Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of core stability exercises with and without yoga exercises on some musculoskeletal variables in patients with knee osteoarthritis

Protocol summary

Study aim

Comparison of the effect of core stability exercises alone and combined core stability exercises with yoga on some musculoskeletal variables in men with knee osteoarthritis.

Design

A controlled clinical trial with parallel groups, double-blinded, randomized using the Randimizer.org site. The study will have three groups consisting of a core stability exercise group (15 people), a core stability exercise with yoga group, and a control group.

Settings and conduct

This research will be conducted in the sports science laboratory of Islamic Azad University, Karaj Branch, where the necessary equipment for evaluating musculoskeletal variables and providing space for performing exercises is available.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having knee pain for at least 6 months before the start of the study. Moderate knee pain intensity equal to or greater than 4 on the Visual Analog Scale (VAS). No history of regular sports activity (at least three sessions per week) in the last six months.
Exclusion criteria: Having undergone physiotherapy in the last year. History of surgery or drug injection in the knee joint.

Intervention groups

Core stability exercise group: Performing core stability exercises three sessions per week for 8 weeks. Core stability exercise group with yoga: Performing core stability exercises plus one yoga session per week. Control group: No exercise intervention.

Main outcome variables

1. Proprioception 2. Pain intensity 3. Functional disability 4. Dynamic balance 5. Static balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240907062968N4**
Registration date: **2025-04-11, 1404/01/22**
Registration timing: **prospective**

Last update: **2025-04-11, 1404/01/22**
Update count: **0**

Registration date

2025-04-11, 1404/01/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-14, 1404/01/25

Expected recruitment end date

2025-05-15, 1404/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of core stability exercises with and without yoga exercises on some musculoskeletal variables in patients with knee osteoarthritis

Public title
The effect of core stability and yoga on knee osteoarthritis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Male, age over 50 Knee pain that has lasted for at least 6 months Knee pain may still persist in the week before the start of the test. Average knee pain intensity greater than or equal to 4 on the visual analog scale for pain intensity. Lack of a history of regular athletic activity (at least three times a week) in the last six months.

Exclusion criteria:
Undergoing physiotherapy in the past year. Patients who are currently or have been in the past three months engaged in exercise or yoga programs for the treatment of any illness. Arthroscopy or open surgery on the index knee in the past six months or planned in the next 6 to 8 months.

Age
From **50 years** old to **65 years** old

Gender
Male

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method will be web-based. Subjects who meet the inclusion criteria for the study will be randomly assigned to the first experimental group, the second experimental group, and the control group using the web-based randomization method (Social Psychology Network, Connecticut, USA) www.randomizer.org. The randomization will be simple. Concealment of random assignment will be done using a computer-generated blocked randomization table, where number 1 is defined for the core stability exercise group, number 2 for the core stability exercise group with yoga exercises, and number 3 for the control group. Subsequently, the site output will randomly divide individuals into 3 equal groups. Also, according to the assignment of groups, the intervention will be continued by the researcher.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, while reviewing the consent form in a 30-minute session, are informed about the study groups and voluntarily participate in this study without having the option to choose a group. The names of the patients are randomly divided into three equal groups using the website http://randomizer.org by a person unaware of the individuals' identity and physical characteristics, and each group is placed in sealed envelopes separately. Then, appropriate training and exercises are provided to each individual based on their assigned group. The analyst and outcome assessor also evaluate the changes that occur before and after eight weeks without knowledge of the hypotheses, study methods, or patient characteristics.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University Karaj branch

Street address
Karaj Branch, Islamic Azad University, Mo'azen Boulevard, Rajai Shahr, Karaj City Alborz Province

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Province
Alborz

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Approval date
2024-09-30, 1403/07/09

Ethics committee reference number
IR.IAU.K.REC.1403.120

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Y balance test

Timepoint
Before and after the intervention

Method of measurement

This test was conducted in three directions: anterior, posterior-internal, and posterior-external, so that the subject stood on one leg at the center of Y and attempted to reach with the other leg while maintaining balance on the supporting leg. The subject would touch the farthest possible point in each of the specified directions without error using the toes. The distance from the point of contact to the center was the reach distance, which would be measured in centimeters. To minimize learning effects, each subject would practice this test in each of the three directions six times with a 15-second rest between attempts. After a 5-minute rest, the subject would perform the main test in the principal directions. In the event of an error, if the foot that was in the center moved or the individual's balance was disrupted, the subject would be asked to repeat the test. To obtain an overall balance score for the individual, the following formula will be used. Given that this test has a significant relationship with leg length, in order to conduct this test and normalize the data, the actual length of the leg will be measured from the anterior superior iliac spine to the medial malleolus while lying supine on the ground using a tape measure before the measurement process begins. It is worth mentioning that the overall reaching score is obtained by summing the reach distances in the three directions, dividing by 3, and multiplying by the length of the limb.

