# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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**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 مفتح و کلینیک درمانی فیزیوتراپی
**Full name of responsible person**
معصومه دشتیان
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tarbiat Modares University
**Full name of responsible person**
yaghoub 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**
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## Person responsible for scientific inquiries

**Contact**
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sedigheh sadat tavafian
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Professor of Health Education
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## Person responsible for updating data

**Contact**
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Tarbiat Modares University
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masoume dashtian
**Position**
student
**Latest degree**
Master
**Other areas of specialty/work**

Health Promotion

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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**