Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of adding Pain neuroscience education to Pilates exercises on reducing on pain and improving function and psychological variables in individuals with knee osteoarthritis

Protocol summary

Study aim
Evaluating if pain neuroscience education plus Pilates exercises will be superior to Pilates exercises on reducing pain and improving function, pain Catastrophizing, kinesiophobia, and self-efficacy in patients with knee OA.

Design
Two arms, randomised trial with blinded outcome assessment

Settings and conduct
Assessments are before and after interventions through blind assessor. Indexes for pain, pain catastrophizing, kinesiophobia, and self- efficacy are filled by patients online. The function assessment is at biomechanics laboratory at Kharazmi university. Education sessions are online, and Pilates exercises are on the health center of Kharazmi university.

Participants/Inclusion and exclusion criteria
Inclusion criteria: male and female above 45 years old, primary complaint of knee OA by an orthopedic physician. Exclusion criteria: knee replacement or any other lower limb surgery, history of inflammatory, metabolic or neurological disease, knee ligament or meniscus injury

Intervention groups
The experimental group includes patients with knee osteoarthritis who receive pain neuroscience education plus Pilates exercises. The control group includes patients with knee osteoarthritis who receive Pilates exercises. Education includes 3 individualized sessions held by a physical therapist. It reframes the patient's negative beliefs about pain by providing information about the nature of pain. This approach can reduce fear avoidance and avoidance behavior, and increase self-efficacy. Each Pilates exercises session (24 in total) will be held by a physical therapist and take 60 minutes including warm-up, exercises and cool-down. The number of repetitions is started from 5 and gradually increased according to the patient's ability. Exercises are based on the previous studies on knee osteoarthritis.

Main outcome variables
Pain, function, pain Catastrophizing, kinesiophobia, and self-efficacy

General information

Reason for update
Adding the start and end dates of the actual subject recruitment and the date of study ending.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210701051754N1**
Registration date: **2021-07-07, 1400/04/16**
Registration timing: **prospective**

Last update: **2023-09-19, 1402/06/28**
Update count: **2**

Registration date
2021-07-07, 1400/04/16

Registrant information

Name
Pouya Rabiei

Name of organization / entity
Kharazmi University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-07-11, 1400/04/20

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

2021-07-13, 1400/04/22

Actual recruitment end date

2021-11-01, 1400/08/10

Trial completion date

2022-03-11, 1400/12/20

Scientific title

Evaluation of adding Pain neuroscience education to Pilates exercises on reducing on pain and improving function and psychological variables in individuals with knee osteoarthritis

Public title

Effect of Pilates 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

- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **54**

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 neuroscience education plus Pilates exercises group and Pilates exercises group. Simple randomization will be used. Concealed allocation is performed using a computer-generated block randomized table of numbers (1 for pain neuroscience education plus Pilates exercises group and 2 for Pilates exercises 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)

Single blinded

Blinding description

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

Placebo

Not 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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No. 3, Fifth Alley, Mir Emad St., Ostad Motahari St., Tehran

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Postal code

1587958711

Approval date

2021-05-19, 1400/02/29

Ethics committee reference number

IR.SSRC.REC.1400.033

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 and after 8 weeks after intervention
Method of measurement
Western Ontario and McMaster Universities Arthritis (WOMAC) Index

Secondary outcomes

1

Description
Function
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Timed “Up & Go” (TUG) test

2

Description
Pain Catastrophizing
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Pain Catastrophizing Scale (PCS)

3

Description
Kinesiophobia
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Tampa Scale for Kinesiophobia (TSK)

4

Description
Self-efficacy
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Pain Self-Efficacy Questionnaire (PSEQ)

5

Description
Physical activity
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Western Ontario and McMaster Universities Arthritis (WOMAC) Index

Intervention groups

1

Description
Intervention group: Individuals in this group receive 3 sessions of pain neuroscience education and 24 session (for 8 weeks) Pilates exercises. Education includes 3 individualized sessions (30 and 60 minutes) held by a physical therapist. It reframes the patient's negative beliefs about pain by providing information about the nature of pain. This approach can reduce fear avoidance and avoidance behavior, and increase self-efficacy. Each Pilates exercises session (24 in total) will be held by a physical therapist and take 60 minutes including warm-up, exercises, and cool-down. The number of repetitions is started from 5 and gradually increased according to the patient's ability. Exercises are based on the previous studies on knee osteoarthritis.
Category
Rehabilitation

2

Description
Control group: This group only receive Pilates exercises. Each Pilates exercises session (24 in total) will be held by a physical therapist and take 60 minutes including warm-up, exercises, and cool-down. The number of repetitions is started from 5 and gradually increased according to the patient's ability. Exercises are based on the previous studies on knee osteoarthritis.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Heath center of the Kharazmi university
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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?
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
Persons

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 Science

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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 Amir Letafatkar letafatkaramir@yahoo.com Bahram Sheikhi sheikhibahram@gmail.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

Trial results

Please tick if results have been published
Yes
Summary result posting date
2023-09-19, 1402/06/28
Table of baseline comparison