2

Description

Static balance

Timepoint

Before and after the intervention

Method of measurement

In this study, static balance will be assessed using the single-leg stance test. In this test, the participant will stand barefoot on their dominant leg, and the time spent standing will be recorded with a stopwatch until the heel of the stance leg lifts off the ground. The test will be repeated three times with a 15-second rest interval, and the best time will be recorded. Errors include the free leg touching the ground, movement of the stance leg, hands separating from the waist, and using the body to assist with balance.

3

Description

Knee proprioception

Timepoint

Before and after the intervention

Method of measurement

In this study, knee proprioception will be measured using the Inclinometer application. The participant will sit on a height-adjustable chair, with their legs hanging off the ground. They will be asked to keep their head aligned with their torso, and their hands and forearms will be placed on the chair's armrests. After setting up the device, it will be calibrated, with the participant’s knee positioned at 90 degrees of flexion, marking this point as the zero reference for the correct posture on the chair. The Inclinometer will be attached to the upper third of the participant's dominant lower leg, and the application will be configured accordingly.The participant will be asked to actively move their lower leg three times to a target angle of 45 degrees, with the examiner providing feedback once the target angle is reached. The participant will then be instructed to hold the position for 5 seconds and remember the exact knee angle. To eliminate visual interference during measurement, the participant’s eyes will be closed using an eye mask, and they will be asked to keep their head stable. After 7 seconds, the participant will be instructed to move their lower leg actively again to reach the target angle of 45 degrees and report it by saying “I’ve reached it.” The difference between the angle created by the participant (the estimated or reconstructed angle) and the target angle (45 degrees) will be recorded as the absolute error, regardless of the direction (positive or negative). Each movement will be repeated three times, and the reliability of this method has been reported as 0.99.Considering that the highest efficiency of muscle spindles as primary proprioceptors occurs within the mid-range of joint motion, the target angle for measuring knee joint position sense should be within the mid-range (40-80 degrees) of flexion. Therefore, in this study, the 45-degree knee flexion angle will be used to reconstruct target angles for measuring knee joint position sense while seated.

4

Description

Functional Disability Assessment

Timepoint

Before and after the intervention

Method of measurement

The level of functional disability of the participants will be assessed using the WOMAC questionnaire. This questionnaire will be used for patients with knee pain and consists of 24 questions divided into three sections: pain (5 questions), joint stiffness (2 questions), and functional disability (17 questions). Participants will be asked about their pain, stiffness, and disability in the past 48 hours while performing daily activities. The total score will range from 0 to 96, with higher scores indicating greater disability. Each question will have 5 options: none, mild, moderate, severe, and very severe, assigned scores from 0 to 4. After answering all the questions, the total score will be calculated.

5

Description

Pain Intensity

Timepoint

Before and after the intervention

Method of measurement

Pain intensity will be measured using the Visual Analog Scale (VAS). This scale consists of a 10 cm line, where 0 represents no pain and 10 represents the most severe pain. The patient will mark their level of pain on the line. This tool is one of the most widely used methods for assessing pain worldwide. Besides its validity and reliability, the main advantage of this tool is its

simplicity. The scale is represented as a continuum from 0 to 10, where higher numbers indicate more pain. A score between 1-3 will indicate mild pain, 4-7 will indicate moderate pain, and 8-10 will indicate severe pain.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The core stability exercise group will perform core stability exercises 3 times per week for 8 weeks.
Category
Rehabilitation

2

Description
Intervention group: Core stability exercises along with yoga exercises, allocating one day a week to yoga exercises in addition to 3 core stability training sessions per week for a period of 8 weeks.
Category
Rehabilitation

3

Description
Control group: The control group will receive no training intervention and will only perform the tests.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad university Karaj Branch
Full name of responsible person
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Sponsors / Funding sources

1

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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
Islamic Azad University
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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Full name of responsible person
Vahid Mazloum
Position
Assistant Professor
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

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

Informed Consent Form

No - There is not 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

Not applicable

Title and more details about the data/document

The data related to the subjects of the control and intervention groups in the pre-test and post-test are shared in an unidentifiable way.

When the data will become available and for how long

Data access is available six months after the publication of the articles.

To whom data/document is available

The data will be available for physiotherapists working in academic institutions, as well as clinicians working in the field of musculoskeletal disorders, and all researchers. Use of the data is permitted with source citation.

Under which criteria data/document could be used

The raw data and results of this study may be used in systematic review studies. Therefore, the raw data and results of this study will be accessible to researchers who are active in the field related to this study.

From where data/document is obtainable

Vahid.mazloum@yahoo.com

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

Applicants must accurately explain their project and how the data/documents of this study will be used in their project. Subsequently, the data/document files will be sent to the applicants via email upon request. This process may take 10-12 business days.

Comments