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
pouya.rabiei.pr@gmail.com

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
Street address
No. 3, Fifth Alley, Mir Emad St., Ostad Motahari St., Tehran
City
Tehran
Province
Tehran
Postal code
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 intervery

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 give 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

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

City
Tehran

Province
Tehran

Postal code
1544733111

Phone
+98 21 2222 8001

Email
info@khu.ac.ir

2

Recruitment center

Name of recruitment center
Rheumatology Center of Shariati Hospital

Full name of responsible person
Pouya Rabiei

Street address
Shariati Hospital, Jalal Al Ahmad St., North Karger St.

City
Tehran

Province
Tehran

Postal code
1411713135

Phone
+98 21 8490 1000

Email
shariatihosp@tums.ac.ir

3

Recruitment center

Name of recruitment center
Rheumatology Center Of Iran

Full name of responsible person
Pouya Rabiei

Street address
No 70, Khosravi Alley, North Kargar St.

City
Tehran

Province
Tehran

Postal code
1411893171

Phone
+98 21 8800 5141

Email
info@rcr.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kharazmi University

Full name of responsible person
Amir Letafatkar

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

City
Tehran

Province
Tehran

Postal code
1571914911

Phone
+98 21 2222 8001

Email
letafatkaramir@yahoo.com

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

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

City
Tehran

Province
Tehran

Postal code
15719-14911

Phone
+98 21 2222 8001

Email
letafatkaramir@yahoo.com

Person responsible for scientific 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

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

City
Tehran

Province
Tehran

Postal code
15719-14911

Phone
+98 21 2222 8001

Email
letafatkaramir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kharazmi university

Full name of responsible person
Amir Letafatkat

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Sports Sciences

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

City
Tehran

Province
Tehran

Postal code
15719-14911

Phone
+98 21 2222 8001

Email
letafatkaramir@yahoo.com

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 sheikhibahram@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