

# 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 Azadina

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2222 0947

###### Email address

azadina.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

##### 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

۱۳۴۹۶۱۴۵۳۵

##### 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

azadina.fatemeh@yahoo.com

**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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**Contact**

**Name of organization / entity**

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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**