Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Therapeutic Effectiveness of Mulligan Mobilization with Movement on Pain, Functional Mobility and Balance, and Spatiotemporal Gait Parameters in people with Knee Osteoarthritis: A Randomized Clinical Trial

Protocol summary

Study aim
To evaluate the effectiveness of Mulligan Mobilization with Movement plus Core Stability Exercises versus Core Stability Exercises alone on pain, functional mobility and balance, and spatiotemporal gait parameters in people with knee osteoarthritis.

Design
Randomized controlled trial with parallel groups, 1:1 allocation, block randomization, concealed allocation via opaque sealed envelopes, outcome assessor- and data analyst-blinded.

Settings and conduct
The trial will be conducted at the Biomechanics Department, Shahid Bahonar University of Kerman. Participants will be recruited from physiotherapy and orthopedic outpatient departments of University of Medical Sciences of Kerman hospitals. The outcome assessor and data analyst will be blinded.

Participants/Inclusion and exclusion criteria
people aged 50 to 75 years with bilateral medial compartment knee osteoarthritis, Kellgren/Lawrence grade 3, chronic knee pain for at least 3 months, moderate pain (VAS 4 to 8 out of 10), and diagnosis confirmed by an orthopedic specialist based on American College of Rheumatology criteria. Exclusion criteria include history of knee surgery or lower limb fracture within 6 months, neurological or musculoskeletal conditions impairing mobility, systemic inflammatory diseases, contraindications to manual therapy, uncontrolled hypertension or cardiovascular limitations, radiating leg pain suggesting radiculopathy, body mass index greater than 40, intra-articular injections within 6 months, current physiotherapy or exercise programs, and inability to perform basic functional tasks.

Intervention groups
Experimental group will receive Mulligan Mobilization with Movement plus Core Stability Exercises. Control group will receive Core Stability Exercises alone. B

Main outcome variables
KOSS; VAS; TUG and 6MWT; balance indices by Biodex Balance System; gait parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180106038234N1**
Registration date: **2026-10-12, 1405/07/20**
Registration timing: **prospective**

Last update: **2026-10-12, 1405/07/20**
Update count: **0**

Registration date
2026-10-12, 1405/07/20

Registrant information
Name
Ehsan Ebrahimipour
Name of organization / entity
Shahid Bahonar University of Kerman
Country
Iran (Islamic Republic of)
Phone
+98 34 3272 4880
Email address
ehsan94324001@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date

2026-10-23, 1405/08/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic Effectiveness of Mulligan Mobilization with Movement on Pain, Functional Mobility and Balance, and Spatiotemporal Gait Parameters in people with Knee Osteoarthritis: A Randomized Clinical Trial

Public title

Therapeutic Effectiveness of Mulligan Mobilization with Movement on Pain, Functional Mobility and Balance, and Spatiotemporal Gait Parameters in people with Knee Osteoarthritis: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1 Participants will be female or male 2 Participants will be aged 50 to 75 years 3 Participants will have bilateral medial compartment knee osteoarthritis 4 The osteoarthritis will be classified as Kellgren/Lawrence grade three 5 Participants will have chronic knee pain for at least 3 months 6 Pain intensity will be moderate (VAS 4–8/10) 7 The diagnosis will be confirmed by an orthopedic specialist 8 The diagnosis will be based on American College of Rheumatology criteria 9 Participants will be referred to physiotherapy and orthopedic outpatient departments of University of Medical Sciences of Kerman hospitals

Exclusion criteria:

1 History of knee surgery (arthroplasty, ligament reconstruction, or meniscectomy) 2 Lower limb fracture within less than 6 months 3 Neurological or musculoskeletal conditions impairing mobility 3 Neurological or musculoskeletal conditions impairing mobility 5 Contraindications to manual therapy (joint instability, acute infection, malignancy) 6 Uncontrolled hypertension (BP >160/100 mmHg) 7 Cardiovascular limitations 8 Radiating leg pain suggesting radiculopathy 9 BMI >40 kg/m² 10 Recent intra-articular injections within less than 6 months 11 Current physiotherapy or exercise programs 12 Inability to perform basic functional tasks (standing from chair unassisted, walking 10 m, or lying prone)

Age

From **50 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, 40 eligible participants will be randomly allocated to either the intervention group (MWM+CSE) or the control group (CSE alone) in a 1:1 ratio. A block randomization method with a fixed block size of 4 will be used to ensure balanced allocation between the two groups throughout the recruitment period. Each block will contain 2 participants for the intervention group and 2 participants for the control group. The randomization sequence will be generated by an independent statistician who will not be involved in recruitment, assessment, or intervention delivery. A computer-based random number generator, such as Random Allocation Software, will be used to produce the sequence. Allocation concealment will be ensured using opaque, sequentially numbered, sealed envelopes (SNOSE method). The envelopes will be stored securely and will be opened only after baseline assessments have been completed. The envelopes will be opened by a person who is not involved in the treatment team. This procedure will prevent selection bias and ensure that group allocation remains concealed until the moment of assignment. The outcome assessor and data analyst will be blinded to group allocation. Participants and treating physiotherapists will not be blinded because of the nature of the intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

