

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Ali Honarvar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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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](http://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

##### City

Karaj

##### Province

Alborz

##### Postal code

3149968111

#### 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 Inclinator 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 Inclinator 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

Ali Honarvar

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Mawazeen Boulevard, Islamic Azad University, Karaj Branch

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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?

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

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Vahid Mazloum

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Sport Medicine

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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.mazloun@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**