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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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 Zarafashan & South Falamak, Qods Town, Tehran, Iran.

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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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Sponsors / Funding sources

1

Sponsor

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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

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Postgraduate Student

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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