

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The added effect of knee orthosis with home-based exercise (tele-rehabilitation) on pain, physical function and thickness of the quadriceps muscle in patients with mild to moderate degrees of knee osteoarthritis

Protocol summary

Study aim

The added effect of knee orthosis with home exercise (tele-rehabilitation) on pain, physical function and thickness of the quadriceps muscle in patients with knee osteoarthritis

Design

Parallel group, Randomized controlled trial with outcome assessor blinded

Settings and conduct

All the assessments, interventions, and data collection steps will be carried out at the School of rehabilitation, iran university of medical science. The outcome assessor and statistician will be blinded.

Participants/Inclusion and exclusion criteria

aged 50-65 years old, Kellgren and Lawrence grade 2 or 3 according to AP knee radiographs, pain intensity at least 4 based on Visual Analog Scale (VAS), standing and walking without assistance

Intervention groups

two groups: home exercise and home exercise with knee orthosis

Main outcome variables

Primary variables: pain via Visual Analog Scale (VAS), physical function via Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire
Secondary variables: quadriceps muscle thickness, functional mobility via Timed Up and GO (TUG) test, lower limb function via 30 sit-stand test, Kinesiophobia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200315046784N6**

Registration date: **2025-07-15, 1404/04/24**

Registration timing: **prospective**

Last update: **2025-07-15, 1404/04/24**

Update count: **0**

Registration date

2025-07-15, 1404/04/24

Registrant information

Name

Fatemeh Azadinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

azadinia.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-26, 1404/05/04

Expected recruitment end date

2026-06-10, 1405/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The added effect of knee orthosis with home-based exercise (tele-rehabilitation) on pain, physical function and thickness of the quadriceps muscle in patients with mild to moderate degrees of knee osteoarthritis

Public title

effects of knee orthosis and home-based exercise in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Kellgren and Lawrence grade 2 or 3 according to AP knee radiographs Pain intensity greater than 4 based on VAS standing and walking without assistance 50 - 65 years old

Exclusion criteria:

History of surgery or trauma in osteoarthritic limb
Physical therapy, chiropractic, or acupuncture treatment, or knee-specific exercises in the past 6 months oral or intra-articular corticosteroid use within the past 6 months or any other intra-articular injections such as hyaluronic acid or PRP Uncontrolled blood pressure, heart disease, insulin-dependent diabetes, impaired kidney function, use of medications that cause dizziness, nervous system disorders, taking muscle relaxant medications history of wearing knee orthoses in past 6 months allergic skin reaction other types of arthritis such as Rheumatoid arthritis BMI>30

Age

From **50 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The group allocation will be performed through permuted block randomization at an assignment ratio of 1:1. For allocation concealment, the randomization codes will be kept in opaque, sealed, sequentially numbered envelopes. Sample size is estimated at 44, however, to take account of potential withdrawals, 50 patients (n=25 per group) will be recruited for the study. First, create and seal 25 treatment A envelopes, and 25 treatment B envelopes. To create a block of 6, we will select 3 treatment A envelopes, and 3 treatment B envelopes. These 6 envelopes will be shuffled thoroughly, and place this block of 6 in a separate pile. To create a block of 4, we will select 2 treatment A envelopes, and 2 treatment B envelopes. Then, we will prepare additional blocks of 6 and 4 until all 25 treatment A, and B envelopes have been used. All additional blocks will be placed in their own individual piles. We will have 3 individuals piles of shuffled blocks of 6, and 8 individuals piles of shuffled blocks of 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor will be blinded to group allocation, because all dependent variables will be measured without the orthosis and the patients will remove their

orthosis before referring for post-intervention assessment. Furthermore, all data will be encoded to prevent bias and to blind the statistician.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Iran University of Medical Sciences

Street address

Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2025-05-25, 1404/03/04

Ethics committee reference number

IR.IUMS.REC.1404.273

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

pain via visual analog scale(VAS)

Timepoint

Before and after 8 weeks intervention

Method of measurement

visual analog scale(VAS)

2

Description

physical function

Timepoint

Before and after 8 weeks intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

Secondary outcomes

1

Description

Quadriceps muscle thickness

Timepoint

before and after 8 weeks intervention

Method of measurement

Ultrasound

2

Description

Functional mobility via Timed-Up and Go (TUG)

Timepoint

before and after 8 weeks intervention

Method of measurement

TUG: measuring the time to get up from a chair, walking at certain distance, turn around, return to the chair, and sitting down again.

3

Description

kinesiophobia

Timepoint

before and after 8 weeks intervention

Method of measurement

Tampa scale

4

Description

lower limb muscles function via sit-to-stand test

Timepoint

before and after 8 weeks intervention

Method of measurement

Counting the number of times the patient comes to a full standing position during 30 sec

Intervention groups

1

Description

Intervention group: home-based exercise, and also flexible knee orthosis. Participants will be asked to wear flexible knee orthosis for 8 weeks except when sleeping or showering. Participants will receive 3 home-based exercise sessions (each session 30-40 minutes) per week for 8 weeks. Exercises will include: Passive knee flexion, Passive knee extension, Isometric quadriceps contraction, Supine Straight leg lift, Leg lift in prone position, Shifting the center of mass, Resistance knee flexion, Resistance knee extension.

Category

Rehabilitation

2

Description

Intervention group: home based exercise. They will receive the same exercises as the other group, but they will not receive knee orthosis.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation School of Iran University of Medical science

Full name of responsible person

Fatemeh Azadinia

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Shahnazari st., Mother Sq., Mirdamad Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Majid Safa

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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

Iran University of Medical Sciences

Proportion provided by this source

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

Fatemeh Azadina

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics and Prosthetics

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Our research findings will be shared with all researchers, and practitioners. We will publish our research findings in scientific journals

When the data will become available and for how long

All documents can be shared 1 year after article publication

To whom data/document is available

Researchers and health practitioners

Under which criteria data/document could be used

Use of data is only possible by mentioning the name and organizational affiliation of the correspond and co-author of the project and the published article.

From where data/document is obtainable

Fatemeh Azadina

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

Send email to corresponding author.
Comments