Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of closed and open kinetic chain exercises combined with blood flow restriction therapy on pain, muscle strength, and function in patients with knee osteoarthritis

Protocol summary

Study aim
To compare the effects of closed versus open kinetic chain exercises combined with blood flow restriction on pain, quadriceps strength, and function in patients with knee osteoarthritis.

Design
A single-blind parallel-group RCT of 40 participants (20 per group), randomized 1:1 by a computer-generated sequence to CKC+BFR or OKC+BFR. The outcome assessor will be blinded.

Settings and conduct
The study will be conducted in Baghdad, Iraq. Eligible patients will be randomly allocated to either intervention group. Treatment will be provided by a physiotherapist, while outcomes will be assessed by a blinded assessor.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 45–60 years, knee osteoarthritis grade II–III, BMI 25–35 kg/m², VAS pain 30–80 mm, malalignment ≤10°, and ability to walk. Exclusion criteria: Knee replacement, recent intra-articular injection, cardiovascular or vascular disease, neurological disorders, or BFR contraindications.

Intervention groups
Participants will be allocated to two groups. Group A will receive closed kinetic chain exercises with blood flow restriction (BFR), while Group B will receive open kinetic chain exercises with BFR. Both groups will receive 12 treatment sessions.

Main outcome variables
Pain will be assessed using VAS, quadriceps strength using a handheld dynamometer, and physical function using WOMAC. Outcomes will be measured before and after the intervention..

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260613069777N1**
Registration date: **2026-08-17, 1405/05/26**
Registration timing: **prospective**

Last update: **2026-08-17, 1405/05/26**
Update count: **0**

Registration date
2026-08-17, 1405/05/26

Registrant information

Name
Taqwa Salwan
Name of organization / entity
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Iraq
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-11, 1405/06/20

Expected recruitment end date
2027-02-09, 1405/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of closed and open kinetic chain exercises

combined with blood flow restriction therapy on pain, muscle strength, and function in patients with knee osteoarthritis

Public title
The effect of exercises with blood flow restriction on pain, muscle strength and function in people with osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults aged 45–60 years. Clinical and radiographic diagnosis of knee osteoarthritis, Kellgren–Lawrence grade II–III. Body mass index (BMI) between 25–35 kg/m². Knee pain intensity between 30–80 mm on a 100-mm Visual Analog Scale (VAS) during daily activities. Mild to moderate lower limb malalignment, defined as varus or valgus deformity ≤10°. Ability to walk independently with or without minimal assistive devices. Willingness to participate and provide written informed consent.

Exclusion criteria:
History of total knee replacement surgery. Intra-articular corticosteroid or hyaluronic acid injection within the past 3 months. Uncontrolled hypertension, unstable angina, or recent myocardial infarction. Peripheral vascular disease, history of deep vein thrombosis (DVT), or clotting disorders. Neurological disorders affecting lower limb strength or mobility. Contraindications to blood flow restriction training, such as severe varicosities, vascular insufficiency, or severe edema.

Age
From **45 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated to two intervention groups in a 1:1 ratio using a computer-generated random sequence. Randomization will be performed using Random Allocation Software. Gender matching will be considered to ensure balanced distribution of male and female participants between the two groups. Allocation concealment will be maintained using sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
The outcome assessor will be blinded to group allocation throughout the study. The assessor will perform the baseline and post-intervention outcome measurements without knowing whether each participant has been allocated to the closed kinetic chain exercise with blood flow restriction group or the open kinetic chain exercise with blood flow restriction group. The physiotherapist providing the intervention and the participants will not be blinded due to the nature of the exercise interventions.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Mirkhani Street (East Nosrat), Tohid Square, Tehran, Iran

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Tehran

Province
Tehran

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1419733171

Approval date
2026-08-01, 1405/05/10

Ethics committee reference number
IR.TUMS.FNM.REC.1405.075

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M17.9

ICD-10 code description
Osteoarthritis of knee, unspecified

Primary outcomes

1

Description
Pain intensity

Timepoint
Before the intervention and after completion of the 12-session intervention.

Method of measurement
Pain intensity will be measured using a 100-mm Visual Analogue Scale (VAS), ranging from 0 (no pain) to 100 (worst imaginable pain).

Secondary outcomes

1

Description
Quadriceps muscle strength
Timepoint
Before the intervention and after completion of the 12 treatment sessions.
Method of measurement
Quadriceps muscle strength will be measured using a handheld dynamometer

2

Description
Physical function and symptoms related to knee osteoarthritis
Timepoint
Before the intervention and after completion of the 12 treatment sessions.
Method of measurement
Measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire.

Intervention groups

1

Description
Intervention group 1: Closed kinetic chain exercises combined with blood flow restriction (CKC+BFR). Participants will receive a supervised 4-week rehabilitation program consisting of 3 sessions per week (12 sessions in total). The closed kinetic chain exercise program will include squat-to-chair, step-up, and Swiss-ball leg press exercises. Blood flow restriction will be applied during exercise at 40–80% of the individually determined limb occlusion pressure (LOP). Exercises will be performed using a low load of 20–30% of one-repetition maximum (1RM), following a 30–15–15–15 repetition scheme with 30–40 seconds of rest between sets. Exercise load will be progressively increased according to participant tolerance while remaining within the prescribed low-load range. Each session will include a standardized warm-up consisting of 5 minutes of low-intensity stationary cycling or brisk walking followed by 2–3 minutes of gentle knee range-of-motion exercises. At the end of the session, participants will perform quadriceps and hamstring stretching, with each stretch held for 30 seconds and repeated twice. All sessions will be supervised by a licensed physiotherapist to ensure correct technique, safety, and adherence to the intervention protocol.
Category
Rehabilitation

2

Description
Intervention group 2: Open kinetic chain exercises combined with blood flow restriction (OKC+BFR). Participants will receive a supervised 4-week rehabilitation program consisting of 3 sessions per week (12 sessions in total). The open kinetic chain exercise program will include seated knee extension, straight leg raise, and hamstring curl exercises. Blood flow restriction will be applied during exercise at 40–80% of the individually determined limb occlusion pressure (LOP). Exercises will be performed using a low load of 20–30% of one-repetition maximum (1RM), following a 30–15–15–15 repetition scheme with 30–40 seconds of rest between sets. Exercise resistance will be progressively increased using external resistance such as ankle weights or elastic resistance bands according to participant tolerance while remaining within the prescribed low-load range. Each session will include a standardized warm-up consisting of 5 minutes of low-intensity stationary cycling or brisk walking followed by 2–3 minutes of gentle knee range-of-motion exercises. At the end of the session, participants will perform quadriceps and hamstring stretching, with each stretch held for 30 seconds and repeated twice. All sessions will be supervised by a licensed physiotherapist to ensure correct technique, safety, and adherence to the intervention protocol.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
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Sponsors / Funding sources

1

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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
Tehran 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

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

Title and more details about the data/document
All data is potentially sharable after unidentified individuals.

When the data will become available and for how long
Access period starts 3 months after the article is published.

To whom data/document is available
For researchers working in academic, scientific and hospital institutions.

Under which criteria data/document could be used
Researchers working in the field of knee osteoarthritis and exercise therapy.

From where data/document is obtainable
Applicants for documentation can contact Dr. Attarbashi Moghadam via email: attarbashi@sina.tums.ac.ir

What processes are involved for a request to access data/document
Once they have the necessary criteria, the information will be provided to them within a month.

Comments