strength, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220105053636N1**

Registration date: **2022-02-05, 1400/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-05, 1400/11/16**

Update count: **0**

Registration date

2022-02-05, 1400/11/16

Registrant information

Name

masoomeh dashtian

Name of organization / entity

Tarbiat Modares

Country

Iran (Islamic Republic of)

Phone

+98 21 82880

Email address

m.dashtyan@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-20, 1399/09/30

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and evaluating an educational package on pain management in women with osteoarthritis of the knee near menopause

Public title

Designing and evaluating an educational package on knee pain management in women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Menopausal age (40-55) - People with moderate knee pain - Knee pain for three months or more (chronic pain) - Dry knee when sitting and standing, No history of trauma - Injury or surgery and Lower limb fractures in the last 6 months - those who have not previously been trained in protective behaviors - have at least a basic education

Exclusion criteria:

Joint surgery, joint replacement, intra-articular injection at 6 months, age over 55, knee joint infections, oral administration of corticosteroids for 6 weeks (present or past), any other disease that affects lower limb function, no participation The patient in one of the training sessions, women with musculoskeletal disabilities (due to limitations in performing therapeutic exercise movements).

Age

From **40 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

For each group, 44 people in each group are determined and finally, according to the probability of reduce sample, 50 people are considered for each group. A total of 100 people will enter this phase of the study for the two study groups (an intervention group and a control group). Cluster sampling was used in this study. For this purpose, first each of Yasuj treatment clinics is considered as a cluster and then we randomly assign one of the clinics to the intervention group and select the other as a control center. . After listing the names of all women in each medical center, we randomly select people who are eligible and interested in participating in the study to provide the required number, which was calculated based on the sampling formula

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Tarbiat Modares University

Street address

No. 7, Jalal Al-Ahmad St.

City

Tehran

Province

Tehran

Postal code

14115-111

Approval date

2019-09-12, 1398/06/21

Ethics committee reference number

IR.MODARES.REC.1398.101

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

1- Protective behaviors 2- Muscle strength 3- Pain

Timepoint

Before, immediately and six months after the study

Method of measurement

Using a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be evaluated based on the design of a randomized controlled trial intervention. In this study, the intervention group includes 50 women who are eligible to enter the study. Educational intervention program based on high-risk behaviors in the interview section and the results of the checklist of knee protection behaviors.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

کلینیک های درمانی شهید مفتاح و کلینیک درمانی فیزیوتراپی

Full name of responsible person

معصومه دشتیان

Street address

Tehran, Jalal Al-Ahmad St., Tarbiat Modares University

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dashtyanmasoome@yahoo.com

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

Tarbiat Modares University

Full name of responsible person

yaghoob fatolahi

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fatolahi@modares.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tarbiat Modares University

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**

Health Education Branch, Faculty of Medical Sciences,

Tarbiat Modares University

Full name of responsible person

sedighe sadat tavafian

Position

Professor of health education and health promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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

Tarbiat Modares University, School of Health, Health Education Branch

Full name of responsible person

sedigheh sadat tavafian

Position

Professor of Health Education

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

masoume dashtian

Position

student

Latest degree

Master

Other areas of specialty/work

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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

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

Informed Consent Form

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

make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I have no decision at the moment

When the data will become available and for how long

31/6/1401

To whom data/document is available

The person evaluating the outcome of the person analyzing the referee's magazine

Under which criteria data/document could be used

Evaluate the outcome of data analysis and check the accuracy of the data under double-blind conditions

From where data/document is obtainable

executor of plan

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

Requested via email to the project manager with the address: tavafian@modares.ac.ir

Comments