

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Effectiveness and durability of intervention pain neuroscience education and selected exercises based on weight management on pain, function and psychological factors in patients with knee osteoarthritis

#### Protocol summary

##### Study aim

The purpose of this study will be to investigate whether a 3-months (36-sessions) selected exercises program (strength, aerobic, mobility, neuromuscular, balance and breathing exercises) combined with 3 sessions pain neuroscience education (PNE) provides greater pain relief and improvement in physical performances and psychological factors in compared PNE and exercise alone, during at 6 months follow-up and whether “booster sessions” in follow-up periods may improve outcomes and increase adherence in a population of patients with knee osteoarthritis.

##### Design

Clinical trial with control group, with four arm factorial groups, one-way blind, randomized, on 129 patients. Block design and with help site will be used for randomization.

##### Settings and conduct

This study will be performed in the Tehran, Rheumatology Research Center of Shariati Hospital on people with knee osteoarthritis. Data evaluators and analyzers will be blind to the participants in each group.

##### Participants/Inclusion and exclusion criteria

Inclusion: Men and women (age 40 years or older) with knee osteoarthritis (Kellgren and Lawrence grade 1 to 3 on the 1-4 scale) Exclusion: Severe osteoporosis and Patellofemoral osteoarthritis

##### Intervention groups

1. Selected exercises using booster sessions (36 sessions) 2. Pain neuroscience education (PNE) (three sessions of PNE given over 2 weeks) 3. PNE+ Selected exercises using booster sessions (exercise three times a week for 3-months combined with three sessions of PNE) 4. Control (educations program comprised of the self-management, an anatomy and physiology (except PNE), daily activities ergonomic, and encouragement to be active)

##### Main outcome variables

Primary Outcomes: pain and WOMAC/ Secondary outcomes: psychological factors; physical function; muscles strength; Active range of motion; risk of fall; quality of life; and the exercise adherence.

#### General information

##### Reason for update

Unfortunately, in the previous update, we forgot to update the abstract with the following changes; We fixed it in this update as soon as we saw it. 1. We included illiterate people with the supervision of a person (caregiver, nurse or child) in the study. 2. At the discretion of the doctor present in this study, we included people with knee osteoarthritis 1 to 3 in this study. 3. We put the primary outcome only pain and other outcomes will be as secondary outcomes variable. 4. According to the sparseness of the city where the participants live, We set up the study as a home exercise (Telerehabilitation) and supervised by the supervisor so that all people have the ability to participate in the study (We tried to avoid bias). 5. In the first registration of our RCT, we registered the sample size without calculating 20% dropout. We have revised this part; The sample size, with the calculation of 20% dropout of the study, will be 129 patients.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220510054814N1**  
Registration date: **2022-06-06, 1401/03/16**  
Registration timing: **prospective**

Last update: **2023-01-24, 1401/11/04**

Update count: **3**

##### Registration date

2022-06-06, 1401/03/16

##### Registrant information

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**Name of organization / entity**

The University of Kharazmi

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**Recruitment status**

**Recruitment complete**

**Funding source****Expected recruitment start date**

2022-06-15, 1401/03/25

**Expected recruitment end date**

2022-08-06, 1401/05/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness and durability of intervention pain neuroscience education and selected exercises based on weight management on pain, function and psychological factors in patients with knee osteoarthritis

**Public title**

Effect of exercises and pain neuroscience education in Heal of knee osteoarthritis.

**Purpose**

Treatment

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

Age 40 years or older A clinical diagnosis of knee osteoarthritis (defined as knee pain for >3 months and minimum 3 times a week, early morning stiffness <30 minutes, crepitus, bony tenderness, and no palpable warmth) Radiographically established knee osteoarthritis (determined by Kellgren and Lawrence grade 1 to 3 on the 1-4 scale) Ability to read and write Persian and having access to and ability to use a smartphone or tablet for a period of follow up or the presence of a person next to the patient to help her/him No participation in formal strength training or physical therapy for more than 30 minutes a week in the past 6-month

**Exclusion criteria:**

Illiterate patients without caregivers (child, nurse, caregiver) Severe osteoporosis Clinical history of tumors or cancer Patients in the post-surgery period or submitted to previous physical therapy (over 30 min) in the past six months or to any health/pain education strategy Active Inflammatory joint diseases (rheumatoid arthritis, gout, calcium pyrophosphate deposition disease) Underwent any lower extremity joint replacement Procedure Alzheimer diseases Severe Patellofemoral osteoarthritis Neurological diseases

(parkinson's disease, stroke, multiple sclerosis, muscular dystrophy, motor neurone disease, huntington's disease) Autoimmune disease, and mental illnesses

