Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Adding Combined Lumbopelvic and Foot Core Stability Exercises to Conventional Physiotherapy on Pain, Function, Time to Clinically Meaningful Pain Response, and Sustainability of Treatment Effects in Patients with Knee Osteoarthritis

Protocol summary

Study aim

To evaluate the effect of adding combined lumbopelvic and foot core stability exercises to conventional physiotherapy on pain, function, and treatment sustainability in knee osteoarthritis.

Design

Two-arm, randomised, controlled, parallel group, single-blind (outcome assessor) trial with 44 patients. Randomisation was performed using balanced block randomisation with blocks of four, and allocation was concealed using opaque, sealed, numbered envelopes. The sample size was calculated with an effect size of 0.96, a power of 80%, and a 15% dropout rate.

Settings and conduct

The study is conducted in the School of Rehabilitation Sciences of Iran University of Medical Sciences. Patients are randomly assigned to two groups. The intervention under physiotherapist supervision. Single-blind (outcome assessor) and allocation concealment is performed using opaque, numbered envelopes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-pregnant men and women, 40 to 70 years, primary symptomatic knee osteoarthritis with clinical and radiographic criteria and Kellgren-Lawrence grade 2 or 3, pain for more than 3 months and at least 3 out of 10, unilateral or bilateral, independent walking, no pain higher than 3 in other joints. Absence of: Joint or rheumatologic disease, knee effusion, neurologic or balance disorder, joint replacement, intra-articular injection within the past 3 months, acute injury or severe low back pain within the past 6 months, body mass index greater than 35

Intervention groups

control group conventional physiotherapy including electrical stimulation and strengthening and stretching exercises; other group same plus progressive lumbopelvic and foot core stability exercises, 12 sessions over 4 weeks.

Main outcome variables

pain intensity in both groups, before intervention, at the end of intervention, and one month later.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260922071158N1**
Registration date: **2026-10-01, 1405/07/09**
Registration timing: **prospective**

Last update: **2026-10-01, 1405/07/09**
Update count: **0**

Registration date

2026-10-01, 1405/07/09

Registrant information

Name

Fateme Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 902 031 2352

Email address

fatemerahimi7913@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date
2027-10-23, 1406/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Adding Combined Lumbopelvic and Foot Core Stability Exercises to Conventional Physiotherapy on Pain, Function, Time to Clinically Meaningful Pain Response, and Sustainability of Treatment Effects in Patients with Knee Osteoarthritis

Public title
Effect of Adding Lumbopelvic and Foot Core Stability Exercises to Conventional Physiotherapy in Patients with Knee Osteoarthritis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Men and non-pregnant women Age between 40 and 70 years Diagnosis of primary symptomatic knee osteoarthritis confirmed by American College of Rheumatology clinical and radiographic criteria with knee pain, at least one osteophyte on radiography, at least one clinical criterion including age above 50 years, morning stiffness less than 30 minutes, or crepitus during active joint movement, and radiographic severity within Kellgren-Lawrence grade 2 or 3 Knee pain for more than 3 months with pain intensity of at least 3 out of 10 on the Visual Analogue Scale in the past week Unilateral or bilateral knee osteoarthritis with the more painful knee selected as the study knee in case of bilateral involvement Ability to walk independently without assistive devices such as cane or walker Ability to read and write in Persian
Exclusion criteria:
Presence of other rheumatologic diseases, including rheumatoid arthritis, gout, spondyloarthropathies, or other inflammatory arthritis. Significant effusion in the study knee Presence of neurological, neuromuscular, or balance disorders affecting lower extremity function including stroke, Parkinson disease, radiculopathy, peripheral neuropathy, brain injury, or vestibular disorders History of knee joint replacement in the study limb Intra-articular injection in the study knee within the past 3 months including corticosteroid, hyaluronic acid, or platelet-rich plasma Presence of acute lower extremity injury, fracture, or severe disabling low back pain within the past 6 months Presence of severe obesity with body mass index greater than 35 kilograms per square meter Presence of uncontrolled cardiovascular, pulmonary, or other systemic diseases that limit safe exercise performance Presence of active cancer or history of cancer with risk of recurrence Cardiac pacemaker or implanted cardiac defibrillator Simultaneous participation in regular physiotherapy, rehabilitation, or knee-related exercise programs during the study period Presence ofpain higher than 3 in other joints except the knee in the past week that could affect the study outcomes
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
After baseline assessments, participants will be randomly assigned to one of two groups (conventional physiotherapy or conventional physiotherapy plus lumbopelvic and foot core stability exercises). The randomization sequence will be generated using the online Sealed Envelope software with the Balanced Block Randomization method using blocks of four (to ensure balanced allocation between the two groups). For allocation concealment, the randomization sequence will be placed in opaque, sealed, and numbered envelopes, and each participant will receive one envelope in sequence after enrollment. The outcome assessor and participants will remain unaware of the envelope contents until allocation
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the intervention, blinding of participants and therapist is not feasible because the therapist is responsible for delivering the exercises and participants are aware of the type of intervention they receive. However, to reduce assessment bias, the outcome assessor will be independent from the therapist and will not be aware of group allocation. Therefore, this study will be designed and conducted as a single-blind trial in which the outcome assessor is blinded
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat

Expressway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2026-09-22, 1405/06/31
Ethics committee reference number
IR.IUMS.REHAB.REC.1405.031

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity
Timepoint
before intervention, at the end of intervention, and one month after the end of intervention.
Method of measurement
Visual Analogue Scale for Pain; this scale consists of a 10-centimeter line, with zero indicating “no pain” and 10 indicating “the worst pain imaginable.” Pain intensity is determined based on the average pain experienced over the previous seven days to reduce the influence of daily fluctuations in pain and provide a more stable estimate of the patient's pain intensity.

