Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 envelops, 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
Street address
Shahnazari st., Mother Sq., Mirdamad Blvd
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 8051
Email
azadinia.fatemeh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid Safa
Street address
Hemmat highway,
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 2504
Fax
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
Fatemeh Azadinia

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Orthotics and Prosthetics

Street address
Shahnazari st., Mother Sq., Mirdamad Blvd

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
azadinia.fatemeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Fatemeh Azadinia

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Orthotics and Prosthetics

Street address
Shahnazari st., Mother Sq., Mirdamad Blvd

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
azadinia.fatemeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Fatemeh Azadinia

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Orthotics and Prosthetics

Street address
Shahnazari st., Mother Sq., Mirdamad Blvd

City
Tehran

Province
Tehran

Postal code
1545913487

Phone
+98 21 2222 8051

Email
azadinia.fatemeh@yahoo.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
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 Azadinia

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

Send email to corresponding author.

Comments