Table 2. Baseline demographic data by intervention group

Characteristic	Total sample (n = 54)	PNE followed by PE (n=27)	PE (n=27)
Age, y	60.5±5.6	59.8±5.1	61.2±6.1
Body height, cm	166.2±6.5	167.3±5.3	164.7±7.3
Body mass, kg	81.2±10.6	82.1±10.1	80.1±11.2
Body mass index, kg/m2	29.5±4.4	29.3±3.4	29.7±5.3
Sex, n (%)			
Female	22 (40.7)	9 (40.9)	13 (59.1)
Male	32 (59.3)	18 (56.3)	14 (43.8)
VAS pain rating (0-100)	54.1±13.2	56.3 ±13.3	51.7±12.8
Pain duration, y	7.8±4.5	7.6 ±4.7	6.7±4.0
Unilateral symptoms, n (%)	13 (24.1)	8 (29.6)	5 (18.5)
Smoking status, n (%)			
Never smoked	36 (66.7)	17 (63.0)	19 (70.4)
Current	9 (16.7)	5 (18.5)	4 (14.8)
Past	9 (16.7)	5 (18.5)	4 (14.8)
Education level, n (%)			
High school or less	27 (50)	12 (44.4)	15 (55.6)
Bachelor’s degree	18 (33.3)	10 (37)	8 (29.6)
Master’s degree or higher	9 (16.7)	5 (18.5)	4 (14.8)
Marital status, n (%)			
Married	37 (68.5)	17 (63.0)	20 (74.1)

Single	3 (5.6)	2 (7.4)	1 (3.7)
Separated/divorced/widowed	14 (25.9)	8 (29.6)	6 (22.2)

Abbreviations: Continuous variables were expressed as mean and standard deviation (SD) and categorical variables as number (n) and percentage (%); VAS, Visual Analog Scale.

Participant flow diagram

https://doi.org/10.1186/s13075-023-03079-7

Table of variable outcomes' results

Table 3. Within- and between-group differences in primary and secondary outcome measures based on the general linear mix model analysis

Variables	Group	Baseline Mean (SD)	Eight weeks Mean (SD)	Change relative to baseline (%)	Group Difference, Mean (95% CI) a	ES ($\eta p2$) †	P-value
Pain (0-20)	PNE followed by PE	10.6 (2.8)	7.3 (2.3)	-31.1	-0.8 (-2.2 to 0.7)	0.04	0.288
	PE	10.7 (3.2)	8.1 (2.9)	-24.3			
Physical limitation (0-68)	PNE followed by PE	29 (8.4)	22.7 (7.2)	-21.7	-0.4 (-4 to 3.1)	0.02	0.812
	PE	28.5 (7.5)	23.1 (5.9)	-18.9			
Pain catastrophizing (0-52)	PNE followed by PE	26.1 (7.2)	16.2 (5.6)	-37.9	-3.9 (-7.2 to -0.6)	0.51¥	**0.021**
	PE	24.9 (8)	20.1 (6.5)	-19.3			
Kinesiophobia (17-68)	PNE followed by PE	43.7 (7.8)	34.3 (7.3)	-21.5	-4.2 (-8.1 to -0.4)	0.39¥	**0.032**
	PE	42.9 (7.5)	38.5 (6.8)	-10.3			
Self-efficacy (0-60)	PNE followed by PE	34.1 (7.5)	47.9 (7.2)	40.5	6.1 (0.7 to 11.5)	0.13	**0.028**
	PE	34.4 (11.8)	41.8 (12.0)	21.5			
Function (s)	PNE followed by PE	12.1 (2)	9.2 (1.6)	-24	-0.8 (-1.8 to 0.1)	0.05	0.069
	PE	12.2 (2.1)	10.1 (1.8)	-17.2			

Abbreviations: †, Effect size (partial eta squared); ¥, Large effect size (0.14); CI, Confidence Interval; PE, Pilates exercises; PNE followed by PE, Pain neuroscience education followed by Pilates exercises.

Table of adverse events

No serious adverse events were reported in any of the intervention groups. Protocol deviations or adjustments did not occur for both group.

First publication date

2023-06-06, 1402/03/16

Abstract of published paper

Results Significant within-group differences were observed in all outcomes in both groups at post-treatment. There were no statistically between-group differences in pain (adjusted mean difference: -0.8; 95% CI -2.2 to 0.7; p = 0.288), physical limitation (adjusted mean difference: -0.4; 95% CI -4 to 3.1; p = 0.812) and function (adjusted mean difference: -0.8; 95% CI -1.8 to 0.1; p = 0.069) at eight weeks. For pain catastrophizing (adjusted mean difference: -3.9; 95% CI -7.2 to -0.6; p = 0.021), kinesiophobia (adjusted mean difference: -4.2; 95% CI -8.1 to -0.4; p = 0.032), and self-efficacy (adjusted mean difference: 6.1; 95% CI 0.7 to 11.5; p = 0.028) statistically between-group improvements were observed favoring PNE followed by PEs group after the treatment.