This trial will be a single-blind study. The outcome assessor and the data analyst will be blinded to group allocation. Participants, the clinical care provider (treating physiotherapist), the principal investigator, and the Data Safety and Monitoring Committee will not be blinded. Participants will be fully informed that they are participating in a randomized controlled trial and will provide written informed consent. Blinding of participants will be impractical because of the nature of the intervention (manual therapy versus no manual therapy). The outcome assessor will be independent from the treatment team and will perform all measurements without knowledge of group allocation. The data analyst will analyze the data using coded labels, and the allocation code will be revealed only after the analysis is completed. Allocation concealment will be ensured using opaque, sequentially numbered, sealed envelopes (SNOSE method).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Working Group/Committee, Baqiyatallah Al-A'zam (AJ) Educational and Medical Center

Street address
Vanak Square, Molla Sadra Street, Sheikh Bahaei Street, Baqiyatallah University of Medical Sciences (AJ)

City
Tehran

Province
Tehran

Postal code
۱۴۳۹۹۱۴۱۵۳

Approval date
2025-11-17, 1404/08/26

Ethics committee reference number
IR.BMSU.BAQ.REC.1404.118

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

Timepoint
Before the intervention and after the intervention period of 4 weeks

Method of measurement
Knee Injury and Osteoarthritis Outcome Score, VAS

Secondary outcomes

1

Description
Functional mobility measured by Timed Up and Go test

Timepoint
Before the intervention and after the 4-week intervention period

Method of measurement
Timed Up and Go test, measuring the time to rise from a standard chair, walk three meters, turn, return, and sit down; average of three trials

2

Description
Walking endurance measured by Six-Minute Walk Test

Timepoint
Before the intervention and after the 4-week intervention period

Method of measurement
Six-Minute Walk Test, measuring the maximum distance walked in six minutes along a straight 30-meter walkway

3

Description
Postural Stability Index in static balance

Timepoint
Before the intervention and after the 4-week intervention period

Method of measurement
Biodex Balance System, static platform condition, eyes open and eyes closed, three trials of 30 seconds each

4

Description
gait spatio-temporal parameters

Timepoint
Before the intervention and after the 4-week intervention period

Method of measurement
Three-dimensional motion analysis system with six infrared cameras and passive reflective markers based on the Plug-in-Gait model, walking along an 8-meter walkway at self-selected comfortable speed, three valid trials

Intervention groups

1

Description
Intervention group: Participants will receive Mulligan Mobilization with Movement followed by Core Stability Exercises. Mulligan Mobilization with Movement will be applied by a single physiotherapist using standardized glides (lateral, medial, or rotational) based on pain-free range improvement. The technique will involve a sustained, pain-free manual glide force to the proximal tibia near the knee joint with a counterforce applied to the femur. The direction of the glide will be chosen based on the movement that results in the greatest improvement in pain-free mobility. While maintaining the sustained glide, participants will be instructed to actively move their affected knee within a pain-free range, either towards flexion or extension. Each session will involve three sets of six to ten repetitions of the most effective technique. In addition, participants will receive moist heat therapy for 15 minutes and a structured core stability exercise program for 20 to 25 minutes, including pelvic bridging, resisted knee flexion, resisted knee extension, mini squats, and heel raises. Participants will also perform a home program of brisk walking for 20 minutes daily on non-clinical days. The intervention will

last for 4 weeks, with 12 sessions, three sessions per week, each session lasting 45 minutes.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Physiotherapy and Orthopedic Outpatient Departments, University of Medical Sciences of Kerman Hospit

Full name of responsible person
Ehsan Ebrahimipour

Street address
Kerman University of Medical Sciences, Haft Bagh Alavi Highway, Kerman, Iran

City
kerman

Province
Kerman

Postal code
7612314892

Phone
+98 34 3132 5000

Email
ehsan94324001@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Ehsan Ebrahimipour

Street address
Biomechanics Department, Faculty of Physical Education and Sport Sciences, Shahid Bahonar University of Kerman, Kerman, Iran

City
kerman

Province
Kerman

Postal code
7672098761

Phone
+98 34 2719 2340

Email
ehsan94324001@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Ehsan Ebrahimipour

Position
researcher

Latest degree
Ph.D.

Other areas of specialty/work
Physical Medicine

Street address
Biomechanics Department, Faculty of Physical Education and Sport Sciences, Shahid Bahonar University of Kerman, Kerman, Iran

City
kerman

Province
Kerman

Postal code
7612748901

Phone
0098342719234

Email
ehsan94324001@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Ehsan Ebrahimipour

Position
researcher

Latest degree
Ph.D.

Other areas of specialty/work
Physical Medicine

Street address
Biomechanics Department, Faculty of Physical Education and Sport Sciences, Shahid Bahonar University of Kerman, Kerman, Iran

City
kerman

Province
Kerman

Postal code
7615289340

Phone
0098342719234
Email
ehsan94324001@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ehsan Ebrahimipour
Position
resaercher
Latest degree
Ph.D.
Other areas of specialty/work
Physical Medicine
Street address
Biomechanics Department, Faculty of Physical Education and Sport Sciences, Shahid Bahonar University of Kerman, Kerman, Iran
City
kerman
Province
Kerman
Postal code
7612389035
Phone
0098342719234
Email
ehsan94324001@gmail.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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available