Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison The Added Effect of External Knee Supports with Home-based Exercise on Pain, Physical Function and Muscular Performance in Patients with Mild to Moderate Degrees of Knee Osteoarthritis

Protocol summary

Study aim
Comparison The Added Effect of External Knee Supports with Home-based Exercise on Pain, Physical Function and Muscular Performance in Patients with Mild to Moderate Degrees of 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 sport sciences and health, Shahid Beheshti University. 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, the American College of Rheumatology classification criteria pain intensity of at least 4, standing and walking without assistance

Intervention groups
Three groups: home-based exercise, home-based exercise plus Kinesiotape, home-based exercise plus flexible knee orthosis

Main outcome variables
Primary outcome measures: Pain via VAS, physical disability via WOMAC. Secondary outcome measures: maximal isometric contracrtion. force sense, force steadiness, kinesiophobia, 30-seconds sit-to-stand test

General information

Reason for update

Acronym
OA

IRCT registration information
IRCT registration number: **IRCT20200315046784N4**
Registration date: **2024-08-27, 1403/06/06**
Registration timing: **prospective**

Last update: **2024-08-27, 1403/06/06**
Update count: **0**

Registration date
2024-08-27, 1403/06/06

Registrant information

Name
Fatemeh Azadinia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-14, 1403/06/24

Expected recruitment end date
2025-07-06, 1404/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison The Added Effect of External Knee Supports with Home-based Exercise on Pain, Physical Function and Muscular Performance in Patients with Mild to Moderate Degrees of Knee Osteoarthritis

Public title

Effects of external knee supports with 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, the American College of Rheumatology classification criteria pain intensity of at least 4 standing and walking without assistance

Exclusion criteria:

corticosteroid injection within the past 6 month Rheumatoid arthritis surgery and or other musculoskeletal disease of involved limb diabetes neurologic disease history of wearing knee orthoses or applying Kinesio-tape for the last 6 months taking medicine which affect nervous system and muscles allergic skin reaction BMI>36

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The group allocation will be performed through permuted block randomization at an assignment ratio of 1:1:1. For allocation concealment, the randomization codes will be kept in opaque, sealed, sequentially numbered envelopes. Sample size is estimated at 54, however, to take account of potential withdrawals, 60 patients (n=20 per group) will be recruited for the study. First, create and seal 20 treatment A envelopes, 20 treatment B envelopes, and 20 treatment C envelopes. To create a block of 6, we will select 2 treatment A envelopes, 2 treatment B envelopes, and 2 treatment C envelopes. We will shuffle these 6 envelopes thoroughly, and place this block of 6 in a separate pile. Then, we will prepare additional blocks of 6 until all 20 treatment A, B, and C envelopes have been used. All additional blocks will be placed in their own individual piles. We will have 10 individuals piles of shuffled blocks of 6.

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 or kinesiotape, and the patients will remove their orthosis / kinesiotape 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

۱۴۴۹۶۱۴۵۳۵

Approval date

2024-05-11, 1403/02/22

Ethics committee reference number

IR.IUMS.REC.1403.108

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 by visual analog scale (VAS)

Timepoint

Before and after 6 weeks intervention

Method of measurement

Visual analog scale

2

Description

Physical disability

Timepoint

Before and after 6 weeks intervention

Method of measurement

WOMAC questionnaire

Secondary outcomes

1

Description
Maximum voluntary isometric contraction
Timepoint
Before and after 6 weeks intervention
Method of measurement
Isokinetic Dynamometer

2

Description
force steadiness
Timepoint
Before and after 6 weeks intervention
Method of measurement
Isokinetic Dynamometer

3

Description
Force sense
Timepoint
Before and after 6 weeks intervention
Method of measurement
Isokinetic Dynamometer

4

Description
30 seconds sit-to-stand test
Timepoint
Before and after 6 weeks intervention
Method of measurement
Counting the number of times the patient comes to a full standing position during 30 sec.

5

Description
kinesiophobia
Timepoint
Before and after 6 weeks intervention
Method of measurement
Tampa scale

Intervention groups

1

Description
Intervention group: home based exercise
Category
Rehabilitation

2

Description
Intervention group: home-based exercise, and also Kinesiotape which will be reapplied every 3 days
Category
Rehabilitation

3

Description
Intervention group: home-based exercise, and also flexible knee orthosis
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
دانشگاه شهیدبهشتی، دانشکده علوم ورزشی و تندرستی
Full name of responsible person
فاطمه آزادی نیا
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Reza Falak
Street address
Hemat highway, next to Milad tower
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1449614535
Phone
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Falak.r@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
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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 Azadinia
What processes are involved for a request to access data/document

Send email to corresponding author.

Comments