

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Feb 2026

### Comparing the influence of pain education and behavioral graded activity with placebo education and behavioral graded activity on pain-related outcomes, central sensitization, function, and psychological factors in individuals with knee osteoarthritis

#### Protocol summary

##### Study aim

Comparing the influence of pain education and behavioral graded activity with placebo education and behavioral graded activity on pain-related outcomes, central sensitization, function, and psychological factors in individuals with knee osteoarthritis

##### Design

A randomized, triple blinded, placebo controlled 3 phase clinical trial with a parallel group design of 160 patients. For randomization, the procedure available on the website <http://randomizer.org/> is used.

##### Settings and conduct

Assessments are done before intervention, week 13, and week 55 in the biomechanics laboratory of Kharazmi University. Education sessions are online and graded behavioral activities are held at the Health Center of Kharazmi University. Participants, outcome assessor, and statistician are blinded of the process of randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: male and female > 45 of age, primary complaint of knee osteoarthritis. Exclusion criteria: knee replacement or any other lower limb surgery, history of inflammatory, metabolic or neurological disease, knee ligament or meniscus injury

##### Intervention groups

Intervention group includes pain education and graded behavioral activities and control group includes placebo education and graded behavioral activities. Pain education aims to reduce fear and avoidance behavior and increasing self-efficacy. Behavioral graded activity is based on time-contingency management and directed at increasing the level of activities in a time-contingent manner, with the goal to integrate these activities in the daily lives of the patients. Placebo education does not include any information about knee osteoarthritis complications or pain. It is based on the individual's wills.

##### Main outcome variables

Pain intensity, movement evoke pain, central sensitization, pressure pain threshold, function, pain catastrophizing, and kinesiophobia

#### General information

##### Reason for update

Adding the Illness Perception variable to the secondary outcomes

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210701051754N3**

Registration date: **2023-03-12, 1401/12/21**

Registration timing: **prospective**

Last update: **2023-07-08, 1402/04/17**

Update count: **2**

##### Registration date

2023-03-12, 1401/12/21

##### Registrant information

###### Name

Pouya Rabiei

###### Name of organization / entity

Kharazmi University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3403 1371

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2023-04-21, 1402/02/01

**Expected recruitment end date**

2023-08-23, 1402/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the influence of pain education and behavioral graded activity with placebo education and behavioral graded activity on pain-related outcomes, central sensitization, function, and psychological factors in individuals with knee osteoarthritis

**Public title**

Effect of a cognitive intervention with pain education in improvement of knee osteoarthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being Persian-native speaker male and female  
Being above 45 years old  
Having primary complaint of knee pain diagnosed as knee OA (>3 months' duration) by an orthopedic physician

**Exclusion criteria:**

Having self-reported knee replacement or any other lower limb surgery 6 months prior to participation  
Having a history of inflammatory, metabolic or neurological disease  
Having knee ligament or meniscus injury in previous year  
Having any mental health conditions  
Using therapeutic modalities 6 months before participation.

**Age**From **45 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**Target sample size: **160****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Following the baseline examination, by using the method shown on the website <http://randomizer.org/> (Social Psychology Network, Connecticut, USA), participants will be randomly assigned into the pain education and behavioral graded activity group and placebo education and behavioral graded activity group. Simple randomization will be used. Concealed allocation is performed using a computer-generated block randomized table of numbers (1 for pain education and behavioral graded activity group and 2 for placebo

education and behavioral graded activity group) created before the start of data collection by a researcher who is not involved in the recruitment or treatment of patients. Then, the random numerical sequence is placed in sealed opaque envelopes. Another researcher, blind to the baseline examination, open an envelope and process with treatment according to the group assignment. An independent assessor who is not known about the study's hypothesis and methods and is blind to the treatment group, assess the outcome measures before the interventions, and 8 weeks after interventions.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In this study, participants, outcome assessor, and statistician are blinded of the process of randomization and division of individuals into two experimental and control groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Sport Sciences Research Institute

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1587958711

**Approval date**

2023-02-19, 1401/11/30

**Ethics committee reference number**

IR.SSRC.REC.1401.141

**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

Pain intensity

#### Timepoint

Before the intervention, week 13, and week 55

#### Method of measurement

Using Persian translated of McGill pain questionnaire as well as numeric rating scale

## Secondary outcomes

### 1

#### Description

Movement evoke pain

#### Timepoint

Before the intervention, week 13, and week 55

#### Method of measurement

Using a 10 cm numeric pain rating scale during standing balance, walking 4 meters at normal speed, and performing 5 repetitions of standing up from a chair.

