Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of combined balance and strength training with and without blood flow restriction on balance, functional strength, pain, physical function, and quality of life in patients with knee osteoarthritis

Protocol summary

Study aim
The primary aim of this study is to examine the effects of two exercise interventions on balance, functional strength, pain, and quality of life in patients with knee osteoarthritis.

Design
A randomized, single-blind, parallel-group controlled clinical trial conducted on 32 patients. Randomization was performed using the RAND function in Microsoft Excel.

Settings and conduct
This study is a randomized, parallel-group, single-blind clinical trial that will be conducted on 32 patients with knee osteoarthritis. The study will take place at the Orthopedic Clinics of Yazd University of Medical Sciences. The trial will be single-blind for participants; that is, participants will not be aware of the existence of the other group or the differences between the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 50 years; Diagnosis of knee osteoarthritis (unilateral or bilateral) based on the American College of Rheumatology criteria; Presence of clinical symptoms such as pain and functional limitation for at least three months; Ability to provide informed consent and willingness to adhere to the study protocol. Exclusion criteria: History of knee surgery; History of any invasive procedure in the affected knee; Concurrent physiotherapy or strengthening exercise program for the affected knee; Any injury affecting lower limb function; Presence of neurological, cardiac, or vascular diseases, including blood coagulation disorders; History of venous thromboembolism; Conditions affecting balance.

Intervention groups
Intervention group: Participants will perform a combination of balance and strengthening exercises with blood flow restriction. Control group: Participants will perform the same balance and strengthening exercises without blood flow restriction.

Main outcome variables
Static and dynamic balance, functional strength, pain, functional activities, quality of life.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241004063260N3**
Registration date: **2025-12-08, 1404/09/17**
Registration timing: **prospective**

Last update: **2025-12-08, 1404/09/17**
Update count: **0**

Registration date
2025-12-08, 1404/09/17

Registrant information

Name
Farzaneh Yazdani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3212 2600

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yazdani_far@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-20, 1404/09/29

Expected recruitment end date
2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of combined balance and strength training with and without blood flow restriction on balance, functional strength, pain, physical function, and quality of life in patients with knee osteoarthritis

Public title

Comparing two exercise methods to improve balance, strength, and reduce pain in people with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 50 years Diagnosis of knee osteoarthritis (unilateral or bilateral) according to the American College of Rheumatology (ACR) criteria. In patients with bilateral knee osteoarthritis, the knee with the worse Kellgren-Lawrence grade will be considered the affected knee. Radiographic evidence of knee osteoarthritis with Kellgren-Lawrence grade II or III. Presence of clinical symptoms such as pain and functional limitation for at least three months. Ability to provide informed consent and willingness to comply with the study protocol

Exclusion criteria:

History of any invasive procedure on the affected knee, including arthroscopy or intra-articular injection within the past 12 months. History of physiotherapy or strength training program for the affected knee concurrently with participation in the research study. Presence of injuries affecting lower limb function (except knee osteoarthritis). Presence of neurological, cardiac, or vascular diseases, including blood coagulation disorders. Other acute or chronic conditions that may affect physical or cognitive function. History of venous thromboembolism. Presence of diseases affecting balance, including inner ear disorders or plantar sensory impairments.

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Block randomization (blocks of 4, pattern aabb) was used to ensure balanced group sizes. Unit of Randomization: Individual participants. Stratification: None. Random Sequence Generation: Blocks were listed in Excel and their order randomized using =RAND(). Allocation Concealment: Sequence was prepared and managed by the researcher (study author) in a password-protected Excel file; group assignment was revealed only after participant enrollment

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only the participants were blinded to group allocation. Participants were not informed about which group they had been assigned to, and no information that could reveal the type of intervention they received was disclosed to them. Therefore, participants were unable to determine their assigned group, and participant-level blinding was maintained. It should be emphasized that all participants entered the study with informed consent and were fully aware that they were taking part in a research project. Thus, participant blinding was implemented solely to preserve the scientific integrity of the trial, and no withholding of information that would violate ethical principles occurred.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Ethics committee, Research and Technology Vice-Chancellor, 7th floor, central building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7198754361

Approval date

2025-10-01, 1404/07/09

Ethics committee reference number

IR.SUMS.REHAB.REC.1404.022

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17.1

ICD-10 code description
Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description
Static Balance
Timepoint
Before, immediately after, and 4 weeks post-intervention
Method of measurement
Single Leg Stance Test

2

Description
Dynamic Balance
Timepoint
Before, immediately after, and 4 weeks post-intervention
Method of measurement
Timed Up and Go Test

3

Description
Functional Strength
Timepoint
before, immediately after, and 4 weeks post-intervention
Method of measurement
30 Second Chair Stand Test

4

Description
Pain
Timepoint
Before, immediately after, and 4 weeks post-intervention
Method of measurement
Numeric Rating Scale

5

Description
Physical Function
Timepoint
Before, immediately after, and 4 weeks post-intervention
Method of measurement
WOMAC Questionnaire

6

Description
quality of life
Timepoint
Before, immediately after, and 4 weeks post-intervention
Method of measurement
KOOS Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group performed a combined program of strength and balance exercises with blood flow restriction (BFR). The program consisted of 10 daily sessions, each lasting approximately 45 minutes. Exercise intensity and volume were individualized according to participants' abilities, and progression was applied throughout the 10 sessions to ensure safety and maximize effectiveness.
Category
Rehabilitation

2

Description
The control group performed the same combined strength and balance exercises without BFR. The number of sessions, session duration, exercise intensity and volume, and progression were identical to the intervention group, ensuring that the only difference between the groups was the application of BFR.The program consisted of 10 daily sessions, each lasting approximately 45 minutes. Exercise intensity and volume were individualized according to participants' abilities, and progression was applied throughout the 10 sessions to ensure safety and maximize effectiveness.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Rehabilitation School
Full name of responsible person
Farzaneh Yazdani
Street address
Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person
Dr. Leila Abbasi

Street address
School of Rehabilitation Sciences, Shahid Doran Campus, Sadra Road

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Yazdani

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation Sciences, Shahid Doran Campus, Sadra Road

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Yazdani

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Title: De-identified Individual Participant Data (IPD) and Statistical Analysis Files Details: The shared files will include de-identified individual participant data related to primary and secondary outcome measures (e.g., balance tests, strength outcomes, functional questionnaires). No identifiable personal information will be shared. Only datasets directly related to the main outcomes of the clinical trial will be available.

When the data will become available and for how long

The data will become available 6 months after publication of the study results and will remain available for 3 years after publication.

To whom data/document is available

The data will be available to qualified researchers who submit a reasonable request and provide a methodologically sound proposal. Access will be granted after approval by the principal investigator.

Under which criteria data/document could be used

Deidentified IPD will be shared only for scientific and non-commercial research purposes, including analyses related to musculoskeletal rehabilitation and osteoarthritis. All requests will be reviewed by the principal investigator to ensure scientific validity, ethical approval, and protection of participant confidentiality.

From where data/document is obtainable

Data can be obtained directly from the principal investigator via email. Farzaneh Yazdani Sadra City Road, Shahid Doran Campus, Faculty of Rehabilitation Sciences 09177135942 yazdani_far@sums.ac.ir

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

Applicants must send a written request to the principal investigator describing the purpose of analysis. Requests will be reviewed for scientific merit, ethical compliance, and confidentiality. Data will be shared after signing a data-sharing agreement.

Comments