Secondary outcomes

1

Description
Total score of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
Timepoint
before intervention, at the end of intervention, and one month after the end of intervention.
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index questionnaire and calculation of the total score according to the standard questionnaire scoring instructions

2

Description
Number of repetitions of the 30-Second Chair Stand Test
Timepoint
before intervention, at the end of intervention, and one month after the end of intervention.
Method of measurement
Counting the number of complete sit-to-stand repetitions from the chair within 30 seconds

3

Description
Time to complete the 40-meter fast-paced walk test
Timepoint
before intervention, at the end of intervention, and one month after the end of intervention.
Method of measurement
Recording the time required to walk the 40-meter path at maximum safe speed using a chronometer

4

Description
Time to complete the four-step stair-climb test
Timepoint
before intervention, at the end of intervention, and one month after the end of intervention.
Method of measurement
Recording the time required to ascend four stairs using a chronometer

5

Description
Percentage of participants achieving a clinically meaningful improvement in pain
Timepoint
At the end of the intervention period (week 4)
Method of measurement
The percentage of participants who achieve a reduction of at least 2 points in pain intensity from baseline, as measured using the Visual Analogue Scale, and maintain this reduction for at least three consecutive days at the end of the intervention period will be calculated. These participants will be classified as treatment responders, and the percentage of responders will be calculated for each group.

6

Description
Time to achieve a clinically meaningful improvement in pain
Timepoint
Daily from the initiation of the intervention through the end of week 4
Method of measurement
To evaluate the temporal pattern of pain changes and determine the speed of treatment response, pain intensity will be recorded daily during the four-week intervention period. Time to clinically meaningful pain improvement is defined as the time interval from the start of intervention to sustained achievement of the minimal clinically important change in pain intensity. In this study, the minimal clinically important change in pain is considered as a reduction of at least 2 points on the Visual Analogue Scale relative to the baseline value. Due to daily fluctuations in pain intensity, only the first

day on which the pain reduction reaches the minimal clinically important change will not be considered as the treatment response time; rather, sustained achievement of treatment response will be recorded when a reduction of at least 2 points relative to baseline is maintained for at least three consecutive days.

Intervention groups

1

Description

Intervention group: The same program as the control group, plus lumbopelvic and foot stabilization exercises. The combined lumbopelvic and foot stabilization program will be performed for 4 weeks, comprising 12 sessions (3 sessions per week), under physiotherapist supervision and in addition to usual physiotherapy. Foot stabilization exercises will be performed for both lower limbs.Lumbopelvic stabilization exercises will aim to improve trunk neuromuscular control, lumbopelvic stability, and lower-limb kinetic-chain control and will include the Abdominal Drawing-in Maneuver, Posterior Pelvic Tilt, Bridge, Supine Marching, Modified Dead Bug, Bird Dog, Modified Side Plank, half-squat, and Pallof Press. Foot stabilization exercises will aim to activate the intrinsic foot muscles, maintain the medial longitudinal arch, improve proprioception, and enhance functional foot stability and will include Short Foot Exercise, Toe Spread Out, Heel Raise, weight-shifting exercises, and double- and single-leg balance exercises on stable and unstable surfaces.Both programs will progressively advance from simple, low-challenge exercises to standing, single-leg, and functional activities. Progression will be based on individual tolerance, movement quality, and the ability to maintain appropriate alignment of the spine, pelvis, ankle, and knee. Throughout the program, emphasis will be placed on maintaining the medial foot arch and neutral spine and pelvic position, avoiding compensatory movements and dynamic knee valgus, and performing all exercises slowly and with controlled movement.

Category

Rehabilitation

2

Description

Control group: Transcutaneous electrical nerve stimulation will be applied for 20 minutes at 80 hertz, with a pulse width of 100 microseconds and tolerable sensory intensity, without muscle contraction. Electrodes will be placed around the medial and lateral aspects of the affected knee, with intensity adjusted as needed to maintain effective sensory stimulation.The exercise program will be performed for both lower limbs under physiotherapist supervision, three sessions per week for four weeks. It will include quadriceps isometric contraction, straight-leg raise, terminal knee extension, side-lying hip abduction, wall-supported mini-squat, and hamstring and gastrocnemius stretching. Exercise volume will progressively increase over the four weeks, with strengthening exercises progressing from 2 sets of 10 to 3 sets of 15 repetitions and stretching duration from 30 to 45 seconds.Progression will depend on pain, muscle soreness, movement quality, and individual tolerance. Exercises will be maintained or regressed if symptoms worsen or compensatory movements occur. Sessions will be stopped if severe pain, significant swelling, joint warmth, substantial range-of-motion limitation, or other safety concerns arise.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

فاطمه رحیمی

Street address

Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Madadkaran St., Shahid Shah Nazari St., Madar Sq., Mirdamad Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 933 743 3599

Email

fatemerahimi7913@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Majid Safa

Street address

5th Floor, Iran University of Medical Sciences, Hemmat Expressway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8862 2703

Email

safa.m@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
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
Iran University of Medical Sciences
Full name of responsible person
Fateme Rahimi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
No. 5, Golestan Dormitory, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Madadkaran Street, Shahid Shah Nazari Street, Madar Square, Mirdamad Boulevard, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 902 031 2352
Fax
Email
fatemerahimi7913@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Roya Khanmohammadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Madadkaran Street, Shahid Shah Nazari Street, Madar Square, Mirdamad Boulevard, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 912 063 4056
Fax
Email
dr.rkhanmohammadi96@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Fateme Rahimi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
No. 5, Golestan Dormitory, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Madadkaran Street, Shahid Shah Nazari Street, Madar Square, Mirdamad Boulevard, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 902 031 2352
Fax
Email
fatemerahimi7913@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

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