**Age**

From **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **129**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patient will have to report agreement to participate in the study and signed the formal consent to participate, a Rheumatologist will run the assessment to determine eligibility. After this initial assessment (blinded assessor), we will enter the number of sets want on the website <http://randomizer.org/> (Social Psychology Network, Connecticut, USA) (Four sets of numbers are required: 1. Selected exercise group 2. pain neuroscience education group 3. Selected exercise combine pain neuroscience education group 4. Control). Participants will randomly be assigned to the control group or 1 of the intervention groups using a randomized permuted block design of block size 8 each participant's group. Another researcher, blind to the baseline examination, opens an envelope and processed with treatment according to the group assignment.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Assessor data analyzer will be blind to group allocation. Participants will not blind to exercise study however they were not aware which treatment will be considered as therapeutic. A blinded outcome assessor who will not know the hypothesis and study methods, measures outcome at baseline, after 3 month post-intervention, and 6 month follow-up.

**Placebo**

Not used

**Assignment**

Factorial

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

empty

**Ethics committees**

## 1

### Ethics committee

#### Name of ethics committee

Research Ethics Committees of Sport Sciences  
Research Institute (SSRI)

#### Street address

Floor 13, Block A, Ministry of Health & Medical  
Education Headquarters, Between Zarafshan &  
South Falamak, Qods Town, Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

1491115719

#### Approval date

2022-05-21, 1401/02/31

#### Ethics committee reference number

IR.SSRC.REC.1401.021

## 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 (Visual Analog Scale, Western Ontario and McMaster  
Universities Osteoarthritis index in knee osteoarthritis),  
Stiffness and physical functional (Western Ontario and  
McMaster Universities Osteoarthritis index in knee  
osteoarthritis).

#### Timepoint

All the primary outcomes will be measured at the initial  
evaluation, after the end of 36 session exercise  
intervention, and after the end of 6-month follow up.

#### Method of measurement

Pain: Visual Analogue Scale, and Western Ontario and  
McMaster Universities Osteoarthritis index in knee  
osteoarthritis. Stiffness and physical functional: Western  
Ontario and McMaster Universities Osteoarthritis index in  
knee osteoarthritis.

## Secondary outcomes

### 1

#### Description

Psychological factors (Pain Self-Efficacy Questionnaire  
(PSEQ), Scales Stress and Anxiety, Depression (DASS),  
Tampa Scale for Kinesiophobia (TSK), Pain  
Catastrophizing Scale (PCS)).

#### Timepoint

All the primary outcomes will be measured at the initial  
evaluation, after the end of 36 session exercise  
intervention, and after the end of 6-month follow up.

#### Method of measurement

Psychological factors: Pain Self-Efficacy Questionnaire  
(PSEQ), Scales Stress and Anxiety, Depression (DASS),  
Tampa Scale for Kinesiophobia (TSK), Pain  
Catastrophizing Scale (PCS).

### 2

#### Description

Physical Function (30 Second Sit to Stand Test and Timed  
UP and Go).

#### Timepoint

All the primary outcomes will be measured at the initial  
evaluation, after the end of 36 session exercise  
intervention, and after the end of 6-month follow up.

#### Method of measurement

Physical Function: 30 Second Sit to Stand Test and Timed  
UP and Go.

### 3

#### Description

Active Range of motion (goniometer).

#### Timepoint

The range of motion will be measured at the initial  
evaluation, after the end of 36 session exercise  
intervention, and after the end of 6-month follow-up.

#### Method of measurement

Range of motion: goniometer.

### 4

#### Description

Muscle strength (dynamometer).

#### Timepoint

The muscle strength will be measured at the initial  
evaluation, after the end of 36 session exercise  
intervention, and after the end of 6-month follow-up.

#### Method of measurement

Muscle strength: dynamometer.

### 5

#### Description

Exercise Adherence (The Exercise Adherence Rating  
scale (EARS)).

#### Timepoint

The adherence to exercise will be measured after the  
end of 6-month follow-up.

#### Method of measurement

Exercise Adherence: The Exercise Adherence Rating  
scale (EARS).

### 6

#### Description

Quality of life (Quality of life: Short Form Health Survey  
(SF-12)).

#### Timepoint

The quality of life will be measured at the initial evaluation, after the end of 36 session exercise intervention, and after the end of 6-month follow-up.

**Method of measurement**

Quality of life: Short Form Health Survey (SF-12).

**7**

**Description**

Risk of fall (Short Falls Efficacy Scale International (FES-I)).

