

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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		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.	
Public title	The effect of exercises with blood flow restriction on pain, muscle strength and function in people with osteoarthritis	Placebo	Not used
Purpose	Treatment	Assignment	Parallel
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.	Other design features	
Age	From 45 years old to 60 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	N/A	1	
Groups that have been masked	Outcome assessor	Ethics committee	
Sample size	Target sample size: 40	Name of ethics committee	Ethics Committee of Tehran University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Mirkhani Street (East Nosrat), Tohid Square, Tehran, Iran
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.	City	Tehran
Blinding (investigator's opinion)	Single blinded	Province	Tehran
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	Postal code	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

Name of recruitment center

AL-Karama Teaching Hospital

Full name of responsible person

Taqwa Salwan Alkhateeb

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Recruitment center

Name of recruitment center

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Full name of responsible person

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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
Tehran University of Medical Sciences
Full name of responsible person
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Bachelor
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3

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Vice Chancellor for Research and Technology, Sixth Foor, Central University Organization, Corner of Quds Street, Keshavarz Boulevard
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Email
research@tums.ac.ir
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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Behrouz Attarbashi Moghadam

Position

Professor

Latest degree

Ph.D.

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Web page address

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