### 2

#### Description

Pressure pain threshold at pain location and far from pain location

#### Timepoint

Before the intervention, week 13, and week 55

#### Method of measurement

Using a manual pressure algometer with a speed of 40 kPa/s

### 3

#### Description

Central sensitization

#### Timepoint

Before the intervention, week 13, and week 55

#### Method of measurement

Using Persian translated of Central sensitization interview

### 4

#### Description

Function

#### Timepoint

Before the intervention, week 13, and week 55

#### Method of measurement

Using 3 tests, standing balance time, walking time of 4 meters at normal speed, and time of standing up from a chair for 5 repetitions

### 5

#### Description

Pain Catastrophizing

#### Timepoint

Before the intervention, week 13, and week 55

#### Method of measurement

Using Persian translated of Pain Catastrophizing Scale

### 6

#### Description

Kinesiophobia

#### Timepoint

Before the intervention, week 13, and week 55

#### Method of measurement

Using Persian translated of Tampa scale of kinesiophobia

### 7

#### Description

Illness Perception

#### Timepoint

Before the intervention, week 13, and week 55

#### Method of measurement

Using Persian translated of Brief Illness Perception Questionnaire

## Intervention groups

### 1

#### Description

Intervention group: People in this group do 3 to 6 sessions of pain education and about 19 sessions during 55 weeks of graded behavioral activities. Pain education includes individual training sessions (30 to 60 minutes) conducted by a pain specialist (native Persian speaker). This intervention is done by providing information about the nature of pain, in order to modify the individual's unhelpful and negative beliefs about pain. This approach can reduce fear avoidance and avoidance behavior, and increase self-efficacy. Graded behavioral activities, including 3 phases. 1. Starting phase (week 1-4) includes: provision of educational messages, selection of problematic activities and treatment goals, and determination of baseline value. 2. Treatment phase (5-13 week) includes: increase of the selected activities, gradually and in a time-contingent way, by means of an exercise program, which is reproduced in performance charts. 3. Integration phase (13-55 week) includes: support and reinforcement of the behavioral change and integration of the increased level of activities in the daily living of the individual (maximum of 7 sessions in 5 determined booster sessions in week 18, 25, 34, 42, and 55).

#### Category

Behavior

### 2

#### Description

Control group: People in this group do 3 to 6 sessions of placebo education and about 19 sessions during 55 weeks of graded behavioral activities. In the placebo education sessions, which last between 30 and 60 minutes individually, no information is given about knee osteoarthritis complications or pain. The discussed subjects are according to the individual's wills. Graded behavioral activities, including 3 phases. 1. Starting

phase (week 1-4) includes: provision of educational messages, selection of problematic activities and treatment goals, and determination of baseline value. 2. Treatment phase (5-13 week) includes: increase of the selected activities, gradually and in a time-contingent way, by means of an exercise program, which is reproduced in performance charts. 3. Integration phase (13-55 week) includes: support and reinforcement of the behavioral change and integration of the increased level of activities in the daily living of the individual (maximum of 7 sessions in 5 determined booster sessions in week 18, 25, 34, 42, and 55).

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Heath center of the Kharazmi university

**Full name of responsible person**

Pouya Rabiei

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Center for Human Movement Sciences of Kharazmi University, Keshvari Sport Complex, Hesari St., Mirdamad St.

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### 2

**Recruitment center**

**Name of recruitment center**

Rheumatology Center of Shariati Hospital

**Full name of responsible person**

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### 3

**Recruitment center**

**Name of recruitment center**

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Kharazmi University

**Full name of responsible person**

Amir Letafatkar

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Center for Human Movement Sciences of Kharazmi University, Keshvari Sport Complex, Hesari St., Mirdamad St.

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**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

This study has been conducted by the researchers and no organizational fund has been received

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Kharazmi University

**Full name of responsible person**

Amir Letafatkar

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sports Sciences

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

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

**Data Dictionary**

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

**Title and more details about the data/document**

Only demographic and outcomes-related data will be shared.

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

After publishing paper(s) extracted from the study.

**To whom data/document is available**

The data can be displayed and shared at the reasonable request of the Iranian Clinical Trial Registration Center, journals, and university individuals /researchers who are conducting research and scientific activities in this field.

**Under which criteria data/document could be used**

Data analysis and the use of documentation can only be done provided that their results are reported in systematic review articles by academic researchers and authors. Requirements for sharing data and documents include: 1. Sending an email (preferably with valid university addresses) to one of the study researchers/authors 2. A brief and logical explanation of how to use the data or documentation 3. Ensuring that the protocol for systematic review studies, requesting

access to data or documentation, is recorded.

**From where data/document is obtainable**

Through asking from Authors Pouya Rabiei Pouya.rabiei.pr@gmail.com, Bahram Sheikhi shekhibahram@gmail.com, and Amir Letafatkar letafatkaramir@yahoo.com

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

The applicant can request details from the researchers within 7 to 10 days using the message sent by email.

**Comments**