**Timepoint**

The Risk of fall will be measured at the initial evaluation, after the end of 36 session exercise intervention, and after the end of 6-month follow-up.

**Method of measurement**

Risk of fall: Short Falls Efficacy Scale International (FES-I).

**Intervention groups**

**1**

**Description**

Intervention group 1: In selected exercise using booster sessions (in follow-up) group: The participants will be submitted to a program of 3-month (36 sessions+ 1 education) of selected exercises (mixed of cardio, strength, neuromuscular, breathing, mobility, balance exercises). The program will be carried out three a week, and will be a telerehabilitation program (Online and home exercise). Then, after the past of 1-month (12-sessions) of initial program, the participants will be invited to perform some functional activities (progression walking program+ step up and down+ semi squat) at home, in addition to the main exercise intervention. Each session will last between 45 to 75 minutes, and always movements will be checked with a physical therapist (Online connection). The participants in 2 groups (Selected exercise and Combined group) will receive booster sessions (through phone call and video call) during at follow-up: 8 sessions in the first 9 weeks at follow-up period, 2 booster sessions at between 8 weeks to end of follow-up period. On the all groups, participants will be received an educations program comprised of the self-management, an anatomy, heat therapy and physiology (except PNE in control group), daily activities ergonomic, and encouragement to be active. Also, in all the groups and during all the sessions, participants will support by automated text messages (for remember sessions and exercises).

**Category**

Treatment - Other

**2**

**Description**

Intervention group 2: pain neuroscience education (PNE) group: In this group, 3 introductory sessions will be held to teach pain management approaches. In this study, 3 training sessions will be held in 2 weeks, which will be conducted by the researcher. The schedule is the same

for all two treatment groups. The first session will be an online group session (duration 30 minutes to an hour) with a maximum of 6 participants in each group, led by a researcher using a PowerPoint presentation. Participants will then be asked to read an instruction booklet containing the same information at home. The second session is home-based online e-learning, which includes 3 explanatory videos. These videos explain the same PowerPoint that was shown during the first session along with its screening. Therefore, in the second session, which is held online, the same issue discussed in the first group session will be explained again. After each clip, participants are asked to complete a questionnaire that will assess their understanding and opinion of the film. The third session will include a 30-minute one-to-one conversation focusing on patients' personal needs: The questions in the second session questionnaire will be analyzed. And how to use this information in the patient's daily life is discussed. On three interventions groups, will be teaching about effect of heat therapy for pain reduced in patient. As well as, In this group, participants will also receive a nutrition education booklet with 60 min education about nutrition. On the all groups, participants will be received an educations program comprised of the self-management, an anatomy and physiology (except PNE in control group), daily activities ergonomic, and encouragement to be active. Also, in all the groups and during all the sessions, participants will support by automated text messages (for remember sessions and exercises).

**Category**

Treatment - Other

**3**

**Description**

Intervention group 3: In combine group (pain neuroscience education and selected exercises): The interventions of this group, will be a combination of two groups (pain neuroscience education and selected exercises). The participants in 2 groups (Selected exercise and Combined group) will receive booster sessions during at follow-up: 8 sessions in the first 9 weeks at follow-up period, 2 booster sessions at between 8 weeks to end of follow-up period. On three interventions groups, will be teaching about effect of heat therapy for pain reduced in patient. On the all groups, participants will be received an educations program comprised of the self-management, an anatomy and physiology (except PNE in control group), daily activities ergonomic, and encouragement to be active. Also, in all the groups and during all the sessions, participants will support by automated text messages (for remember sessions and exercises).

**Category**

Treatment - Other

**4**

**Description**

Control group: 4 group: In this group, participants will be received an educations program comprised of the self-management, an anatomy and physiology (except PNE),

heat therapy, daily activities ergonomic, and encouragement to be active (1-session, 60 to 75 minutes). Also, in all the groups and during all the sessions, participants will support by automated text messages (for remember sessions).

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rheumatology Research Center (RRC), Dr. Shariati Hospital, Tehran University of Medical Sciences (TU

**Full name of responsible person**

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

Yes

**Title of funding source**

Rheumatology Research Center (RRC), Dr. Shariati Hospital

**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**

The University of Kharazmi

**Full name of responsible person**

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**Latest degree**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

Only part of the data, such as the dependent variables,  
The average of all samples, can be shared in scientific  
articles.

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

Access period starts 6 months after the results are  
published.

**To whom data/document is available**

Personal information is confidential and general results  
are available to anyone in the article.

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

Information is not available to anyone. General results  
are available to anyone in the article.

**From where data/document is obtainable**

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

6 months after the publication of the results, the  
applicant can have the data by sending an email.

**Comments**